Competition policy in Bismarck and Beveridge healthcare systems:

Competition law, merger control and the relationship between competition authority and sectoral regulator in Dutch and English healthcare

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Thesis submitted for the degree of Doctor of Philosophy

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Date of Submission: August 2016

Word Count: 90,262.

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Abstract

This thesis examines two competition provisions (sections 72 and 79) of the Health and Social Care Act 2012 by reference to the Dutch experience of applying identical or very similar laws (relating to competition law and merger control, respectively) and establishing equivalent institutional arrangements following wide-ranging reforms in 2006. Therefore the overarching legal framework – which also applies to other liberalised sectors – belies differences between the Dutch health insurance system and the English taxation-funded NHS which have implications for the ways in which competition can develop.

Thus both countries have been confronted with the apparently inconsistent applicability of EU competition law to healthcare providers, but not purchasers. Although applicability of general merger control has attracted less ambiguity, both countries have developed a range of amendments which can collectively be termed "healthcare-specific" merger control. The creation of healthcare regulators and their relationship with competition authorities with regard to applying competition law is also examined, since this has proved more controversial than that regarding merger control.

The discussions of the thesis are underpinned by three frameworks developed from health law and competition law literature and juxtapose conceptions from each. Firstly, a 'healthcare structure' comprising levels relating to state intervention, purchasers and providers. Secondly, a 'continuum' reflecting the move away from healthcare provision as a public service overseen exclusively by government to a market-based system overseen by a competition authority. Thirdly, 'competition-centric' and 'healthcare-centric' approaches are juxtaposed to reflect perceptions that healthcare may be different to other sectors thus merit special treatment.

Overall, the thesis contributes to both health and competition law literature by offering a comprehensive analysis of competition in English healthcare as well as by its comparative approach. It further marks a contribution in terms of legal literature to a subject area more typically associated with economics and political science.

i

Contents

Abstract	i
Table of Figures	x
Acknowledgements	xii
Chapter 1	1
Introduction	1
1.1. Introduction – Motivation	1
1.2. Research Questions and Methodology	6
1.3. Thesis discussion frameworks	11
I. The "healthcare structure" – macro, meso and micro levels	13
II. The continuum between healthcare provision as a public service overseen by government and a competitive marketplace overseen by a competition authority	17
III. A "competition-centric" or a "healthcare-centric" approach	18
1.4. Competition in Dutch and English healthcare – the Dutch "healthcare triangle" and the "four categories of English healthcare"	21
I. The Dutch "healthcare triangle"	21
II. The "Four Categories of English healthcare"	22
2.5. Thesis outline: contributions and limitations	23
Chapter 2	27
Setting the scene: context of competition in Dutch and English healthcare	27
2.1. Introduction	28
2.2. Thesis Discussion Frameworks and the discussions of this chapter	28
I. The "healthcare structure" - macro, meso and micro levels	29
A. The macro level – state intervention	29
B. The meso level – healthcare purchasers	31
C. The micro level – healthcare providers	31
II. The continuum between healthcare provision as a public service overseen by government and a competitive marketplace overseen by a competition authority	32
III. A "competition-centric" or "healthcare-centric" approach	33
2.3. Competition in healthcare (1): General context	35
I. Defining the market	35
A. General remarks	35
B. The Netherlands	38
B1. The Dutch healthcare provision market	39
B2. The Dutch healthcare purchasing market	40

B3. The Dutch health insurance market 41
C. England
C1. The wider NHS and Private Healthcare (PH) markets and the four categories of English healthcare
C2. The NHS and PH purchasing markets47
C3. The NHS and PH healthcare provision markets defined by reference to the four categories of English healthcare
II. Is healthcare different?
A. What are the implications of healthcare being different in the context of the
Dutch and English reforms as discussed in this thesis?
 B. Dutch and English healthcare as markets in transition:
2.4. Competition in healthcare (2): Country contexts
I. The Netherlands
A. Legislation underpinning the 2006 reforms relevant to the discussions of this thesis
B. Notable events 2006-2016 relevant to the discussions of this thesis
III. England
A. The HSCA 2012 and elaboration of competition in the English NHS
B. Notable events 2012-2016 relevant to the discussions of this thesis
2.5. Conclusions
Chapter 3
How does applying competition law impact healthcare provision in the Netherlands and England?71
3.1. Introduction
3.2. Thesis discussion frameworks and the discussions of this chapter
I. The "healthcare structure" – macro, meso and micro levels
II. The continuum between healthcare provision as a public service overseen by
government and a competitive marketplace overseen by a competition authority
III. A "competition-centric" or "healthcare-centric" approach
3.3. The applicability of EU and national competition law – the "undertaking" framework
I. The EU competition law framework as defined by reference to the
"undertaking" concept
A. Overview of the "undertaking" concept78
B. AOK Bundesverband
C. FENIN

II. The EU competition law framework and the Dutch and English healthcar sectors			
A. Creating a national framework for applying competition law in national			
healthcare cases (1) – interaction between general competition law and he			
reforms			
A1. The Netherlands			
A2. England	8/		
B. Creating a national framework for applying competition law in national healthcare cases (2) – parallel application of national and EU competition r	ules 98		
B1. The Netherlands			
(a) Art. 48 Wmg – SMP:			
(b) Art. 45 Wmg – contract powers:			
B2. England	101		
3.4. Application of competition law in Dutch and English healthcare	102		
I. Applying the anticompetitive agreements and abuse of dominance provisio			
the healthcare sector – general remarks			
A. Anticompetitive agreements and healthcare			
B. Abuse of dominance and healthcare			
C. Competition law and healthcare – general concluding comments			
II. The Netherlands:			
A. Application of the anticompetitive agreements provisions			
A1. Continuity of care			
A2. Professional associations in the Dutch healthcare sector			
A3. Anticompetitive agreements in Dutch healthcare – concluding remar			
B. Application of the abuse of dominance provisions			
III. England			
A. Application of the anticompetitive agreements provisions:	117		
A1. NHS providers in the PH sector (category 3):			
A2. The English NHS (Categories 1 and 2):	118		
B. Application of the abuse of dominance provisions	121		
3.5. Conclusion:	123		
Chapter 4	127		
How should the new sectoral regulators for healthcare work with the compe- authorities in applying competition law?			
4.1. Introduction:			
4.2. Thesis Discussion Frameworks			
I. The "healthcare structure" – macro, meso and micro levels			
	iv		

II. The "continuum" between healthcare as the quintessential public service overseen by government and a market overseen by the competition authority
III. A "competition-centric" or "healthcare-centric" approach135
4.3. Models of Regulation in the Netherlands and England
I. The Netherlands – a "separate powers" model136
A. The NZa's competition powers, 2006-2015137
A1. SMP powers (Artide 48 Wmg)137
A2. Power to intervene in the drafting of contracts (Article 45 Wmg)140
A3. Possible "overlap" between NZa and ACM powers, 2006-2015141
B. Future direction143
II. England – a "concurrent powers" model146
A. The position of the competition authority vis-à-vis the healthcare sector in England before and after enactment of the HSCA 2012147
B. Defining the scope of concurrent powers by reference to s.72 HSCA 2012, ERRA 2013 and the 2014 Concurrency Regulations149
B1. S.72 HSCA 2012 – the substantive scope of concurrent powers in English healthcare
B2. ERRA 2013 and the 2014 Concurrency Regulations – the institutional scope of concurrent powers in English healthcare151
C. Monitor's "separate", "competition-related" powers:155
C1. The Competition Oversight Condition of the NHS Provider Licence156
C2. The 2013 Regulations158
C3. Relationship between Monitor's "competition-related" powers and its concurrent powers160
4.4. Factors influencing the relationship between regulator and competition authority
I. The regulator's focus on patients163
A. The Netherlands: the NZa's "separate powers" and the "general consumer interest"
A1. Overview of the "general consumer interest" under Article 3(4) Wmg163
A2. The NZa's "separate powers" and the "general consumer interest" framework
A3. Effect of the "general consumer interest" on the "separate powers" model
B. England: the "concurrent powers" model and Monitor's focus on patients .168
B1. Monitor's duty and the different "types" of patient in England169
B2. Monitor's duty and its concurrent powers172
B3. Effect of Monitor's duty on the "concurrent powers" model175 v

II. The role of government in connection with the relationship between the regulator and competition authority176
A. The Netherlands: the "separate powers" model and the NZa's and ACM's relationships with the Minister for Health, Wellbeing and Sport
A1. The relationship between the NZa and the Minister for Health, Wellbeing and Sport
A2. The relationship between the ACM and the Minister for Health, Wellbeing and Sport
B. England: the "concurrent powers" model and Monitor's relationship with the Secretary of State for Health179
B1. The establishment of NHS England180
B2. Post-HSCA 2012 system of referral of decisions regarding licence modifications and the NHS tariff to the CMA182
4.5. Conclusions
Chapter 5
What can "healthcare-specific" merger control achieve in Dutch and English healthcare?
5.1. Introduction190
5.2. Thesis discussion frameworks and the discussions of this chapter195
I. The "healthcare structure" – macro, meso and micro levels
1. The field date structure findero, meso and microfevers
II. The continuum between healthcare provision as a public service overseen by government and a competitive marketplace overseen by a competition authority .196
II. The continuum between healthcare provision as a public service overseen by
II. The continuum between healthcare provision as a public service overseen by government and a competitive marketplace overseen by a competition authority .196
 II. The continuum between healthcare provision as a public service overseen by government and a competitive marketplace overseen by a competition authority .196 III. A "competition-centric" or "healthcare-centric" approach
 II. The continuum between healthcare provision as a public service overseen by government and a competitive marketplace overseen by a competition authority .196 III. A "competition-centric" or "healthcare-centric" approach
 II. The continuum between healthcare provision as a public service overseen by government and a competitive marketplace overseen by a competition authority .196 III. A "competition-centric" or "healthcare-centric" approach
 II. The continuum between healthcare provision as a public service overseen by government and a competitive marketplace overseen by a competition authority .196 III. A "competition-centric" or "healthcare-centric" approach
 II. The continuum between healthcare provision as a public service overseen by government and a competitive marketplace overseen by a competition authority .196 III. A "competition-centric" or "healthcare-centric" approach
 II. The continuum between healthcare provision as a public service overseen by government and a competitive marketplace overseen by a competition authority .196 III. A "competition-centric" or "healthcare-centric" approach
 II. The continuum between healthcare provision as a public service overseen by government and a competitive marketplace overse en by a competition authority .196 III. A "competition-centric" or "healthcare-centric" approach
 II. The continuum between healthcare provision as a public service overseen by government and a competitive marketplace overse en by a competition authority .196 III. A "competition-centric" or "healthcare-centric" approach
 II. The continuum between healthcare provision as a public service overseen by government and a competitive marketplace overseen by a competition authority .196 III. A "competition-centric" or "healthcare-centric" approach
 II. The continuum between healthcare provision as a public service overseen by government and a competitive marketplace overseen by a competition authority .196 III. A "competition-centric" or "healthcare-centric" approach

C. Relationship between the jurisdictional aspects and general merger control
III. Substantive assessment aspects223
A. The Netherlands223
A1. Additional assessment criteria for the ACM223
A2. NZa Opinions, 2006-2015
B. England225
B1. Monitor's advisory function under s.79(5) HSCA 2012
C. Relationship between the "substantive assessment aspects" and general merger control
5.4. What is "healthcare-specific" merger control intended to achieve?
I. "Selling" competition reforms and engaging with the healthcare sector229
II. Ensuring appropriate oversight of mergers in a sector in transition231
III. Counteracting the limitations of a competition-based test
IV. Elaborating the appropriate place of merger control in a sector heavily dependent upon cooperative relationships234
5.5. Conclusions – what can "healthcare-specific" merger control achieve in Dutch and English healthcare?
Chapter 6
Conclusions
6.1. Overview of findings chapter-by-chapter and thesis contributions240
I. Chapter 3 – How does applying competition law impact healthcare provision in the Netherlands and England?
II. Chapter 4 – How should the new sectoral regulators for healthcare work with the competition authorities in applying competition law?
III. Chapter 5 – What can "healthcare-specific" merger control achieve in Dutch and English healthcare?243
6.2. Conclusions by thesis discussion framework243
I. The "healthcare structure" – macro, meso and micro levels
A. The macro level – state intervention243
B. The meso level – healthcare purchasers245
C. The microlevel – healthcare providers246
II. The "continuum" between healthcare as a public service overseen by government and a market-based system overseen by a competition authority247
III. A "competition-centric" or "healthcare-centric" approach
6.3. Broader conclusions by theme and policy recommendations:251
I. General observations arising from examination of the Dutch experience251

https://competitionpolicy.wordpress.com/2015/05/05/what-could-repeal-of- the-health-and-social-care-act-2012-mean-for-the-application-of-competition- law-and-the-english-nhs/liii				
Competition Policy Blog				
Appendix O – May 2015 Blog Postliii				
Appendix N – Official Documentsxlvi				
Appendix M - Table of Legislationxxxix				
Appendix L - Table of Cases				
Appendix K – Chapter 5 - Overview of relationship between "healthcare-specific" merger control and general merger control in Englandxxxiii				
Appendix J – Chapter 5 - Overview of relationship between "healthcare-specific" merger control and general merger control in the Netherlands, 2006 - 2015xxxii				
Appendix I - A note on terminology and translationsxxix				
Appendix H - Thesis Acronyms and Abbreviationsxxvii				
Appendix G – Glossary - English Healthcare Sectorxvii				
Appendix F – Glossary - Dutch Healthcare Sectorxi				
Appendix E - Thesis Timelineix				
II. Overview of themes and provisions in connection with English healthcareviii				
I. The four categories of English healthcarevii				
Appendix D - England – perspective in overviewvii				
II. Overview of themes and provisions in connection with Dutch healthcare: vi				
I. The Dutch "healthcare triangle"v				
Appendix C - The Netherlands – perspective in overviewv				
The "healthcare structure" – chapter overviewiv				
Appendix B – Thesis Discussion Framework (1): iv				
Appendix A - Discussion Framework (1): The "healthcare structure" – Actorsiii				
Appendicesi				
Bibliography262				
6.4. Future directions of research arising from the thesis				
V. The need to understand and acknowledge the interactions between the NHS and PH sector in England and the absence of a single, unified "healthcare" sector258				
IV. The need for modifications to general law to accommodate the specificities of the healthcare sector				
III. The limits of importing regulatory structures from other sectors in connection with developing competition in healthcare256				
II. The relationship between the EU competition law framework and the emergent national competition policies in healthcare				

What could repeal of the Health and Social Care Act 2012 mean for the application of competition law and the English NHS?
Appendix P – February 2013 blog post Ix
Monitor's Advice to the OFT and the New Healthcare Regulation ${\sf Ix}$
Appendix Q – October 2013 Blog PostIxiii
The Meaning of 'Relevant Customer Benefits' in the Context of Health Care:
Monitor's Advice and the Competition Commission's ResponseIxiii
Appendix R – Medical Law Review Article Ixvi
Website addresses are correct as at 30 June 2016.

Table of Figures

Chapter 1

Figure 1: Macro-Meso-Micro Healthcare Structure. Page 14.

Figure 2: the Dutch "healthcare triangle". Page 22.

Figure 3: Relationship between the NHS and PH sectors as demonstrated by the purchaser/provider separation. Page 23.

Chapter 2

Figure 1: Office of Health Economics (OHE) competition feasibility framework with hypothetical examples.Page 36.

Figure 2: Propensity to fulfil conditions for effective competition in health systems. Page 37.

Figure 3: the Dutch "healthcare triangle". Page 39.

Figure 4: Top reasons for switching / not switching. Page 42.

Figure 5: Patients and providers move between the NHS and PH sectors. Page 44.

Figure 6: Relationship between the NHS and PH sectors as demonstrated by the purchaser/provider separation. Page 46.

Figure 7: Key provider types across the NHS and contribution of independent sector organisations. Page 49.

Figure 8: "Regulation and Competition will always play an important role". Page 65.

Figure 9: Commissioners decide when and how to use competition. Page 66.

Chapter 3

Figure 1: The Dutch "healthcare triangle". Page 86.

Figure 2: Relationship between the NHS and PH sectors as demonstrated by the purchaser/provider separation. Page 88.

Figure 3: Overview of the NZa's SMP powers and the ACM's abuse of dominance powers. Page 115.

Chapter 4

Figure 1: Overview of the varying scope of "overlap" 2006-2015. Page 142.

Figure 2: "Concurrent powers" under s.72 HSCA 2012 in light of a broad interpretation of "healthcare services" (as encompassing categories 1-4).Page 150.

Figure 3: "Concurrent powers" under s.72 HSCA 2012 in light of a narrow interpretation of "healthcare services" (as encompassing categories 1 and 2 only). Page 151.

Figure 4: how concurrent powers under s.72 HSCA 2012 operate following amendments by Regulations 5 and 8 of the 2014 Concurrency Regulations. Page 154.

Figure 5: Monitor's choice of powers. Page 160.

Figure 6: Overview of the "general consumer interest" in light of exclusionary and exploitative behaviour. Page 165.

Chapter 5

Figure 1: Overview of "healthcare-specific" merger control. Page 193.

Figure 2: Lower turnover thresholds applicable to Dutch healthcare mergers 2008-2018. Page 208.

Figure 3: Overview of the applicability of the EA02 to NHS mergers. Page 212.

Figure 4: Types of "Transaction" available to ensure NHS Trust sustainability. Page 218.

Figure 5: The institutional relationship between the ACM, NZa and IGZ in healthcare merger assessment, 2006-2015. Page 229.

Acknowledgements

Over the course of writing this thesis (October 2012 – August 2016), I have presented my research to a wide variety of audiences in the UK and abroad and worked on two publications. First and foremost, therefore, thanks are due to my supervisors at UEA, Professor Michael Harker and Professor Morten Hviid, for their patience and continuous support throughout.

The research in this thesis has also benefitted from a wide range of discussions, in particular with Dr André Den Exter, Professor Tamara Hervey, Dr Okeoghene Odudu, Frank Pellikaan, Leonie Schakel, Dr Albert Sánchez Graells, Professor Erika Szyszczak and Professor Johan Van de Gronden.

Particular thanks are due to Professor Wolf Sauter, whose encouragement has been invaluable and from whom I continue to learn.

Feedback from internal audiences and the following external audiences in particular has helped to develop the research in this thesis: the "Old Markets, New Markets: Health Law after the 2012 Act" workshop of the Health Law and Policy Research Group (Sheffield June 2013), British Association of Comparative Law Postgraduate Workshops (Essex April 2013 and UEA April 2015), Competition Law and Economics European Network (CLEEN) workshops (UEA June 2014 and Tilburg May 2015), Social Justice workshop (LSE August 2014), and the Antitrust Law and Healthcare workshop (EUI Florence November 2014).

I am grateful to be part of two exceptional academic environments – UEA Law School and the Centre for Competition Policy (CCP) – which have contributed to the enjoyment of completing this thesis and working as an Associate Tutor. Thanks for support are due in particular to Gillian Daly, Dr Michael Hamilton, Professor Rob Heywood, Professor Peter Kunzlik, Dr Sebastian Peyer, Dr David Reader, Claudina Richards and Dr Gareth Spark, as well as the Law School postgraduate research community.

This thesis is dedicated to my father, William Robert Guy, and the memory of my mother, Joan Winefride Strawson Guy (1948-2009).

xii

Chapter 1

Introduction

Contents

1.1.	Introduction – Motivation	. 1
1.2.	Research Questions and Methodology	. 6
1.3.	Thesis discussion frameworks	11
١.	The "healthcare structure" – macro, meso and micro levels	13
	The continuum between healthcare provision as a public service overseen by emment and a competitive marketplace overseen by a competition authority	17
III. A	"competition-centric" or a "healthcare-centric" approach	18
	Competition in Dutch and English healthcare – the Dutch "healthcare ngle" and the "four categories of English healthcare"	21
١.	The Dutch "healthcare triangle"	21
II.	The "Four Categories of English healthcare"	22
1.5.	Thesis outline: contributions and limitations	23

1.1. Introduction – Motivation

The significance of competition policy in healthcare is a developing issue in the Netherlands and England,¹ which represent the two EU Member States to have gone the furthest in terms of healthcare liberalisation. In both countries, we see the coexistence of general competition law (the provisions governing anticompetitive agreements and abuse of dominance, as well as merger control) as well as sector-specific rules. These are overseen by varying relationships between the competition authority - the Authority for Consumers and Markets (ACM) and the Competition and Markets Authority (CMA) – and

¹ The focus on England as opposed to the wider UK is deliberate in view of the prevalence of market-based reforms in the English NHS, and different approaches in the NHS of other countries of the UK.

sectoral regulators – the Dutch Healthcare Authority (NZa) and Monitor (now NHS Improvement).²

The nature of a competition policy in Dutch healthcare (that is, the coexistence of national regulatory rules as applied by the NZa and national and EU competition law as applied by the ACM) has been thought fundamental for two reasons – that healthcare merits special treatment under competition policy because it is almost entirely composed of vulnerable transition markets, and the central importance of a successful competition policy in healthcare to the success of, and/or support for, liberalisation.³

These reasons have equal relevance to English healthcare in view of the reforms of the Health and Social Care Act 2012 (HSCA 2012). The competition provisions of the HSCA 2012 proved controversial as much for establishing that the CMA and Monitor (as well as NHS England) would have increased oversight of the English National Health Service (NHS) with a reduced role for the Secretary of State for Health as raising questions about how competition in the NHS can operate and the mechanics of applying general competition law.

This thesis examines the HSCA 2012 competition provisions by reference to the experience of the Netherlands, where significant reforms implemented in 2006 led to the creation of a similar architecture for implementation involving a clearly-defined relationship between a sectoral regulator, the NZa and the ACM. Furthermore, the law underpinning the introduction of competition comprises fundamentally the same provisions (in connection with competition

² NHS Improvement came into existence on 1 April 2016 as an overarching organisation encompassing Monitor and the NHS Trust Development Authority (NHS TDA), both developed by the Health and Social Care Act 2012. However, reference is made in this thesis to "Monitor" as there is a need to distinguish this from the NHS TDA (for example, in connection with merger control in Chapter 5), to avoid confusion regarding references in legislation, policy documents and literature.

³ Wolf Sauter, 'Experiences from the Netherlands: The Application of Competition Rules in Health Care', Chapter 14 in Johan Van de Gronden, Erika Szyszczak, Ulla Neergaard, Markus Krajewski (eds), *Health Care and EU Law* (TMC Asser Press 2011).

law)⁴ or very similar provisions (as regards merger control).⁵ Where there are differences – for example in the NZa's competition powers – this offers additional perspectives on wider considerations (such as whether the same approach in regulating the utilities sectors can also work in healthcare) or additional potential lessons.

The HSCA 2012 proved a difficult piece of legislation to enact,⁶ with the competition provisions representing a particular source of contention. Indeed, some of the elements evident in the original White Paper⁷ were fundamentally changed following the "listening exercise" which the coalition government was effectively obliged to conduct during the passage of the Health and Social Care Bill in 2011. Perhaps most notably, the original intention for Monitor to have a duty to promote competition was removed⁸ in favour of a re-focusing of competition – effectively as a means to securing greater choice in a more cost effective way.⁹ This is interesting in light of the view that patient choice may, but need not, be related to competition.¹⁰ Other aspects of the Bill were also modified, such that the emphasis was ultimately on competition on quality, not price.

Criticism of the HSCA 2012 competition reforms encompass a range of perspectives from both academic and policy quarters, including: that the HSCA 2012 reforms have negative implications in "juridifying" public policy;¹¹

<<u>http://www.kingsfund.org.uk/topics/nhs-reform/health-and-social-care-act-2012-timeline</u>>.
⁷ Department of Health, 'Equity and Excellence: Liberating the NHS', July 2010.

⁴ Both the Chapter I and Chapter II prohibitions of the UK Competition Act 1998 (CA 98) and Articles 6 and 24 of the Dutch Competition Act 1998 (*Mededingingswet* (Mw)) reflect the equivalent EU provisions relating to anticompetitive agreements and abuse of dominance under Articles 101 and 102 Treaty on the Functioning of the European Union (TFEU), respectively.

⁵ This is discussed further in Chapter 5, but for the purposes of introducing this comparison, it is enough to note that both countries operate a two-stage test.

⁶ For the most comprehensive account thus far, see Nicholas Timmins, *Never Again? The story of the Health and Social Care Act 2012 – A study in coalition government and policy making*, The King's Fund and Institute for Government, 2012. For an overview, see The King's Fund, "The Health and Social Care Act: the tale in a timeline".

⁸ NHS Future Forum, 'Choice and Competition – Delivering Real Choice. A report from the NHS Future Forum', June 2011. Page 9.

⁹ Ibid, page 4.

¹⁰ European Commission, Expert Panel on Effective Ways of Investing in Health (EXPH), "Competition among health care providers in the European Union – Investigating Policy Options", 17 February 2015. Page 6.

¹¹ ACL Davies, 'This Time, It's For Real' [2013] M.L.R. 76(3), 564-588.

alternatively, that competition in the NHS is fundamentally positive, but the HSCA 2012 competition reforms have "set back for a generation the cause of market-based reform in the NHS",¹² or detract from the framework of general competition law.¹³ Also noteworthy is that the criticism continued on both sides of the UK general election in May 2015: from manifesto pledges to repeal the HSCA 2012 by the Labour, Liberal Democrat and Green parties¹⁴ to subsequent considerations that "the legislative chaos and complexity [of the HSCA 2012] has left us with some pretty unworkable ideas embedded in primary legislation".¹⁵ Furthermore, the HSCA 2012 reforms were also distinguished from the approach taken to competition in healthcare at EU level by supporters of the "Remain" campaign in connection with the referendum on UK membership of the EU in June 2016.¹⁶ However, it has since been suggested that "Brexit" may have limited impact on the implementation of competition law regarding the NHS.¹⁷

In view of this ongoing controversy, it is perhaps not surprising that explicit reference to the HSCA 2012 reforms and competition is not to be found in either NHS England's strategy, the NHS Five Year Forward View (NHS FYFV) published in October 2014,¹⁸ or the 25-year vision set out by the current

¹² Comments attributed to the former Labour Secretary of State for Health, Alan Milburn, in the context of a public event hosted by the Institute for Government think tank to examine past attempts to increase choice and competition in health. See Tom Gash and Theo Roos, 'Choice and competition in public services: learning from history', Institute for Government, August 2012. This is notable as Milburn oversaw various of New Labour's competition reforms.

¹³ Arguably implicit in Sánchez Graells' view that Monitor's duty under s.62(3) HSCA 2012 to balance anticompetitive behaviour with patient interests, and Regulation 10, National Health Service (Procurement, Patient Choice and Competition) (No.2) Regulations 2013 as an essentially worrying development as regards the application of both competition law and the public procurement rules. See Albert Sánchez Graells, 'Monitor and the Competition and Markets Authority', (2014) University of Leicester School of Law Research Paper No.14-32; and 'New rules for health care procurement in the UK: a critical assessment from the perspective of EU economic law', [2015] P.P.L.R, 1, 16-30.

 ¹⁴ For a discussion of this, see Mary Guy, 'What could repeal of the Health and Social Care Act 2012 mean for the application of competition law and the English NHS?', Competition Policy Blog, Centre for Competition Policy (CCP), University of East Anglia (UEA), May 2015.
 ¹⁵ Kieran Walshe, 'Queen's Speech: We can't avoid legislation for ever', Health Service

Journal, 28 May 2015.

¹⁶ See, for example, Martin McKee, 'The NHS is safest inside the EU', (*Open Democracy, Our NHS*, 6 April 2016).

¹⁷ Andrew Taylor, 'Brexit and NHS competition and procurement rules' (*NHS Competition Regulation*, 28 June 2016).

¹⁸ NHS England, 'Five Year Forward View', October 2014.

Secretary of State for Health, Jeremy Hunt in July 2015.¹⁹ However, this is not to say that potential competition issues may not arise: in connection with the NHS FYFV it has already been recognised that collaborations forming the new care models will need to be mindful of the competition rules.²⁰ In addition, some of the HSCA 2012 reforms, particularly concerning Monitor's role, have been cited in connection with the wider enterprise of the coalition and Conservative governments to open up public services to competition.²¹

So it may appear that suggestions that the HSCA 2012 reforms have not been implemented properly²² are premature: that competition law, and the HSCA 2012 have not gone away has been recognised among practitioners.²³ However, scepticism about the HSCA 2012 reforms, as distinct from competition in the NHS more generally, is also evident.²⁴ As discussions are emerging about the implementation of the HSCA 2012 reforms, ²⁵ this analysis of the HSCA 2012 competition reforms is timely.

This chapter provides an overview of aspects relevant to the discussions and analyses of this thesis as follows. Section 2 frames the thesis discussions by outlining the research questions and methodology. Section 3 sets out three frameworks which underpin and link the discussions of the thesis. Section 4 introduces the Dutch "healthcare triangle" and the "four categories of English

¹⁹ 'Making healthcare more human-centred and not system-centred' Speech given by Jeremy Hunt at The King's Fund, London, 16 July 2015.

<<u>https://www.gov.uk/government/speeches/making-healthcare-more-human-centred-and-not-system-centred</u>>.

²⁰ Chris Ham, Richard Murray, 'Implementing the NHS Five Year Forward View: aligning policies with the plan', The King's Fund, February 2015.

²¹ For a succinct general overview of the shift in policy embraced by the former Office of Fair Trading (OFT), see Okeoghene Odudu, 'Why it matters – Selling competition law in the new frontier', Competition Law Insight, 10 December 2013.

²² Walshesupra n15.

 ²³ Baker & McKenzie, 'A snap shot of competition law in the NHS', (*Lexology*, 24 July 2015).
 <<u>http://www.lexology.com/library/detail.aspx?g=6199b1e3-94b2-4730-aa9c-68c9eb629d95</u>>.
 ²⁴ Andrew Taylor, 'Competing over health – What's next for the National Health Service in England?', Competition Law Insight, 16 February 2016.

²⁵ For example, the Health Foundation hosted discussions of merger control in the NHS in November 2015. See Andrew Taylor, 'Using patient referrals to analyse hospital competition' (*NHS Competition Regulation*, 26 November 2015). See also Albert Sánchez Graells, 'Conflicts of interest in healthcare: NHS procurement rules must be clarified', University of Bristol and PolicyBristol Policy Briefing 31/2016.

healthcare" by way of further orientation of the thesis discussions. Section 5 outlines the contributions made by the thesis and its limitations.

1.2. Research Questions and Methodology

This thesis relies fundamentally on a combination of doctrinal and comparative legal research. This comprises analysis of relevant national (English/UK and Dutch) and EU case law and legislation, as well as policy documents produced by the national governments, competition authorities and healthcare regulators. Academic literature from both countries and commentary by UK think tanks is also considered. Where relevant, international and US literature is also included (particularly with reference to health economic analyses).²⁶ The comparative approach is motivated by the focus on the law underpinning competition in Dutch and English healthcare. This offers a starting-point of presumption of similarity,²⁷ as opposed to the Bismarck/Beveridge distinction, which suggests a presumption of difference. On the basis that healthcare comprises three types of competition²⁸ – for health insurance, for collectivelypurchased health services and for individual treatments - the latter two are common to both the Dutch and English systems as outlined above, while health insurance features to varying degrees in the two systems. This, together with an overall focus on healthcare provision, suggests a sufficient basis for a comparative analysis.

The provisions²⁹ examined in detail in this thesis are, in numerical order:

 Section 72 HSCA 2012, which provides for Monitor and the CMA to share concurrent powers with regard to applying national and EU

²⁶ Aside from health economic literature being used to establish the context for discussion, this thesis makes no claim to adopt a "law and economics" approach.

²⁷ Thus tending more towards the methodological approach adopted by Zweigert and Kötz and rejected by LeGrand. See Geoffrey Samuels, *An Introduction to Comparative Law – Theory and Method*, (Hart Publishing, 2014). Page 164.

²⁸ Peter C. Smith, 'Market Mechanisms and the Use of Health Care Resources', Chapter 2 in OECD, *Achieving Better Value for Money in Health Care*, OECD Health Policy Studies, 2009. Pages 56-66.

²⁹ Some provisions, such as sections 76-8 HSCA 2012, are more procedural in nature, so beyond the scope of this thesis.

provisions governing anticompetitive agreements and abuse of dominance, subject to certain exceptions.

 Section 79 HSCA 2012, which provides that general merger control will be applied to NHS Foundation Trusts (NHS FTs) and clarifies a role for Monitor to advise on relevant customer benefits within the merger assessment by the CMA.

However, recourse is also made to other provisions, where relevant, such as section 75 HSCA 2012, which enabled Monitor to develop the National Health Service (Procurement, Patient Choice and Competition) Regulations (No.2) 2013, and which appear intended to provide a complementary, NHS-specific competition regime. Monitor's general duties under s.62 HSCA 2012 are also examined as these delineate the scope of the HSCA 2012 competition reforms in combination with other provisions, such as the Enterprise and Regulatory Reform Act 2013 (ERRA 2013) and the Competition Act 1998 (Concurrency) Regulations 2014.³⁰

Chapter 2 outlines the premise of competition in healthcare and the development of competition in the Dutch and English healthcare sectors to facilitate discussion of how these provisions operate. The thesis is divided into three further – related - research questions as subsequent Chapters 3-5 based on the above provisions as follows, before Chapter 6 concludes with policy recommendations.

How does applying competition law impact healthcare provision in England and the Netherlands? (Chapter 3)

The first question is important for setting the scene as the applicability and application of competition law have proved contentious. This engages with one

³⁰ The discussions of concurrency in this thesis may also have relevance to s.73 HSCA 2012, which provides that Monitor and the CMA have concurrent powers in respect of market investigations. This provision has yet to be used, and is not considered further in this thesis as no direct equivalent exists in the Dutch system.

element of s.72 HSCA 2012. The other, concurrent powers, is addressed in connection with regulation in Chapter 4.

It is to be noted that "competition law" for the purposes of this chapter has a definition limited to a focus on the provisions governing anticompetitive agreements and abuse of dominance. Detailed discussions of state aid are therefore beyond the scope of this thesis.

As two EU member states, the competition law in both the UK (thus England) and the Netherlands reflects the equivalent provisions of the Treaty on the Functioning of the European Union (TFEU), thus is fundamentally the same. The interest therefore lies in whether differences arise in how the provisions are applied, and to what types of behaviour. The possibility of an inconsistent approach to applying EU (as distinct from national) competition rules arising from what has been described as a process of "spontaneous harmonisation"³¹ has been raised with the suggestion that what emerges are "Euro-national competition rules for healthcare".³² Of particular interest in this regard is whether the distinction between Bismarck and Beveridge healthcare system models is material, or whether there are fundamentally common characteristics associated with healthcare provision in either system for the same, or similar, aspects arise. As regards comparison, the starting-point of EU law suggests a positive analysis, which may highlight issues of harmonisation, rather than proposing an approach which might see the Dutch experience transplanted to England.

How should the new sectoral regulators for healthcare work with the competition authorities in England and the Netherlands? (Chapter 4)

Institutions are important for implementing law, and where the relationship between institutions is defined in statute, this may influence how the law is implemented. In the Dutch and English healthcare sectors, enforcement is

³¹ Johan Van de Gronden, 'The Treaty Provisions on Competition and Health Care' in Johan Willem van de Gronden, Erika Szyszczak, Ulla Neergaard, Markus Krajewski (eds), *Health Care and EU Law* (TMC Asser Press 2011).

³² On this point, see Van de Gronden (2011) supra n31 and Johan van de Gronden and Erika Szyszczak, 'Introducing Competition Principles into Health Care Through EU Law and Policy: A Case Study of the Netherlands' [2014] 22(2) Medical Law Review 238-254.

carried out by two institutions, the competition authority (the ACM and CMA) and sectoral regulator (the NZa and Monitor). The relationship between these agencies is defined by statute in both countries and has prompted criticism that this explains in part a relative absence of competition cases in the Netherlands³³ and represents an unnecessary complication of the competition regime in England.³⁴ Both countries are experiencing significant reform at present with the transfer of the NZa's competition powers to the ACM in the Netherlands, and the development of NHS Improvement in England.

In terms of comparing the two countries, the existence of the NZa and Monitor reveal perhaps surprising elements of similarity and difference.

As regards similarity, both countries have been influenced by the experience of sectoral regulators in other sectors and have elaborated a relationship between the competition authority and sectoral regulator. In addition, tensions arising from the approach to be taken to competition issues (such as whether by the competition authority or sectoral regulator, or *ex ante* or *ex post* intervention) and from the public nature of healthcare which lead to questions about the residual role of the Minister.

The differences which emerge are notable. For example, that the UK conception of "concurrency" in sectoral regulation should in theory place Monitor on an equal footing with the CMA, in contrast to the distinctly discrete roles of the NZa and ACM between 2006 and 2015. In addition, the noted tension between the NZa's competition and regulatory functions, with the latter bringing the NZa closer to the Minister, may or may not eventually find reflection in the cooperation between Monitor and NHS England, which has no competition function, but sets the strategic direction for the NHS in England.

This second research question therefore builds on Chapter 3 to explore how the regulator and competition authority work together regarding the

³³ In particular, as a result of the overlap between the NZa's competence to conduct Significant Market Power (SMP) investigations and the ACM's competence to apply the abuse of dominance provisions. See Wolf Sauter, 'The balance between competition law and regulation in Dutch healthcare markets' (2014) TILEC Discussion Paper, DP 2014-041. ³⁴ Sánchez Graells (2014) supra n13.

application of competition law in connection with s.72 HSCA 2012. This anticipates Chapter 5 as the relationship differs between competition law and merger control assessments.

What can "healthcare-specific" merger control achieve in Dutch and English healthcare? (Chapter 5)

The third research question is significant because hospital merger activity is the most developed and active aspect of competition in healthcare in both the Netherlands and England examined in this thesis:³⁵ there have been six mergers involving NHS FTs in England subsequent to the HSCA 2012 reforms³⁶ and fifteen hospital mergers between 2012 and 2014 in the Netherlands.³⁷

Although this is also an area which contributes to discussions of the roles of the regulator and the competition authority, the clearly-defined roles of each within merger control mean that discussion is confined to this chapter.

With regard to the analysis of merger control, it is true that ostensibly different tests are applied: the Significant Impediment to Effective Competition (SIEC) test in the Netherlands, and the Substantial Lessening of Competition (SLC) test in UK. However, the distinction between SIEC and SLC is not material for the purposes of this thesis: what is more relevant to the present discussion is the fact that both countries have made provision for a two-stage test, and few mergers have proceeded to the second stage of assessment.

Of further relevance are the ways in which the tests have been modified in both countries to enable consideration of healthcare-specific, or non-competition concerns, and how the competition authorities and sectoral regulators interact with regard to merger assessment. This offers a basis primarily of similarity. For example, in both countries, it is the competition authority which has exclusive competence to approve or block a merger, with the regulator's role restricted

 ³⁵ Procurement is also a fruitful area in the English NHS, but is beyond the scope of this thesis.
 ³⁶ For an overview, see Taylor (2016) supra n24.

³⁷ This marks an increase on the nine hospital mergers assessed between 2004 and 2011. Ron Kemp, Marie-Louise Leijh-Smit and Krijn Schep, Concentratietoezicht ACM in de

ziekenhuissector – Inzichtin en reflectie op de praktijk, ('ACM merger control in the hospital sector – insights into and reflections on practice') Markt en Mededinging Juli 2015 Nr. 3.

to an advisory function. In addition, while the development of healthcarespecific merger tests differ in how and when they have been used,³⁸ sectorspecific modification may ultimately be deemed to serve the overall purpose of enabling application of general merger control to the healthcare sector. Indeed, both countries may currently report some degree of success in this regard.³⁹

Research Questions and Methodology: concluding remarks:

Overall, while the two main HSCA 2012 provisions examined in this thesis form discrete lines of enquiry, the research questions underscore that there are common features linking the three chapters, most notably the underlying roles of, and relationships between, the sectoral regulator and competition authority. While the focus of the thesis on specific provisions may suggest a "micro" approach to legal research, the inherently comparative aspects of the questions imply a "macro" approach.⁴⁰ This is because the purpose of examining these rules is to illustrate not only where differences in approach exist between the Netherlands and England, but also where the Dutch experience might offer lessons primarily for England, and the experience of both countries – as representing the Bismarck/Beveridge categorisation typically applied – may prove informative for other EU Member States, as well as representing the vanguard of healthcare liberalisation in Europe.

1.3. Thesis discussion frameworks

Having elaborated the research questions with a view to understanding the operation and interaction of the laws underpinning competition in healthcare,

³⁸ For example, what might be termed an "NHS-specific" merger test was used from 2009 effectively to implement successive government policy since 2004 for NHS Trusts to achieve NHS FT status prior to, and alongside, the HSCA 2012 application of general merger control to NHS FTs under s.79 HSCA 2012. In contrast, the Dutch "healthcare-specific" merger test was implemented in January 2014 after previous modifications and a period of concern about widespread approval of hospital mergers.

³⁹ In the Netherlands, a hospital merger was blocked for the first time in July 2015. In England, September 2015 saw the first Phase II approval of an NHS FT merger following the prohibition of the first NHS FT merger subsequent to the HSCA 2012 reforms in October 2013 and some Phase I approvals.

⁴⁰ Siems distinguishes between "micro" and "macro" legal questions with regard to originality in legal research. Matthias Siems, 'Legal Originality' [2008] 28(1) Oxford Journal of Legal Studies 147-164.

it is useful to establish frameworks to give further structure to the discussions of the thesis.

To this end, various permutations have been considered: for example, distinctions between primary and secondary healthcare provision, between general medical care and long-term care and between public and private healthcare provision.

Each of these distinctions has merit, but risks linking the thesis discussion too closely with only one of the two countries, thus undermining the scope for comparative analysis. For example, the distinction between primary and secondary care is reflected in the differing types of competition introduced in England with the creation of Clinical Commissioning Groups (CCGs) by the HSCA 2012, following similar initiatives. The distinction between general medical care and long-term care reflects the 'cure'/ 'care' distinction drawn in the Netherlands, with competition being developed more in connection with the former. The distinction between public and private healthcare sites the discussion firmly in England with less scope for drawing on the Dutch experience. All three permutations have therefore been rejected for being too restrictive.

What is needed is a more flexible approach to accommodate discussion potentially of the three aspects of primary and secondary care, long-term and general medical care, and public and private provision. A flexible approach is also needed since a discussion of competition in healthcare has relevance to practitioner and academic audiences comprising both those with a particular interest in healthcare, and those with a competition background. Thus the thesis primarily seeks to address not only a competition law audience, but also a health law audience.⁴¹

⁴¹ It is recognised that a growing body of literature has emerged in the past few years which includes analysis of competition reforms in healthcare by competition, EU and health lawyers. See, for example, Tamara K Hervey and Jean V McHale, EU Health Law: Themes and Implications (Cambridge University Press, 2015). Johan Willem van de Gronden, Erika Szyszczak, Ulla Neergaard, Markus Krajewski (eds), Health Care and EU Law (TMC Asser Press 2011). Elias Mossialos, Govin Permanand, Rita Baeten, Tamara K Hervey (eds), Health Systems Governance in Europe – The Role of European Union Law and Policy, (Cambridge University Press, 2010). This thesis contributes to this literature by focusing on two national systems.

With this in mind, three frameworks have been developed which draw on influences familiar to health and competition lawyers, as well as exploiting perceived tensions between competition authorities and the Dutch and English healthcare sectors evidenced in early cases.⁴² The three frameworks are as follows.

I. The "healthcare structure" – macro, meso and micro levels

The purpose of this framework is primarily to establish where and how competition, and the application of related laws, is taking place. This enables an understanding of where problems and limitations may become apparent.

This framework is derived from health law discussions of the organisation of healthcare provision.⁴³ However, the simplified structure offers a useful perspective for discussing the laws underpinning the introduction of competition in healthcare in this thesis:

⁴² For example, decisions by the ACM have, on appeal, been criticised for not taking account of the specific nature of the Dutch healthcare sector. See Van de Gronden and Szyszczak (2014) supra n32. In England, the blocking of the first NHS FT merger following enactment of the HSCA 2012 was thought in part to be due to communication difficulties between the CMA and the healthcare merging parties For a discussion of this, see Fod Barnes, 'Competition law and patient choice in the NHS: help or hindrance?'(*Oxera Agenda*, January 2014).
⁴³ Derived from descriptions of the structure of the NHS in Christopher Newdick, 'The Organisation of Healthcare' in Andrew Grubb (ed), *Principles of Medical Law* (2nd edn, OUP 2004).

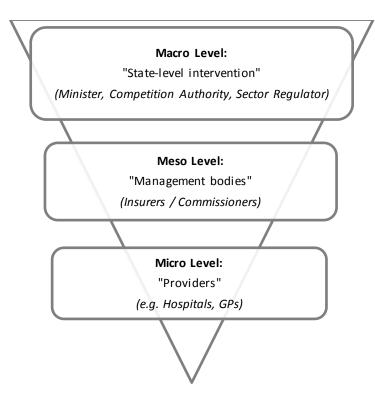


Figure 1: Macro-Meso-Micro Healthcare Structure.

The above implies a continuum with the state design of a healthcare system and policies at one extreme (the macro level), and providers (ultimately the doctor-patient relationship) at the other (the micro level). The meso level serves to link the two, and is populated by healthcare purchasers (private health insurers in the Netherlands and NHS Commissioners in England).⁴⁴ Overviews of the actors within the "healthcare structure" in the Netherlands and England, and how this framework relates to the thesis chapters are provided in Appendices A and B.

The macro level of state intervention is fundamental to any discussion of competition in healthcare due to the considerable degree of political sensitivity which the sector attracts. Even though it may appear counterintuitive to suggest that there is – and should be – a role for Ministers to play within a competitive system ultimately overseen by a competition authority and a sectoral regulator, it cannot be denied that Ministerial intervention is ongoing, whether directly or indirectly. This has been seen recently by the call by the Dutch Minister for Health, Wellbeing and Sport for a reduction in the variety of

⁴⁴ Also described as "managing bodies" by, inter alia, Van de Gronden (2011) supra n31, in the context of discussions about EU competition law and healthcare.

insurance policies offered to aid patient choice.⁴⁵ Ministerial intervention can also extend to the law underpinning competition – for example via the change in statute to accommodate a "healthcare-specific" merger test in the Dutch Healthcare (Market Regulation) Act 2006 (Wmg).⁴⁶ The macro level is also flexible enough to incorporate the move away from Ministerial responsibility to oversight by the competition authorities and sectoral regulators. Indeed it is at this level that we see distinctions between the Netherlands and England: in the former, tensions still exist between the competition and tariff-setting functions of the NZa, which have led to it being deemed to be too close to the Minister.⁴⁷ In England, the HSCA 2012 reforms transfer the tariff-setting function of the Department of Health to NHS England and Monitor.⁴⁸ Whether this serves to remove intervention by the Secretary of State completely remains to be seen.

The meso/micro level distinction between purchasers and providers is a useful one for several reasons. Firstly, it is a distinction which helps facilitate competition within Enthoven's models of "managed competition" adopted in varying degrees in England and the Netherlands – perhaps most notably with the NHS internal market, although the purchaser/provider split persists today, but also the Dutch "healthcare triangle" discussed in Chapter 2. Secondly, this distinction is also present – however illogically – with regard to the applicability of EU competition law as discussed in Chapter 3. EU cases to date⁴⁹ have drawn a distinction between independent medical providers, who are subject to

⁴⁵ Ministerie van Volksgezondheid, Welzijn en Sport, 'Schippers wil minder verschillende zorgpolissen', Nieuwsbericht, 30 juni 2015. (Ministry of Health, Wellbeing and Sport, 'Minister calls for fewer types of policy', Press Release, 30 June 2015).

⁴⁶ Inserted as Art. 49a and 49b Dutch Healthcare (Market Regulation) Act 2006 (Wmg).
⁴⁷ For example, in 2014 reports by AEF and the Borstlap Committee. Andersson Elffers Felix (in samenwerking met Radicand Economics and Tilburg Law and Economics Center (TILEC)), 'Ordening en Toezicht in de zorg: Evaluatie van de Wet marktordening gezondheidszorg (Wmg) en de Nederlandse Zorgautoriteit (NZa)', September 2014. (AEF in cooperation with Radicand Economics and TILEC, 'Oversight and regulation in healthcare: Assessment of the Dutch Healthcare (Market Regulation) Act 2006 (Wmg) and the Dutch Healthcare Authority (NZa)') September 2014. H Borstlap, PFM van der Meer Mohr, LIE Smits, 'Het rapport van de onderzoekscommissie intern functioneren NZa', 2 September 2014. ('Report of the investigation committee on the internal operation of the NZa'), 2 September 2014.

⁴⁹ For a comprehensive overview of these, see Liam Goulding, 'Is the NHS subject to competition law?' (*EUtopia*, 19 July 2013).

competition law because they are deemed to engage in "economic activities", and healthcare purchasers, who are not, following *FENIN⁵⁰* in connection with Beveridge healthcare systems and AOK Bundesverband⁵¹ in Bismarck health insurance systems. Thirdly, the distinction between purchasers and providers finds reflection in modification of the various laws. For example, modified versions of merger control have been applied to providers in both the Netherlands and England, whereas purchasers have either been subject to general merger control (Dutch health insurers) or to a completely separate regime (for the new NHS CCGs). In addition, the new 2013 Regulations appear to blur the distinction between purchasing and providing by applying competition principles (if not law) to CCGs. Finally, drawing a distinction between purchasers and providers highlights further issues in healthcare provision, such as private provision of NHS services and integrated care. The distinction between purchasers and providers is also useful for highlighting conflation of the two functions - perhaps most notably in connection with CCGs in England – and the difficulties which may arise from a legal perspective when this occurs. The distinction between purchasers and providers is also relevant because it suggests a distinction between two principal-agent relationships present in healthcare: between patients and providers on the one hand, and between taxpayers/insured parties and purchasers (whether NHS commissioners or Dutch health insurers) on the other.

What is difficult to incorporate explicitly within this framework, and which may initially appear missing from the above diagram, is patients. This is not a deliberate oversight in view of the importance of patients and patient choice as the justification for competition-based reforms. Despite this, the space afforded to patients might be difficult to ascertain. For example, EU competition cases relating to healthcare thus far have been deemed not to consider the effects on patients as the "end users"/ "ultimate consumers" of healthcare.⁵² Consequently, patients feature (or at least are reflected) at each

⁵⁰ Case C-205/03, FENIN [2006] ECR I-6295.

⁵¹ Joined Cases C-264/01, C-306-01 and C-355/01, AOK Bundesverband [2004] ECR I-2493.

⁵² Wolf Sauter, 'The Impact of EU Competition Law on National Healthcare Systems' [2013] E.L. Rev. 38(4), 457-478.

of the three levels – macro, meso and micro – as a focus for each of the actors: state, purchasers and providers.

II. The continuum between healthcare provision as a public service overseen by government and a competitive marketplace overseen by a competition authority

This second framework might be understood simply as a permutation within the macro level outlined above, but also gives focus to discussions of how the law surrounding competition has been modified, and to what end.

This conception clearly draws on Littlechild's description of the purpose of economic regulation in the UK being to "hold the fort" until competition arrives,⁵³ with the implication that modifications/divergence are not necessary beyond a transition phase as healthcare can fundamentally be regarded as a market like any other. In other words, in this conception the emphasis is on the healthcare sector to adapt its ways of working to accommodate general competition law.

The purpose of this second framework is to enable a certain degree of evaluation of the competition provisions of the HSCA 2012 and thus the overall competition policy for the English healthcare sector and to enable policy recommendations to be made based on the findings.

Within this framework, the application of general competition law and merger control by a competition authority represents the end point of a continuum which started with healthcare provision as a public service overseen by government. In this conception, any divergence from this (for example, amendments to general merger control, use of competition principles in regulatory tools, or even the presence of a sectoral regulator) may merely represent points along the continuum as the end point of healthcare being a market amenable to oversight only by general competition rules has not yet

⁵³ Stephen Littlechild, 'Regulation of British Telecommunications' Profitability', Department of Trade and Industry, London, 1984. Para 4.11.

been reached. Insofar as modifications/divergences are geared towards achieving this end point, they might be described as "prospective" in nature.

Alternatively, modifications to, and divergences from, the application of general competition law by a competition authority might be seen instead as marking a change of direction. To the extent that these emerge subsequent to the application of general competition law by a competition authority, or scope for this to happen (in the case of the English NHS), they might be described as "reactive" in nature. This view suggests that modifications/divergences are not necessarily mere temporary mechanisms to facilitate an ultimate application of general competition law/implementation of a market model in healthcare, but rather represent necessary accommodations of the specificities of the healthcare sector, because it differs from other markets. In other words, in this conception there is an implication that there is scope for development within the application of general competition law by the competition authority, as much as the healthcare sector needing to adapt.

III. A "competition-centric" or a "healthcare-centric" approach

The third framework is an attempt to situate the thesis discussion against a background of perceived tensions between equity and efficiency concerns.

Despite the obvious differences between the Dutch and English healthcare systems, the purpose for introducing competition may be considered broadly similar. Indeed, this may be described in clear terms – as reducing costs and improving population health,⁵⁴ and to this end, modernising healthcare provision while ensuring that the public interests of accessibility, affordability and quality continue to be respected.

This "twofold" purpose of competition inevitably leads to tensions which can be neatly encapsulated as the difficulties of attempting to reconcile efficiency

⁵⁴ Andrew Street, 'Overview' in Anita Charlesworth and Elaine Kelly (eds), *Competition in UK health care – Reflections from an expert workshop*. (Nuffield Trust and IFS Research Report, December 2013).

and equity. Such broad themes have generated two broad starting-points in discussing the purpose of introducing competition and its consequent effect on the regulator and its relationship with the competition authority.

The first starting-point -a "competition-centric" approach - essentially starts from the basis of competition law and interprets healthcare provision in view of this. Thus there has been a notable focus – and general convergence – on whether the "economic activity" criterion is satisfied to trigger the application of competition law in Dutch and English healthcare. Beyond this, the "competition-centric approach" may take the ambitious view that competition law is capable of reconciling efficiency and equity concerns, or at least that the latter will be addressed by (typically unspecified) other means. It is at this point that the "competition-centric approach" appears to fragment along familiar lines, apparently influenced by wider debates regarding the purposes of competition law and whether it is capable of (and amenable to) accommodating non-economic interests.⁵⁵ As its name suggests, this view appears to encompass a range of opinions which seem to increase in intensity, ranging from the possibility of expressing public interests of healthcare in terms of economic efficiencies⁵⁶ to the requirement for a strict application of competition law to satisfy the public interests of healthcare.⁵⁷

The second starting-point can be characterised, conversely, as a "healthcarecentric" approach. This view proceeds from the basis of modernising healthcare provision. It recognises that competition (and the application of competition law) <u>can</u> play a beneficial role in the wider modernisation of healthcare provision, but that this role is considerably more modest than might be inferred from the "competition-centric" approach. Indeed, in this sense, the "healthcare-centric" approach appears consistent with the intention of the legislators for the Wmg (with the emphasis on "competition where possible,

 ⁵⁵ For a thorough overview of the literature in this area, see Ioannis Lianos, 'Some reflections on the goals of EU competition law', in Ioannis Lianos and Damien Geradin (eds), Handbook in EU Competition Law: Substantive Aspects, (Edward Elgar, 2013), 1-85.
 ⁵⁶ Sauter (2013) supra n52.

⁵⁷Edith Loozen, 'Public healthcare interests require strict competition enforcement' [2015] 119(7) Health Policy 882-888.

regulation where necessary"58) and the HSCA 2012 (with the effective clarification of competition "as a means to an end, not an end in itself").⁵⁹ It further recognises that introducing competition in healthcare comprises more than just the application of general competition law by a competition authority. Thus there is a need for a more nuanced approach - for example, between ex ante and ex post intervention, now being recognised by the ACM with the transfer of SMP competence. Furthermore, there may be aspects of competition in healthcare which fall outside the scope of general competition law. For example, maintaining private sector involvement in delivering NHS services may be better facilitated by the National Health Service (Procurement, Patient Choice and Competition) Regulations (No.2) 2013, than by trying to establish whether NHS bodies are engaged in anticompetitive agreements or abusing any dominant position they may hold within a specific market definition. However, this is not to say that there are no instances where general competition law will be the most suitable response, but simply recognising that these may be relatively few and determined by a range of factors (not least the prioritisation policies of the competition authorities themselves), and not just the *applicability* of competition law.

What is becoming evident in both the Netherlands and England is the need to be clear about what competition law can achieve and what the government's role within this might be, even if the emphasis is on the competition authority and the regulator as independent agencies to implement policy in practical terms. Thus in the Netherlands, the ACM appears to have given a cautious welcome to its new SMP powers, pointing out that enforcement action is only possible where competition rules are engaged.⁶⁰ In addition, the former CEO of

⁵⁸ Kamerstukken II, 2004-05, 30 186, 3 'Regels inzake marktordening, doelmatigheid en beheerste kostenontwikkeling op het gebied van de gezondheidszorg (Wet marktordening gezondheidszorg)', Nr.3 Memorie van Toelichting. (Second Chamber documentation, Parliamentary Session 2005-06, 30 186, 3 (Explanatory Memorandum) 'Rules governing market organisation, efficiency and managed cost development in healthcare (Dutch Healthcare (Market Regulation) Act 2006 (Wmg)').

⁵⁹ Arguably implicit in the recommendations of the NHS Future Forum to safeguard the use of competition – 'Competition in itself should never be the driving factor'. NHS Future Forum (2011) supra n8, P.9.

⁶⁰ See ACM, Spreekpunten Henk Don bij rondetafelgesprek 'kwaliteitloont' in de Tweede Kamer op 17 april 2015. ('Points for discussion by Henk Don at the "Quality Pays" round table discussion in the Second Chamber 17 April 2015').

Monitor has criticised the Secretary of State for Health for a perceived lack of support for Monitor's enforcement of the 2013 Regulations.⁶¹

It should be noted that the distinctions drawn above between "competitioncentric" and "healthcare-centric" approaches are merely intended to offer starting-points for the unfolding development of competition in healthcare, and should be treated with caution beyond this. For example, it is recognised that these approaches inevitably overlap: thus analysis of the "undertaking" concept in a healthcare context and consideration of how the public values in healthcare may equate to efficiencies are clearly pertinent to both approaches.

1.4. Competition in Dutch and English healthcare – the Dutch "healthcare triangle" and the "four categories of English healthcare"

In addition to the thesis discussion frameworks, two further points of orientation recur throughout the thesis in order to navigate discussions of competition in healthcare at a national level in the Netherlands and England. These are introduced briefly here, and an overview of how these relate to the thesis overall is provided in Appendices C and D in the "perspectives in overview" of the Netherlands and England.

I. The Dutch "healthcare triangle"

Put simply, the Dutch "healthcare triangle" ⁶² demonstrates the interaction between patients, healthcare providers and health insurers and associated markets which underpin the system of mandatory health insurance introduced in 2006. This is illustrated as follows:

⁶¹ Crispin Dowler, 'Bennett: Government 'micromanagement' creating 'dependency mindset' among leaders' Health Service Journal, 5 November 2015.

⁶² Wolf Sauter, 'Is the general consumer interest a source of legitimacy for healthcare regulation? An analysis of the Dutch experience' [2009] 2-3 European Journal of Consumer Law 419-434.

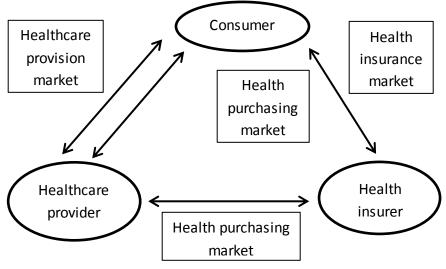


Figure 2: the Dutch "healthcare triangle".

The relationships between the parties, and how the system of mandatory health insurance operates is discussed for the purposes of this thesis in Chapter 2. However, the "healthcare triangle" is also useful for clarifying national provisions to facilitate the application of competition law in Chapter 3, and the focus of the Dutch healthcare regulator (NZa) on consumers and promoting the "general consumer interest"⁶³ is also relevant to the discussions of the relationship between the NZa and ACM in Chapter 4 and the NZa's role in merger control in Chapter 5.

II. The "Four Categories of English healthcare"

As noted above, the focus of the thesis is on the competition provisions of the HSCA 2012, thus on competition in the English NHS. However, the perceived distinction between the NHS (public) and PH (private) healthcare in England, combined with the separation of the purchasing and providing functions⁶⁴ produces four categories as follows:

⁶³ As required by Article 3(4) Dutch Healthcare (Market Regulation) Act 2006 (Wmg). For a comprehensive discussion of this, see Sauter (2009) supra n62.

⁶⁴ This underpinned the limited degree of competition of the NHS internal market (1989-1997) and was retained.

1.	2.	3.	4.
Public Purchaser	Public Purchaser	Private Purchaser	Private Purchaser
and	and	and	and
Public Provider	Private Provider	Public Provider	Private Provider

Figure 3: Relationship between the NHS and PH sectors as demonstrated by the purchaser/provider separation.

These categories have been used to delineate the PH market⁶⁵ (as comprising categories 3 and 4 only) and the additional numbering has facilitated discussion of the applicability of competition law.⁶⁶ The use of these categories here is intended to build on these previous discussions, as well as to underpin the analysis of this thesis. Categories 1-4 are considered in more detail in the context of competition in English healthcare in Chapter 2. However, the distinction between categories 1 and 2 (NHS healthcare provision) and categories 3 and 4 (PH provision) is pertinent to the applicability of competition law as discussed in Chapter 3, the respective roles of Monitor and the CMA in applying competition law in Chapter 4 and the different tests used to assess mergers in Chapter 5.

2.5. Thesis outline: contributions and limitations

There are various related aspects which are not examined in this thesis, mainly because they are too peripheral to the explicit focus of the thesis on the HSCA 2012 reforms. For example, the development of Private Finance Initiative (PFI) in connection with English hospitals. While an important aspect of healthcare development which started with the Conservative governments of the early 1990s and expanded under New Labour, this is too linked with wider procurement concerns to feature here, although competition concerns may

⁶⁵ Office of Fair Trading (OFT), 'Private Healthcare Market Study', December 2011, OFT1396. Page13.

⁶⁶ See Okeoghene Odudu, 'Competition Law and the National Health Service' (*Competition Bulletin: Competition Law Views from Blackstone Chambers*, 8 October 2012).

well emerge in this connection. In addition, the Transatlantic Trade and Investment Partnership (TTIP), while courting controversy in relation to the NHS from various quarters, is also excluded. A more difficult exclusion has been the respective development of Personal Health Budgets in England and Personal Care Budgets in the Netherlands with regard to long-term care. While these initiatives may prove informative with regard to patient choice policies, they again are beyond the scope of the HSCA 2012 reforms.

By focusing on the competition provisions of the HSCA 2012, this thesis offers an early analysis and assessment of a relatively new and controversial piece of legislation which may prove tested by the implementation of the NHS Five Year Forward View in the next few years. In addition, the thesis responds to recognised needs for research into how the laws underpinning competition apply to the English NHS.⁶⁷ Furthermore, this thesis seeks to make contributions to various related areas of literature which encompass broadly competition law and health law.

First and foremost, it makes a contribution to discussions of competition in English healthcare. This is an area currently in development, but which has received comparatively little attention from a legal perspective thus far. Related to this, the comparative approach of the thesis enables a contribution to be made to growing literature which draws on individual national healthcare systems as case studies within wider considerations of EU law within healthcare and social sectors more generally. It also complements EU-level literature in this area.

Secondly, this thesis makes an original contribution both to health law and competition law. While it is possible that health may represent a niche area within wider competition law and competition perhaps little more than an afterthought within health law, the thesis seeks to assert that the correct place for discussions of competition in healthcare can both benefit, and benefit from,

⁶⁷ For example, it has been considered that 'Analysis regarding how competition law could apply to trusts in England's NHS is an open question worth further study.' See Julia Lear, Elias Mossialos, Beatrix Karl, 'EU competition law and health policy', in Elias Mossialos, Govin Permanand, Rita Baeten, Tamara K Hervey (eds), *Health Systems Governance in Europe – The Role of European Union Law and Policy*, (Cambridge University Press, 2010). Page 346.

both the fields of health law and competition law as health and competition lawyers can learn from each other.⁶⁸

Chapter 2 provides an overview of the introduction of competition and relevant legal provisions in both England and the Netherlands. While the introduction of competition has been discussed in various fora in the Netherlands, this chapter represents one of the first attempts to set the HSCA 2012 reforms in the context of previous developments within the English NHS regarding competition. Although this chapter may appear primarily descriptive rather than analytical, the contextual information it offers is essential to follow the discussions which follow in the thesis.

Chapter 3 focuses on both the *applicability* of the anticompetitive agreements and abuse of dominance provisions and *how* these have been applied to the Dutch and English healthcare systems thus far. In so doing, the chapter builds on previous considerations which tended to be restricted to whether competition law is *applicable*.⁶⁹ The analysis of this chapter suggests that the applicability of competition law to the English NHS is such that future enforcement activity may continue to focus on the PH sector. This may include NHS PPUs in light of the potential for an expansion of these following the removal of the private patient income cap by s.165 HSCA 2012.

Chapter 4's examination of the relationship between the competition authorities and new sectoral regulators for healthcare expands existing literature on sectoral regulation in healthcare from a law perspective.⁷⁰ The analysis of this chapter considers the differing relationships between the competition authority and regulator in the Netherlands (a "separate powers"

⁶⁸ An early endeavour in this regard can be found in André P. den Exter and Mary J. Guy, 'Market Competition in Health Care Markets in The Netherlands: Some Lessons for England?' [2014] 22(2) Medical Law Review 255-273.

⁶⁹ See, for example, Okeoghene Odudu, 'Are State-owned healthcare providers undertakings subject to competition law?' [2011] 32(5) European Competition Law Review 231-241.
⁷⁰ See, for example, Lindsay Stirton, 'Back to the Future? Lessons on the Pro-Competitive Regulation of Health Services' [2014] 22(2) Medical Law Review 180-199. Tony Prosser, 'Monitor, the Independent Regulator of NHS Foundation Trusts', Chapter 7 in Tony Prosser, *The Regulatory Enterprise – Government, Regulation and Legitimacy* (Oxford University Press, 2010), pages 136-152. More generally, see Jan-Kees Helderman, Gwyn Bevan and George France, 'The Rise of the Regulatory State in Healthcare: A Comparative Analysis of the Netherlands, England and Italy' [2012] 7(1) Health Economics, Policy and Law 103-124.

model) and England (a "concurrent powers" model) and suggests that the experience of other sectors is limited in view of how these relationships are developing.

Chapter 5's analysis of the use of general merger control and related modifications advances our knowledge of these provisions as they apply to healthcare. A legal perspective in this area is a useful addition to redress the balance as much of the literature thus far has focused on the economic aspects of merger assessment.⁷¹ In addition, this chapter is among the first, and certainly recent, considerations of mergers within the NHS from a law perspective.⁷² The analysis of this chapter examines how modifications respond to the specificities of the healthcare sector, and raise questions about the nature of collaboration in healthcare in light of the respective perceptions and reach of merger control and the anticompetitive agreements provisions.

Chapter 6 concludes with policy recommendations arising from the preceding chapters.

 ⁷¹ For example, Marco Varkevisser and Frederik Schut, 'The impact of geographic market definition on the stringency of hospital merger control in Germany and the Netherlands' [2012] 7(3) Health Economics, Policy and Law 363-381.

⁷² For example, Kiran Desai, 'Public hospital mergers: a case for broader considerations than competition law?' [2013] 34(12) European Competition Law Review 646-653.

Chapter 2

Setting the scene: context of competition in Dutch and English healthcare

Contents

2.1. Introduction	. 28
2.2. Thesis Discussion Frameworks and the discussions of this chapter	. 28
I. The "healthcare structure" - macro, meso and micro levels	. 29
A. The macro level – state intervention	. 29
B. The meso level – healthcare purchasers	. 31
C. The micro level – healthcare providers	. 31
II. The continuum between healthcare provision as a public service overseen by government and a competitive marketplace overseen by a competition authority	. 32
III. A "competition-centric" or "healthcare-centric" approach	. 33
2.3. Competition in healthcare (1): General context	. 35
I. Defining the market	. 35
A. General remarks	. 35
B. The Netherlands	. 38
B1. The Dutch healthcare provision market	. 39
B2. The Dutch healthcare purchasing market	. 40
B3. The Dutch health insurance market	. 41
C. England	. 43
C1. The wider NHS and Private Healthcare (PH) markets and the four categories English healthcare	
C2. The NHS and PH purchasing markets	. 47
C3. The NHS and PH healthcare provision markets defined by reference to the for categories of English healthcare	
II. Is healthcare different?	. 51
A. What are the implications of healthcare being different in the context the Dutch and English reforms as discussed in this thesis?	
B. Dutch and English healthcare as markets in transition:	. 57
2.4. Competition in healthcare (2): Country contexts	. 58
I. The Netherlands	. 59

	0	islation underpinning the 2006 reforms relevant to the discussions of this	50
	B.	Notable events 2006-2016 relevant to the discussions of this thesis	
11.		d	
	A.	The HSCA 2012 and elaboration of competition in the English NHS	
	В.	Notable events 2012-2016 relevant to the discussions of this thesis	67
2.	5. Conc	lusions	69

2.1. Introduction

This Chapter sets the scene for the subsequent substantive discussions of Chapters 3-5 by elaborating contextual aspects of competition in healthcare, as well as aspects specific to the Netherlands and England, respectively.

Section 2.2 builds on the explanations of the three thesis discussion frameworks outlined in Chapter 1 to add to this contextualisation.

Section 2.3 examines the general context of competition in healthcare by reference to market definition and the question of whether healthcare is different, thus merits special treatment.

Section 2.4 outlines the country-specific context of competition in healthcare in England and the Netherlands by reference to the legislative framework in each country and an overview of notable events relevant to the thesis discussions subsequent to the 2006 and HSCA 2012 reforms which are shaping their development.

Section 2.5 concludes.

2.2. Thesis Discussion Frameworks and the discussions of this chapter

This section develops the overview of the thesis discussion frameworks set out in Chapter 1.

I. The "healthcare structure" - macro, meso and micro levels

Appendices A and B set out in overview the different actors in the Netherlands and England at the different levels of the "healthcare structure", and how this is considered in connection with the chapters of this thesis.

A. The macro level – state intervention

The macro level typically comprises Ministerial intervention, but also includes the relationship between the competition authority and healthcare regulator as these effectively assume at least some of the oversight previously reserved to government in healthcare provision.

Counterintuitive developments appear to be emerging in the Netherlands and England in view of the 2006 and HSCA 2012 reforms. While the model of "managed competition" in the Netherlands would appear to rely more on independent agencies, intervention by the Minister for Health, Wellbeing and Sport is a recurrent theme. This stems in part from the Minister's role being to develop health policy, but day-to-day implementation being in the hands of the NZa and the ACM. Indeed, it has been suggested that considerations of market organization are subordinated to cost control as the driving political objective behind liberalization.¹ In contrast, while greater Ministerial oversight might be anticipated in a taxation-funded system such as the English NHS, the HSCA 2012 reforms reduce the role of the Secretary of State for Health considerably, and transfer much responsibility for healthcare provision to NHS England, which works with Monitor and the NHS Trust Development Authority (NHS TDA) (now NHS Improvement). While it may not be surprising that the Secretary of State for Health makes few public comments² about competition in the NHS in view

¹ Wolf Sauter, 'The balance between competition law and regulation in Dutch healthcare markets' (2014) TILEC Discussion Paper, DP 2014-041.

² For example, Jeremy Hunt recently drew a distinction between "good competition" and "bad competition" in response to a question about how to foster collaboration and integration within a system and culture based on competition during a Question and Answer session during the Nuffield Trust Health Policy Summit, 3 March 2016. "I think the answer to that, bluntly, is that there's good competition and there's bad competition. I don't think all competition is bad. I think we need to spur innovation, and I think you see some of the most extraordinary innovations coming from private sector operators in this country, in other countries, from voluntary sector and charities and we never want to close our eyes and ears to the potential that comes with that innovation. At the same time we don't want competition to prevent the joining-up of services that is so important for vulnerable patients

of his limited role foreseen by the new institutional architecture, he has not avoided criticism for a perceived lack of support for the HSCA 2012 reforms.³ What emerges from the foregoing is a complex picture in which state intervention may be undesirable but necessary to deliver policy objectives. It also raises important questions about potential misunderstandings about what competition (and consequently competition law enforcement) can achieve in respect of healthcare modernisation. Certainly the ACM has recently reiterated its stance that its capability is limited to taking action where there are breaches of competition law, which may be different to delivering a particular policy.⁴ The focus of the new NHS Improvement (formerly Monitor and the NHS TDA) on integration and downplaying of the importance it may attach to competition and mergers may also be construed in this light.⁵

As regards the substantive discussions of this thesis, general state intervention is considered in Chapter 3 in connection with the *applicability* of competition law, and in Chapter 5 with regard to the modifications of merger control for hospital mergers. Ministerial intervention, and the relationship between the

with complex needs that are going to be interacting with the service on a daily basis. I think that the Milburn view of the world was coloured by the simplicity of saying that if you want a single, discrete piece of elective care, a hip or a knee replaced, then it's very easy to say well let's have a choice of providers and you can go to somewhere where you wait the shortest amount of time and you're happiest with the quality. And that's fine, and I think it works well. But when it comes to integrated care, I think it's absolutely right that the commissioners should choose in a competitive process the best people to provide elements of care, but then they need to join it up, so that from the patient's point of view it is seamless and integrated and, as you say, one NHS." <<u>http://www.summit.nuffieldtrust.org.uk/agenda-2016/2015/12/18/session-3-politics-keynote</u>>at 34-36 minutes.

³ The previous CEO of Monitor, David Bennett, criticised Jeremy Hunt for not supporting Monitor's implementation of the 2013 Regulations. Crispin Dowler, 'Bennett: Government 'micromanagement' creating 'dependency mindset' among leaders' Health Service Journal, 5 November 2015.

⁴ See ACM, Spreekpunten Henk Don bij rondetafelgesprek 'kwaliteitloont' in de Tweede Kamer op 17 april 2015. ('Points for discussion by Henk Don at the "Quality Pays" round table discussion in the Second Chamber 17 April 2015').

⁵ See comments by Ed Smith to the Health Select Committee on 19 January 2016 in response to Question 33 regarding the balance between putting contracts out to tender with use of public money. "It is important in the short term that we absolutely focus on the key issues. The key issues are getting the money right in the system. The reports from the King's Fund and others have shown in the past that mergers and other forms of integration have not necessarily achieved benefit. [...] There are examples of where competition has not worked, but, equally, there are good examples of where competition does work."

Minister, regulator and competition authority is considered specifically in Chapter 4.

B. The meso level – healthcare purchasers

The meso level comprises the private health insurers in the Netherlands and NHS Commissioners (the new Clinical Commissioning Groups (CCGs) and NHS England) in England. Purchasing functions are considered primarily in connection with the *applicability* of competition law (Chapter 3). However, the Dutch health insurers play an important role in defining the NZa's focus on patients as discussed in Chapter 4 as well as being referenced in connection with merger control (Chapter 5). NHS commissioners are also considered in connection with Monitor's powers to censure potential anticompetitive behaviour under the National Health Service (Procurement, Patient Choice and Competition) Regulations (No.2) 2013 (Chapter 4).

C. The micro level – healthcare providers

The micro level comprises healthcare providers. These feature throughout the thesis, with an emphasis on hospitals in connection with merger control in Chapter 5. Discussion of healthcare providers in England is also particularly relevant to Chapters 3 and 4 regarding the *applicability* of competition law and the respective remits of Monitor and the CMA in applying this. This is due to the need to distinguish divergences in approach according to whether a private provider is operating in the PH sector, or delivering services for the purposes of the NHS. Further considerations emerge, conversely, regarding whether an NHS provider is delivering NHS or private services.

A further complication regarding healthcare providers in England arises where these assume purchasing functions, most obviously in the case of the new CCGs. Conflation of purchasing and providing functions raises additional questions regarding the *applicability* of competition law, so is examined further in Chapter 3.

II. The continuum between healthcare provision as a public service overseen by government and a competitive marketplace overseen by a competition authority

At first glance, it might appear that the continuum framework is better suited to analysing the changes taking place in England in light of the HSCA 2012 reforms. However, the Bismarck corporatist model of Dutch healthcare does not detract from the idea of the continuum, despite relying to a greater degree on the private sector delivering public services than has been the case previously in connection with the Beveridge taxation-funded system of English healthcare. This is because the continuum is as concerned with a change in oversight (that is, ranging from exclusively Ministerial oversight to exclusive oversight by a competition authority).

Thus concerns arising from the Minister for Health, Wellbeing and Sport retaining competence for setting policy direction, while the NZa and increasingly the ACM implement policy in practice offer an additional perspective on the conception of competition in healthcare developing independently. The continuum framework is relevant to all three substantive chapters (Chapters 3-5), particularly in view of the current transfer of the NZa's competition powers to the ACM, which suggests a situation more complicated than the end point of the continuum being reached.

Categories 1 to 4 of English healthcare appear to form a continuum between exclusively public funding and provision (or healthcare as the quintessential public service overseen by government) and exclusively private funding and provision (or a market-based system overseen exclusively by a competition authority). However, whether categories 2 and 3 merely mark points along the continuum with the ultimate aim of arriving at category 4 is questionable in light of the ongoing relationship between the NHS and PH sectors. While this continuum is useful for sketching a conceptual framework to discuss what may (or may not) be happening with regard to competition in healthcare, it is important to understand that the relationship between the NHS and PH markets should not necessarily be understood in these terms. Rather, the

supplementary nature of PH, and the increasingly complex interactions between the PH and NHS markets suggest a picture more complicated than a simple narrative of the NHS ceding ground to the PH sector, although it has been suggested that the HSCA 2012 reforms have their roots in proposals to this effect.⁶ With regard to the NHS, the narrative of developing competition leads less to a competitive marketplace overseen by a competition authority and more to a change of direction, in view of the suggestion that the NHS competition regime represented something different⁷ and the HSCA 2012 reforms build on this. The continuum framework is relevant primarily to the discussion of "NHS-specific" merger tests (Chapter 5), but is also associated with the *applicability* of competition law (Chapter 3) and the relationship between the CMA and Monitor in applying this (Chapter 4).

III. A "competition-centric" or "healthcare-centric" approach

As suggested in Chapter 1, these approaches attempt to conceptualise a framework for examining the 2006 and HSCA 2012 reforms in light of the more general question of whether healthcare is different to other sectors, therefore merits special treatment. This question is further considered in Section 2.3 below.

In essence, a "competition-centric" approach suggests that healthcare is sufficiently similar to other sectors as not to merit special treatment, so the general law can be applied by the competition authority with few, if any modifications to this approach. In contrast, a "healthcare-centric" approach suggests that healthcare is different, therefore modifications to the general law, and involvement of a regulator may be necessary and even desirable beyond an initial transition phase.

⁶ For a comprehensive overview in light of the proposed Health and Social Care Bill, see Lucy Reynolds and Martin McKee, 'Opening the oyster: the 2010-11 NHS reforms in England' [2012] 12(2) Clinical Medicine 128-32.

⁷ Ioannis Lianos, 'Toward a Bureaucracy-Centred Theory of the Interaction between Competition Law and State Activities', Chapter 2 in Thomas K. Cheng, Ioannis Lianos, and D. Daniel Sokol (eds), *Competition and the State* (Stanford University Press 2014).

Within the Dutch healthcare system, there appear to be suggestions of both approaches, although it might be inferred that the "competition-centric" approach predominates.

The "healthcare-centric" approach is implicit in the very existence of the NZa and its competition powers (at least between 2006 and 2015) and the development of a "healthcare-specific" merger test.

In contrast, a "competition-centric" approach appears reinforced by the elaboration that the Dutch Competition Act (Mw) applies to the private health insurers, and by equity concerns being addressed to a certain extent by the classification of the risk equalisation scheme (RES) as a Service of General Economic Interest (SGEI). This serves to give effect in competition law to the model of competition illustrated by the Dutch "healthcare triangle". The transfer of the NZa's competition powers to the ACM may be included this approach.

In the English system, the tension between the two approaches can be related to the distinction between the NHS and the Private Healthcare (PH).

In the PH market, a "competition-centric" approach might be inferred due to the supplementary nature of PMI and PH. The supplementary nature⁸ of PH means that it can be treated as (closer to) a standard market than the NHS. Thus there is scope for entry and exit by providers as the NHS effectively fulfils a "provider of last resort" function vis-à-vis the PH sector (where NHS FTs are not acting as PH providers themselves via their Private Patient Units). This is evidenced by the inclusion of statistics regarding the transfer of PH patients to NHS facilities among the information to be made available by the Private Healthcare Information Network (PHIN) to PH patients as the PH sector is developed further following the CMA's market investigation.

⁸ As distinct from the complementary nature of private health insurance and provision found in other countries, for example, France. For a discussion of private health insurance in Europe, see Sarah Thomson and Elias Mossialos, 'Private health insurance and the internal market', Chapter 10 in eds. E. Mossialos, G. Permanand, R. Baeten, T.K.Hervey, *Health Systems Governance in Europe – The Role of European Union Law and Policy*. Cambridge University Press, 2010.

In contrast, the NHS market can perhaps be characterised by a "healthcarecentric" approach, which is perhaps more typical of healthcare markets elsewhere in Europe in view of the principle of universal access restricting the development of competition and limiting provider exit. Certainly the idea that merely elements of competition are desirable in healthcare was very much in evidence in the enactment of the HSCA 2012, which saw the coalition government's initial pro-competition proposals being scaled back to refocus on competition on quality, not price, and to replace Monitor's original function of promoting competition with a balancing act of anticompetitive behaviour with patients' interests.⁹

Overall, both approaches are discussed in connection with the applicability of competition law (Chapter 3), the relationship between the CMA and Monitor in applying this (Chapter 4), and merger control (Chapter 5).

2.3. Competition in healthcare (1): General context

I. Defining the market

A. General remarks

For the purposes of this thesis, 'healthcare' is understood in terms of three markets: health insurance, healthcare provision and healthcare purchasing.¹⁰ These three markets make up the Dutch "healthcare triangle" (outlined below and introduced in Chapter 1 and Appendix C), while in England, the focus is on healthcare purchasing and provision within the wider NHS and PH markets as health insurance is specific to the PH sector only.

 ⁹ On this point, see, inter alia, s.62(3) HSCA 2012 and NHS Future Forum, 'Choice and Competition – Delivering Real Choice. A report from the NHS Future Forum', June 2011. Page 9.

¹⁰ Smith describes these as "competition for health insurance", "competition for collectivelypurchased health services" and "competition for individual health services". Peter C. Smith, Market Mechanisms and the Use of Health Care Resources, Chapter 2 in OECD, Achieving Better Value for Money in Health Care, OECD Health Policy Studies, 2009.

While health insurance and healthcare purchasing may play important roles in developing competition in a healthcare sector as discussed below, competition regarding healthcare provision has received greater attention.¹¹

The feasibility of developing competition in connection with healthcare provision is subject to a range of factors, including institutional/political aspects as well as demand and supply-side factors. This is illustrated in overview as follows:

					Elective hip replacement	Major trauma services	Supporting diabetes patients	Cancer chemo- therapy	End of life palliative care	Community based mental health care
	Demand density	High	Medium	Low	High	Medium	High	High	High	High
Demand factors	Willingness to travel	High	Medium	Low	Medium	N/A	Low	Low	Low	Low
	Health impact of travel time	None	Minor	Major	None	Major	None	Minor	None	None
	Demand variability	Low	Medium	High	Low	High	Low	Law	Law	Low
Ease of acquiring	Search costs	Low	Medium	High	Medium	Low	Medium	Medium	Law	High
information	Switching costs	Low	Medium	High	Low	High	Low	Medium	Low	Medium
about output quality	Ease of defining & monitoring output & quality	Easy	Medium	Difficult	Easy	Medium	Medium	Medium	Easy	Difficult
	Economies of scale from fixed costs	Small	Modest	Large	Small	Large	Small	Small	Small	Small
	Sunk costs/specific assets	None	Small	Large	Small	Large	None	None	None	None
	Economies of scale from learning by doing	None	Modest	Large	Modest	Large	None	None	None	None
Cost/technology	Economies of scope	None	Modest	Large	Modest	Large	None	None	None	None
factors	Transactions costs with multiple providers	Low	Modest	High	Law	High	Low	Low	Low	High
	Dependence on network infrastructure	None	Modest	Large	None	Large	Modest	Modest	None	Modest
	Scope for cherry picking and/or dumping	None	Minor	Major	Minor	Minor	Minor	None	None	Minor
	Existing providers of same or substitute services	Several	Few	One	Several	Few	Several	Several	Several	Few
Short term supply side	Spare capacity in existing providers	Substantial	Modest	None	Modest	Modest	Modest	Modest	Modest	None
factors	Asymmetric competitive constraints	None	Modest	Substantial	None	None	Modest	None	None	Modest
	Input shortages (especially key staff)	None	Modest	Substantial	None	Modest	None	None	None	Modest
	Ownership	Private	Mixed	Public	Mixed	Public	Public	Public	Private	Mixed
Institutional/	Too important too fail	No	Maybe	Yes	No	Yes	No	No	No	No
political factors	Incumbent's reputation	Low	Moderate	High	Varies	High	Varies	Varies	High	Varies
	Fear of "hold-up"-low credibility of payers	None	Minor	Major	None	None	None	None	Major	Minor
Entry deterrence	Strength of entry deterrence by incumbents	None	Weak	Strong	None/weak	Strong	None/weak	None/ weak	None/ weak	None/weak

Figure 1: Office of Health Economics (OHE) competition feasibility framework with hypothetical examples.¹²

¹¹ See, for example, European Commission, Expert Panel on Effective Ways of Investing in Health (EXPH), 'Competition among health care providers in the European Union – Investigating Policy Options', 17 February 2015.

¹² Office of Health Economics (OHE): *Competition and the English NHS*. January 2012.

Overall, the framework indicates areas where introducing competition may be possible based on factors indicating ease, some concerns and difficulty (coded green, yellow and red, respectively). Thus from an institutional perspective, public ownership of providers of major trauma services may represent a barrier to developing competition, and the framework suggests that there is greater scope for competition within end-of-life palliative care or elective hip replacement.

An alternative conception of competition feasibility regarding healthcare provision is offered by the EU Expert Panel on effective ways of investing in health (EXPH), which defines "conditions for effective competition in health systems" as including the existence of multiple providers, easy entry and exit, standardised products and reliable and transparent information.¹³ In view of this framework, the EXPH assesses the propensity of different aspects of healthcare provision and ancillary activities thus:

Good conditions	Average conditions	Conditions unlikely to be met	
Pharmaceuticals	Hospital care	Emergency room	
Pharmacy distribution	Primary care	Pre-hospital emergency	
Patients' transportation	Preventive care	Intensive care	
Imaging	Long term nursing care		
Laboratorial tests	Long term home care		
	Medical specialists		
	Renal dialysis		

Figure 2: Propensity to fulfil conditions for effective competition in health systems.¹⁴

What emerges from the foregoing is a broad overview of how markets for healthcare provision can be defined. Market definition in healthcare proves difficult in view of the limitations of typical econometric tools such as the Small but Significant and Non-transitory Increase in Price (SSNIP) test in view of the "third party pays" principle. It further appears that questions of substitutability may vary according to different levels: thus for consumers there is little to no

¹³ EXPH (2015) supra n11. Section 1.2.3, 'Conditions for effective competition', paras 66-108, pages 31-43.

¹⁴ Ibid. Table 4 'Propensity to fulfil conditions for effective competition in health systems'. Page 72.

substitution for diagnoses (for example, hip treatment is not a useful substitute for heart surgery), but a limited degree of supply substitution may be possible (for example, an orthopaedic surgeon can operate on knees and shoulders alike).¹⁵ These aspects are considered further in Chapter 5 in connection with merger control, where hospital merger cases reveal market definition typically based on specialty, although a distinction is drawn in England between the NHS and PH sector.

How healthcare markets are defined specifically in Dutch and English healthcare in order to set the scene for the discussions of this thesis is now considered.

B. The Netherlands

In order to gain a sense of perspective on the Dutch healthcare market, it is useful to bear in mind the following statistics. As at January 2016, the Dutch population is approx. 17 million, healthcare expenditure is approximately ξ 70 billion (representing approximately 10% of GDP) and there are roughly 1.1 million people employed in the healthcare field.¹⁶

The focus of this thesis is primarily on the "cure" sector¹⁷ which relates to general medical care and has seen the most significant development of competition in line with the 2006 reforms.

For the purposes of this thesis, therefore, Dutch healthcare comprises three markets – healthcare provision, health purchasing and health insurance - illustrated in connection with the Dutch "healthcare triangle" introduced in Chapter 1 as follows:

¹⁵ Wolf Sauter, 'Experiences from the Netherlands: The Application of Competition Rules in Health Care', Chapter 14 in J Van de Gronden, E Szyszczak, U Neergaard, M Krajewski (eds), *Health Care and EU Law* (TMC Asser Press 2011). Page 345.

¹⁶ Ministry of Health, Wellbeing and Sport, *Healthcare in the Netherlands*, January 2016. Page 5.

¹⁷ As distinct from the "care" sector which relates to long-term care, and which has seen less development of competition. However the ACM has investigated anticompetitive activity in the "home care" sector and that further competition may be intended as one type of personal care budget (*persoonsgebonden budget*) has been brought within the purview of the Dutch Health Insurance Act 2006 (Zvw).

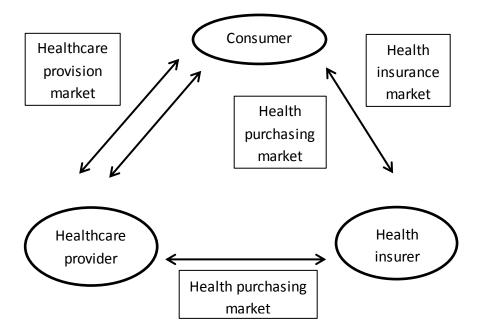


Figure 3: the Dutch "healthcare triangle".¹⁸

In essence, the framework established by the Dutch Health Insurance Act 2006 (Zvw) – namely, the obligation on all adults living and working in the Netherlands to take out a basic package of health insurance – underpins the development of a competitive health insurance market. From this, it is intended that competition will filter through to healthcare provision markets as insurers try to gain competitive advantage by securing the best deal possible from healthcare providers, and that consultants will be put under pressure to provide high quality competitive services by provider combinations such as hospitals.¹⁹

Each market is now considered in overview and related to the discussions of the thesis.

B1. The Dutch healthcare provision market

The healthcare provision market comprises healthcare providers (typically practitioners and hospitals). In its 2015 Annual Report, the NZa distinguishes

¹⁸ Wolf Sauter, 'Is the general consumer interest a source of legitimacy for healthcare regulation? An analysis of the Dutch experience' [2009] 2-3 European Journal of Consumer Law 419-434.

¹⁹ Sauter (2011) supra n15.

three categories of provision: specialist medical care (hospitals),²⁰ curative mental health care and primary care. The former Dutch Competition Authority (NMa) distinguished between different professionals and types of care on the basis that a physiotherapist cannot exercise competitive pressure on a dentist.²¹ Examples of healthcare provision markets identified in NMa cases include care for people with learning difficulties,²² mental health²³ and hospital care.²⁴ This thesis makes reference to cases involving hospital mergers (Chapter 5), and pharmacists and professional associations (Chapter 3).

B2. The Dutch healthcare purchasing market

The healthcare purchasing market comprises most obviously private health insurers, but also patients (particularly in connection with long-term care). Under the Dutch Health Insurance Act 2006 (Zvw), health insurers purchase care for policies where benefits may be delivered in kind. Thus within healthcare purchasing markets, further distinction can be drawn between, for example, the type of professional group (such as dentists, GPs or physiotherapists) or type of institution (such as hospitals or nursing homes).²⁵ Under Article 11 Dutch Health Insurance Act (Zvw), health insurers have a "duty of care"²⁶ to deliver healthcare or offer compensation. This has been interpreted as meaning, inter alia, that health insurers must pay attention to patient preferences, for example, for a healthcare provider within a certain distance, and purchase healthcare accordingly.²⁷ Thus the NMa suggested that the purchasing market for GP care would be local on the basis that a patient in

²⁰ In 2015, specialist medical care comprised 81 general hospitals, 8 university medical centres, 65 non-affiliated hospitals (which typically treat specific categories of patient – see glossary in Appendix F) and 198 independent treatment centres.

²¹ ACM, *Richtsnoeren voor de zorgsector* ('Guidelines for the Healthcare Sector') March 2010, para 82, page 26.

²² Ibid, para 85, page 26.

²³ Ibid, para 86, page 27.

²⁴ Ibid, para 87, page 27. Den Exter and Guy also consider a further aspect of the 2016 reforms, namely the expanded scope for entry by providers to the Dutch hospital market in the context of the Dutch Health Facilities Admission Act 2007 (*Wet Toelating Zorginstellingen* (WTZi)). See André P. Den Exter and Mary J. Guy, 'Market Competition in Health Care Markets in The Netherlands: Some Lessons for England?' [2014] 22(2) Medical Law Review 255-273.
²⁵ ACM (2010) supra n21, para 80, page 26.

²⁶ See glossary in Annex F for further information.

²⁷ ACM (2010) supra n21, para 81, page 26.

The Hague is unlikely to want to see a GP in Amsterdam.²⁸ It is envisaged that selective contracting in primary care by health insurers may spur competition, but the NZa has acknowledged that this occurs to only a limited degree due to limited insight into differences in quality.²⁹ In connection with mental health, selective contracting based on treatment effects does not occur because these are not yet sufficiently comparable.³⁰ However, health insurers are engaging with more selective contracting initiatives in connection with specialist medical care.³¹ While the influence of healthcare purchasing is evident in the discussions in this thesis, it is compared and contrasted with healthcare provision (for example regarding the applicability of competition law in Chapter 3 and countervailing buyer power as a justification for approving hospital mergers in Chapter 5).

B3. The Dutch health insurance market

As regards the health insurance market, it has been noted that while prior to liberalisation, there were around 100 hospitals and 30 independent health insurers, in 2014 there were about 85 hospitals and four large health insurers (with an amalgamate of smaller regional insurers acting as a fifth player in the health insurance market).³² The four largest health insurers had a combined market share of 88.8% in 2015.³³

There are two elements of relevance to the discussions of this thesis.

Firstly, competition in the "cure" sector,³⁴ that is, the "basic package" of health insurance and system of mandatory private health insurance which enables

²⁸ Ibid.

²⁹ NZa, 'Stand van de zorgmarkten 2015' ('2015 Annual Report'), page 21.

³⁰ Ibid.

³¹ Ibid.

³² Sauter (2014) supra n1.

³³ NZa (2015) supra n29, page 20. This shows a slight decrease on 2014, where the market share was 89.6%.

³⁴ However, it should be noted that the Dutch health insurance market comprises two further elements: long-term care which is not generally amenable to insurance in a competitive marketplace, and supplementary health insurance (over and above the mandatory basic package of health insurance) which is subject to competition. See, for example, Marc Wiggers, De NMa en de NZa in de curatieve zorgsector – Een toetsing aan het Europees

mededingingsrecht ('The NMa and the NZa in the curative healthcare sector – an assessment against EU competition law') (Kluwer 2013), pages 322-326.

patients to choose three types of policy – "benefits-in-kind", "reimbursement" or "combination" – which essentially vary in terms of cost and an associated lesser or greater choice of provider. Thus a "benefits-in-kind" policy is cheaper than a "reimbursement" policy, but the latter affords free choice of provider (that is, to include providers with whom the insurer may not have a contract). This restriction is mitigated by Article 13 Dutch Health Insurance Act 2006 (Zvw), which provides that a patient with a "benefits-in-kind" policy may nevertheless exercise greater choice, and is entitled to a level of compensation as determined by the insurer.

Patients have the option of switching insurers and policies on an annual basis, and in 2015, 7.3% of patients did so.³⁵ Of the three policies, "benefits in kind" appears to be the most popular – with 55% of Dutch patients opting for this policy type in 2015, and a decline observed in the other two types.³⁶ The motivation for switching (or not) has been explained by the NZa thus:³⁷

Top 3 reasons for not switching	Top 3 reasons for switching			
46% satisfied with the coverage	23% chose a new health insurance			
of the policy as a whole	package with a lower total			
	premium			
30% have been with their current	14% expected their healthcare			
insurer for a long time	use to change			
20% are satisfied with the service	14% opted for a collective (as			
provided by their current insurer	opposed to individual) health			
	insurance			

Figure 4: Top reasons for switching / not switching.

Secondly, that the health insurance market is further subdivided into two categories: the "A segment", comprising services with tariff prices, and the "B segment", comprising services with liberalised prices. As at the end of 2015, approximately 70% of hospital service prices in specialist medical care had been

³⁵ An increase on 7% in 2014. NZa (2015) supra n29, p.22.

³⁶ Ibid.

³⁷ Ibid, page 22.

liberalised,³⁸ and in 2015, prices were liberalised for physiotherapy, exercise therapy, diet advice, care pathways and pharmaceutical care.³⁹ While the maximum tariff is still in place for speech therapy, the NZa has recommended to the Minister for Health, Wellbeing and Sport that prices be liberalised here too as they are currently below the tariff.⁴⁰

C. England

In order to get a sense of perspective on the markets comprising healthcare in England – broadly, the distinction between the NHS and the PH sector – it is useful to bear the following in mind. In 2013, total healthcare expenditure accounted for 8.8% of GDP.⁴¹ Spending on both the NHS and the PH sector generally increased in the period 1997-2013.42 However, since 2009 there have been no real-terms increases, which coincides with the recession in the private economy and related period of public sector austerity.43 Publicly-funded healthcare (NHS) accounts for 83% of total healthcare expenditure and reached an estimated £127.5 billion in 2013.44

C1. The wider NHS and Private Healthcare (PH) markets and the

four categories of English healthcare

This thesis focuses on the HSCA 2012 reforms, thus competition within the English NHS. However, these reforms can best be understood within the within

³⁸ Ibid, page 48.

³⁹ Ibid, page 50.

⁴⁰ Ibid, page 21.

⁴¹ Office of National Statistics (ONS), 'Expenditure on Healthcare in the UK: 2013', March 2015.

http://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/healthcaresy stem/articles/expenditureonhealthcareintheuk/2015-03-26#toc>. This is less than the Netherlands - for an overview of how this compares to other countries (based on OECD Health Data 2015), see The King's Fund, 'Health Care Spending Compared to Other Countries', 11 January 2016.<http://www.kingsfund.org.uk/projects/nhs-in-a-nutshell/health-carespending-compared>.

⁴² Spending on the NHS rose from £63.8 billion in 1997 to £127.5 billion in 2013. While spending on private healthcare (that is, spending by patients on PH, as distinct from NHS purchase of PH services) also increased, a significant decline was noted in 2008-9, consistent with the economic downturn. See Nuffield Trust, 'UK spending on public and private healthcare'. <<u>http://www.nuffieldtrust.org.uk/data-and-charts/uk-spending-public-and-</u> private-health-care>.

the context of the wider relationship between the English NHS and the PH sector which has existed since the inception of the NHS. In particular, it is useful to recall two – related - concessions made by Aneurin Bevan necessary to implement the NHS in 1948: the option of part-time contracts which enabled consultants to continue with private practice alongside their NHS workload,⁴⁵ and the "peculiarly British compromise"⁴⁶ of private beds in NHS hospitals ("NHS pay-beds"),⁴⁷ now largely superseded by Private Patient Units (PPUs) which may be operated by either NHS Foundation Trusts (NHS FTs) or by PH companies, thus form part of the PH market.⁴⁸

The concessions suggest that – at least in very general terms – the relationship between the NHS and PH sectors might be described thus:

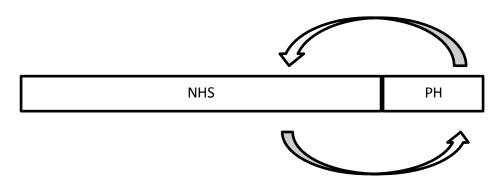


Figure 5: Patients and providers move between the NHS and PH sectors.

These two concessions are significant from a competition perspective because they effectively created – however unintentionally – the basis for a framework of demand and supply-side substitution between the NHS and PH sectors. This

<http://news.bbc.co.uk/1/hi/events/nhs_at_50/special_report/119803.stm>.

⁴⁵ Famously described in colourful terms by Bevan as "stuffing their mouths with gold". BBC News Website, 'Making Britain Better',

⁴⁶ Nicholas Timmins, *The Five Giants – A Biography of the Welfare State* (Harper Collins 2001), page 332.

⁴⁷ NHS pay-beds are to be distinguished from "amenity beds", which have also existed since the inception of the NHS and which enable an NHS patient to pay for an individual room for privacy without compromising their treatment within the NHS. Aneurin Bevan suggested that the number of amenity beds should be increased, while pay-beds represented a "defect" of the NHS which undermined the fundamental principle of equality of treatment. See Aneurin Bevan, 'A Free Health Service', Chapter 5 in Aneurin Bevan, *In Place of Fear* (Quartet Books 1978), page 115. It appears that "amenity beds" still exist, but may be located in private wards within NHS hospitals. See, for example, Papworth Hospital NHS Foundation Trust website, 'Important Information'.

<<u>http://www.papworthhospital.nhs.uk/content.php?/patients_visitors/patient_information/i</u> <u>mportant_information</u>>.

⁴⁸ CMA, Private Healthcare Market Investigation Final Report, April 2014, para 6, page 1.

is important because while typically patients have little to no substitution for a particular diagnosis, reforms in the NHS have resulted in a choice of NHS or PH provider for various elective treatments. In addition, while there may be some degree of substitution of surgeons performing operations within a particular specialty, the NHS/PH distinction offers an additional dimension to this.

In this conception, the PH sector comprises a competitive market in which the NHS can be regarded effectively as a provider of last resort. While this view is typically articulated by opponents of market-based reform, it nevertheless appears to be borne out among recent developments to the PH sector which include the provision of information regarding the amount of patients being transferred from a PH hospital to the NHS for treatment.⁴⁹

However, the relationship between the English NHS and the PH sector is ultimately more complex and may be based on cooperation as well as competition. Indeed, various of the NHS reforms underpinning the HSCA 2012 reforms involve the NHS as a consumer of PH services. This might be considered more cooperative, even symbiotic, since uptake of private medical insurance and access to private medical care can decline based on wider circumstances – for example, in periods of greater spending on the NHS under New Labour and during the economic crisis.⁵⁰ An awareness of the relationships between the NHS and PH sectors is useful since competition in the quasi-market of the NHS mirrors this, and indeed was used to "sell" patient choice reforms:

"The overriding principle is clear. We should give poorer patients [...] the same range of choice [i.e. the ability to choose a private provider] the rich have always enjoyed".⁵¹

⁴⁹ CMA Press Release, 'Better information for private patients moves closer', 1 December 2014.

⁵⁰ Sandeepa Arora, Anita Charlesworth, Elaine Kelly and George Stoye, 'Public payment and private provision – the changing landscape of health care in the 2000s'. Institute for Fiscal Studies / Nuffield Trust Research Report, May 2013. Page 30.

⁵¹ Tony Blair, 'We Must Not Waste This Precious Period of Power'. Speech Given at South Camden Community College, London, 23 January 2003. Cited in Zack Cooper, 'Competition in Hospital Services', OECD Working Party No.2 on Competition and Regulation, DAF/COMP/WP2(2012)2.

While the dynamics of the relationship between the NHS and PH can be utilised to create competitive tension with a view to improving efficiency, competition in the NHS has developed from a modified version of Enthoven's "managed competition" model in the form of the separation of purchasing and providing functions which underpinned the NHS internal market of the late 1980s and were retained by New Labour and still evident today.

The legacy of the purchaser/provider split and the relationship between the NHS and PH sectors provide the framework for the four categories of English healthcare discussed below and referenced throughout the thesis. It also made it possible to speak of healthcare purchasing and healthcare providing within the wider NHS and PH sector markets as follows:⁵²

1.	2.	3.	4.	
Public	Public	Private	Private	
Purchaser	Purchaser	Purchaser	Purchaser	
and	and	and	and	
Public	Private	Public	Private	
Provider	Provider	Provider	Provider	

Figure 6: Relationship between the NHS and PH sectors as demonstrated by the purchaser/provider separation.

The focus of this thesis is on the healthcare *provision* markets of primarily the NHS (categories 1 and 2), but the PH sector (categories 3 and 4) is considered briefly, most notably where NHS providers (typically NHS Foundation Trusts) treat private patients via PPUs in category 3. However, it is worth first noting briefly the composition of the *purchasing* markets of the NHS and PH sector for the sake of completeness.

⁵² Adapted from the relationships as set out in Office of Fair Trading (OFT), 'Private Healthcare Market Study', December 2011, OFT1396. Page13, and Okeoghene Odudu, 'Competition Law and the National Health Service' (*Competition Bulletin: Competition Law Views from Blackstone Chambers*, 8 October 2012).

C2. The NHS and PH purchasing markets

The NHS purchasing market (categories 1 and 2) comprises primarily NHS commissioners, typically the new Clinical Commissioning Groups (CCGs) for most services, but NHS England for specialist services. In addition, there appear to be limited circumstances in which an NHS patient may pay for care, but still remain within the NHS as opposed to becoming a private patient in the PH sector, and movement between the two may be possible subject to rules outlined by initially the Department of Health and subsequently NHS England.⁵³

The PH purchasing market (categories 3 and 4) comprise self-funding patients and patients with private medical insurance.

C3. The NHS and PH healthcare provision markets defined by reference to the four categories of English healthcare

The categories are now examined in turn, although generally reference will be made to the NHS and PH markets. As regards the composition of the provision markets as defined by the new licensing regime, currently 154 NHS FTs with a licence, and 108 "other providers" (that is, private or voluntary sector providers) with a licence.⁵⁴

Category 1 – Public Purchaser and Public Provider

Category 1 can describe the scenario of an NHS patient receiving treatment at an NHS Trust or a Foundation Trust (NHS FT), hence combining public purchase of healthcare (via taxation) and public provision. NHS Trusts are secondary care institutions (typically hospitals) conceived as part of the NHS internal market model to offer some degree of provider competition. New Labour developed these to introduce NHS FTs in 2004, which have a greater degree of financial autonomy from the Department of Health and have been overseen by an independent regulator, Monitor (in its original conception). Although NHS FTs

47

 ⁵³ Department of Health, 'Guidance on NHS patients who wish to pay for additional private care', 23 March 2009. NHS Commissioning Board (now NHS England), 'Commissioning Policy: Defining the boundaries between NHS and Private Healthcare'. April 2013. Ref: NHSCB/CP/12.
 ⁵⁴ NHS Improvement, 'NHS Foundation Trust Directory and Register of Licensed Healthcare Providers'. <<u>https://www.gov.uk/government/publications/nhs-foundation-trust-directory</u>>.
 Data provided regarding NHS FTs and other providers is up-to-date as at 1 July 2016.

have greater independence from government, their legal status is public benefit corporation so are to be distinguished from private providers, and thus Category 2.⁵⁵

Category 1 also offers an illustration of competition as envisaged by the NHS internal market whereby the then newly-constituted NHS Trusts (public providers) competed for NHS contracts with District Health Authorities (DHAs)⁵⁶ (public purchasers). In the intervening period, this arrangement has largely persisted, although additional providers have emerged in the form of NHS FTs, and alternative purchasers have existed, such as Primary Care Trusts (PCTs), now superseded by CCGs.

The subsequent discussions of this thesis reference Category 1 in various ways. For example, chapter 3 engages with the applicability of general competition law to NHS Trusts and NHS FTs. Chapter 4 builds on this by considering the differing agencies involved in oversight of NHS Trusts and NHS FTs. The distinction between NHS Trusts and NHS FTs is most evident in considerations of merger control in chapter 5, as s.79 HSCA 2012 confirms that general merger control is applicable to mergers involving NHS FTs.

Category 2 – Public Purchaser and Private Provider

Category 2 can potentially refer to any of the instances of PH delivery of NHS care for NHS patients facilitated by the Concordat signed by the NHS and the Independent Health Association (IHA) in 2000 as part of New Labour's NHS Plan. One example of such NHS-PH arrangements saw the establishment of Independent Sector Treatment Centres (ISTCs), as private clinics dedicated to treating NHS patients in order to reduce waiting lists. The Concordat thus paved the way for private providers to deliver NHS services (at the NHS tariff) in connection with various types of healthcare. The following diagram gives an indication of how arrangements under the Concordat have expanded beyond the original intention to harness PH capacity to manage NHS waiting lists to

 ⁵⁵ Odudu (2012) supra n52 similarly discusses NHS FTs in the context of category 1.
 ⁵⁶ For clarification of DHAs and the NHS Internal Market, see "NHS Internal Market" in Appendix G – Glossary – English healthcare sector).

cover a wide range of healthcare provision in cooperation with the NHS in the intervening fifteen years:

Type of service	Public provision	Type of provision by the Independent sector	Independent sector providers involved in this project
Primary care	NHS primary care trusts (until 2012) NHS community trusts (since 2012)	 General practice (mainly self- employed, surgeries and clinics) Dentistry (mainly self-employed, surgeries and clinics) Optometry (self-employed, private companies) Pharmacy (self-employed, private companies) 	 The Practice Group Eyecare Medical Ltd Oasis Healthcare Horizon Health Choices Ltd Care UK LloydsPharmacy Online Doctor
Secondary care	NHS acute trusts	 Private hospitals (routine elective) Independent sector treatment centres (ISTCs) 	 Ramsay Health Care BMI Healthcare Spire Healthcare Nuffield Health
Tertiary and specialist care	NHS acute trusts (subset)	Specialist care	 Trinity Hospice Fresenius Medical Care Renal Services Ltd
Urgent & Emergency care	 NHS ambulance services NHS acute trusts (via urgent care centres, A&E departments, and non- elective offering) 	Urgent care centres	Greenbrook Healthcare Care UK
Mental healthcare	NHS mental health trusts	Mental health services	The Priory Together Care UK
Community care	NHS care trusts (previously primary care trusts)	Community care services	 Care UK Virgin Care ORLA Healthcare Ltd Advantage Healthcare Group Healthcare at Home Independent Clinical Services Group
Social care	NHS care trusts Local authorities	Social care services	 Virgin Care Care UK Advantage Healthcare Group Healthcare at Home
Pharmaceuticals, devices/Pharmacy	 NHS acute trusts GP surgeries 	A range of prescription services	LloydsPharmacy Online Doctor
Wellbeing and prevention	 Public Health England NHS care trusts Local authorities 	 Health risk assessments, prevention and rehabilitation services Exercise, fitness and dietary services Digital fitness proposition 	Nuffield Health LloydsPharmacy Online Doctor
Diagnostics and scanning services	 NHS acute trusts Some GP surgeries 	 MRI scans Ultrasound Pathology testing Vascular testing 	 Alliance Medical Ltd InHealth Viapath LLP Independent Vascular Services (IVS) Horizon Health Choices Ltd Cobalt

Figure 7: Key provider types across the NHS and contribution of independent sector organisations⁵⁷

The above table sets out how NHS and private providers can deliver services within broad categories of "healthcare provision", such as "primary care", "community healthcare" and so forth within the NHS market. So, for example, although most secondary care may be delivered by NHS Trusts/Foundation Trusts, routine elective care may be delivered via private providers.

⁵⁷ NHS Partners Network/NHS Confederation, '15 Years of Concordat: reflection and renewal', June 2015. Figure 2.2 "The NHS provider landscape and independent sector provision", page 9.

Within this category, the NHS may represent a customer of the PH sector, although there are distinctions to be drawn between different types of care. For example, in the hospital setting, non-NHS providers compete for NHS work under the fixed national tariff. In contrast, there is no system of national pricing in community health and mental health services, so local commissioners determine the quality and price parameters of any contracting.⁵⁸ A rapid increase in independent sector provision of the latter has been observed.⁵⁹

As regards the substantive discussions of this thesis, Category 2 is significant. For example, a category 2 relationship illustrates the tension arising out of the *FENIN⁶⁰* judgment since it potentially involves private providers which would be subject to competition law (following Pavlov) not being subject to competition law by virtue of their providing healthcare for the purposes of the NHS. Category 2 relationships are further important to discussions of the relationship between competition authority and regulator since the HSCA 2012 makes several delineations where healthcare is provided for the purposes of the NHS, thus circumscribing scope for oversight by the CMA, inter alia under the Competition Act 1998 (Concurrency) Regulations 2014. In relation to merger control, however, category 2 relationships are least well represented, although scope is recognised for mergers involving NHS and PH providers.

Category 3 – Private Purchaser and Public Provider

If Category 2 can be regarded as including instances where PH providers operate within the NHS, then Category 3 offers a kind of mirror image, with NHS providers operating in the PH sector, for example by means of NHS FTs operating Private Patient Units (PPUs).⁶¹

Although the focus of this thesis is on the NHS (thus categories 1 and 2), category 3 is referenced where necessary as being fundamental to the point

⁵⁸ Sarah Lafond, Sandeepa Arora, Anita Charlesworth, Andy McKeon, 'Into the red? The state of the NHS' finances – An Analysis of NHS Expenditure between 2010 and 2014'. Nuffield Trust Research Report, July 2014.

⁵⁹ Ibid.

⁶⁰ Case C-205/03, FENIN [2006] ECR I-6295.

⁶¹ Other arrangements in this category might include public-private arrangements arising in the context of Private Finance Initiative (PFI) projects. Odudu (2012) supra n52 cites contracts to lease buildings and land by way of example.

made in the Introduction: that it is <u>essential</u> to be clear about whether a given situation involves PH providers operating in the NHS, or NHS providers operating in the PH sector. This is necessary because different consequences – regarding applicability of competition law and oversight by Monitor or the CMA – arise as a result of the HSCA 2012 reforms.

Category 4 – Private Purchaser and Private Provider

Category 4 is mentioned here for the sake of completeness only as it refers exclusively to the PH sector, thus is beyond the scope of this thesis because the HSCA 2012 reforms do not affect category 4 relationships or activities. However, it is important to note that in its guidance on competition law to private providers,⁶² the CMA emphasizes that the advice relates to PH sector activity (category 4), not NHS work (category 2).

II. Is healthcare different?

Whether or not healthcare is different is a question which has received perhaps most attention among health economists, with divergences of opinion appearing to influence competition lawyers engaging with competition in healthcare. In essence, the question "is healthcare different?" can be answered in two ways, with associated diverging implications.

On the one hand, healthcare may be perceived as being different from other sectors, with the implications that consumers and firms may behave differently, and that exit and entry by firms may not reflect experience of other sectors. Thus a range of standard assumptions regarding the benefit of competition may simply not hold true for healthcare. Perhaps most obviously, concerns about price competition are significant in (if not unique to) healthcare since lower prices are equated with lower quality. Such concerns have therefore prompted a focus on competition on quality. This represents the "healthcare-centric" approach framework.

⁶² CMA, '60-second summary – Private medical practitioners: information on competition law', 3 December 2015.

On the other hand, healthcare may be perceived as being either the same as, or sufficiently similar to, other sectors with the implication that standard assumptions regarding consumer and firm behaviour hold. Thus healthcare can be compared to automobile repair⁶³ on the basis that both involve relationships characterised by information asymmetry and principal-agent problems. This represents the "competition-centric" approach framework.

However, answers to the question of whether healthcare is different typically focus on an individual level, whereas the introduction of competition in healthcare involves change beyond this, at a systemic level. This appears to generate different comparisons. For example, perhaps a useful comparison is found in the US health economist Alain Enthoven's personal experience of moving from working in the US defence department to health:

"Like National Defence, medical care involved issues of life and death, values, uncertainty, complex and changing technology, and professional cultures that were not much concerned about cost vs. benefit."⁶⁴

Defence offers an interesting comparison since it would also be subject to a certain degree of political sensitivity, which characterises healthcare. Enthoven's insight is interesting since it is his model of "managed competition" which forms the underlying framework of the Dutch healthcare reforms and a modified version of this can be found in the NHS Internal Market and subsequent emphasis on the purchaser/provider distinction.

A further area of potential comparison opens up in the English context between the HSCA 2012 reforms and the coalition and Conservative governments' wider enterprise of opening public services up to competition and the evolution of the CMA's approach in this regard. That is to say that comparisons may become possible between social sectors, such as healthcare and education.⁶⁵ Some

⁶³ Martin Gaynor, 'Competition in Hospital Services', OECD Directorate for Financial and Enterprise Affairs Competition Committee, Working Party No.2 on Competition and Regulation, DAF/COMP/WP2(2012)3 06 Feb 2012.

⁶⁴ Alain Enthoven, 'Introduction' in Alain Enthoven, *Health Care, the Market and Consumer Choice* (Edward Elgar 2012).

⁶⁵ At least in England in view of the coexistence of state and independent schools and possible link between the development of NHS FTs and encouragement by the current Conservative government of schools to apply for Academy status.

aspects of the HSCA 2012 reforms appear largely in keeping with wider conceptions, for example, of competitive neutrality⁶⁶ and the development of choice tools such as NHS Choices and iwantgreatcare.org.⁶⁷ However, it is possible to discern potential divergence between these wider reforms and developments in the NHS – for example, Monitor's work regarding continuity regimes as an example of mechanisms making provision for exit from public markets on the one hand,⁶⁸ and the development of a "success regime", which has a direct link to the development of new care models in line with NHS England's Five Year Forward View⁶⁹ on the other.

Furthermore, attempts to emphasize comparisons between healthcare and other sectors may focus on questions of efficiency, whereas the real concern is about equity. This marks a significant point of divergence between healthcare in the United States and Europe,⁷⁰ it being acknowledged regarding the former that efficiency has assumed priority over equity.⁷¹ Equity can be understood in terms of "healthcare solidarity", or the principle of healthcare provision based on clinical need, rather than the ability to pay. A focus on equity implies a different demand function not based on willingness to pay and a divergence from the process of competition which generally requires a focus on winners and losers.

The principle of universal access to necessary healthcare, irrespective of a patient's ability to pay represents the ideational point upon which all Member States of the EU converge, regardless of the Bismarck/Beveridge model distinction.⁷² This therefore has relevance to examination of both the Dutch

⁶⁶ See, for instance, OFT, 'Competition in Mixed Markets: Ensuring Competitive Neutrality', OFT1242.

⁶⁷ See OFT, 'Empowering consumers of public services through choice-tools', OFT1321, April 2011. P.17-18.

⁶⁸ As referenced in OFT, 'Orderly Exit – Designing continuity regimes in public markets', OFT1468, December 2012.

⁶⁹ NHS, 'Five Year Forward View – The Success Regime: A whole systems intervention', 3 June 2015.

⁷⁰ On this point see Timothy Stoltzfus Jost, Diane Dawson, André Den Exter, 'The Role of Competition in Health Care: A Western European Perspective' [2006] Journal of Health Politics, Policy and Law, 31(3), 687-703.

⁷¹ Gaynor (2012) supra n63.

⁷² Tamara K. Hervey, 'Public Health Services and EU Law', Chapter 7 in Marise Cremona (eds), Market Integration and Public Services in the European Union (Oxford University Press 2011). Page 186.

and English reforms. Indeed, the wider English healthcare sector offers an additional dimension to discussions of efficiency and equity in healthcare. While the NHS represents concerns about ensuring equitable access to healthcare, private medical insurance is *supplementary*,⁷³ which may achieve a minimum standard, but does not address equity. This suggests that the PH sector can both operate in a manner closer to other sectors⁷⁴ yet represent an anomaly by reference to European healthcare systems.

The question of whether healthcare is different is relevant to the discussions of this thesis because of the implications which may follow in terms of applying general competition law. This is now considered.

A. What are the implications of healthcare being different in the context of the Dutch and English reforms as discussed in this thesis?

At first glance, the implication of healthcare being the same as, or similar to, other sectors is that no special treatment is required, and that application of general competition rules achieves enhancement of consumer welfare as per other sectors. Conversely, if healthcare is different, then modifications, or even separate, "healthcare-specific" rules, are needed to ensure that competition is beneficial. Certainly the latter appears to offer the most accurate reflection of the approach of the legislators and competition agencies in implementing the competition reforms in both the Netherlands and England. This suggests that the question of strict enforcement of general competition rules is inextricably linked with the idea that healthcare is the same as other sectors. However, it appears possible to separate the two and acknowledge that healthcare is

⁷³ As distinct from *complementary* health insurance found in other European systems such as France. For a discussion of private health insurance in Europe, see Sarah Thomson and Elias Mossialos, 'Private health insurance and the internal market', chapter 10 in Elias Mossialos, Govin Permanand, Rita Baeten, Tamara K Hervey (eds), *Health Systems Governance in Europe* – *The Role of European Union Law and Policy*, (Cambridge University Press, 2010).

⁷⁴ For example, by allowing failing firms to exit the market.

different, yet nevertheless best served by the strict application of general rules (and exceptions), not "healthcare-specific" modifications.⁷⁵

Recent literature⁷⁶ analysing the Dutch and English reforms typically references the distinctive nature of healthcare, based on the US health economist Kenneth Arrow's elaboration⁷⁷ of the particular market failures of adverse selection and information asymmetry.⁷⁸ This enables discussion of whether and how general and "healthcare-specific" rules can be applied. This thesis contributes to this literature by considering, inter alia, the extent to which "general" provisions and mechanisms, such as concurrent powers and general merger control hold for the English NHS.

However, it is also important to consider the alternative view – that healthcare shares sufficient similarities with other sectors as not to merit special treatment. This is because such comparisons have been drawn in connection with both the Dutch and English reforms, even if these are not extended to discussions of the implementation of the reforms.

Thus the presumption of similarity has been used to "sell", or simply attempt to explain, competition reforms in healthcare. For example, in connection with the HSCA 2012 reforms in England, the former CEO of Monitor likened the HSCA 2012 reforms to the experience of liberalising utilities:

"We did it in gas, we did it in power, we did it in telecoms. We've done it in rail, we've done it in water. So there is actually 20 years' experience of taking monopolistic, monolithic markets and providers and exposing them to economic regulation."⁷⁹

⁷⁵ Edith Loozen, 'Public healthcare interests require strict competition enforcement' [2015]
119(7) Health Policy 882-888.

⁷⁶ For example, Loozen (2015) supra n75; Lindsay Stirton, 'Back to the Future? Lessons on the Pro-Competitive Regulation of Health Services' [2014] 22(2) Medical Law Review 180-199. Sauter (2011) supra n15.

⁷⁷ K Arrow, 'Uncertainty and the Welfare Economics of Medical Care' (1963) 53 Am Econ Rev 941.

⁷⁸ However, it is recognised that these particular market failures are found in other sectors, such as automobile repair.

⁷⁹ C Smyth, 'Gas and power markets are a model for the health service'. The Times. 25 February 2011.

In the Netherlands, the connection between having greater choice of provider and more expensive premia led to a parallel being drawn between health insurance and cable TV.⁸⁰

Blanket comparisons between healthcare and other sectors need to be mindful of the differing scope for competition in different healthcare system models. There is deemed to be greater scope for competition *in* the market within a Bismarck insurance system than in a Beveridge taxation-funded health service,⁸¹ and a greater degree of competition *for* the market in the latter.⁸²

However, some general distinctions can be drawn regarding "healthcare" in general terms, such as the greater number of providers in healthcare and the range of services they provide, the difficulty of measuring quality in healthcare (comparable with technical standards applied in electricity and gas markets) and the tension between competitive and integrated services being more acute in the healthcare sector.⁸³ Furthermore, from a distinctly English perspective, the following aspects set healthcare aside from utilities in particular: funding of the English NHS by general taxation, clinical networks, and the complex role of GPs as advisers, providers and commissioners.⁸⁴ This would appear to undermine comparisons between competition in the English NHS and the experience of liberalising utilities.⁸⁵ However, this is not to say that all comparisons are unhelpful. For example, comparative competition as used in

⁸⁰ BN De Stem, Zorg en kabel-tv: ze lijken op elkaar, ("healthcare and cable TV are similar") Interview with Marcel Canoy and Wolf Sauter, 7 February 2009.

<<u>http://www.bndestem.nl/algemeen/economie/zorg-en-kabel-tv-ze-lijken-op-elkaar-1.371011</u>>.

⁸¹ See, for example, Leigh Hancher and Wolf Sauter, *EU Competition and Internal Market Law in the Health Care Sector* (OUP 2012).

⁸² See OHE (2012) supra n12.

⁸³ Anna Dixon, Tony Harrison, Claire Mundle, 'Economic regulation in healthcare – what can we learn from other regulators?' The King's Fund, November 2011.

⁸⁴ Ibid. However, it is recognised that this multifaceted role may be shared with other providers of "repair" services.

⁸⁵ Indeed, in the same Times interview (supra n79), Bennett qualified his remarks thus: "It is too easy to say, 'How can you compare buying electricity with buying healthcare services?' Of course they are different. I would say...there are important similarities and that's what convinces me that choice and competition will work in the NHS as it did in those other sectors."

the water sector may provide a better basis for competition in the NHS than patient choice.⁸⁶

B. Dutch and English healthcare as markets in transition:

Related to the question of whether healthcare is different is the question of whether general, or sector-specific rules are most appropriate. One implication flowing from this is that sector-specific rules may be appropriate during a period of transition, but ultimately general rules will suffice, reflecting the "continuum" discussion framework.

The extent to which healthcare markets can be described as being "in transition" depends upon the type of healthcare system model, there being greater scope for competition within a Bismarck insurance model than a Beveridge taxation-funded system.⁸⁷ Thus the incremental changes to the Dutch system prior and subsequent to the 2006 reforms may be more accurately described as transitional.

In England, the situation regarding the NHS appears more complex. The competition reforms of the NHS instituted by the NHS internal market and continued under New Labour form part of "quasi-market" reforms of wider public services in the 1990s and 2000s. By definition, "quasi-markets" are not standard markets, so it follows that the general rules may not apply, or only in combination with sector-specific rules. Thus part of the New Labour reforms included the introduction of an "NHS-specific" competition regime for the NHS "quasi-market". This comprised the NHS Principles and Rules for Cooperation and Competition (NHS PRCC) and a merger regime to facilitate the "upgrade" of NHS Trusts to NHS FT status, overseen by the NHS Co-operation and Competition Panel (NHS CCP).⁸⁸ The NHS PRCC have been described, variously, as comprising the principles of competition law,⁸⁹ representing an "alternative

⁸⁶ Andrew Taylor, 'A Model of Data Transparency and Comparative Competition for the NHS?' (*NHS Competition Regulation* 5 February 2015).

⁸⁷ Hancher and Sauter supra n81, paragraphs 8.24-8.25, pages 232-3.

⁸⁸ Ben Bradshaw MP described the NHS Co-operation and Competition Panel thus, "We have created, in effect, the NHS' own Competition Commission". HC Deb, 24 February 2009, Column 66WH.

⁸⁹ Okeoghene Odudu, 'Are State Owned Healthcare Providers That Are Funded By General Taxation Undertakings Subject To Competition Law?' [2011] ECLR 32(5), 231-241.

source" of competition law,⁹⁰ and offering a "new style" of competition law for quasi-markets.⁹¹

An important question is therefore whether the competition policy instituted by the HSCA 2012 reforms serves to move the NHS away from a "quasi-market", with all the implications this may entail for applying general law. Answering this question would go well beyond the scope of this thesis, although the HSCA 2012 provisions examined in detail in this thesis – regarding the application of general competition law and general merger control – suggest that this may be the case. However, it should be noted that the 2013 Regulations (discussed in Chapter 4) resulted from the coalition government's proposal to put the NHS PRCC on a statutory footing,⁹² which suggests that the NHS may still be distinctive. Furthermore, more recourse has been had to the 2013 Regulations than to general competition law.⁹³

2.4. Competition in healthcare (2): Country contexts

It is important to bear in mind that competition is introduced in healthcare with a particular policy aim in mind, as distinct from the generic purpose of competition law being to enhance consumer welfare. For example, in the Netherlands, cost containment appears emphasized over and above the functioning of the market.⁹⁴ In England, the intention behind New Labour competition reforms as being to improve choice and quality was clearly articulated, and even made claims to enhance equal access.⁹⁵ The HSCA 2012 reforms appear an attempt to build on previous reforms. For example, at the time of the listening exercise conducted during the passage of the Health and Social Care Bill, David Cameron outlined the aims of the reforms as being, inter

⁹⁰ Odudu (2012) supra n52.

⁹¹ Lianos (2014) supra n7.

⁹² In response to the NHS Future Forum's recommendation that competition in the NHS be refocused.

⁹³ There have been five cases presented under the 2013 Regulations. The CMA has recently confirmed that in the 2015-16 financial year, no cases were brought requiring the use of concurrent powers. See CMA, 'Annual Report on Concurrency 2016', 28 April 2016, CMA54. This is consistent with activity in 2013-14 and 2014-15.

⁹⁴ On this point, see Sauter (2014) supra n1.

⁹⁵ Discussed in Cooper (2012) supra n51.

alia, to ensure a continuing free health service, promoting choice and enabling access to the best.⁹⁶

International comparisons suggest that competition and market-type mechanisms offer a solution to increasing pressures on healthcare systems. Consequently, the issue for policy makers thus is not whether markets are good or bad, but determining whether fostering some aspects of competition and markets in the health sector can lead to more rational use of resources, and which aspects of competition have the greatest potential to get results.⁹⁷

This section considers the legislative and policy frameworks underpinning the 2006 and 2012 reforms, as well as notable events in both countries relevant to the discussions of this thesis.

I. The Netherlands

A. Legislation underpinning the 2006 reforms relevant to the discussions of this thesis

While the 2006 reforms are wide-ranging, this thesis focuses on two aspects for reasons of space: the framework of mandatory health insurance as set out in the Dutch Health Insurance Act 2006 (Zvw 2006) which underpins the competition reforms, and the institutional framework of the competition reforms as elaborated by the Dutch Healthcare (Market Regulation) Act 2006 (Wmg 2006).

The Dutch Health Insurance Act 2006 (Zvw 2006):

The Zvw both governs the relationship between health insurers and healthcare providers, and sets out obligations on all adults⁹⁸ living or working in the Netherlands to take out a basic package (*basispakket*) of health insurance. The contents of this basic package of health insurance are determined by the

⁹⁶ PM's speech on the NHS, 14 June 2011. <<u>https://www.gov.uk/government/speeches/pms-speech-on-the-nhs</u>>.

⁹⁷ OECD, 'Introduction' in *Achieving Better Value for Money in Health Care*, OECD Health Policy Studies, 2009.

⁹⁸ Subject to limited exceptions. For an overview of the Dutch health insurance system, see <<u>https://www.government.nl/topics/health-insurance</u>>.

Minister for Health, Wellbeing and Sport and typically includes GP care, hospitalisation, specialist mental health care, and physiotherapy for people with chronic illnesses.⁹⁹ The private health insurance companies in the Netherlands must offer the basic package of health insurance to everyone at the same premium.¹⁰⁰ The basic package of health insurance is subject to a mandatory excess (€385 in 2016).¹⁰¹ Supplementary insurance is available for medical treatment and services not included in the basic package – thus deemed to be of the patient's own responsibility. It is possible for patients to choose one health insurance.

Competition within this system is based on patient choice of insurer and/or provider, depending upon the type of policy chosen, as noted above. The logic behind the system can be summarised thus: by competing among and between themselves for patients (according to different types of insurance policy), healthcare providers and health insurers are spurred into more efficient behaviours which contribute to the overall aim of competition in Dutch healthcare of saving costs.

The restriction of choice under a "benefits in kind" policy is mitigated by Art. 13 Dutch Health Insurance Act (Zvw), which provides that insurers are obliged to offer a certain degree of compensation to patients for treatment by providers with whom they have no contract. Although not considered in detail in this thesis, this provision is important for demonstrating the political sensitivity which attaches to access to healthcare. This was demonstrated by the 2014 "Christmas crisis" of the Dutch Labour/Liberal coalition government. This saw a near collapse of the government following opposition by Dutch Labour MPs to the Liberal Minister for Health, Wellbeing and Sport's proposals to restrict the "free choice of provider" (*vrije artsenkeuze*) accorded to "benefits in kind" policyholders. Although this was subsequently resolved in the wider refocusing

 ⁹⁹ See Ministry of Health, Wellbeing and Sport (2016) supra n16, pages 7-8.
 ¹⁰⁰ <<u>https://www.government.nl/topics/health-insurance/contents/standard-health-insurance</u>>.

¹⁰¹ Ministry of Health, Wellbeing and Sport (2016) supra n99, page 10.

of competition efforts, it nevertheless provides an important illustration of the need to be aware of healthcare values and the need to balance these with the primarily economic concerns of the competition rules.

The Dutch Health Insurance Act (Zvw) also contains an important provision from a competition law perspective. Article 122 Zvw provides that the Dutch health insurers are subject to Dutch competition law, which, at least at a national level, resolves the anomaly arising from the EU *AOK Bundesverband*¹⁰² judgment regarding healthcare purchasers in an insurance-based system. This is considered further in Chapter 3.

The Dutch Healthcare (Market Regulation) Act 2006 (Wmg 2006):

The Wmg supports the above system by establishing the Dutch healthcare regulator (NZa) with *ex ante* competition powers relating to Significant Market Power (SMP) investigations and contract terms¹⁰³ and defining its relationship with the ACM with its *ex post* powers to apply competition law,¹⁰⁴ and the Dutch quality regulator (IGZ).¹⁰⁵ The Wmg also outlines the relationship between the NZa and the Minister for Health, Wellbeing and Sport by empowering the NZa to set tariffs and determine which hospital services can be opened up to price negotiation. The Wmg also elaborated procedures involving merger control, although these were clarified further by soft law documentation such as the ACM-NZa Cooperation Protocols.

The Wmg is currently subject to amendment in light of the transfer of the NZa's powers regarding SMP and merger control to the ACM.

 ¹⁰² Joined Cases C-264/01, C-306-01 and C-355/01, *AOK Bundesverband* [2004] ECR I-2493.
 ¹⁰³ Articles 48 and 45 Wmg respectively.

¹⁰⁴ A relationship elaborated further via a series of Cooperation Protocols (*Samenwerkingsprotocollen*) in 2006, 2010 and 2015.

¹⁰⁵ Article 19 Wmg provides that the NZa is bound to follow the guidance of the IGZ with regard to advice on quality.

B. Notable events 2006-2016 relevant to the discussions of this

thesis

Since 2006, there have been a range of events which have influenced the development of competition in Dutch healthcare following the introduction of the Zvw and Wmg. The most relevant events to the discussions of this thesis are summarised here.

(i) Creation of the ACM in 2013:

Alongside the "healthcare-specific" competition reforms in the period covered by this thesis, there have also been significant changes to Dutch general competition policy, with the former Dutch competition authority (NMa) being incorporated into the ACM along with the former Dutch Consumer Authority and the former postal and telecoms regulator (OPTA). Although this appears to have had little bearing on the formal relationships which existed between the NMa and NZa,¹⁰⁶ it is relevant to the discussions of this thesis for at least two reasons.

Firstly, it was suggested that the NZa should also be incorporated (along with OPTA) into the new ACM.¹⁰⁷

Secondly, the inception of the ACM has accompanied an increase in "sectorspecific" regulation which includes rules in the water and media sectors as well as the NZa's competition powers.¹⁰⁸

Both aspects are relevant to the discussion of the relationship between the sectoral regulators and competition authorities in Chapter 4, particularly in

¹⁰⁶ Insofar as the relationship between the two agencies under the Wmg was subject to a mere substitution of NMa for ACM. While some amendments are evident in the ACM-NZa Cooperation Protocol, these primarily reflect the ACM's adoption of the former Consumer Authority's interests, so are beyond the scope of this thesis.

¹⁰⁷ Government proposal discussed in Barbara Baarsma and Martijn Snoep, 'Voeg toezichthouders NMa, OPTA, NZa en Consumentenautoriteit samen' ('Merge the NMa, OPTA, NZa and the Consumer Authority') (*MeJudice – Economen in debat*, 22 October 2010).
¹⁰⁸ For discussions of this, see Wolf Sauter, 'Sectors pecifiek mededingingsrecht en fusietoetsing' ('Sector-specific competition law and merger control'), Regel Maat (2013) (28) 2 and E.M.H. Loozen, 'Inrichting van meervoudig toezicht op marktwerking' ('Introduction of multisector regulation of competition'), Regel Maat (2013) (28) 2.

view of the current implementation of proposals to transfer the NZa's competition powers to the ACM (see (iii) below and Chapter 4).

(ii) Independent reviews of the NZa and Wmg 2006 in 2009 and 2014:

The development of the 2006 reforms has been monitored at different stages, which has helped inform the overall picture of competition in Dutch healthcare as discussed in this thesis.

In 2009 the Boer & Croon consultancy agency conducted a review of the first three years of the NZa's operation.¹⁰⁹ Its report therefore encompassed the initial issues of the NZa being created out of two previous agencies under the pre-2006 sickness funds scheme and its development in relation to this in view of continued functions (such as tariff-setting) and new role of "market umpire" (*marktmeester*) in respect of its competition functions under Art. 45 Wmg (power to intervene in contracts) and Art.48 Wmg (power to conduct SMP investigations). Boer & Croon concluded that the NZa had made a good start in difficult circumstances, but suggested that more was needed to establish the NZa as a truly autonomous agency independent of government. In 2009, a review was also conducted by academics which evaluated the Dutch Healthcare (Market Regulation) Act 2006 (Wmg).¹¹⁰

In 2014, Andersson Elffers Felix (AEF) consultants conducted a review of the NZa¹¹¹ which built on the 2009 report by Boer & Croon. Also in 2014, a separate, independent internal investigation was carried out into the NZa's working practices by the Borstlap Committee.¹¹² This was prompted by the suicide of an NZa employee, Arthur Gotlieb, and the investigation encompassed how Gotlieb

¹⁰⁹ Boer & Croon, *Evaluatie CVZ en NZa* ('Assessment of the Dutch Healthcare Insurance Board (CVZ) and NZa'), 25 September 2009.

¹¹⁰ R.D. Friele (eds), *Evaluatie Wet marktordening gezondheidszorg* ('Assessment of the Dutch Healthcare (Market Regulation) Act 2006 (Wmg)') (ZonMw, Den Haag 2009).

¹¹¹ Andersson Elffers Felix (in samenwerking met Radicand Economics and Tilburg Law and Economics Center (TILEC)), 'Ordening en Toezicht in de zorg: Evaluatie van de Wet marktordening gezondheidszorg (Wmg) en de Nederlandse Zorgautoriteit (NZa)', (AEF in cooperation with Radicand Economics and TILEC, 'Oversight and regulation in healthcare: Assessment of the Dutch Healthcare (Market Regulation) Act 2006 (Wmg) and the Dutch Healthcare Authority (NZa)') September 2014.

¹¹² H Borstlap, PFM van der Meer Mohr, LIE Smits, 'Het rapport van de onderzoekscommissie intern functioneren NZa', ('Report of the investigation committee on the internal operation of the NZa'), 2 September 2014.

had been treated as well as concerns he had raised about aspects of the NZa's work and relationship with the Ministry for Health, Wellbeing and Sport.

These reports have, to a greater or lesser extent, highlighted issues surrounding the NZa's status as an independent regulator in view of its position effectively between the Ministry for Health, Wellbeing and Sport on the one hand, and the ACM on the other. These issues are considered further in Chapter 4 in respect of the relationship between the sectoral regulators and competition authorities.

(iii) Transfer of NZa competition powers to the ACM in 2015:

Following the 2014 reports by AEF and the Borstlap Committee, the Minister for Health, Wellbeing and Sport has proposed important changes to the Wmg. This is intended in part to address the concerns that the NZa is perceived to lack sufficient independence from the Ministry for Health, Wellbeing and Sport on the one hand, and to strengthen competition in the healthcare sector on the other.¹¹³

Of the changes proposed, the most relevant to this thesis is the transfer of two of the NZa's competition powers – relating to SMP and the "healthcare-specific" merger test – to the ACM.¹¹⁴ While the ACM will have oversight over the day-to-day implementation of these tools, policy decisions in respect of these will remain with the Minister for Health, Wellbeing and Sport.¹¹⁵

These changes – and the implications for the relationship between the NZa and the ACM – are considered primarily in Chapters 4 and 5.

¹¹³ Edith Schippers, 'Kwaliteitloont' ('Quality Pays'), Letter from the Minister for Health, Wellbeing and Sport to the Chairman of the Second Chamber, 6 February 2015.
¹¹⁴ The power to intervene in contracts under Article 45 Wmg is to remain with the NZa.
¹¹⁵ The ACM is accountable ultimately to the Minister for Economic Affairs. However, this arrangement – whereby the ACM has oversight over the practical implementation of specific tools, but policy decisions fall under the remit of the sector-specific Minister – is found elsewhere, for example, in connection with transport.

III. England

A. The HSCA 2012 and elaboration of competition in the English NHS

In designing the system eventually implemented by the HSCA 2012, the Department of Health produced high-level guidance outlining how competition and regulation may operate in the English NHS.¹¹⁶ Thus it appears that while regulation and competition were deemed to always play an important role, a vision was set out of varying degrees of regulation as follows:

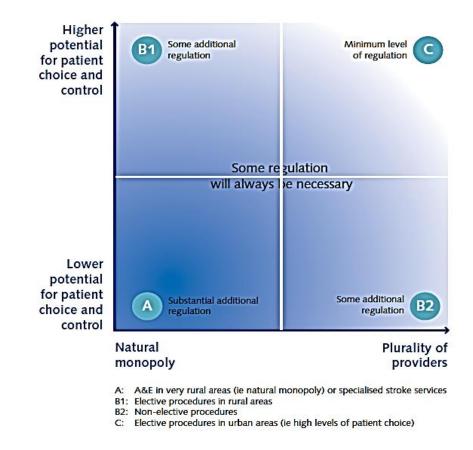


Figure 8: "Regulation and Competition will always play an important role"¹¹⁷

This demonstrates that distinctions were drawn between the natural monopoly elements of healthcare (such as emergency services in rural areas or specialised

¹¹⁶ This appears to be entirely separate from contemporary guidance produced by the then OFT regarding the wider enterprise of opening up public sector markets which reference some initiatives by Monitor, for example, in connection with choice tools and failure regimes. See for example, OFT documents supra n66 and n67.

¹¹⁷ Department of Health, 'Protecting and Promoting Patients' Interests: the role of Sector Regulation', page 19. December 2011.

<<u>https://www.gov.uk/government/publications/protecting-and-promoting-patients-interests-</u> <u>the-role-of-sector-regulation</u>>.

stroke services) and elements where varying degrees of competition may be possible (elective and non-elective procedures in rural and urban areas).

Furthermore, in implementing the HSCA 2012 reforms, it was envisaged that commissioners would be responsible for deciding whether to use competition, and if so, which form would be appropriate: ¹¹⁸

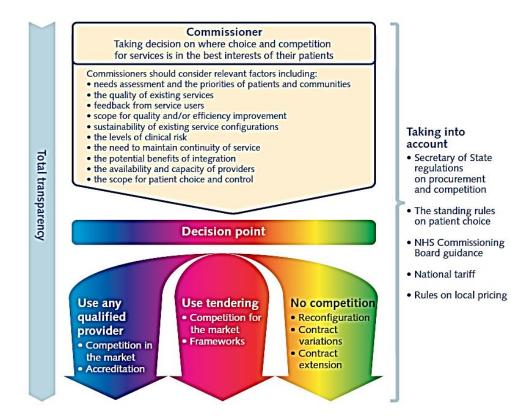


Figure 9: Commissioners decide when and how to use competition.

This approach distinguishes between the limited scope for competition *in* the market in the English NHS (activated by the "any qualified provider" (AQP) policy¹¹⁹ enabling choice of accredited NHS, private or voluntary sector providers) and greater range of competition *for* the market via procurement exercises. The option of choosing "no competition" is significant for underscoring the refocusing of competition within the NHS by the NHS Future Forum as noted previously.

¹¹⁸ Department of Health, 'Figure 5' in 'Sector Regulation – a short guide to the Health and Social Care Bill. What you need to know as a provider of NHS services', February 2012. <<u>https://www.gov.uk/government/publications/sector-regulation-a-short-guide-to-the-health-and-social-care-bill</u>>.

¹¹⁹ For further information on AQP, see the glossary in Annex G.

The suggestion that competition – and by extension, competition law – is something which can be applied or disapplied at will by NHS commissioners is controversial in view of the functional triggers for these laws and the potential for inconsistencies in approach. Rather, the emphasis shifts to the purpose of a competition policy vis-à-vis the NHS as simply designed to serve ends of advocacy and compliance, or whether to actually offer a basis for active enforcement of competition law. Experience from the Netherlands – where questions of whether competition law applies to private health insurers is considerably less controversial – suggests the former, as the latter enforcement has been minimal, partly as a result in part of a detailed regulatory framework.¹²⁰

This decision-making framework owed much to the foundation offered by New Labour reforms - notably AQP and compliance with the NHS PRCC.¹²¹ However, while development of the HSCA 2012 reforms has marked a period of change (discussed below), this framework can still operate as intended.

B. Notable events 2012-2016 relevant to the discussions of this thesis

As noted in Chapter 1, the HSCA 2012 proved a difficult piece of legislation to enact, being subject to a three-month pause which resulted in a scaling back of the original ambitions of the White Paper, *Liberating the NHS*. The most notable change to the competition provisions was the recommendations by the NHS Future Forum for a refocusing of competition and the removal of Monitor's duty to promote competition. A further proposal was to transplant the soft law provisions of the NHS Principles and Rules for Competition and Cooperation (NHS PRCC) into the secondary legislation which became the National Health Service (Procurement, Patient Choice and Competition) Regulations (No.2) 2013.

In view of such amendments, it may be tempting to question what the HSCA 2012 provisions actually change with regard to applying competition law to the

¹²⁰ On this point, see Sauter (2014) supra n1.

¹²¹ Department of Health (2012), supra n118.

English NHS. Certainly this question appears more pertinent to general competition law than merger control, which has proved a more active area in the interim. However, other HSCA 2012 reforms are very evident in their implementation – for example, the establishment of NHS England and associated reduction in Secretary of State for Health oversight of the NHS.

Since the enactment of the HSCA 2012, there have been three notable changes regarding competition in English healthcare which are relevant to the discussions of this thesis: the wider concurrency reforms of the Enterprise and Regulatory Reform Act 2013 (ERRA 2013) and the Competition Act 1998 (Concurrency) Regulations 2014 are examined in Chapter 4, while the development of the NHS Five Year Forward View (NHS FYFV) by NHS England in December 2014, and the establishment of NHS Improvement in April 2016 are considered briefly here.

(i) The NHS Five Year Forward View (NHS FYFV)

The relative lack of cases thus far subsequent to the HSCA 2012 reforms may be attributed to a certain extent to the current reorganisation of the English NHS in line with the NHS Five Year Forward View. This was developed by NHS England and other agencies in December 2014 and sets out a range of new care models, suggesting a move away from the Trust/FT distinction. Whereas previously, successive government policy since 2004 had been to "upgrade" NHS Trusts to NHS FT status (a process subsequently named the "Foundation Trust pipeline"), there has recently been indications that ratings of hospitals and other providers by the Care Quality Commission (CQC) provide better quality indicators than NHS FT status. In addition, it has been acknowledged that not all NHS Trusts are able to meet the requirements for NHS FT authorisation. Since 2013, alternative forms of organisation have been trialled for the remaining NHS Trusts (in a process described as the "Transactions pipeline"). The implications for changes in structure of NHS providers are examined in the context of merger control in Chapter 5. A further, important aspect of the NHS FYFV is a renewed emphasis on cooperation and integration with no mention of competition. This is significant for apparently suggesting

68

a move away from the purchaser/provider split which has underpinned competition reforms in the NHS since the NHS internal market.

Insofar as the HSCA 2012 competition provisions may be based upon an NHS structure which is now in evolution, the consequences for competition are unclear. However, the four categories of English healthcare can continue to offer a useful framework for future discussions, as can the distinction between the NHS and PH sectors. Indeed, new care models and organizational arrangements which depend on private sector involvement suggest that further relationships and activities will develop within category 2 (public purchasing and private provision).

(ii) NHS Improvement

Another recent significant change in NHS organisation has been the absorption of Monitor and the NHS Trust Development Authority (NHS TDA) into a new body called NHS Improvement. This has been achieved without recourse to primary legislation, since Monitor and the NHS TDA effectively comprise two elements under the "umbrella" organisation of NHS Improvement. This might be interpreted as a further retreat from the original White Paper proposal of having a sectoral regulator which promoted competition within the English NHS. However, it should be noted that no amendments to the HSCA 2012 provisions appear forthcoming. Indeed, the CMA has recently published its Memorandum of Understanding with NHS Improvement,¹²² which references the concurrency relationship elaborated with Monitor by the Competition Act 1998 (Concurrency) Regulations 2014. This is examined in detail in Chapter 4.

2.5. Conclusions

This Chapter has examined a range of aspects relating to both competition in healthcare generally, as well as aspects specific to the Netherlands and England. Together with the overviews and additional information provided in Appendices A-H in particular, the Chapter offers a point of reference for, and

¹²² CMA and NHS Improvement, Memorandum of Understanding between the Competition and Markets Authority and NHS Improvement, 1 April 2016.

contextual information underpinning the following substantive discussions relating to the applicability of competition law, the relationship between the competition authority and healthcare regulator, and modifications to general merger control (Chapters 3-5). This is useful as the notable developments outlined here suggest that the development of the 2006 and HSCA 2012 reforms may be taking on a different character to what was originally intended, namely, an apparent alignment of healthcare with other sectors vis-à-vis wider competition reforms.

Chapter 3

How does applying competition law impact healthcare provision in the Netherlands and England?

Contents

3.1. Introduction				
3.2. Thesis discussion frameworks and the discussions of this chapter				
I. The "healthcare structure" – macro, meso and micro levels				
II. The continuum between healthcare provision as a public service overseen by government and a competitive marketplace overseen by a competition authority				
III. A "competition-centric" or "healthcare-centric" approach				
3.3. The applicability of EU and national competition law – the "undertaking" framework				
 The EU competition law framework as defined by reference to the "undertaking" concept				
A. Overview of the "undertaking" concept				
B. AOK Bundesverband				
<i>C. FENIN</i>				
II. The EU competition law framework and the Dutch and English healthcare sectors				
A. Creating a national framework for applying competition law in national healthcare cases (1) – interaction between general competition law and healthcare reforms 85				
A1. The Netherlands85				
A2. England				
B. Creating a national framework for applying competition law in national healthcare cases (2) – parallel application of national and EU competition rule				
B1. The Netherlands				
(a) Art. 48 Wmg – SMP:				
(b) Art. 45 Wmg – contract powers:100				
B2. England				
3.4. Application of competition law in Dutch and English healthcare102				
I. Applying the anticompetitive agreements and abuse of dominance provisions to the healthcare sector – general remarks				
A. Anticompetitive agreements and healthcare103				

	B. A	buse of dominanœ and healthcare	105
	C. Competition law and healthcare – general conduding comments		
П	The Netherlands:		
	Α.	Application of the anticompetitive agreements provisions	108
	A1. Continuity of care		
	G	eneral continuity of care – out-of-hours service provision	109
	Ir	nformation-sharing and electronic networks	110
	A2. Professional associations in the Dutch healthcare sector		
	A3. Anticompetitive agreements in Dutch healthcare – concluding remarks		
	В.	Application of the abuse of dominance provisions	114
II	l.	England	116
	Α.	Application of the anticompetitive agreements provisions:	117
	A1. NHS providers in the PH sector (category 3):		
	A2. The English NHS (Categories 1 and 2):		
	В.	Application of the abuse of dominance provisions	121
3.	5.	Conclusion:	123

3.1. Introduction

One of the controversial aspects of the Health and Social Care Act 2012 (HSCA 2012) was the apparent underscoring of the *applicability* of competition law to the English NHS. While there had been a growing consensus that competition law – with its functional trigger requirement for an undertaking – was indeed applicable,¹ in response to the New Labour reforms discussed in Chapter 2, the enactment of the HSCA 2012 may nevertheless mark a turning-point in terms of the consequences of making this explicit.²

¹ Boeger and Prosser suggest that the radical changes introduced by New Labour may well have been enough for the NHS to have moved from a system organised on the basis of solidarity to one subject to competition law. See Nina Boeger and Tony Prosser, 'United Kingdom', Chapter 18 in Markus Krajewski, Ulla Neergaard, Johan Van de Gronden (eds), *The Changing Legal Framework for Services of General Interest in Europe – Between Competition and Solidarity*, (TMC Asser Press, 2009), page 367. Okeoghene Odudu, 'Are State Owned Healthcare Providers That Are Funded By General Taxation Undertakings Subject To Competition Law?' [2011] ECLR 32(5), 231-241. Ben Collins, 'Procurement and Competition Rules – Can the NHS be exempted?' The King's Fund Briefing, March 2015. ² See, for example, ACL Davies, 'This Time, It's For Real' [2013] M.L.R. 76(3), 564-588, Ioannis Lianos, 'Toward a Bureaucracy-Centred Theory of the Interaction between Competition Law and State Activities', Chapter 2 in Thomas K. Cheng, Ioannis Lianos, and D. Daniel Sokol (eds),

This controversy can be related to more general concerns about the undermining of the founding principles of the English NHS, and perhaps a misunderstanding about what applying competition law can achieve on the other. Certainly, subsequent to the HSCA 2012 reforms, it appears increasingly suggested that recourse may not be had to general competition law, in view of the development of the Competition Oversight condition of the NHS Provider Licence.³

However, the applicability of competition law to healthcare more generally has also generated much discussion in light of the framework established by EU case law.⁴ In general terms, a distinction has been drawn between providers and purchasers, whereby the former are subject to competition law, but the latter are not. This has influenced how competition law is perceived at a national level, with the *AOK Bundesverband*⁵ and *FENIN*⁶ judgments proving particularly influential in, respectively, the Netherlands and England.

Section 72 HSCA 2012 provides that Monitor and the CMA share concurrent powers to apply the UK and EU provisions governing anticompetitive

Competition and the State (Stanford University Press 2014), Marie Sanderson, Pauline Allen and Dorota Osipovic, 'The regulation of competition in the National Health Service (NHS): what difference has the Health and Social Care Act 2012 made?' (2016) Health Economics, Policy and Law, FirstView Article, May 2016, pp.1-19.

³ See, for example, Duncan Sinclair, "Undertakings" in competition law at the public-private interface – an unhealthy situation', [2014] ECLR 35(4), 167-171.

⁴ See, for example, Tony Prosser, 'EU competition law and public services' in Elias Mossialos, Govin Permanand, Rita Baeten, Tamara Hervey (eds), *Health Systems Governance in Europe: The Role of European Union Law and Policy* (CUP 2010), Julia Lear, Elias Mossialos and Beatrix Karl, 'EU competition law and health policy' in Mossialos et al. (eds), *Health Systems Governance in Europe: The Role of European Union Law and Policy* (CUP 2010), Johan Van de Gronden, 'The Treaty Provisions on Competition and Health Care' in Johan Van de Gronden,

Erika Szyszczak, Ulla Neergaard, Markus Krajewski (eds), *Health Care and EU Law* (TMC Asser Press 2011), Leigh Hancher and Wolf Sauter, *EU Competition and Internal Market Law in the Health Care Sector* (OUP 2012), Wolf Sauter, 'The Impact of EU Competition Law on National Healthcare Systems' [2013] E.L. Rev. 38(4), 457-478.

⁵ Joined Cases C-264/01, C-306-01 and C-355/01, *AOK Bundesverband* [2004] ECR I-2493. ⁶ Case C-205/03, *FENIN* [2006] ECR I-6295.

agreements⁷ and abuse of dominance⁸ in respect of the provision of health care services in England. This provision is examined in terms of substantive content in this chapter and institutional relationship (Monitor and the CMA's concurrent powers) in Chapter 4. This focus on s.72 HSCA 2012 means that references in this chapter (and thesis) to "competition law" are to be understood as comprising the anticompetitive agreements and abuse of dominance provisions only, in contrast to other aspects such as state aid.⁹ As the focus is on the applicability of competition law arising from s.72 HSCA 2012, limited reference is made to the Services of General Economic Interest (SGEI) exception as this has not received formal recognition in the English context.¹⁰

In order to understand what the effects of applying competition law on healthcare provision may mean in practical terms, this chapter examines the framework established by EU case law and the Dutch and English responses to this, as well as national cases and guidance thus far.

With the foregoing in mind, this chapter is structured as follows.

Section 3.2 demonstrates how the thesis discussion frameworks underpin the present discussions. Section 3.3 examines the framework established by EU and national competition law by reference to the "undertaking" concept which determines the *applicability* of competition law. Section 3.4 elaborates how the

⁷ The choice of the more generic term, "anticompetitive agreements", is chosen throughout this thesis since a range of agreements may be at issue – not only the most "hard core" example of cartels. It is recognised that this is in contrast to Dutch and EU-related literature, which references the "cartel prohibition" to refer both to Article 101 TFEU and Art. 6 Mw. See for example, Van de Gronden (2011) and Hancher and Sauter (2012) (both supra n4) for an EU focus and, with regard to the Netherlands, Wolf Sauter, 'The balance between competition law and regulation in Dutch healthcare markets' (2014) TILEC Discussion Paper, DP 2014-041, Wolf Sauter, 'Experiences from the Netherlands: The Application of Competition Rules in Health Care', Chapter 14 in Johan Van de Gronden, Erika Szyszczak, Ulla Neergaard, Markus Krajewski (eds), *Health Care and EU Law* (TMC Asser Press 2011).

⁸ Sections 2 and 18 Competition Act 1998 (CA98) (the "Chapters I and II prohibitions") and Articles 101 and 102 Treaty on the Functioning of the European Union (TFEU), respectively. ⁹ A further motivation for this specific focus arises from the consideration that how competition law operates in connection with healthcare is not well understood, whereas the contours of the state aid regime have been considered largely clarified – see Hancher and Sauter (2012) supra n4, para 9.66, page 282. However, it is recognised that how the state aid rules operate in connection with the English NHS continues to merit further research. See Boeger and Prosser (2009) supra n1.

¹⁰ Although it has been considered that NHS legislation may be capable of giving effect to this exception. See, for example, Boeger and Prosser (2009) supra n1.

provisions governing anticompetitive agreements and abuse of dominance can apply to healthcare and how these have been applied to Dutch and English healthcare thus far. Section 3.5 concludes.

3.2. Thesis discussion frameworks and the discussions of this chapter

I. The "healthcare structure" – macro, meso and micro levels

With regard to the *applicability* of competition law, the "healthcare structure" effectively mirrors the aforementioned distinctions between purchasers (meso level) and providers (micro level). However, the macro level of state intervention in healthcare also allows for a distinction to be drawn between instances where the state may engage in economic activities, thus be subject to competition law, and where it may not. For example, where a municipality grants a licence to sell tobacco, it is acting in its public authority capacity, whereas a public clinic selling flu shots is engaged in an economic activity.¹¹ However, the principle of imperium (regarding the exercise of sovereign powers) does not offer a blanket exemption so a case-by-case analysis will be necessary.¹² A further dimension to the macro level might be illustrated in two ways by the potential tension between the EU and Member State interaction. Firstly, a tension between Art.168(7) TFEU which defines the design of healthcare provision as a matter of Member State competence, and the decision of Member States to experiment with mixed public and private arrangements for healthcare provision, thus potentially triggering the applicability of competition law.¹³ Put simply: the choice of system is up to

¹² Lear et al.(2010) supra n4. Page 341.

¹¹ Lear et al. (2010) supra n4, page 341. For further discussion of the regulatory functions of the state in a healthcare context not being subject to competition law, see Erika Szyszczak, 'Modernising Healthcare: Pilgrimage for the Holy Grail?' in Markus Krajewski, Ulla Neergaard, Johan Van de Gronden (eds), *The Changing Legal Framework for Services of General Interest in Europe: Between Competition and Solidarity* (TMC Asser Press, 2009).

¹³ On this point, see Van de Gronden (2011) supra n4 and Johan W Van de Gronden, 'The Internal Market, the State and Private Initiative. A Legal Assessment of National mixed publicprivate arrangements in the light of European Iaw' (2006) Legal Issues of Economic Integration 33(2): 105-137. Van de Gronden and Szyszczak suggest that while Article 168(7) TFEU may be capable of curtailing the effects that result from the CJEU's case Iaw on competition, it may also expand the limits of the EU's role in public health relative to the

national authorities but they must accept the consequences of their decisions.¹⁴ Secondly, the triggering of EU competition law appears to prompt concerns about divergent approaches in individual Member States, thus "Euro-national" competition rules.¹⁵

II. The continuum between healthcare provision as a public service overseen by government and a competitive marketplace overseen by a competition authority

This framework is useful for discussing the applicability and application of competition law in terms of the tensions which arise between state and market actors. The use of market forces to provide healthcare inevitably leads to political tension on various levels. The fundamental conflict can be described as the unresolved tensions between a universalist model of health service, which emphasizes the principles of equal access and equal treatment of patients, and a market-driven model which emphasizes efficiency, innovation and market choice.¹⁶ This is exacerbated by the incompatibility of enhancing consumer choice and distributing goods and services on the basis of willingness (and ability) to pay on the one hand, and values of equal treatment and provision of treatment for free, on the other. ¹⁷ This continuum may also be conceptualised in terms of a binary distinction between a solidarity-based system and a competition-based system which appears to influence some EU case law, but which is ultimately problematic as most healthcare systems combine elements of both,¹⁸ and the distinction is unhelpful for the gradual, or

¹⁵ Van de Gronden (2011) supra n4. See also Johan van de Gronden and Erika Szyszczak, 'Introducing Competition Principles into Health Care Through EU Law and Policy: A Case Study of the Netherlands' [2014] 22(2) Medical Law Review 238-254.

previous Article 152 EC. See Johan Van de Gronden and Erika Szyszczak, 'Conclusions: Constructing a 'Solid' Multi-Layered Health Care Edifice', Chapter 19 in eds. J.W. van de Gronden, E. Szyszczak, U. Neergaard, M. Krajewski, *Health Care and EU Law*, TMC Asser Press, 2011.

¹⁴ Prosser (2010) supra n4.

¹⁶ Tony Prosser, *The Limits of Competition Law* (OUP 2005), p.9.

¹⁷ Prosser (2010) supra n4. These aspects are further summarised by the constitutional argument that citizenship rights are not well protected through markets because we do not come to markets as equals; our market power as consumers is determined by the existing distribution of wealth in which we are placed, and this determines our ability to satisfy our preferences in a market system. Prosser (2005) supra n16, p.29.

¹⁸ On this point, see, inter alia, Nina Boeger, 'Solidarity and EC competition law' [2007] EL Rev 319, Boeger and Prosser (2009) supra n1, Prosser (2010) supra n4.

even partial introduction of competition which may be necessary in political terms.¹⁹

III. A "competition-centric" or "healthcare-centric" approach

The discussions of this chapter regarding the applicability of competition law are necessary to either approach. However, this framework is concerned less with the mechanics of applying competition law and more with how it is interpreted – that is, whether it can accommodate healthcare values such as affordability, accessibility and quality.²⁰ In practice, competition law itself, rather than being concerned with the pure pursuit of consumer welfare through efficiency maximization, has weighed competing values and is perfectly capable of factoring into its own operation the distinctive needs of public services²¹ (thus healthcare).

3.3. The applicability of EU and national competition law– the "undertaking" framework

I. The EU competition law framework as defined by reference to the "undertaking" concept

This chapter is concerned with clarifying the defining features of the *applicability* of competition law and how this is being translated into actual *application* in practice within Dutch and English healthcare. Therefore, the focus of this section is on the "undertaking" concept in view of the fact understanding of other "boundaries" which may trigger the *applicability* of EU competition law are very much in development.²² Furthermore, consideration of the delineation of the *applicability* of EU competition law is limited to acknowledging the existence of the wider related EU concepts of Services of

¹⁹ Wolf Sauter, 'Services of general economic interest and universal service obligations as an EU law framework for curative health care' TILEC Discussion Paper 29, Tilburg University (2007).

 ²⁰ On this point see, inter alia, Van de Gronden (2011) and Sauter (2013), both supra n4.
 ²¹ Prosser (2005) supra n16, p.24.

²² For example, the state action doctrine. For a comprehensive discussion, see Sauter (2013), supra n4.

General Interest (SGI), ²³ and specifically Services of General Economic Interest (SGEI). This is because these "exceptions" have not been engaged in connection with applying competition law to healthcare *provision* in England and the Netherlands.²⁴ However, this may form a fruitful area for future research in view of recent attempts to connect the English NHS with both the SGI²⁵ and SGEI²⁶ concepts.²⁷ This section now considers the "undertaking" concept in overview before considering the *AOK Bundesverband* and *FENIN* judgments as these have proved respectively influential in shaping national frameworks for applying competition law in Dutch and English healthcare.

A. Overview of the "undertaking" concept

It is well established that the definition of an "undertaking" is functional, that is, the legal status of an entity under national law is not determinative. To this end, the basic test of whether or not there is an "economic activity" established

²³ An extensive literature exists in this area, and includes healthcare as a case study. By way of example, Wolf Sauter, *Public Services in EU Law*, (Cambridge University Press 2015), and Markus Krajewski, Ulla Neergaard, Johan Van de Gronden (eds), *The Changing Legal Framework for Services of General Interest in Europe – Between Competition and Solidarity*, (TMC Asser Press, 2009).

²⁴ Although the SGEI exception has been engaged in connection with the Risk Equalisation Scheme of the Dutch insurance systems regarding the state aid rules. See Hancher and Sauter (2012) supra n4.

²⁵ The National Health Service Bill 2015-2016 tabled by the Green MP Caroline Lucas was due to receive a Second Reading on 22 April 2016. Clause 1 of the Bill substitutes s.1 National Health Service 2006 regarding the duty of the Secretary of State vis-à-vis the English NHS, and clarifies that "the 'comprehensive health service' is for the purposes of Protocol (No.26) to the Treaty on European Union *[sic]* (Services of General Interest), a non-economic service of general interest".

²⁶ The National Health Service (Amended Duties and Powers) Bill tabled by the Labour MP Clive Efford received significant support on its second reading in November 2014 (241 Ayes, 18 Noes). It was eventually abandoned at Committee stage in March 2015 following protracted and circular discussions of the concept of "solidarity". Clause 1(2)(b) of the Bill sought to amend s.1 NHS Act 2006 regarding the Secretary of State's duty vis-à-vis the English NHS by imposing an obligation to "ensure that the health service is a public service which delivers services of general economic interest and operates on the basis of social solidarity." ²⁷ The possibility that the SGEI exception may afford some degree of protection to healthcare systems in general, and the English NHS in particular, has been widely acknowledged. See, for example, Odudu (2011) supra n1, Szyszczak (2009) supra n11, Albert Sánchez Graells, 'Monitor and the Competition and Markets Authority' (2014) University of Leicester School of Law Research Paper No.14-32. In addition, the organization of the English NHS has been considered to meet requirements for establishing SGEI (notably an act of entrustment with an SGEI). See, for example, Boeger and Prosser (2009) supra n1 and Tamara Hervey, Abigail Stark, Alison Dawson, José-Luis Fernandez, Tihana Matosevic and David McDaid, 'Long-term care for older people and EU Law: the position in England and Scotland', [2012] Journal of Social Welfare and Family Law 34(1), 105-124.

in *Höfner-Macrotron*²⁸ (clarified further as the offering of goods or services on a market by *Commission v Italy*)²⁹ appears deceptively straightforward. In practice, designation of an activity as "economic" or "non-economic" may be complicated as this is a problem of where to draw the dividing line and that it is hard to tell where the market ends and social solidarity starts.³⁰ Furthermore, the *AOK Bundesverband* and *FENIN* judgments respectively suggest that it is contingent upon a range of factors such as the potential for profit (as distinct from actual profit-making), the degree of competition within a healthcare system and the ultimate purpose of the activity, thus distinguishing between upstream and downstream activities.

Indeed, the expansive definition of an "economic activity" would appear to suggest that the threshold of establishing a "non-economic" activity is high. Thus within a healthcare context, this would require reliance upon a "non-excludability criterion", by reference to the example of smallpox vaccination, which requires a high degree of compliance to be effective.³¹ Interestingly, this appears not to have led to numerous calls for extending the wide-ranging *application* of competition law, but produced a more nuanced approach as opinions converge on the possibility for exceptions afforded by the SGEI mechanism.³²

As noted above, a distinction has been drawn between purchasers and providers by the EU courts, with the applicability of competition law to purchasers being questioned by connections being drawn between purchasing and solidarity.³³

²⁸ Case C-41/90 Klaus Höfner and Fritz Elser v Macrotron GmbH [1991]I-1979.

²⁹ Case C-35/96 Commission v Italy [1998] ECR I-3851.

³⁰ For a discussion of this in the context of state aid in Commission decision 2015/248 concerning compulsory health insurance in Slovakia, see Phedon Nicolaides, 'Non-Economic Activities', *Stateaidhub.eu* blog, 10 March 2015.

³¹ Odudu (2011) supra n1.

³² On this point, see variously Odudu (2011) supra n1, Szyszczak (2009) supra n11 and Prosser (2010) supra n4.

³³ Following Joined Cases C-159/91 and 160/91 *Poucet and Pistre* [1993] ECR I-637, as distinct from Case C-67/94, *Albany International v Stichting Bedrijfspensioenfonds Textielindustrie* [1999] ECR I-5751. For further discussion of the distinctions between these lines of cases, see, for example, Boeger (2007) supra n18 and Liam Goulding, 'Is the NHS subject to competition law?' (*eutopia law*, 19 July 2013).

In general terms, social solidarity is the idea that the state has duties to ensure equal treatment of citizens irrespective of their economic resources.³⁴ This appears to demonstrate a fundamental underpinning of European healthcare systems in general in the sense of universal access to healthcare,³⁵ and certainly the English NHS in the conception of providing healthcare according to clinical need, not the ability to pay. Solidarity has therefore been described as incompatible with a market-based view of citizenship underlying the full application of competition law to public sevices.³⁶ However, the concept has been criticised as increasingly opaque and overly complex, due in part to problems of assessment, but also to the fact that there is no one single type of institution whose activities will be considered "exclusively social".³⁷

In terms of EU case law relating to the healthcare sector, the approach appears to have evolved from solidarity providing a complete exemption from the competition rules in *Poucet & Pistre*,³⁸ via solidarity as a balancing mechanism to be weighed against competitive elements, such as we see in *AOK Bundesverband*. Ultimately, it might be considered that solidarity has effectively come full circle and ceased to function as a means of exempting the applicability of competition law. This can be seen in the further permutations of "internal" and "external" solidarity developed to allow the application of competition law in the UK *BetterCare* case.³⁹

The applicability of competition law to healthcare *providers* has proved relatively uncontroversial, and has relied on the functional approach of *Höfner*,

³⁴ Prosser (2005) supra n16, p.35.

³⁵ Indeed, solidarity has been hailed as an element which distinguishes the European approach to healthcare from the US. See Timothy Stoltzfus Jost, Diane Dawson and André Den Exter, 'The Role of Competition in Healthcare: A Western European Perspective' Journal of Health Politics, Policy and Law [2006] Volume 31, Number 3: 687-703. See also Tamara K. Hervey, 'Public Health Services and EU Law', Chapter 7 in Marise Cremona (eds), Market Integration and Public Services in the European Union (Oxford University Press 2011). Page 186.

³⁶ Prosser (2005) supra n16, p.35.

³⁷ Boeger (2007) supra n18.

³⁸Joined cases C-159/91 and C-160/91 Poucet & Pistre [1993] ECR I-00637.

³⁹ Case 1006/2/1/01 BetterCare Group Limited v Director General of Fair Trading [2002] CAT 6, [2002] Comp.A.R.229.

as evidenced for instance by *Pavlov*⁴⁰ and *Ambulanz Glöckner*.⁴¹ The *Pavlov* case established that an independent medical specialist who assumes financial risk and receives remuneration is an undertaking subject to competition law. *Ambulanz Glöckner* examined other criteria, such as public service obligations (PSOs), but linked these to the determination of an SGEI rather than the existence of an undertaking. The extent to which hospitals are subject to competition law appears to be influenced by the degree of state control, despite the fact that the TFEU does not discriminate between public or private ownership.⁴² Although public hospitals which provide services for free and receive state financing can be distinguished from self-employed doctors, ⁴³ these have nevertheless been recognised as undertakings by national competition authorities.⁴⁴

B. AOK Bundesverband

The *AOK Bundesverband* case saw German sickness funds (*Krankenkassen*) exempted from competition law as they fulfilled an exclusively social function based on their non-profit making status and inability to influence the level of benefits or contributions paid. This outcome has been considered hard to predict,⁴⁵ and criticised for not giving greater significance to the possibility for price competition within the system.⁴⁶ Ultimately, the finding of the predominance of solidarity elements (i.e. a risk equalisation scheme) over competition (on price via contribution rates, and on management and organisation by offering different services to consumers) in *AOK* has been described as controversial, and a step backwards from previous cases.⁴⁷

In using solidarity effectively as a reason for *not* applying competition law, it becomes a balancing mechanism and marks a departure from the functional

⁴⁰ Joined Cases C-180/98 to C-184/98, Pavel Pavlov et al Stichting Pensioenfonds Medische Specialisten [2000] ECR I-6451.

⁴¹ Case C-475-99, Ambulanz Glöckner [2001] ECR I-8089.

⁴² Art. 345 TFEU (ex Art.295 TEC).

 ⁴³ John Temple Lang, 'Privatisation of Social Welfare: EU Competition Law Rules', in Michael Dougan and Eleanor Spaventa (eds) *Social Welfare and EU Law* (Hart Publishing, 2005).
 ⁴⁴ For a comprehensive overview, see Odudu (2011) supra n1.

⁴⁵ Hancher and Sauter (2012) supra n4.

⁴⁶ Van de Gronden (2011) supra n4.

⁴⁷ Laura Nistor, *Public Services and the European Union: Healthcare, Health Insurance and Education Services* (TMC Asser Press, 2011), p.167.

approach. Instead of using the straightforward "potential economic activity" test of *Höfner*, the *AOK* case established a "potential for competition" criterion (considered by the CJEU as a consequence of, and by AG Jacobs as a condition for, the finding of an economic activity).⁴⁸ This is more elaborate because it considers not only the nature of the activity, but also its aim and legal framework. A potential consequence is that the existence of economic activities may be ruled out if the legislator has decided to exclude competition or to impose anticompetitive conduct in the general interest.⁴⁹ (The likelihood of these two extremes occurring may be increased by the view that competition and solidarity represent "two sides of the same coin").⁵⁰

The relative lack of clarity resulting from "some room for competition" ultimately had implications for the Dutch healthcare reforms in 2006 which are discussed below.

C. FENIN

Whether or not purchasing activities by managing bodies within taxationfunded NHS systems amount to economic activities was examined by the European courts in the Spanish *FENIN* case. This case involved claims that Spanish NHS bodies abused their dominant position, by making systematic late payments for medical goods and equipment used in Spanish hospitals. What was ultimately determined in this case, however, was whether the managing bodies were undertakings of the purposes of competition law. In *FENIN*, the distinction was drawn between upstream and downstream activities so that the ultimate purpose for the purchased goods, i.e. to provide free medical treatment within a publicly-funded system, was determinative in concluding that the Spanish NHS managing bodies were not undertakings, therefore not subject to competition law. This logic is useful for clarifying that bodies

⁴⁸ Julio Baquero Cruz, 'Beyond Competition: Services of General Interest and European Community Law' in Grainne De Búrca (ed), *EU Law and the Welfare State: In Search of Solidarity* (OUP 2005).

⁴⁹ Ibid, p.184.

⁵⁰ Somaya Belhaj and Johan Van de Gronden, 'Some room for competition does not make a sickness fund an undertaking. Is EC competition law applicable to the health care sector? (Joined cases C-264/01, C-306/01, C-453/01 and C-355/01 AOK)' [2004] E.C.L.R. 25(11), 682-687.

otherwise not regarded as undertakings are not subject to competition law "by the back door" because they engage in purchasing activities with private providers.⁵¹

More recently, dissatisfaction with the situation vis-à-vis English healthcare following *FENIN* has led to a proposed test whereby "actual or potential" economic activity on a downstream market can determine the *applicability* of competition law to either providers or purchasers.⁵² Whether this would succeed in clarifying the applicability of competition law to the English NHS is unclear. However, this test should be welcomed both for acknowledging that buying and selling amount to two sides of a single transaction, and also in view of the difficulty which can arise of separating purchasing and providing functions in healthcare.

The foregoing demonstrates the complexity of defining "undertakings" in healthcare and suggests that further clarification – if not refinement – would be beneficial of when a healthcare purchaser or provider is likely to be subject to challenge under the competition rules. There has been conceptualisation of the functional test of *Höfner* as an "abstract" test and consideration of additional criteria in *AOK Bundesverband* and *FENIN* as a "concrete" test.⁵³

The framework regarding the *applicability* of EU competition law outlined above has generated various issues regarding the application of EU competition law at a national level in the Netherlands and England. (This is a separate matter from the development of *ex ante*, regulatory rules which may amount to a "healthcare-specific" competition regime at a national level.) Such issues comprise an EU dimension and a national dimension.

⁵¹ Markus Krajewski and Martin Farley, 'Non-economic activities in upstream and downstream markets and the scope of competition lawafter FENIN' [2007] ELRev 29(6).
⁵² Sinclair (2014) supran3.

⁵³ See Johan W. van de Gronden, 'Purchasing care: economic activity or service of general (economic) interest?' [2004] ECLR 25(2).

II. The EU competition law framework and the Dutch and English healthcare sectors

The foregoing suggests a framework which may be limited in its ability to respond to the characteristics of individual Member States (where competition may depend as much upon purchasers as providers) and the increasing possibility that the EU rules may be triggered in view of healthcare providers in one member state delivering services in another.

This gives rise to concerns at both EU and national levels.

Perhaps the most obvious concern in this regard from an EU perspective is the need to ensure consistent application of EU competition law across (potentially) twenty-eight Member States. This is complicated not only by variations of healthcare system models (even within the broad Bismarck and Beveridge categories), but also the extent to which Article 168(7) TFEU⁵⁴ may protect the delivery of healthcare provision as a matter of Member State competence.⁵⁵

Despite the suggestion of the subsidiarity principle in Article 168(7) TFEU, which may imply that it is inappropriate for action at EU level, it has been considered that a process of "spontaneous harmonisation" has been taking place in the majority of Member States with regard to competition law whereby national competition authorities (and courts) may be confronted with healthcare cases to which they will have to apply national competition rules shaped in accordance with Articles 101 and 102 TFEU.⁵⁶ These have been termed "Euronational competition rules" for healthcare.⁵⁷ In terms of national perspectives

⁵⁴ Article 168(7) TFEU provides "Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of resources assigned to them. [...]".

⁵⁵ Van de Gronden and Szyszczak suggest that while Article 168(7) TFEU may be capable of curtailing the effects that result from the CJEU's case law on competition, it may also expand the limits of the EU's role in public health relative to the previous Article 152 EC. See Van de Gronden and Szyszczak (2011) supra n13.

⁵⁶ Van de Gronden (2011) supra n4.

⁵⁷ Ibid. For further discussion of this, see Van de Gronden and Szyszczak (2014) supra n15.

on applying competition law at a national level, two concerns are evident in both the Netherlands and England.

Firstly, how to make use of competition law to underpin competition reforms in view of the broad exemptions implicit as a consequence of the *AOK Bundesverband* and *FENIN* cases. This includes how to ensure that equivalent standards are applied to both sides of an economic transaction: that is, to allow for the possibility of applying competition law to healthcare purchasers (whether health insurers or NHS commissioners) as well as to healthcare providers in view of the inconsistent approach arising out of EU case law.

A further, but separate consideration is ensuring compliance with EU law in the development of national (regulatory) sector-specific competition rules in cases where parallel application may be an issue.

A. Creating a national framework for applying competition law in national healthcare cases (1) – interaction between general competition law and healthcare reforms

A1. The Netherlands

In the Netherlands, the *AOK Bundesverband* judgment created a certain degree of confusion about the applicability of competition law to the then Dutch sickness funds (*ziekenfondsen*) in operation prior to the 2006 reforms, as these had previously been deemed subject to Dutch competition law.⁵⁸

It will be recalled from Chapter 2 that the way competition works in the Dutch "cure" sector since 2006 can be illustrated as a triangle:⁵⁹

⁵⁸ For a discussion of this, see Van de Gronden (2004) supra n53.

⁵⁹ Wolf Sauter, 'Is the general consumer interest a source of legitimacy for healthcare regulation? An analysis of the Dutch experience' (2009) European Journal of Consumer Law 2 - 3/2009.

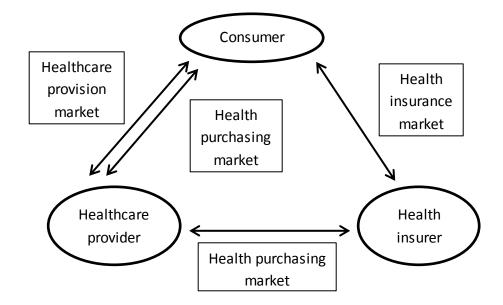


Figure 1: The Dutch "healthcare triangle".

Within this "triangle", there was little doubt that healthcare providers were "undertakings", but the status of the private health insurers was less clear in light of the *AOK Bundesverband* judgment. To clarify matters in light of the then incoming 2006 reforms, the formulation of Article 122 Dutch Health Insurance Act 2006 (Zvw) provided that even if the private health insurers are not "undertakings" for the purposes of Article 101 TFEU, they are nevertheless regarded as "undertakings" in the sense of Article 1 of the Dutch Competition Act (Mw).⁶⁰ The Explanatory Memorandum to the Zvw therefore drew a distinction between the 'not-for-profit' character of the German sickness funds performing their legal obligations in the *AOK Bundesverband* case and the system of mandatory private health insurers to be "undertakings" because the Zvw may only be implemented by insurers, and also due to their "for-profit" character.⁶² However, while the Dutch government acknowledged that its

⁶¹ Kamerstukken II, 2003-04, 29763, 3 - Regeling van een sociale verzekering voor geneeskundige zorg ten behoeve van de gehele bevolking (Zorgverzekeringswet). Nr.3, Memorie van Toelichting. (Second Chamber documentation, Parliamentary Session 2003-04, 29763, 3 (Explanatory Memorandum) - Regulation of social insurance for curative care for the whole population (Dutch Health Insurance Act 2006 (Zvw)).

⁶⁰ Article 1(f) Mw provides that an "undertaking" has the same meaning as "undertaking" under Article 101 TFEU.

<<u>https://zoek.officielebekendmakingen.nl/kst-29763-3.html</u>>, p.28. ⁶² Ibid.

designation had no decisive influence on any finding by the European courts, which may decide otherwise in respect of the health insurers, it considered that Article 122 Zvw offered a safety net to ensure adequate regulation of competition.⁶³ At least at a national level, Art.122 Zvw thus appears to enable equivalent standards to be applied to both sides of a transaction as both purchasers (the private health insurers) and sellers (healthcare providers) are potentially subject to competition law. This would appear to be consistent with the intention that both insurers and providers compete for patients.

A further aspect of the Dutch national framework for applying competition law in national healthcare cases arises from the development of a risk equalisation scheme (RES) to ensure universal coverage and avoid the market failure of adverse selection. This was given informal approval by correspondence in 2003 between Hans Hoogervorst (the then Minister for Health, Wellbeing and Sport) and Frits Bolkestein (the then Commissioner for the Internal Market).⁶⁴ Although the legal status of Bolkestein's response was unclear, the RES was formally categorised as an SGEI by the Commission in a State aid case.⁶⁵

The delineating framework of Article 122 Zvw and the SGEI classification therefore appear to operate both to ensure universal coverage and to enable competition law to be applied to both insurers and providers, thus giving effect to the "healthcare triangle" in line with the 2006 reforms.

A2. England

In order to understand the applicability of competition law vis-à-vis the English NHS, it is useful to recall the "four categories of English healthcare" introduced in Chapter 2 which demonstrate the purchaser/provider separation and the

⁶³ Ibid.

⁶⁴ The development of the Dutch private health insurance model is discussed in detail, particularly in connection with the Third Non-Life Insurance Directive, by Sarah Thomson and Elias Mossialos, 'Private health insurance and the internal market', Chapter 10 in eds. E. Mossialos, G. Permanand, R. Baeten, T.K.Hervey, *Health Systems Governance in Europe – The Role of European Union Law and Policy*. Cambridge University Press, 2010.

⁶⁵ For discussion of this decision, see inter alia Hancher and Sauter (2012) supra n4.

distinction between the NHS (categories 1 and 2) and the PH sector (categories 3 and 4):⁶⁶

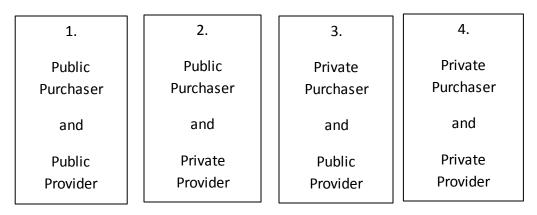


Figure 2: Relationship between the NHS and PH sectors as demonstrated by the purchaser/provider separation.

In overview, the *applicability* of competition law is uncontroversial in respect of the PH sector, whether category 4 or category 3 which may include NHS providers as these are not exempt by virtue of their "public", taxation-funded status.⁶⁷ This is evidenced by examples of enforcement activity being undertaken in respect of NHS FTs exchanging commercially sensitive information about their Private Patient Units (NHS PPUs) in category 3,⁶⁸ and anticompetitive information exchange and pricing agreements in the private ophthalmology sector in category 4.⁶⁹

However, a similar uncertainty to that experienced in the Netherlands arose regarding the applicability of competition law to the English NHS whereby the Competition Appeals Tribunal (CAT) had established in *BetterCare* that NHS Trusts (providers) in Northern Ireland involved in purchasing care home places were undertakings for the purposes of competition law, but the subsequent

⁶⁶ Based on the classification in Office of Fair Trading (OFT), 'Private Healthcare Market Study', OFT1396, p.13, and discussions in Okeoghene Odudu, 'Competition Law and the National Health Service', Competition Bulletin: Competition Law Views from Blackstone Chambers, 8 October 2012.

⁶⁷ For a robust explanation, see Odudu (2011) supra n1.

⁶⁸ OFT, 'OFT welcomes action by NHS trusts to ensure compliance with competition law' (OFT Press Release 71/12, 16 August 2012).

⁶⁹ CMA Case Reference CE/9784-13, Private Ophthalmology: investigation into anticompetitive information exchange and pricing agreements. Infringement decision 20 August 2015.

FENIN judgments of the General Court and the CJEU confirmed that purchasing activities with an ultimately social aim were not economic activities.

Two aspects arise from this: the relevance of *BetterCare* to the English NHS (categories 1 and 2), and the extent of incompatibility between *BetterCare* and *FENIN*.

The relevance of *BetterCare* – a case specific to a trust in Northern Ireland - to the English NHS has been considered difficult in view of the variations in health system structure and degree of private sector involvement in the NHS in the various countries of the UK.⁷⁰ However, as the English NHS is distinctive in the extent to which it has adopted a market-based approach, if it is possible to establish that a Trust in another, more publicly-oriented NHS, this will likely be the case in England as well. A further consideration is that BetterCare involved the purchase of care home places, and, by analogy with the Dutch "cure"/ "care" distinction, the characteristics of care home markets differ from healthcare services purchased in other contexts of the English NHS. For example, the care home market is deemed more responsive to competition than the English hospital sector.⁷¹ Whereas the latter may well be provided "free at the point of delivery" within a taxation-funded system in keeping with the principles of universal access, the former is subject to myriad funding arrangements⁷² with entitlement to NHS funding being determined by a distinction between "healthcare needs" and "social care needs".73 Considerations such as these suggest that drawing parallels between BetterCare and categories 1 and 2 ought to be approached with some caution.⁷⁴

⁷⁰ Lear et al. (2010), supra n4, p.346.

⁷¹ Andrew Street, "Overview" in Anita Charlesworth and Elaine Kelly (eds), *Competition in UK health care – Reflections from an expert workshop*. (Nuffield Trust and IFS Research Report, December 2013).

⁷² Which in England may involve Local Authorities as well as the NHS.

⁷³ For insights into this, see case law surrounding NHS Continuing Care Funding (now partially superseded by NHS personal health budgets). For example, R v North and East Devon HA Ex p.Coughlan [2000] 2 WLR 622 and R (on the application of Grogan) v Bexley NHS Care Trust [2006] EWHC 44 (Admin).

⁷⁴ On a related note, the impact of EU law of long-term care arrangements in England and Scotland have been considered by Hervey et al (2012) supra n27.

The extent of incompatibility between *BetterCare* and *FENIN* may be less than first appears.⁷⁵ After all, *BetterCare* was cited with approval by AG Maduro in *FENIN*, *FENIN* has been considered to amount to a pyrrhic rather than a substantive victory for shielding public healthcare provision from the application of competition law,⁷⁶ and, significantly, that *FENIN* should not be understood as overruling *BetterCare*.⁷⁷ This latter point arises in view of questions left unanswered by *FENIN*, perhaps most notably the lack of consideration of competition between providers⁷⁸ (a significant factor in *BetterCare*).⁷⁹

The discrepancy between treatment of purchasers and providers arising from *BetterCare* and *FENIN* appears to set a framework whereby competition law is applicable to healthcare providers, but not to purchasing activities unless the purchaser is also a provider. This appears to have informed the former OFT's 2004 policy note⁸⁰ in closing cases which involved purchasers which were not also providers, as well as its more recent guidance from 2011.⁸¹

Furthermore, the distinction between purchasing and providing functions may produce paradoxical results when these are conflated, for example in the new Clinical Commissioning Groups (CCGs). Thus the *applicability* of competition law to CCGs appears to risk being treated effectively as a question of whether purchasing "trumps" providing, or vice versa. Certainly it has been suggested

⁷⁵ However a point of divergence has been identified in connection with the funding issue. In *FENIN*, evidence of provision of services in the Spanish system to tourists for remuneration was deemed inadmissible so not considered by the Court when determining whether the purchasing operations were economic activities. In contrast, the CAT considered the a ctual percentages paid by individual residents in *BetterCare*. On this point, see Barry J. Rodger, 'The Competition Act 1998 and State Entities as Undertakings: promises to be an interesting debate' CLaSF working Paper Number 1 2003.

⁷⁶ Jennifer Skilbeck, 'Just when is a public body an 'undertaking'? Fenin and BetterCare compared', [2003] PPLR 4 NA75-77.

⁷⁷ Boeger and Prosser (2009) supra n1.

⁷⁸ AG Maduro proposed that further findings be made to determine whether the activities of the healthcare providers were themselves economic in nature, or based on the principle of solidarity. Case C-205/03, *FENIN* [2006] ECR I-6295, Opinion of AG Maduro, para 70(1). ⁷⁹ For a thorough consideration of the relationship between *BetterCare* and *FENIN*, see inter alia Skilbeck (2003) supra n76, Rodger (2003) supra n75, Prosser (2005) supra n16, Boeger and Prosser (2009) supra n1 and Prosser (2010) supra n4.

⁸⁰ OFT, The Competition Act 1998 and Public Bodies, Policy Note1/2004, August 2004, OFT443.

⁸¹ OFT, Competition Law and Public Bodies, 2011, OFT1389.

that if the former, then CCGs are unlikely to be subject to competition law (following FENIN and based on the logic that purchasing activities for the NHS would satisfy the solidarity principle of *Poucet et Pistre*),⁸² but if the latter, then NHS commissioners are indeed undertakings for the purposes of competition law.⁸³ The distinction between purchasing and providing functions is undoubtedly significant, for example, for clarifying the relative scope of competition law and procurement rules and understanding where gaps may exist for the purposes of tackling anticompetitive behaviour by purchasers.⁸⁴ However, while it is recognised that opinions diverge regarding whether anticompetitive behaviour by purchasers merits the same attention as that by providers, the separation of purchasing and providing functions by the NHS internal market underpinned an emphasis on provider competition, and there remains a significantly greater focus on competition for, rather than in the market as regards the NHS.⁸⁵ Thus the enactment of Art. 122 Zvw to clarify that competition law applies to health insurers to counteract AOK Bundesverband is logical to give effect to the "healthcare triangle" and "managed competition" model in the Netherlands, but it does not necessarily follow that an equivalent national provision in England to counteract FENIN may be either necessary or even desirable. This is not to deny that purchasing activity can be anticompetitive, but rather that the emphasis of the limited scope for competition within the English NHS (categories 1 and 2) is on providers, not purchasers. NHS patients do not choose commissioners in the way that patients choose insurers in the Netherlands.⁸⁶ However, it is acknowledged that the

⁸² As suggested by Goulding (2013) supra n33.

⁸³ For a thorough elaboration of this view, see Albert Sánchez Graells, 'Why are NHS Commissioners 'undertakings' and, consequently, subject to competition law?' (*How to crack a nut*, 2 June 2014).

⁸⁴ Odudu (2012) supra n66 suggests that the logic behind the CJEU's judgment in *FENIN* - that instead of competition law, the purchaser is subject to public procurement rules – would make sense if procurement law can be said to address all the risks as sociated with monopsony power.

⁸⁵ For an overview, see Office of Health Economics (OHE), *Competition in the NHS*, January 2012.

⁸⁶ Indeed, it might be considered that the only scope for purchaser competition exists in connection with the PH market (categories 3 and 4) via choice of private medical insurers. Whether the situation of a patient deciding to pay for healthcare provision themselves (as a "self-pay" patient) rather than "choosing" an NHS commissioner as purchaser amounts to purchaser competition is questionable.

apparent legal uncertainty arising from *FENIN* is unhelpful in the implementation of the HSCA 2012 reforms.

A more convincing explanation of the CMA's approach in practice stems from the consideration that the OFT's interpretation of *FENIN* may be too simple.⁸⁷ Rather, what was not clear from FENIN was the extent to which the provision of healthcare services itself was subject to competition.⁸⁸ Thus what may prove determinative is less the distinction between purchasing and providing, and more the scope for competition between providers in a given system. In other words, the greater the scope for competition between providers, the more likely it is that competition law is applicable. Without revisiting discussions of the relationship between solidarity and competition,⁸⁹ it is sufficient to note that such binary distinctions may not exist in practice⁹⁰ and are unhelpful for governments wishing to, or it being politically expedient to, experiment with only limited degrees of competition in healthcare.⁹¹ This is clearly demonstrated by the English experience, which amounts to a complicated marriage involving the embrace of competition and patient choice (triggering the applicability of competition law) and a longstanding and ongoing⁹² commitment to an NHS which is free at the point of delivery and based on clinical need, not the ability to pay (which may suggest a solidarity-based system not subject to competition law).

In practical terms, this suggests that different standards may apply depending upon whether a provider is operating in the NHS or the PH sector. Thus CMA guidance addressed to private providers is explicit that this does not apply to

⁸⁷ Boeger and Prosser (2009) supra n1.

⁸⁸ Ibid.

⁸⁹ See, inter alia, Boeger (2007), supra n18.

⁹⁰ On this point see Boeger and Prosser (2009) supra n1 and Boeger (2007) supra n18.

⁹¹ Sauter (2007) supra n19.

⁹² "The Government is committed to providing for patients and the public the highest quality, most compassionate health and care service in the world, built on the guiding principles of the NHS: that access to health care is based on need and not the ability to pay, and that services are comprehensive and available to all". Department of Health, 'The Government's Mandate to NHS England for 2016-17', January 2016, Introduction, para 1.1. "[...] if the NHS is to continue to thrive as a universal health service, free at the point of delivery – something which Monitor is committed to [...]" Monitor, 'Monitor's Strategy 2014-2017 – Helping to redesign healthcare provision in England', Summary.

their activities under employment with the NHS.⁹³ Conceivably, then, a private provider in category 2 may engage in anticompetitive activity regarding their NHS activities without fear of recourse, but not their PH activities in category 4. Conversely, as we have seen, NHS FTs are subject to competition law in respect of their PPU activities which fall within category 3, but possibly not with regard to their NHS activities in category 1 as these may not amount to economic activities.

This situation appears paradoxical as the radical changes under New Labour mean that it could well be that the [English] system has moved from one organised on the basis of solidarity to one to which competition law applies.⁹⁴ As the key question appears to be the degree of competition within a system, the greater autonomy of NHS FTs and increased private sector provision under Concordat arrangements would certainly seem to suggest a greater degree of competition. However, it has been recognised that "there are markets and markets, some highly regulated and others operating more freely".⁹⁵ In order to understand the degree of competition within the English NHS, and whether this may be sufficient to trigger the applicability of competition law, it is useful to consider briefly the type of market, as "there are markets and markets"⁹⁶. Thus the NHS Internal Market differed from textbook competitive markets⁹⁷ and accordingly the government's approach of applying the spirit of contemporary competition law⁹⁸ via internal Department of Health guidance⁹⁹ was criticised on the grounds that competition in the public sector would operate differently from that in the private sector.¹⁰⁰ The New Labour reforms which retained the purchaser/provider separation, created NHS FTs and dramatically increased private sector provision of NHS services moved the NHS

⁹³ CMA, '60-second summary – Private medical practitioners: information on competition law', 3 December 2015.

⁹⁴ Boeger and Prosser (2009) supra n1, p.367.

⁹⁵ Prosser (2010) supra n4, p.324.

⁹⁶ Ibid.

⁹⁷ ACL Davies cited in Prosser (2010) supra n4.

⁹⁸ That is, the pre-CA98 regime of the Fair Trading Act 1973.

⁹⁹ NHS Executive, 'The operation of the NHS internal market: Local Freedoms, National Responsibilities - Health Service guidelines', 1994.

¹⁰⁰ Diane Dawson, 'Regulating competition in the NHS. The Department of Health guide on mergers and anti-competitive behaviour', University of York Centre for Health Economics Discussion Paper 131, March 1995.

decisively towards the applicability of competition law. However, these were described as "quasi-market" reforms¹⁰¹ and the "NHS-specific" competition regime (notably the NHS Principles and Rules for Cooperation and Competition (PRCC)) has been described as a "new style of competition law"¹⁰² apparently precisely because it related to a quasi-market, which may suggest that this did not amount to sufficient competition for general competition law to apply. This appears to raise the question of whether the changes of the HSCA 2012 have been sufficient to trigger the unequivocal applicability of competition law. This relates in part to whether the English NHS can now be regarded as closer to a "textbook competitive market" or whether it remains a "quasi-market". On balance, the combination of private and voluntary sector provision of NHS services and initiatives to promote patient choice¹⁰³ may prove sufficient to trigger the *applicability* of competition law. However, this is tempered by two factors.

Firstly, it remains the case that the NHS does not necessarily behave as standard markets, particularly in respect of scope for provider exit. Thus although provision has been made for failure regimes by Monitor,¹⁰⁴ this is undermined at a more general level by the establishment of the "success regime" ensuring the viability of NHS bodies (typically NHS Trusts which cannot achieve NHS Foundation Trust status) in connection with the Five Year Forward View.¹⁰⁵

Secondly, the relationship between the NHS and PH sector is more nuanced than competitive tension, although this has been exploited in various ways over time, perhaps most notably in the context of the New Labour reforms in promoting choice of NHS or private provider for certain elective treatments within the NHS. Thus we see that private healthcare companies have appeared

¹⁰¹ Julian Le Grand, *The Other Invisible Hand: Delivering Public Services through Choice and Competition* (Princeton University Press, 2007).

¹⁰² Lianos (2014) supra n2.

 ¹⁰³ See OFT, 'Competition in Mixed Markets: Ensuring Competitive Neutrality', OFT1242.OFT, 'Empowering consumers of public services through choice-tools', OFT1321, April 2011.
 ¹⁰⁴ OFT, 'Orderly Exit – Designing continuity regimes in public markets', OFT1468, December 2012.

¹⁰⁵ NHS, 'Five Year Forward View – The Success Regime: A whole systems intervention', 3 June 2015.

to appreciate NHS work where there has been less uptake of private medical insurance or access of private healthcare (for instance during the economic downturn).¹⁰⁶ Furthermore, the NHS may be defined effectively as a "provider of last resort" relative to the PH sector. This might be inferred from the provision of information to private patients including data concerning referrals from a PH provider to the NHS.¹⁰⁷ Overall, this appears to suggest a picture in which competition law is indeed applicable in principle to the English NHS, but that the SGEI exception may be relevant. This suggests an area for future research.

The English situation might therefore be understood as suggesting that it is possible to have a relatively high degree of competition in healthcare provision (presumably exceeding the "some competition" threshold of *AOK Bundesverband*) *and yet* the apparent ongoing support by the government and Monitor for an English NHS which is based on clinical need, not the ability to pay,¹⁰⁸ coupled with the sense in which competition is a means to an end, not an end in itself (arising out of the NHS Future Forum recommendations), suggest a surprising fundamental adherence to solidarity which questions the (extent of the) applicability of competition law.

It would therefore appear that the situation regarding the English NHS post-FENIN remains unresolved, and that the *applicability* of competition law to categories 1 and 2 is unclear. Of these two categories, perhaps this lack of clarity regarding category 2 is least satisfactory, as the idea that if the purchaser and provider are the same legal entity, there is no relationship to which competition law can attach,¹⁰⁹ would appear to reflect category 1 to a greater extent.

¹⁰⁶ A number of private hospital groups recorded in their annual reports that the increased demand for private provision within the NHS and this new income from the NHS was used to compensate for falls in private patient numbers. See Sandeepa Arora, Anita Charles worth, Elaine Kelly and George Stoye, 'Public payment and private provision – the changing landscape of health care in the 2000s'. Institute for Fiscal Studies / Nuffield Trust Research Report, May 2013. Page 30.

¹⁰⁷ CMA Press Release, 'Better information for private patients moves closer', 1 December 2014.

 ¹⁰⁸ As articulated in the NHS Mandate and Monitor's Strategy 2014-2017. See supra n92.
 ¹⁰⁹ Odudu (2012) supra n66.

Curiously, it is on this uncertainty which s.72 HSCA 2012 builds, by providing that Monitor and the CMA share concurrent powers in applying general competition law in respect of healthcare provision. The formulation "healthcare provision" may be interpreted broadly to encompass both the NHS and PH sector (categories 1-4), or narrowly as limited to the NHS only (categories 1 and 2), both of which have implications for the operation of concurrent powers which are discussed in Chapter 4.

In substantive terms, the focus on "healthcare provision" is potentially very wide in theory, encompassing both the NHS and PH markets (categories 1-4). This is because "healthcare" is defined broadly,¹¹⁰ and does not distinguish between the NHS and PH. This is in contrast to other competition provisions of the HSCA 2012, such as Monitor's duty to balance anticompetitive behaviour with patient interests in connection with the "provision of services for the purposes of the NHS" under s.62(3) HSCA 2012, and the requirement to draft regulations in connection with the commissioning of "health care services for the purposes of the NHS" under s.75 HSCA 2012.¹¹¹ On the other hand, "provision" appears to be more restrictive, drawing a distinction between this and activities on ancillary markets (such as pharmaceuticals and medical devices) and suggesting a separation between purchasing and providing activities, which may be difficult to sustain in respect of CCGs and the greater emphasis on integration in the NHS Five Year Forward View.

¹¹⁰ A view supported by the interpretation provisions of the HSCA 2012. The general interpretation provision, s.150 HSCA 2012, provides that "health care" and "health care service" have the meaning provided in s.64 HSCA 2012 which supplements Monitor's general duties. S.64(3) HSCA 2012 provides: ""Health care" means all forms of health care provided for individuals, whether relating to physical or mental health, with a reference in this Part to health care services being read accordingly; and for the purposes of this Part it does not matter if a health care service is also an adult social care service [...]." A further permutation is made in the HSCA 2012, namely, "health services", which are specifically linked to the NHS. "Health services" are stipulated in sections 23 and 26 HSCA 2012 which amend the National Health Service Act 2006 in respect of functions of NHS England and CCGs respectively (S.26 HSCA 2012 includes the interpretation provision of s.14Z24, and s.23 HSCA 2012 the interpretation provision of s.13Z4. Both define "health services" as "services provided as part of the health service"). This is unsurprising in view of the remits of NHS England and CCGs being limited to the NHS as distinct from the PH sector, but should be treated as a separate matter from Monitor's competition functions and the meaning of "health care services" under s.72 HSCA 2012.

¹¹¹ S.79 HSCA 2012 also has an explicit NHS focus by setting out provisions for "Mergers involving NHS Foundation Trusts".

In practice, however, the focus of s.72 HSCA 2012 may be narrow because it cannot extend the *applicability* of competition law from categories 3 and 4 (the PH sector) to categories 1 and 2 (the English NHS). Thus s.72 HSCA 2012 may be understood as providing for a continuation of cases relating to categories 3 and 4, such as anticompetitive behaviour in connection with PPUs. Although NHS providers, or indeed private providers delivering NHS services (i.e. categories 1 and 2) could in theory be subject to competition law, the legacy of *FENIN* serves to obviate this.

This might be interpreted as suggesting that an equivalent standard of application of competition law has been achieved at national level – but effectively by a (tacit) non-application of general competition law to NHS/private providers engaged in NHS activities, rather than by extending *applicability* to NHS purchasers as well as NHS/private providers. This paves the way for potential anticompetitive behaviour to be addressed not by the application of general competition law, but by a broader regulatory regime comprising the NHS Provider Licence and the 2013 Regulations. The relationship between this and EU competition law is considered next, and the implications with regard to Monitor and the CMA's concurrent powers under s.72 HSCA 2012 is examined in Chapter 4.

Overall, it might appear that s.72 HSCA 2012 largely enshrines the situation regarding the applicability of competition law which existed prior to its enactment – that is, competition law is actively applied to the PH sector (categories 3 and 4), but not the NHS (categories 1 and 2). While the focus on provider competition of s.72 HSCA 2012 carves out a space in which general competition law can be applied, the effectiveness of this is unclear. Unlike the Dutch system, which has delineated the scope for applying competition law by reference to its risk equalisation scheme being classified as an SGEI, no formal recourse to the SGEI mechanism has been made in respect of the HSCA 2012 reforms. However, what develops in practice may nevertheless amount to an informal classification of the English NHS (categories 1 and 2) as an exception to the application of general competition law. Whether the HSCA 2012

terminology "for the purposes of the NHS" amounts to an act of entrustment for the purposes of activating the SGEI exception is, however, unclear.

B. Creating a national framework for applying competition law in national healthcare cases (2) – parallel application of national and EU competition rules

It is notable that in both countries, national, "healthcare-specific" competition rules have been introduced to support the competition reforms. These create a potential source of tension between the competition authority and the healthcare regulator which is considered in detail in Chapter 4. However, there is also a need to consider whether these national rules raise any concerns with regard to the parallel application of national and EU competition rules.

The framework regarding the parallel application of EU and national competition rules is set out in Article 3 of Regulation 1/2003,¹¹² with differing limitations for anticompetitive agreements and abuse of dominance provisions, respectively.

Article 3(1) provides in essence that national competition authorities or national courts shall apply both national and TFEU provisions governing anticompetitive agreements and abuse of dominance.¹¹³

Article 3(2) provides in essence that stricter national laws regarding the prohibition of agreements, decisions by associations or concerted practices which may affect trade between Member States may not be applied.¹¹⁴

¹¹² Article 3, "Relationship between Articles 81 and 82 of the Treaty and national competition laws". Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty. (Hereafter "Regulation 1/2003").

¹¹³ Article 3(1) "Where the competition authorities of the Member States or national courts apply national competition law to agreements, decisions by associations of undertakings or concerted practices within the meaning of Article 81(1) of the Treaty which may affect trade between Member States within the meaning

of that provision, they shall also apply Article 81 of the Treaty to such agreements, decisions or concerted practices. Where the competition authorities of the Member States or national courts apply national competition law to any abuse prohibited by Article 82 of the Treaty, they shall also apply Article 82 of the Treaty."

¹¹⁴ Article 3(2): "2. The application of national competition law may not lead to the prohibition of agreements, decisions by associations of undertakings or concerted practices which may affect trade between Member States but which do not restrict competition within the meaning of Article 81(1) of the Treaty, or which fulfil the conditions of Article 81(3) of the

However, an equivalent approach to unilateral conduct does not exist, so national laws may be stricter in prohibiting or sanctioning this.

Article 3(3) provides that Articles 3(1) and(2) do not preclude the application of provisions of national law that predominantly pursue an objective different from that pursued by Articles 101 and 102 TFEU.¹¹⁵

B1. The Netherlands

The Dutch Healthcare (Market Regulation) Act 2006 (Wmg) grants the NZa two powers which have potential to interact with the application of general competition law,¹¹⁶ namely competence to conduct Significant Market Power (SMP) investigations under Art.48 Wmg, and to intervene in the drafting of contracts under Art.45 Wmg. As how these powers interact with the ACM's powers under the Dutch Competition Act (Mw) is examined in detail in Chapter 4, discussion here is reserved to the substantive standards and how these may affect parallel application of national and EU competition rules in cases where there may be an effect on cross-border trade.

(a) Art. 48 Wmg – SMP:

In terms of compatibility with EU law for the purposes of parallel application of national and EU competition rules, it has been considered that the SMP competence may benefit from the exception of Article 3(2) Regulation 1/2003 on the grounds that the restriction on national laws being more demanding than EU competition law does not apply to unilateral conduct, which SMP clearly does.¹¹⁷ In the appeal decision in *Menzis v Van Dalen Pharmacy*,¹¹⁸ the

Treaty or which are covered by a Regulation for the application of Article 81(3) of the Treaty. Member States shall not under this Regulation be precluded from adopting and applying on their territory stricter national laws which prohibit or sanction unilateral conduct engaged in by undertakings."

¹¹⁵ Article 3(3): "3. Without prejudice to general principles and other provisions of Community law, paragraphs 1 and 2 do not apply when the competition authorities and the courts of the Member States apply national merger control laws nor do they preclude the application of provisions of national law that predominantly pursue an objective different from that pursued by Articles 81 and 82 of the Treaty."

¹¹⁶ A third power under the Wmg also exists, namely, a role in merger assessment and subsequently oversight of a "healthcare-specific" merger test. This is discussed in detail in Chapter 5.

¹¹⁷ Sauter (2014) supra n7.

¹¹⁸ Which involved an expedited decision under Art. 49 Wmg as well as examination under Art. 48 Wmg. NZa, Besluitals bedoeld in artikel 49 lid 1 van de Wmg 18 november 2009 ('Decision under Art. 49(1) Wmg of 18 November 2009'). NZa, Besluit 22 februari 2011, eerste

first case to consider SMP, the court considered the issue of compatibility between the SMP competence and Art. 3(2), but established that there was no effect on trade, which has been described as arguably the easiest solution to the problem¹¹⁹ as there appeared to be an implicit lack of clarity as to whether the unilateral exception would apply.

(b) Art. 45 Wmg – contract powers:

Art. 45 Wmg provides that:

"The NZa may, with regard to the transparency of healthcare markets or the promotion of competition, develop rules regarding the drafting of agreements relating to healthcare or tariffs and regarding the conditions of such agreements".

Most notably to date, the Art. 45 Wmg powers have formed the basis of an Electronic Networks Regulation¹²⁰ which imposes mandatory access to agreements concerning the use of electronic networks to exchange patient and medication data. This effectively codifies previous ACM decisions which dealt with concerns about information exchange, but which failed to resolve nearly identical issues occurring elsewhere in the Netherlands.¹²¹ The Electronic Networks Regulation sets out a general prohibition whereby agreements between healthcare providers regarding setting up and maintaining healthcare-related electronic networks may not include provisions which may restrict the subsequent access of new participants to the agreement.¹²² This general prohibition has been criticised as deviating from the intended purpose of Art.45 Wmg - which emphasizes general obligations – and thus raising questions of compliance of the Electronic Networks Regulation with EU lawin view of Article

¹²¹ Sauter (2014) supra n7.

toepassing van aanmerkelijke marktmachtbevoegdheid (art.48 Wmg) ('Decision involving the first application of SMP competence under Art. 48 Wmg of 22 February 2011'). These cases are discussed further in Chapter 4 at page 139, footnotes 51 and 52.

¹¹⁹ Sauter (2014) supra n7.

¹²⁰ NZa, 'Regeling CI/NR-100.099. REGELING voorwaarden voor overeenkomsten inzake elektronische netwerken met betrekking tot zorg'. ('Regulation CI/NR-100.099. Regulation on Conditions for Agreements involving Electronic Networks relating to Healthcare'). (Hereafter "NZa Electronic Networks Regulation").

¹²² NZa Electronic Networks Regulation supra n120, Art.2(1).

3(2) Regulation 1/2003.¹²³ However, strictly speaking, there is no conflict with Art.3(2) Regulation 1/2003 since Art. 45 Wmg does not comprise a prohibition, but an ex ante competence for the NZa to impose rules.¹²⁴ Rather, the Art.45 Wmg power may benefit from the exception in Art.3(3) Regulation 1/2003. This is because Art.45 Wmg serves a different purpose,¹²⁵ namely, promoting the emergence and functioning of markets in a liberalisation context (where they did not exist previously), as opposed to enforcing existing competition.

B2. England

The national rules developed in connection with the HSCA 2012 reforms comprise the Competition Oversight condition of the NHS Provider Licence and Regulation 10 of the National Health Service (Procurement, Patient Choice and Competition) Regulations (No.2) 2013.

As *FENIN* excludes the applicability of competition law to purchasers, there is no question of parallel application regarding Regulation 10.¹²⁶

However, if *FENIN* does not exclude the application of EU competition rules to providers, then recourse may be had to Article 3(3) Regulation 1/2003 where parallel application is permitted where national competition authorities and courts apply provisions of national law that predominantly pursue an objective different from that pursued by Articles 101 and 102 TFEU. This has relevance in respect of subsections (a) and (b) of the Competition Oversight condition insofar as a distinction might be drawn between effectively delivering a universal service obligation (implicit in "the provision of healthcare services for

¹²³ On this point, see Marc Wiggers, *De NMa en de NZa in de curatieve zorgsector – Een toetsing aan het Europees mededingingsrecht* ('The NMa and the NZa in the curative healthcare sector – an assessment against EU competition law') (Kluwer 2013), pages 322-326.

¹²⁴ See Wiggers (2013) supra n123, p.150 and José Bijkerk, Wolf Sauter, 'Een nieuwe mededingingsbevoegdheid voor de NZa? Artikel 45 Wmg over ingrijpen in de voorwaarden en de wijze van totstandkomen van overeenkomsten met betrekking tot zorg of tarieven'. ('A new competition power for the NZa? Article 45 Wmg and intervention in the conditions and formulation of agreements relating to healthcare or tariffs'). (2010) Markt en Mededinging, 13(4), pp.145-156.

¹²⁵ Sauter (2014) supra n7.

¹²⁶ However, insofar as *BetterCare* may be considered good law, questions of parallel application may still be relevant.

the purposes of the NHS") and enhancing consumer welfare – the stated (but apparently ambiguous¹²⁷) objective of EU competition law.¹²⁸

3.4. Application of competition law in Dutch and English healthcare

It is important to understand that actual application of competition law to Dutch and English healthcare provision - as distinct from ancillary activities has been limited thus far. Indeed, this appears to reflect activity at EU level.¹²⁹ This can be explained in part by the existence of separate (but related) national competition rules for the healthcare sector and relationship between the competition authority and healthcare regulator in both countries, and these aspects are discussed in detail in Chapter 4.

However, the substantive elements of the anticompetitive agreements and abuse of dominance provisions can pose difficulties when applied to healthcare provision in general, over and above considerations of whether these provisions can reflect healthcare-specific values such as affordability and accessibility.¹³⁰ This section therefore considers these general elements before examining specific examples of cases in Dutch and English healthcare.

¹²⁷ On this point see Victoria Daskalova, 'Consumer Welfare in EU Competition Law: What Is It (Not) About?' (2015) Competition Law Review 11(1), 133-162. Katalin Cseres, 'The Controversies of the Consumer Welfare Standard' (2007) Competition Law Review 3(2), 121-173.

¹²⁸ As the PH sector is subject only to general competition law, concerns do not arise in this regard either.

¹²⁹ Although the General Court has considered the case of French Pharmacists (ONP) (Commission Decision of 8 December 2010 based on Article 101 TFEU in Case 29510 - ONP, discussed in Hancher and Sauter (2012) supra n4, and Johan W. van de Gronden and Catalin S. Rusu, 'EU Competition Law and Policy and Health Systems', in eds. Tamara K. Hervey and Calum A. Young, Research Handbook on EU Health Law and Policy, Edward Elgar (forthcoming 2017), generally cases have dealt with issues in the pharmaceutical market (For instance, the IMS Health, AstraZeneca, Sot. Lélos v GlaxoSmithKline AEVE cases. For a comprehensive discussion of these, see Hancher and Sauter (2012) supra n4, pp.244-246).

¹³⁰ For discussions of this, see Van de Gronden (2011) supra n4.

I. Applying the anticompetitive agreements and abuse of dominance provisions to the healthcare sector – general remarks

A. Anticompetitive agreements and healthcare

The anticompetitive agreements provisions – Article 101 Treaty on the Functioning of the European Union (TFEU), Section 2 Competition Act 1998 (CA98)¹³¹ and Article 6 Dutch Competition Act 1998 (Mw) – comprise a prohibition on agreements between undertakings, decisions by associations of undertakings and concerted practices which have as their object or effect the prevention, restriction or distortion of competition within a national market or the internal market. While the additional stipulation of Article 101 TFEU that agreements may affect trade between Member States may once have been deemed unlikely to be relevant to healthcare provision, which typically comprises markets which are regional or national in nature, this may now be changing as even NHS healthcare provision in England can rely on input from French providers.¹³² However, as observed above, limited recourse has been had to Article 101 TFEU in respect of healthcare *provision*.

The challenges of applying the anticompetitive agreements provisions might be described as twofold, namely, identifying those agreements which are likely to be caught by the provisions (and not protected by exceptions) and distinguishing between "object" and "effect" analysis.

As regards the reach of the anticompetitive agreements provisions, we have already seen the difficulties of defining "undertakings" in healthcare. While "concerted practices" may prove as difficult to establish in healthcare as other sectors, decisions of "associations of undertakings" have been found in some national cases regarding professional associations.¹³³ As regards exceptions, it appears that Article 106(2) TFEU may offer greater protection to the healthcare sector as Article 101(3) TFEU has been considered to be limited in connection

<http://www.southkentcoastccg.nhs.uk/news/news-articles/?blogpost=7639>.

¹³¹ The "Chapter I" prohibition.

¹³² See, for example, South Kent Coast Clinical Commissioning Group, 'French elective care contracts', News article, 8 September 2015.

¹³³ See, for example, Lear et al (2010) supra n4, Odudu (2011) supra n1.

with public services (and thus healthcare).¹³⁴ It has further been suggested¹³⁵ that exceptions based on pursuit of legitimate objectives and inherent restrictions¹³⁶ developed in the context of *Wouters*¹³⁷ and *Meca-Medina*¹³⁸ may prove relevant to healthcare provision on the basis that healthcare providers are guided by a specific medical deontology (from the Hippocratic Oath onwards) and might apply rules that are "inherent" in the organization of healthcare.¹³⁹ However, a distinction can be drawn between achieving *legitimate* and *public* objectives,¹⁴⁰ which may suggest that this approach may offer less protection to agreements in healthcare than may first be thought.¹⁴¹

A further delineation in determining the *applicability* of the anticompetitive agreements provisions lies in separating cooperation required by the State from agreements to cooperate,¹⁴² as only the latter are subject to competition law. Indeed the focus may be on collusive tendering, joint negotiation (collective buying or selling) and information exchange (both collection and dissemination).¹⁴³ This appears to have been borne out already. For example, although no cases have been decided on bid rigging, guidance by the ACM clearly distinguishes colluding on a tender which could be submitted

¹³⁴ Prosser (2005) supra n16, p.27. However, connections have been drawn between the exception under Article 101(3) TFEU and a strict interpretation of Monitor's general duty to balance anticompetitive behaviour with patient interests under s.62(3) HSCA 2012. On this point, see Albert Sánchez Graells (2014) supra n27 and 'New rules for health care procurement in the UK: a critical assessment from the perspective of EU economic law' (2015) P.P.L.R., 1, 16-30.

¹³⁵ The view that the exception afforded to collective bargaining agreements by *Albany* may also have limited application in healthcare is considered by Lear et al (2010) supra n4.
¹³⁶ See, inter alia, Van de Gronden (2011) and Lear et al (2010) both supra n4.

 ¹³⁷ Case C-309/99 JCJ Wouters, JW Savelbergh and Price Waterhouse Belastingadviseurs BV v
 Algemene Raad van de Nederlandse Orde van Advocaten (Wouters) [2002] ECR I -1577.
 ¹³⁸ Case C. 540 (AD De iddhae Madine and Lean Madrae Conversion) (2002)

¹³⁸ Case C-519/04P David Meca-Medina and Igor Majcen v Commission (Meca-Medina) [2006] ECR I-6991.

¹³⁹ On this point, see Hancher and Sauter (2012) supra n4.

¹⁴⁰ Emphasis added. On this point, see Hancher and Sauter (2012) supra n4, para 8.46, pages 239-240.

¹⁴¹ Certainly the approach taken by the Commission regarding French pharmacists in ONP may suggest a reluctance to extend these exceptions to healthcare. See Hancher and Sauter (2012) supra n4, paras 8.29-8.31, pages 234-5.

¹⁴² Odudu (2011) supra n1.

¹⁴³ Ibid.

independently, from "combination agreements"¹⁴⁴ made because providers may be unable to tender independently so a more lenient view is likely.

As regards the distinction between "object" and "effect" analysis, the focus of competition authorities will be on the latter in light of the difficulties of reliably predicting the welfare consequences of conduct in healthcare which may justify an "object" approach in other sectors.¹⁴⁵

The foregoing suggests that applying the general anticompetitive agreements provisions to healthcare provision is by no means a straightforward matter. The fundamental aspect of agreements to healthcare provision, whether providers sharing facilities and equipment, providing support services to one another, undertaking clinical research or ensuring that care is sufficiently "joined up" where it cannot be provided independently, suggest a need to proceed carefully and to be clear about what is to be achieved by applying the anticompetitive agreements provisions. While some agreements may be common to any healthcare system, such as sharing patient information to ensure continuity of care or providing integrated care, further complications lie in country-specific features.

B. Abuse of dominance and healthcare

The abuse of dominance provisions – Article 102 TFEU, Section 18 CA98¹⁴⁶ and Article 24 Mw – comprise a prohibition on any abuse by undertakings of a dominant position within a national market or the internal market. This comprises two elements –establishment of a dominant position on a defined market and establishment of abusive conduct. It is important to note that each element poses particular difficulties when applied to healthcare provision.

Firstly, defining markets in healthcare is complex. This is largely due to the limitations imposed on standard tests of substitutability (such as the SSNIP/ "hypothetical monopolist" test) by the 'third party pays principle' and the consequent patient insensitivity to price which arises in both Bismarck and

¹⁴⁴ ACM, *Richtsnoeren voor de zorgsector* ('Guidelines for the healthcare sector'), March 2010, para 267.

¹⁴⁵ Odudu (2011) supra n1.

¹⁴⁶ The "Chapter II" prohibition.

Beveridge systems.¹⁴⁷ The presumption of dominance may appear relatively straightforward, insofar as the definition of 50% market share established by AKZO¹⁴⁸ can apply to the healthcare sector. However, factors such as the existence of barriers to entry arising from law and regulation in highly regulated sectors such as healthcare can prove determinative.¹⁴⁹ Thus, it is necessary to distinguish barriers to entry that are natural features of the market from those created by the State, and those created by undertakings, because competition law will focus on the latter.¹⁵⁰ For example, a Dutch health insurance company which provides insurance to 65% of inhabitants in a given region is not automatically deemed to hold a dominant position.¹⁵¹ This is because its ability to act independently of its competitors is contingent upon other factors, such as whether a particular aspect of GP care is included in the statutorily-defined "basic package" of health insurance. A further determining factor is the type of insurance policy involved, as this may entail a contract between the patient and GP with the insurer providing reimbursement, but having no contract directly with the GP. In addition, distinctions can be drawn between different categories of healthcare provider - with entry into the hospital market likely to be more difficult than for an individual medical practitioner in view of the far lower investments needed and lighter regulatory burden involved.¹⁵²

Secondly, with regard to abusive practices, a distinction is to be drawn between exclusionary conduct (such as predatory pricing) and exploitative conduct (such as unfair trading conditions). Certainly at EU level, priority has been given to combating exclusionary rather than exploitative abuses. The reasons for this are twofold: firstly, it is very difficult to use general competition rules to combat exploitation; and secondly, fighting exploitation can be counter-productive if

¹⁴⁷ This has led to the development of alternative econometric tests being used to define markets for assessing hospital mergers in the Netherlands. This is discussed further in Chapter 5.

¹⁴⁸ Case C-62/86 AKZO Chemie BV v Commission [1991] ECR I-3359.

¹⁴⁹ See Hancher and Sauter (2012) supra n4, para 8.53, page 242.

¹⁵⁰ Odudu (2011) supra n1.

¹⁵¹ ACM (2010) supra n144, para 100.

¹⁵² Hancher and Sauter (2012) supra n4, para 8.53, page 242.

regulation is introduced and leads to a lack of efficiency.¹⁵³ This approach appears to be replicated in the Netherlands and England.

A further consideration in connection with abuse of dominance concerns in healthcare is the apparent bias towards challenging monopoly power rather than monopsony power. In the Netherlands, selling power has been deemed a policy priority of the NZa regarding SMP,¹⁵⁴ and although the ACM has been asked by healthcare providers to address concerns regarding insurer buyer power, its intervention thus far has been limited. This is explained in part by its approach of not intervening unless consumer choice is threatened, but also by the statutory priority given to the NZa's SMP competence.¹⁵⁵ This is examined further in connection with abuse of dominance below, and in Chapter 4. In England, any focus on monopoly power vis-à-vis the NHS may be attributed to the legacy of FENIN, in which Advocate General Maduro considered that the existence of a monopsony neither poses a serious threat to competition since it does not necessarily have any effect on the downstream market, nor that a monopsonist has an interest in bringing such pressure to bear on its suppliers that they become obliged to leave the upstream market.¹⁵⁶ However, there are examples of abuse of monopsony power - such as the restriction of patient choice as a consequence of purchasing decisions by former NHS Primary Care Trusts as sole buyers,¹⁵⁷ or the purchase of care home places at a discounted rate by Local Authorities in England to the detriment of self-funding patients¹⁵⁸ - where no obvious recourse is available following FENIN.¹⁵⁹ This is because the non-application of competition law does not mean that conduct can be addressed under the public procurement rules.¹⁶⁰

¹⁵³ Ibid, paras 8.55 – 8.57.

¹⁵⁴ Sauter (2011) supra n7.

¹⁵⁵ For further discussion, see Sauter (2014) supra n7.

¹⁵⁶ Opinion of AG Maduro in *FENIN*, supra n78, para 66.

¹⁵⁷ Steve Bojakowski, 'Market power: a PCT acting as a monopsony' [2012] British Journal of Healthcare Management, Vol. 18, No. 2.

 ¹⁵⁸ Morten Hviid, 'Procurement By Dominant Buyers'. CCP Research Bulletin. May 2011.
 ¹⁵⁹ Although *BetterCare* might suggest that competition law is applicable to the latter scenario.

¹⁶⁰ For a consideration of this, see Odudu (2011) supra n1.

C. Competition law and healthcare – general concluding comments

The foregoing suggests that the application of competition law in general terms in respect of healthcare provision may be difficult to determine for various reasons, and that establishing the existence of an "undertaking" may merely represent the first (albeit significant) hurdle. It is against this background that cases and guidance from the Netherlands and England are now considered.

II. The Netherlands:

A. Application of the anticompetitive agreements provisions

Thus far, various aspects of healthcare provision in the Netherlands have been considered in light of the anticompetitive agreements provisions. Cases have spanned both the "cure" and the "care" sectors.¹⁶¹ In view of the focus of the chapter, decisions involving healthcare providers are considered, although it is recognised that the ACM has also issued guidance to health insurers, for example informal opinions regarding the development of a "preference policy" prior to the 2006 reforms.¹⁶² It is recognised that some initial decisions in provider cases pre-date the 2006 reforms, but appeals¹⁶³ have, to a greater or lesser extent, acknowledged ongoing changes in the sector. A selection of cases is considered,¹⁶⁴ grouped under the headings of "continuity of care" and "professional associations".

¹⁶¹ Although it has been suggested that competition is less well developed in the "care" sector (Sauter (2011) supra n7) as discussed previously, the focus of the cases has been on providers. The regional "care" agencies (*zorgkantoren*) involved in purchasing long-term care have been deemed not to be engaged in economic activities, thus not undertakings for the purposes of competition law. See further the discussion in Van de Gronden (2004) supra n55. ¹⁶² Considered further by Wiggers (2013) supra n123.

¹⁶³ ACM decisions can be appealed initially to the Rotterdam District Court (Rotterdam Rechtbank, Rb) and then to the Tribunal for Trade and Industry (College voor Beroep, CBb).
¹⁶⁴ Further cases concerning market-sharing by home care organizations (ACM, Case 6108, Thuiszorg Kennemerland (Home Care in Kennemerland), 19 September 2008; ACM, Case 5851, Thuiszorg 't Gooi (Home Care in het Gooi), 19 September 2008) are considered by Van de Gronden and Szyszczak (2014) supra n15, Sauter (2014) and (2011) both supra n7, Edith M.H. Loozen, 'Public healthcare interests require strict competition enforcement'. Journal of Health Policy (2015) Volume 119, Issue 7, pages 882-888.

A1. Continuity of care

It has been recognised that locum services are an important means to guarantee the public interest of availability of care.¹⁶⁵ However, ensuring continuity of care can include a range of activities and parties, from sharing patient data between hospitals and GPs, to out-of-hours pharmacy opening to cooperation between a variety of healthcare professionals to provide a package of integrated care. These three examples can be found in guidance and cases in the Netherlands.

General continuity of care – out-of-hours service provision

Although ensuring continuity of healthcare provision is widely recognised in both countries as being in patients' interests, it risks censure under the competition rules because it is frequently implemented by agreements between parties who would typically compete with each other (such as GPs providing out-of-hours cover, or pharmacists running a 24-hour service). The conflict arises from a need to maintain services which are inherently less profitable (for example, in sparsely populated areas, or outside general business hours) and under a strict interpretation of the competition rules, such agreements may amount to market sharing.

However, there is evidence to suggest that the competition authorities are willing to take a more flexible view in light of the fundamental need to ensure continuity of care. For example, ACM guidance recognises that it is unreasonable to expect a single provider to be available day and night, seven days a week so suggest that locum schemes do not generally conflict with the anticompetitive agreements provisions.¹⁶⁶ However, competition concerns arise when members of a locum scheme collectively hold a position of market power which may lead to others being excluded.¹⁶⁷ This issue is compounded in The Netherlands in cases where GP participation in agreements may be a

¹⁶⁵ Johan van de Gronden, 'Een upgrade van het zorgbeleid van de ACM: de derde versie van de Richtsnoeren voor de zorgsector', ('Upgrade of the ACM's healthcare policy: the third edition of the Guidelines for the Healthcare Sector'), [2010] Markt & Mededinging, No. 6, December 2010.

¹⁶⁶ ACM (2010) supra n144, paras 289-291.

¹⁶⁷ Ibid, Para 291.

condition of contract with health insurers.¹⁶⁸ The ACM has determined that cooperation may not exceed what is strictly necessary for the scheme: if the cooperation includes services which can be provided independently by providers, this aspect must be reviewed in light of the anticompetitive agreements provisions¹⁶⁹. In addition, the ACM determined that specific conditions – for example regarding availability and accessibility – must be imposed on such agreements in Regenboogapotheek v Apothekersvereniging Breda/Dienstapotheek Breda B.V.¹⁷⁰ In that case, a locum scheme was established to cover evening, night and weekend services which required pharmacies to agree to close during these periods. The Regenboog pharmacy opened on Saturdays. When it applied to join the locum scheme, it was initially refused, then subsequently admitted on the condition that it paid a fee 25% higher than that paid by the other pharmacies participating in the locum scheme because of its Saturday opening. The ACM held that imposing closure periods not only restricted competition between pharmacies, but also consumer choice as consumers could not benefit from more extensive opening hours.¹⁷¹ As a result, only conditions which are objective, transparent and nondiscriminatory may be attached to participation in substitution schemes or to fees arising from such locum schemes.¹⁷² This suggests that the ACM distinguishes between legitimate locum schemes necessary to ensure continuity of care, and situations where continuity of care may be used as a smokescreen for anticompetitive activity. In other words, the ACM has looked at the effect, and not the object of the agreement.

Information-sharing and electronic networks

Concerns about the sharing of information have arisen in the Netherlands regarding the use of electronic networks developed to store patient data. It is worth noting with regard to the Netherlands that the importance of healthcare providers participating in an electronic network in order to maintain their

¹⁶⁸ Ibid. Para 289.

¹⁶⁹ Ibid. Para 291.

¹⁷⁰ Decision of the Director General of the NMa (ACM) of 5 September 2003 in case 3169/37 of 5 September 2003, discussed in ACM (2010) supra n144.

¹⁷¹ Ibid.

¹⁷² Ibid.

position on the market is underscored by such participation being a condition for a contract with health insurers.¹⁷³ As the existence of the networks leads to obvious benefits to patients, the concerns are more directed towards how these are managed, and who has access.

In the case Breda Foundation for computerising healthcare,¹⁷⁴ the ACM took an apparently very lenient approach as consultations with the partnership of GPs and pharmacies involved led to the pharmacies refraining from making access to an electronic network conditional on satisfying subjective criteria. This approach may reflect the transitional state of the market at the time.¹⁷⁵ Although less lenient, the ACM also stopped short of using its *ex post* sanction powers in the Assen Out-of-Hours Pharmacy case.¹⁷⁶ In this case, eight pharmacies set up an electronic data network to give access to patient data to the participating pharmacies for their out-of-hours service. An external pharmacy requested 24-hour access to the network, but was refused and filed a complaint with the ACM. The ACM held that restricting access to the network restricted competition for both the network members and potential new entrants and deemed that network access must be granted to other (new entrant) pharmacies and be accessible 24-hours per day. As the ACM considered a fine inappropriate and instead imposed a periodic penalty payment, this led to criticism that it acted more as a regulator than making full use of its *ex post* powers.¹⁷⁷ As this precedent had hardly any effect on similar exclusionary practices elsewhere, the NZa adopted a general regulation¹⁷⁸ on access to electronic networks in healthcare¹⁷⁹ using its contract powers under Art.45 Wmg, effectively to codify ACM decisions in this area. The Electronic Networks Access Regulation provides that any agreement between healthcare providers regarding the establishment and maintenance of an electronic

¹⁷³ Wiggers (2013) supra n123.

¹⁷⁴ NMa (ACM) Decision, Case no. 3022-205, Stichting Automatisering Gezondheidszorg Breda ('Breda Foundation for Computerising Healthcare'), 15 November 2004.

¹⁷⁵ Wiggers (2013) supra n123.

¹⁷⁶ NMa (ACM) Decision, Caseno. 2501, Dienstapotheek Assen ('Assen Out-of-Hours Pharmacy'), 21 June 2004.

¹⁷⁷ See discussion in Wiggers (2013) supran123.

¹⁷⁸ NZa supra n120.

¹⁷⁹ Sauter (2011) supra n7.

network may not contain any provisions which restrict new entrants to the agreement¹⁸⁰ and that any conditions attached to membership of the network must be reasonable, objective¹⁸¹ and non-discriminatory.¹⁸² This Electronic Networks Regulation is discussed further in light of the relationship between ACM and NZa powers in Chapter 4.

A2. Professional associations in the Dutch healthcare sector

While the wide range of trade associations and professional bodies in the healthcare sector play an important role in, inter alia, disseminating clinical knowledge and sharing best practices, this must be distinguished from conduct (which may take the form of rules, regulations and recommendations) which infringes the competition rules. This can happen where a situation is created in which members engage in coordinated behaviour rather than compete.

In terms of the application of competition law, it has been considered in the Netherlands that professional associations qualify as "associations of undertakings".¹⁸³ This (comparatively rare) designation has been applied to professional groups of psychologists¹⁸⁴ and GPs, as opposed to their conduct merely representing an agreement between undertakings".¹⁸⁵

As regards *how* professional associations could infringe the competition rules, two clear examples are by their role in negotiating fees (or sharing information about typical fees for a service), or imposing discriminatory rules in access to the association, where membership is necessary to practice the profession.

In the *Dutch Psychologists' Associations (NIP, LVE, NVP, NVVP)* case,¹⁸⁶ the ACM established that price recommendations issued by the associations infringed

¹⁸⁰ NZa Electonic Networks Regulation (supra n120), Art. 1.

¹⁸¹ Ibid, Art. 2.

¹⁸² Ibid, Art. 3.

¹⁸³ Professional groups of anaesthetists, consultants and eye surgeons have similarly been scrutinised in the context of the UK PH market. See OFT Decision: Anaesthetists' groups, No. 15/04/2003. CMA, Private Healthcare Market Investigation Final Report, "Consultant Groups", paras 46-50.

¹⁸⁴ ACM: Case 3309. Decision. NIP, LVE, NVP, and NVVP and related appeal judgements.
¹⁸⁵ Marcel Canoy and Wolf Sauter, 'De recidivist onder het mes: NMa beboet de Landelijke Huisartsenvereniging' ('Repeat offender under the knife: the NMa fines the Dutch GPs' Association') [2012] Markt & Mededinging 15, 92-98.

¹⁸⁶ ACM: Case 3309, supra n184.

the anticompetitive agreements provisions on the grounds that prices were coordinated. This decision was first appealed to the District Court of Rotterdam (Rb. Rotterdam) which rejected the ACM's findings on the basis that it had not established that price recommendations were restrictive of competition. In addition, the ACM had failed to consider the role of GPs and health insurers in connection with tariffs. A further appeal to the Dutch Trade and Industry Appeals Tribunal (CBb) confirmed these findings.¹⁸⁷ As a result, the ACM revoked its original decision and paid compensation to the associations.

In the *Dutch GPs' Association (LHV)* case,¹⁸⁸ the ACM established that the LHV's practice of allowing established GPs in an area to determine whether or not to permit entry to GP groups or partnerships¹⁸⁹ by new GPs infringed the anticompetitive agreements provisions. A particular concern was the need for GPs to be allowed to join GP groups and thus locum schemes in order to be able to enter into contracts with insurers. However, the LHV had received previous warnings about its conduct, so was fined. The LHV disputed this decision on the basis, inter alia, that the fine was disproportionate and this was subsequently reduced by the ACM. ¹⁹⁰ However, on appeal, the Rotterdam District Court (Rb) overturned the ACM's finding that the anticompetitive agreements had been breached.¹⁹¹

A3. Anticompetitive agreements in Dutch healthcare – concluding remarks

Aside from the difficulties outlined above, there are specific arrangements in Dutch healthcare which have raised concerns in connection with the anticompetitive agreements provisions.

¹⁸⁷ Further discussion of this case can be found in Van de Gronden and Szyszczak (2014) supra n15, Loozen (2015) supra n164 and Sauter (2014) supra n7.

¹⁸⁸ ACM: Case 6888/435 (LHV). Decision. 30 December 2011. ACM: Case 6888_1/510 (LHV). Decision. 3 February 2014.

¹⁸⁹ For a discussion of the different working arrangements of Dutch GPs, see Canoy and Sauter (2012) supra n185.

¹⁹⁰ Cases discussed in Canoy and Sauter (2012) supra n185, Wiggers (2013) supra n123 p.221-229 and M. Wiggers, R. Struijlaart and J. Ruigewaard, 'Landelijke Huisartsen Vereniging' ('Dutch GPs' Association'), M&M 2014/4.

¹⁹¹ ECLI:NL:RBROT:2015:9352 decision of 17 December 2015.

For example, the various structures of "care groups" which deliver integrated care in the Netherlands mean that the anticompetitive agreements provisions apply to agreements between providers, or between providers and a "care group" which is a legal entity forming a link between health insurers and healthcare providers which remain independent undertakings, ¹⁹² but not where providers are members of a "care group" as this comprises cooperation taking place within a single undertaking.

A further concern has been the use of "healthcare intermediaries" by healthcare providers to negotiate with health insurers leading to coordination of market behaviour.¹⁹³

B. Application of the abuse of dominance provisions

Although the ACM has received complaints from healthcare providers concerning abuse of dominance by health insurers,¹⁹⁴ use of the abuse of dominance provisions has been limited. Indeed, it has been considered that there have been no notable abuse of dominance cases.¹⁹⁵ While smaller healthcare providers have complained about being effectively obliged to enter into potentially unfavourable contracts with all four major health insurers,¹⁹⁶ the ACM has declined thus far to intervene absent threats to consumer choice or erosion of quality.¹⁹⁷

The absence of abuse of dominance cases is attributed to the existence of the NZa's competence to conduct SMP investigations and the statutory priority given to these by Art. 18 Wmg.

The distinction between the *ex ante* SMP powers of the NZa, and the ACM's *ex post* abuse of dominance powers can be summarised thus:¹⁹⁸

¹⁹² NMa, NZa, Richtsnoeren Zorggroepen ("Guidelines for Care Groups"), August 2010, para73.

¹⁹³ ACM (2010) supra n144, para 252.

¹⁹⁴ For an overview of these, see Wiggers (2013) supra n123.

¹⁹⁵ Sauter (2011) and (2014), both supra n7.

¹⁹⁶ The insurance market having become increasingly concentrated – from 30 to 4 insurers. For further discussion, see Sauter (2014) supra n7.

¹⁹⁷ Ibid.

¹⁹⁸ Based on table clarifying the different functions of the ACM and NZa more generally. ACM (2010) supra n144, para 35.

Power	Role of ACM	Role of NZa
Abuse of dominance	e / Enforcement of	May impose obligations
significant mar	et prohibition on abuse of	on parties with
power (SMP)	a dominant position	significant market
	(Art. 24 Mw). Repressive	power (Art. 48 Wmg).
	(ex post) assessment of	Preventive (<i>ex ante</i>)
	conduct. Possibility of	test of conduct.
	imposing sanctions.	

Figure 3: Overview of the NZa's SMP powers and the ACM's abuse of dominance powers.

ACM guidance acknowledges that certain types of behaviour – such as a dominant hospital providing orthopaedic care at predatory rates, an insurer imposing unreasonable contract terms on a healthcare provider and a GP being refused membership of an out-of-hours service¹⁹⁹ - falls within the remit of either the ACM or NZa, but that statute determines that the NZa is the first point of contact.²⁰⁰

The issue of who should deal with market power and how has recently been considered in the context of specialist partnerships (*maatschappen*) in The Netherlands. A regional specialist partnership comprises a group of consultants with a particular specialism which can affect the relationships between hospitals and other providers to such an extent that concerns arise about, for example, restrictions on selective contracting. While the partnerships may be dealt with by means of the anticompetitive agreements provisions, or in terms of unilateral conduct,²⁰¹ it has also been suggested that the partnerships do not

¹⁹⁹ This is distinguished from conduct likely to be addressed by the anticompetitive agreements provisions on the grounds that the decision to refuse membership is that of an individual healthcare provider (the service) and not a result of an agreement between competing undertakings (healthcare providers). ACM (2010) supra n144, p.14.
²⁰⁰ Art. 18 Wmg, discussed further in Chapter 4.

²⁰¹ Marco Varkevisser et al., 'Instellingsoverstijgende maatschappen: Huidige ontwikkelingen, mogelijke gevolgen en de aanpak van eventuele mededingingsproblemen. Eindrapport'. Maart 2013. ('Cross-institution partnerships: current developments, possible consequences and managing potential competition problems. Final Report' March 2013).

constitute "undertakings" for the purposes of competition law, but may be regarded as creating a collective (as opposed to unilateral) instance of SMP.²⁰²

The SMP competence is examined further in Chapter 4, but it is worth noting here that this has been transferred to the ACM. How the decision to use *ex ante* SMP or *ex post* abuse of dominance powers will develop in future remains to be seen.

III. England

The distinction drawn between the NHS (categories 1 and 2) and the PH sector (categories 3 and 4) is useful not only for discussing competition in English healthcare in general terms, but also for clarifying the *applicability* of competition law vis-à-vis English healthcare. It follows, then, that the guidance issued by the CMA and Monitor should reflect this distinction. Indeed, the distinction appears entrenched as, in its guidance to PH providers regarding competition law, the CMA is explicit in emphasizing that its remit encompasses categories 3 and 4, since

"This advice does not apply to work carried out under employment with the NHS in relation to NHS funded services".²⁰³

This is not to suggest that the general competition law may be applied to different standards, or in divergent ways, in the two markets as a matter of bad practice by either agency. Rather, the obvious implication is that there are differences between the two markets, and arising out of the EU legal framework outlined above which may influence scope not only for anticompetitive behaviour, but also for enforcing competition law. An example of the former is the existence of the National Tariff which limits scope for price-fixing within the NHS, and the latter is demonstrated by the relevance of *FENIN* to the NHS (categories 1 and 2), but not the PH sector (categories 3 and 4).

²⁰² Edith Loozen, 'Mededingingstoezicht op maatschappen van zorgaanbieders: welke rol is weggelegd voor ACM respectievelijk NZa?' ('Competition regulation of healthcare provider partnerships: what roles do the ACM and NZa play?')[2013] Tijdschrift voor Gezondheidsrecht (37) 7.

²⁰³ See, for example, CMA (2015) supra n93.

Furthermore, there may be distortions which mean one market affects the other, which may be acknowledged and lead to action being taken outside the scope of competition law enforcement. An example of this can be seen in the perceived distortive effect of NHS contracts on private dentistry, whereby private dental practices are obliged to accept NHS patients at tariff rates. This led the former OFT to conclude that the existing (as at 2012) NHS dental contract in England act as a barrier to entry and expansion in the dental market.²⁰⁴

A. Application of the anticompetitive agreements provisions:

From recent guidance by the CMA and Monitor,²⁰⁵ it is clear that working together and collaborative arrangements are recognised as integral parts of healthcare provision. A distinction is therefore drawn between emphasizing where competition law may be infringed: for instance, where collaborating to share commercially sensitive information (unless this meets the tests for exemptions), but not where providers share knowledge around clinical practice and making referrals based on objective reasons/clinical need.²⁰⁶

Points of divergence emerge in the guidance between the particular types of behaviour emphasized by the two agencies, such that it might be concluded that the CMA's focus is on pricing issues²⁰⁷ and the structures within which private providers work (such as Limited Liability Partnerships (LLPs)). While Monitor's guidance seems broader in that it references a wider range of possible anticompetitive behaviours, the influence of the CMA's general competition law guidance is clear. A point of similarity between both agencies' guidance, however, lies in what might perceived to be its "educative" function,

²⁰⁴ OFT, Dentistry – an OFT Market Study, May 2012, OFT1414, para 1.4.

²⁰⁵ See CMA (2015) supra n93 and 'Guidance–Private medical practitioners: information about fees', 3 December 2015. Also Monitor, 'The application of the Competition Act 1998 in the healthcare sector', 12 September 2014.
²⁰⁶ Ibid.

²⁰⁷ CMA (2015) supra n205.

that is, making healthcare providers aware of the potential consequences of their conduct²⁰⁸ as these may be generally unfamiliar with competition law.

How the anticompetitive agreements provisions may be applied to healthcare provision in England is now considered.

A1. NHS providers in the PH sector (category 3):

In view of the focus of this thesis on the HSCA 2012 reforms, the OFT's intervention regarding PPUs is briefly revisited here. This saw the then OFT issue warnings to NHS FTs involved in exchanging commercially sensitive information about their PPUs. The OFT subsequently accepted commitments by the NHS FTs to desist from the offending activity.²⁰⁹ While this may amount to a "light touch" approach, it is appropriate for a market in transition, that is, NHS providers operating in the PH market, which may expand as s.165 HSCA 2012 also removed the private income cap to which NHS FTs were subject. However, while additional scrutiny of PPUs has been deemed necessary in the context of merger control (discussed in Chapter 5), it is unclear what any future approach by the CMA may be in this regard.

A2. The English NHS (Categories 1 and 2):

Monitor's guidance to NHS providers with regard to the application of the CA 98 in the healthcare sector²¹⁰ is complemented by its guidance in respect of the Competition Oversight licence condition²¹¹ and a range of hypothetical scenarios.²¹² While the general guidance inevitably draws heavily on, and directs providers to, the CMA's general guidance on competition law, the hypothetical scenarios make concessions to what might be described as "NHS-specific" characteristics.

 ²⁰⁸ Odudu underlines the importance of "selling" competition law in this way, with a first step being to "convince [...] that they inhabit a market". Okeoghene Odudu, 'Why it matters – Selling competition law in the new frontier', Competition Law Insight, 10 December 2013.
 ²⁰⁹ See OFT supra n68.

²¹⁰ Monitor (2014) supra n205.

²¹¹ Monitor, 'Choice and competition licence conditions: guidance for providers of NHS-funded services', 12 September 2014.

²¹² Monitor, 'Choice and competition: hypothetical scenarios for NHS healthcare providers',12 September 2014.

Thus we see that the national tariff for many procedures constrains the scope for price-fixing in connection with NHS provision, which is free to patients with the prices being paid by commissioners.²¹³ However, this may still occur where community service providers agree not to go below a certain price level in their negotiations with CCGs regarding non-tariff services.²¹⁴ Concerns about market sharing are expressed in relation to area (involving referrals to a designated clinic for an agreed postcode) or procedure (where CEOs of NHS Trusts may agree to concentrate on different procedures).²¹⁵ Other examples of anticompetitive agreements include denying competitors access to necessary inputs (such as adequate supplies of input or outsourced services or sufficient volumes of patient referrals),²¹⁶ exchanging information that places competitors who do not participate in the exchange at a significant competitive disadvantage, limiting competitors' ability to participate in tenders (such as sub-contracting agreements which might prevent the sub-contractor from bidding for future contracts with commissioners) and reaching agreements with commissioners that enable them to influence strategic aspects of tenders such as service specifications, bundling of services and timing.²¹⁷

Perhaps of most relevance to the NHS, in view of the significant focus of competition *for*, rather than *in* the market, is the elaboration of concerns about bid-rigging, which is expressed in terms of a scenario involving selective participation in tenders:

"You are the finance director of trust X. Commissioners from your region and neighbouring regions are planning to tender for various healthcare services over the next 2 years. You agree with the finance directors of trusts Y and Z in neighbouring regions B and C not to bid for tenders outside your current region: you will only bid for tenders in region A, Y will only bid for the tenders in region B, and Z for tenders in region C."²¹⁸

²¹³ Ibid, Scenario 3, "price-fixing".

²¹⁴ Ibid, Scenario 3, "price-fixing".

²¹⁵ Ibid, Scenarios 1 "market-sharing by area" and 2 "market-sharing by procedure".

²¹⁶ Ibid, Scenario 5 "agreement preventing referrals".

²¹⁷ Ibid, Scenario 5 "agreement preventing referrals".

²¹⁸ Ibid, Scenario 4 "selective participation in tenders".

As with the other scenarios listed, this is analysed in terms of effects on patients, possible benefits to the agreement, and conduct which is unlikely to raise concerns. In terms of the effects on patients, the concern is that selective participation in tenders reduces the range of providers which commissioners can choose from, so may not be able to choose the most capable provider offering the best value for money.²¹⁹ On the provider side, the concern is that NHS trusts will have a reduced incentive to develop the most attractive offer (the best quality service for the best value for money) to maximise their chances of winning the tender.²²⁰

In addition to the foregoing hypothetical scenarios in respect of secondary care providers, Monitor has also outlined scenarios – apparently based on real queries - for GPs working together²²¹ as part of its wider work on GP services.²²² The five scenarios cover a range of aspects, from bidding together for contracts, commissioners favouring GP arrangements, arrangements containing terms that prevent members competing, excluding some providers from an arrangement and arrangements between GPs and hospitals.²²³

As with cooperation between secondary care providers, Monitor recognises that there are good reasons why GPs may wish to work together – to improve quality, increase the scope of services provided to patients and enable services to be delivered more efficiently.²²⁴ However, a further motivation for providing detailed guidance to GPs presumably stems from the introduction of the NHS Five Year Forward View, which sets out new models of care which involve increased cooperation between different GP practices, and between GP practices and other providers (such as hospitals).²²⁵

Monitor's guidance also sets out criteria for assessing exceptions from the anticompetitive agreements provisions. These typically comprise a need for

²²⁵ Ibid.

²¹⁹ Ibid, para 4.2.

²²⁰ Ibid, para 4.2.

²²¹ Monitor, 'Choice and competition toolkit: scenarios for GPs working together', 1 June 2015.

²²² Monitor, 'Improving GP services: commissioners and patient choice', 1 June 2015.

²²³ Monitor, supra n221.

²²⁴ Ibid, Section 1, Introduction.

providers (NHS trusts, consultants and community-based providers) to demonstrate possible benefits of anticompetitive agreements in terms of, for example, the nature of the benefits, whether these could have been achieved without restricting choice and competition and the benefits being passed on to patients.²²⁶ This is in keeping with Monitor's duty under s.62(3) HSCA 2012 to balance anticompetitive conduct with patient interests. A strict interpretation of the concept of patient interests has been deemed necessary to ensure compliance with EU competition law,²²⁷ however, it is difficult to see why this may be problematic in view of the apparently exceedingly limited scope for applying general competition law to the English NHS (categories 1 and 2).

B. Application of the abuse of dominance provisions

In contrast to the guidance surrounding the anticompetitive agreements provisions, the information provided by both the CMA (regarding categories 3 and 4) and Monitor (regarding categories 1 and 2) is less detailed. For example, CMA guidance merely refers providers to their generic guides,²²⁸ which may lead to the inference that it attaches less importance to the effects of abuse of dominance within the PH sector in view of its relative size compared to the NHS. In contrast, Monitor sets out the factors it would consider in the analysis of the following scenario:²²⁹

"You are a manager at Hospital A, which is the major hospital in a local area. You agree to provide ultrasound diagnostic services (UDS) for a consortium of GP surgeries in the local area, provided that the surgeries refer at least 85% of all their patients requiring UDS to you. Hospital A is one of 5 providers of UDS in the area. It currently provides the majority of UDS in the area and benefits from an established reputation. Other local providers are relatively small and community based."

²²⁶ Monitor supra n212, paras 2.4, 3.3, 4.3 and 5.3.

²²⁷ On this point, see Sánchez Graells (2014) supra n27 and (2015) supra n134.

²²⁸ CMA, 'Guidance – Competition law for private medical practitioners: cans, can'ts and maybes', 3 December 2015.

²²⁹ Monitor supra n212, Section 6.1, Scenario 6.

With regard to the exclusive purchasing obligation in this scenario, Monitor clarifies that this limits choice of provider for patients which in turn may precipitate provider exit, reduce provider incentives to introduce new services or enhance existing services, or deter provider entry.²³⁰ Monitor further clarifies that the approaches it would take in respect of this scenario by means of the Competition Oversight licence condition and competition law differ. Whereas Monitor may take account of a range of benefits in connection with the licence condition, it is restricted to there being an objective justification for the conduct under competition law (for example, by Hospital A arguing that a minimum volume of referrals is needed to justify substantial investment in additional capacity or new technology to improve service quality for patients).²³¹

It might be inferred from the foregoing that any focus of the abuse of dominance provisions would be on category 1 (in view of the foregoing example effectively referencing CCGs and a "major" hospital presumably being an NHS FT), and category 2 (on the grounds that private providers delivering services for the NHS may have a greater motivation to instigate a claim). If this analysis holds, then it remains to be seen what sort of enforcement action would follow. However, whether and how this offers insights into scenarios involving providers such as that outlined above is less clear. Elements which would benefit from further clarity include who would bear any financial penalty (as passing this on to taxpayers in the form of reduced services seems difficult to justify).

The foregoing suggests that the complexities surrounding abuse of dominance are very much country, or system-specific, although some, such as problems of market definition, may be common to England and the Netherlands.

²³⁰ Ibid, Section 6.2 Effects on patients.

²³¹ Ibid, Section 6.3 Monitor's analysis.

3.5. Conclusion:

This chapter has examined the question of how applying competition law impacts healthcare provision in the Netherlands and England by reference to the EU law framework of the "undertaking" concept as well as cases and guidance from both countries which give an impression of practice thus far.

The expansive definition of an "undertaking" would appear to suggest that a wide range of healthcare provision may be subject to competition law. However, it is evident from enforcement activity in both countries that this potentially wide scope of *applicability* is not translating directly into actual *application*. There may, of course, be myriad reasons for this, some of which relate to the existence of the new healthcare regulators and their roles vis-à-vis the competition authorities and are explored further in Chapter 4.

What emerges from the foregoing analysis, however, is that there are no clear conclusions about how applying competition law impacts healthcare provision in a Bismarck and a Beveridge system.

On the one hand, it is possible to adopt a "granular" approach and conclude that, within a Bismarck system where competition is (acknowledged to be)²³² more feasible (via the "managed competition" model in the Netherlands)²³³, the application of competition law may affect primarily the "edges" of healthcare provision. Thus, access to professional associations or, membership of locum schemes. These aspects represent mere details in the broader perspective of universal provision of healthcare and how competition may operate to support this. A further distinction is to be drawn with "patient choice" policies,²³⁴ although the inclusion of practitioners within a specific locum scheme may be justified on the basis that it legitimizes patient choice. The idea that the application of competition law to healthcare *provision* is likely

²³² See Hancher and Sauter (2012) supra n4.

²³³ Or, on a smaller scale, in the PH sector in the UK.

²³⁴ The EU Commission's Expert Panel on Effective Ways of Investing in Health (EXPH) is unequivocal that patient choice may operate independently of competition. Expert Panel on effective ways of investing in Health (EXPH), *Report on Investigating policy options regarding competition among providers of health care services in EU Member States*, 7 May 2015, page 4.

to – and indeed, should – only be appropriate in a small number of instances is uncontroversial in light of considerations that only "average conditions" for effective competition have been established for hospital care and primary care, whereas "good conditions" exist for activities ancillary to healthcare provision, such as pharmacy distribution and patient transportation.²³⁵

On the other hand, a "broad-brush" approach is discernible within the wide category of English healthcare, whereby traditional distinctions between the NHS and PH sectors remain evident subsequent to the HSCA 2012 reforms. Thus the question of which aspects of healthcare provision may relate to the NHS/PH distinction rather than specific examples.

The residual ambiguity left by FENIN has enabled a significant (even disproportionate) amount of attention to be paid to defining "economic activities" in connection with the English NHS and the apparently inconsistent approach distinguishing purchasing and providing activities. What appears to emerge in practice thus far is that the English NHS (categories 1 and 2) has been accorded a kind of "informal SGEI" status in light of the reluctance to engage openly with the formal SGEI conditions. This can be attributed to the universal service aspect of NHS provision as well as the NHS' apparent status as a "provider of last resort" vis-à-vis the PH sector.²³⁶ This would appear to explain the apparent conundrum in English healthcare of ongoing commitments to keeping the NHS as a taxation-funded service free at the point of delivery, which would suggest a solidarity-based system exempt from the *applicability* of competition law, but a system which relies on private and voluntary sector provision and mixed public/private arrangements to achieve this. On the face of it, this would appear to describe a situation of competitive provision of a public service obligation.²³⁷ However, this may be to over-simplify the

²³⁵ Ibid, p.72.

²³⁶ As part of efforts to address concerns arising from the PH Market Investigation, the Private Healthcare Information Network (PHIN) is to make information regarding private hospitals. See CMA (2014) supra n107. This information is to include number of patients transferred to an NHS hospital from a private hospital, hence the inference of "provider of last resort" status.

²³⁷ Sauter discusses competitive provision of PSO/USO as a new direction in public services at EU level. See Sauter (2015) supra n23, p.232-4.

relationship between the NHS and PH sector as perpetually being in competition, where the reality is more nuanced. After all, CEOs of PH companies welcomed provision of NHS services during the financial crisis, when uptake of private healthcare, and specifically private medical insurance, was in decline.²³⁸ It may be equally appropriate to conceptualise the NHS as a "consumer" of PH services in need of protection against anticompetitive conduct. Insofar as the *FENIN* legacy may serve effectively to exempt private providers of NHS services (category 2) from the reach of competition law, this may not be a welcome development, although abusive conduct may be managed via the NHS Provider Licence instead.

The foregoing appears to suggest that very different approaches are emerging between the Netherlands and England in terms of how the question of the applicability of competition law affects healthcare provision.

However, some points of comparison emerge in respect of the thesis discussion frameworks.

With regard to the "healthcare structure", it can be seen that the macro level of state intervention facilitates understanding of the "undertaking" concept as distinguishing the functions of state and market. The meso level of healthcare purchasing appears most controversial with regard to the applicability of competition law in both a Bismarck and Beveridge system. While the micro level of providers would seem to suggest that applicability of competition law is uncontroversial, the reality appears more complex in view of the conflation of purchasing and providing functions in CCGs in England, as well as the ambiguity remaining about the distinction following *FENIN*.

In terms of the continuum, it appears uncontroversial to suggest that the relative absence of cases thus far points towards a divergence from an "end point" of applying competition law.

Finally, it is interesting to note a divergence in approach between the EU and the Netherlands and England. In view of judgments such as *AOK Bundesverband*

²³⁸ See Arora et al. (2013) supra n106, page 30.

and *FENIN*, the EU courts appear mindful of a range of factors and sensitivities surrounding healthcare provision, thus is adopting a "healthcare-centric" approach. In contrast, the development of additional provisions (specifically Art. 122 Zvw) and regulatory rules (such as the SMP provisions and the 2013 Regulations) at national level would appear to suggest that the Netherlands and England are opting more for a "competition-centric" approach by extending the spirit of general competition law if not its actual *applicability* to healthcare provision.

Of course, as noted in the introduction, the *applicability* and actual application of competition law are distinct but related. This relationship is explored further in the scope for interaction between the competition authorities and healthcare regulators in Chapter 4.

Chapter 4

How should the new sectoral regulators for healthcare work with the competition authorities in applying competition law?

Contents

4.1. Introduction:	128	
4.2. Thesis Discussion Frameworks		
I. The "healthcare structure" – macro, meso and micro levels		
II. The "continuum" between healthcare as the quintessential public service over by government and a market overseen by the competition authority		
III. A "competition-centric" or "healthcare-centric" approach	135	
4.3. Models of Regulation in the Netherlands and England	136	
I. The Netherlands – a "separate powers" model	136	
A. The NZa's competition powers, 2006-2015	137	
A1. SMP powers (Artide 48 Wmg)	137	
A2. Power to intervene in the drafting of contracts (Article 45 Wmg)	140	
A3. Possible "overlap" between NZa and ACM powers, 2006-2015	141	
B. Future direction	143	
II. England – a "concurrent powers" model	146	
A. The position of the competition authority vis-à-vis the healthcare sector i England before and after enactment of the HSCA 2012		
B. Defining the scope of concurrent powers by reference to s.72 HSCA 2012, ERRA 2013 and the 2014 Concurrency Regulations	149	
B1. S.72 HSCA 2012 – the substantive scope of concurrent powers in English healthcare	150	
B2. ERRA 2013 and the 2014 Concurrency Regulations – the institutional scope concurrent powers in English healthcare		
C. Monitor's "separate", "competition-related" powers:	155	
C1. The Competition Oversight Condition of the NHS Provider Licence	156	
C2. The 2013 Regulations	158	
C3. Relationship between Monitor's "competition-related" powers and its concurrent powers	160	
4.4. Factors influencing the relationship between regulator and competition		
authority	162 127	

١.	Т	he regulator's focus on patients16	;3
	A. inte	The Netherlands: the NZa's "separate powers" and the "general consumer erest"	53
	A1.	Overview of the "general consumer interest" under Artide 3(4) Wmg16	3
		The NZa's "separate powers" and the "general consumer interest" mework	55
	A3.	Effect of the "general consumer interest" on the "separate powers" model .16	57
	В.	England: the "concurrent powers" model and Monitor's focus on patients .16	8
	B1.	Monitor's duty and the different "types" of patient in England16	;9
	B2.	Monitor's duty and its concurrent powers17	'2
	B3.	Effect of Monitor's duty on the "concurrent powers" model17	'5
II. re		he role of government in connection with the relationship between the ator and competition authority17	<i>'</i> 6
	A. rela	The Netherlands: the "separate powers" model and the NZa's and ACM's ationships with the Minister for Health, Wellbeing and Sport17	<i>'</i> 6
		The relationship between the NZa and the Minister for Health, Wellbeing and prt17	
		The relationship between the ACM and the Minister for Health, Wellbeing and prt	
	B. Sec	England: the "concurrent powers" model and Monitor's relationship with the retary of State for Health17	
	B1.	The establishment of NHS England18	0
		Post-HSCA 2012 system of referral of decisions regarding licence modification the NHS tariff to the CMA18	
4.	5. C	onclusions	34

4.1. Introduction:

The development of competition in the Dutch and English healthcare systems has been accompanied by the establishment of sectoral¹ regulators for

¹ The term "sectoral regulator" is used in preference to "economic regulator" in this thesis to underscore the ambiguity of the regulator's role vis-à-vis competition law, and because competition powers may represent merely one of the regulator's functions. In connection with the NZa, commentary has mentioned its "competition functions" and included it in wider discussions of "sector-specific regulation". See, for example, Wolf Sauter, 'Sectorspecifiek mededingingsrecht en fusietoetsing' ('Sector-specific competition law and merger control'), RegelMaat (2013) (28) 2 and E.M.H. Loozen, 'Inrichting van meervoudig toezicht op marktwerking' ('Introduction of multisector regulation of competition'), RegelMaat (2013) (28) 2. In England, Monitor's original conception as independent regulator of NHS FTs led to it being described as closer to economic regulators. See Tony Prosser, 'Monitor, the

healthcare, the Dutch Healthcare Authority (NZa) by the Dutch Healthcare (Market Regulation) Act 2006 (Wmg) and Monitor by the Health and Social Care Act 2012 (HSCA 2012), respectively. Both the Wmg and the HSCA 2012 make provision for the regulators to work with the competition authorities in applying general competition law – that is, the provisions governing abuse of dominance and anticompetitive agreements.

This particular relationship between the competition authority and sectoral regulator forms the focus of this chapter because, while outlined by the Wmg and HSCA 2012, how it can, or should, operate in practical terms is less clearcut than the relationship between the two agencies in respect of merger control.² In addition, it is recognised that this relationship has also received attention with regard to other sectors.³

Another factor which makes this relationship worthy of consideration is the benefit of country comparisons in view of the relative novelty of economic regulation in healthcare (the NZa being established in 2006 and Monitor's designation as sectoral regulator dating from 2012), amid wider change within competition policy – both the ACM and CMA are new agencies. However, while the establishment of the ACM and CMA mark a significant change in institutional architecture relative to their predecessors,⁴ this is not necessarily material to their treatment of healthcare cases. A further consideration is the

Independent Regulator of NHS Foundation Trusts', Ch. 7 in Tony Prosser, *The Regulatory Enterprise: Government, Regulation, and Legitimacy* (OUP 2010). However, as part of the NHS Future Forum's recommendations to refocus competition within the NHS, it proposed that Monitor's initial designation as "economic regulator" be dropped in favour of "sector regulator for health". See NHS Future Forum NHS Future Forum, 'Choice and Competition – Delivering Real Choice. A report from the NHS Future Forum', June 2011, page 9. ² Where both the Wmg and HSCA 2012 essentially allow for the competition authority to have

exclusive competence in approving or blocking a merger, and an advisory function for the regulator. This is discussed in detail in Chapter 5 on merger control.

³ See, for example, Cosmo Graham, 'UK: The Concurrent Enforcement by Regulators of Competition Law and Sector-Specific Regulation'. (2016) Journal of European Competition Law and Practice (Advance Access published 26 May 2016). Maher M. Dabbah, 'The Relationship between Competition Authorities and Sector Regulators'. (2011) Cambridge Law Journal, 70(1), March 2011, pp.113-143.

⁴ The ACM comprises the former Dutch Competition Authority (NMa), telecoms regulator (OPTA) and consumer authority (CA). The CMA comprises the former Office of Fair Trading (OFT) and Competition Commission (CC).

distinction between healthcare and other sectors as the experience of these has shaped the development of the NZa and Monitor.⁵

In the Netherlands, the NZa has powers to conduct Significant Market Power (SMP) investigations and to intervene in the drafting of agreements.⁶ These represent "separate" powers to complement the ACM's powers in respect of applying the provisions governing abuse of dominance and anticompetitive agreements, respectively. Collectively, they comprise a "sector-specific" competition regime operating in parallel to general competition law, with all the benefits and trappings this may entail.⁷

In England, Monitor and the CMA share "concurrent" powers – also described (more accurately) as "co-competence"⁸ and "parallel jurisdiction"⁹ – to apply the general provisions,¹⁰ apparently in line with the experience of other sectoral regulators in the UK. Monitor also has "separate" competition-related powers independent of the CMA's general competition law competence. These comprise the Competition Oversight condition of the NHS Provider Licence and the National Health Service (Procurement, Patient Choice and Competition)

⁵ With regard to the English experience, it has been considered that using utility regulation as an analytical lens offers greater value in identifying issues to be resolved rather than offering an appropriate model for healthcare. See Lindsay Stirton, 'Back to the Future? Lessons on the Pro-Competitive Regulation of Health Services' (2014) Med Law Rev 22 (2): 180.

⁶ Under Articles 48 and 45 Wmg, respectively.

⁷ For discussions on this point, see Wolf Sauter, 'Experiences from the Netherlands: The Application of Competition Rules in Health Care', Chapter 14 in J Van de Gronden, E Szyszczak, U Neergaard, M Krajewski (eds), Health Care and EU Law (TMC Asser Press 2011), Wolf Sauter, 'The balance between competition law and regulation in Dutch healthcare markets' (2014) TILEC Discussion Paper, DP 2014-041, Edith M.H. Loozen, 'NMa en NZa: houd je bij je leest! Een analyse van de mededingings bevoegdheden van beide toezichthouders aan de hand van het Samenwerkingsprotocol NMa-NZa 2010' ('NMa and NZa, stick to what you're good at! An analysis of the competition powers of both agencies in light of the NMa-NZa Cooperation Protocol 2010'), Tijdschrift voor Toezicht (2011) 4, 22-5-47, Edith M.H. Loozen, 'Public healthcare interests require strict competition enforcement'. Journal of Health Policy (2015) Volume 119, Issue 7, pages 882-888, Marc Wiggers, De NMa en de NZa in de curatieve zorgsector – Een toetsing aan het Europees mededingingsrecht ('The NMa and the NZa in the curative healthcare sector – an assessment against EU competition law') (Kluwer, 2013). ⁸ As described by Albert Sánchez Graells, 'Monitor and the Competition and Markets Authority' (2014) University of Leicester School of Law Research Paper No.14-32. ⁹ As described by Niamh Dunne, 'Recasting Competition Concurrency under the Enterprise and Regulatory Reform Act 2013'. (2014) 77(2) MLR 254-276.

¹⁰ Section 72 HSCA 2012. Similar provision is made by section 73 HSCA 2012 for Monitor and the CMA to share concurrent powers in respect of market investigations. While this is beyond the scope of this chapter, many of the issues surrounding concurrency are likely to be relevant to s.73 HSCA 2012 too.

Regulations (No.2) 2013 (hereafter "the 2013 Regulations") and might be considered complementary.

It is notable that the impact (actual in the Netherlands and potential in England) of these statutory relationships between the competition authority and regulator regarding the application of competition law and pursuit of cases has already been highlighted as a matter of concern.¹¹

A proposed solution in both countries¹² is to transfer the regulator's competition powers to the competition authority – something which has formally taken effect in the Netherlands in 2015 with the transfer of SMP investigations¹³ to the ACM, prompted by formal reviews of the NZa's role in 2014.¹⁴

This apparently common solution is curious in view of the obvious differences between both countries: not only regarding consensus about the *applicability* of competition law, and the distinctions between the Bismarck and Beveridge models which affect the feasibility of competition in healthcare, but also regarding the difference between "separate" and "concurrent" powers.

In response to these proposals, this chapter asks the question of *how* the regulators should work with the competition authorities – in other words, whether a common solution is even feasible, let alone desirable.

In order to answer this overarching question, this chapter first considers the relationship in general terms by reference to the thesis discussion frameworks in Section 4.2. Section 4.3 elaborates the "separate powers" model of the Netherlands and "concurrent powers" model of English healthcare. Section 4.4 examines two further factors which may impact the relationship between the

¹¹ On this point with regard to the Netherlands, see in particular Loozen and Wiggers, both supra n7. With regard to England, see Sánchez Graells (2014) supra n8, and 'New rules for health care procurement in the UK: a critical assessment from the perspective of EU economic law' (2015) P.P.L.R., 1, 16-30.

¹² Championed in the Netherlands inter alia by Wiggers, supra n7 and in England by Sánchez Graells, supra n8.

¹³ The NZa's "healthcare-specific" merger assessment powers have also been transferred, but this is discussed in Chapter 5.

¹⁴ Edith Schippers, 'Kwaliteitloont' ('Quality Pays'), Letter from the Minister for Health, Wellbeing and Sport to the Chairman of the Second Chamber, 6 February 2015.

regulator and the competition authority, namely, the regulators' focus on patients and the evolving role of government in connection with the relationship between regulator and competition authority. Section 4.5 concludes.

4.2. Thesis Discussion Frameworks

I. The "healthcare structure" – macro, meso and micro levels

While the focus of the regulators on patients may suggest that part of the present discussion is beyond the healthcare structure, the focus of this chapter is evidently on the macro level of state intervention. This is because the introduction of competition into Dutch and English healthcare and development of the relationship between competition authority and sectoral regulator have entailed a greater or lesser reformulation of the role of the Minister/government. Indeed, this recasting of the Minister's role in light of the respective scope for competition in the Netherlands and England appears counterintuitive.

In the Netherlands, it might be anticipated that the Minister's role would be reduced as the 2006 reforms become more developed as there is thought to be greater scope for competition within a Bismarck insurance system. So we may expect to see greater competence accruing to the NZa and ultimately the ACM. However, the relationship between the Minister for Health, Wellbeing and Sport and the NZa has been such as to suggest that the NZa's independence is compromised.¹⁵ This relationship has revealed tensions regarding the differing focus of the Minister and the NZa.¹⁶ The perceived lack of regulator

¹⁵ As underscored by the conclusions of the AEF and Borstlap reports discussed in Chapter 2. Andersson Elffers Felix (in samenwerking met Radicand Economics and Tilburg Law and Economics Center (TILEC)), 'Ordening en Toezicht in de zorg: Evaluatie van de Wet marktordening gezondheidszorg (Wmg) en de Nederlandse Zorgautoriteit (NZa)' (AEF in cooperation with Radicand Economics and TILEC, 'Oversight and regulation in healthcare: Assessment of the Dutch Healthcare (Market Regulation) Act 2006 (Wmg) and the Dutch Healthcare Authority (NZa)'), September 2014. H Borstlap, PFM van der Meer Mohr, LIE Smits, 'Het rapport van de onderzoekscommissie intern functioneren NZa', ('Report of the investigation committee on the internal operation of the NZa'), 2 September 2014.

independence appears to have been instrumental in the current augmenting of the ACM's competition competence in healthcare. Interestingly, however, the Minister is to retain responsibility for policy direction regarding competition in healthcare with the ACM assuming responsibility for implementation in practical terms of this. As this largely replicates the relationship between the Minister and the NZa with regard to competition, it remains to be seen whether similar concerns will arise regarding independence.

In England, conversely, it might be anticipated that the Secretary of State's role would be greater in view of the lesser scope for competition within a Beveridge taxation-funded system. This may have unclear implications for the regulator role, and a limited function for the competition authority as a result. However, undoubtedly a significant HSCA 2012 reform is the establishment of NHS England.¹⁷ This agency leads the NHS in England, sets the priorities and direction of the NHS and encourages and informs the national debate to improve health and care¹⁸ at arms' length from the Department of Health, but is ultimately accountable to the Secretary of State.¹⁹ NHS England works in partnership with Monitor in various ways but has no competition function. What is interesting about this arrangement is whether NHS England may have a similar constraining effect on the development of competition as a Minister may. NHS England and Monitor now have responsibility for setting the NHS tariff, with the CMA able to resolve any disputes which may arise regarding this. This was formerly the province of the Department of Health and is considered further in Section 4.4.

whereas the NZa may be dealing with hundreds of millions of Euros spent on unjust payments. See Skipr, 'NZa-topman soms gefrustreerd door reacties politiek' ('NZa boss frustrated by politicians' reactions'), 14 December 2012.

¹⁷ Although the idea of, and desire for, the day-to-day running of the English NHS to be removed from Ministerial control is not new and has been endorsed by both Labour and Conservative governments. Points of divergence emerge in connection with *how*, as opposed to *whether*, this might be achieved. Thus the former Labour Secretary of State for Health Alan Johnson has suggested that the Brown administration mooted the creation of an independent body, but with different characteristics to those granted to NHS England. See further the discussions in Nick Timmins, Edward Davies, *Glaziers and Window Breakers – Secretaries of State for Health in their own words*. (The Health Foundation, May 2015). ¹⁸ <https://www.england.nhs.uk/about/>.

¹⁹ The Secretary of State outlines ambitions for NHS England via an annual "Mandate" <<u>https://www.england.nhs.uk/wp-content/uploads/2014/06/simple-nhs-guide.pdf></u>.

II. The "continuum" between healthcare as the quintessential public service overseen by government and a market overseen by the competition authority

The question of *how* the competition authority and regulator should work together suggests movement along the "continuum" between healthcare as a public service overseen by government and a market overseen by the competition authority. Perhaps counterintuitively, this is more pronounced in England than in the Netherlands in light of the reduction in the Secretary of State for Health's role and creation of NHS England.

In the Netherlands, the current transfer of NZa competition powers to the ACM might be understood as the Dutch having reached the end of the continuum, with sole oversight by the competition authority. However, such a generalisation should be treated with extreme caution for at least two reasons. Firstly, the establishment of the NZa in 2006 followed a period in which the then Dutch competition authority (NMa) had exclusive oversight of the healthcare sector. Indeed, the NZa was subsequently deemed to assume the NMa's "market umpire" (marktmeester) function, which suggests a change in direction, rather than reaching the end of the continuum. Secondly, the "dual function" of the NZa in creating and monitoring markets reinforces a link with the government with regard to tariff-setting which comprises an important element of competition in Dutch healthcare. This suggests that the NZa has an active function in developing competition, and is not merely "holding the fort". Thirdly, even if the establishment of the NZa is seen as a change in direction away from the end point of a market overseen by the ACM, the current transfer of power suggests that there may be a different end point as a result of this change, rather than a deviation which terminates at the original (mythical) end point. This is supported by the ongoing role for the Minister for Health, Wellbeing and Sport as retaining responsibility for policy direction.

In England, the establishment of Monitor as sectoral regulator follows a period in which the CMA (then OFT) had oversight of the UK private healthcare sector

134

but was "exempt by fiat"²⁰ from oversight of NHS activity. Following enactment of the HSCA 2012, the situation is at once more complex but retains significant similarities in that CMA oversight is effectively reserved to the PH sector and Monitor has oversight over the NHS. This creates complications for the relationship between the CMA and Monitor based on "concurrent powers" discussed below, suggesting that importing this model of regulation from other sectors is misguided for competition in English healthcare.²¹ Furthermore, if the continuum as applied to other liberalised sectors might be described as a sequence of "privatisation-regulation-liberalisation", this may not hold for healthcare. Rather, based on the development of the HSCA 2012 reforms thus far, it is perhaps possible to suggest that the sequence may follow "regulation" (by Monitor) - "liberalization" (in a continuation of the Concordat policy and commitment to a fair playing field of private and voluntary sector providers delivering NHS services) - "privatization". However, it may be that the sequence does not extend beyond "liberalization", since experiments with "privatization" in the sense of 'taking into private ownership'22 thus far have been restricted to limited franchising arrangements.²³

III. A "competition-centric" or "healthcare-centric" approach

Of the two approaches considered in this thesis, the "separate powers" model of the Netherlands is related more closely to a "healthcare-centric" approach. This is because this approach offers greater scope for regulator intervention and may even propose a collaborative approach which in varying degrees connects the government, regulator and competition authority. It further recognises that introducing competition in healthcare comprises more than just

²⁰ As described by Martin Gaynor and Robert J. Town, 'Competition in Health Care Markets', Chapter 9 in M Pauly et al. (eds), *Handbook of Health Economics, Part 2*, (North-Holland, Elsevier, 2012). Page 559.

²¹ Indeed, Dunne has queried the logic of granting powers to Monitor and the CMA in light of the uncertainty surrounding the applicability of competition law to the English NHS. See Dunne (2014) supra n9.

²² "Privatization" appears to be used as a blanket term to criticise very different aspects of NHS reform, such as the increased autonomy of NHS FTs and the Concordat arrangements involving private and voluntary sector providers in delivery of NHS services.

²³ See, for example, BBC, 'Hinchingbrooke Hospital: Circle to hand back to the NHS by end of March' <<u>http://www.bbc.co.uk/news/uk-england-cambridgeshire-31104003</u>>.

the application of general competition law by a competition authority. Thus there is a need for a more nuanced approach – for example distinguishing between *ex ante* and *ex post* intervention. The transfer of NZa competition powers to the ACM does not change this view, since the tension between balancing *ex ante* and *ex post* intervention would appear to remain.

It is questionable whether the concurrent powers model in England can solely be associated with either category. On the one hand, insofar as concurrent powers have been "imported" from other liberalised sectors, this suggests a "competition-centric" approach. On the other hand, the motivation for concurrent powers articulated by the NHS Future Forum – to ensure sectorspecific expertise and guard against inappropriate use of competition – suggests a "healthcare-centric" approach. This latter also suggests a link with the "social solidarity" rationale for regulation.²⁴

4.3. Models of Regulation in the Netherlands and England

I. The Netherlands – a "separate powers" model

The Dutch "separate powers" model in operation between 2006 and 2015 was established by the Wmg and further elaborated through a series of "Cooperation Protocols" between the ACM and the NZa in 2006, 2010 and 2015.²⁵ Thus the Cooperation Protocols deal with the relationship between the ACM's general competition law powers and the NZa's SMP and contract powers.

It is recognised that the NZa's powers, although *ex ante* in nature, may intersect with the ACM's *ex post* powers regarding anticompetitive agreements²⁶ and

²⁴ Tony Prosser, 'Regulation and Social Solidarity', Journal of Law and Society (2006), 364.
²⁵ These are based primarily on Art. 17 Wmg, which requires the NZa to develop protocols with different bodies to ensure effective and efficient decision-making with regard to matters of mutual interest and the collection of information. The 2015 Protocol has extended this legal basis to include Art. 5.1.(2)(c) Dutch Consumer Protection (Enforcement) Act (Whc), which requires the ACM to develop protocols with different bodies and reflects the ACM's extended remit compared to that of the former Dutch competition authority (NMa).
²⁶ Art.6 Dutch Competition Act (Mw) (also known as the "cartel prohibition").

¹³⁶

abuse of dominance²⁷ under the Dutch Competition Act (Mw).²⁸ This has been described as "overlap" (*samenloop*)²⁹ and is defined in Article 18(2) Wmg as referring specifically to the overlap between SMP and abuse of dominance.³⁰ Where "overlap" occurs, parties should address concerns to the NZa first.³¹ Furthermore, in instances of such "overlap", the NZa's SMP competence takes precedence over the ACM's abuse of dominance power, unless the two agencies agree that the ACM is better placed to act, or that the two agencies should act together.³² Consistency is ensured by the NZa applying the same definitions as the ACM with regard to competition law.³³ Thus SMP is defined by reference to "dominance",³⁴ namely that namely the ability of one or more healthcare providers or health insurers to behave independently of its competitors or consumers, whether individually or collectively, and thereby to restrict the development of competition on the Dutch market or a part thereof.

In order to understand how the effects these "separate powers" and "overlap" might have and why this approach has been criticised,³⁵ it is first useful to consider the NZa's competition powers under Articles 48 and 45 Wmg.

A. The NZa's competition powers, 2006-2015

A1. SMP powers (Article 48 Wmg)

It will be recalled from Chapter 3 that Art. 48 Wmg empowers the NZa to impose obligations (ranging from separating types of service provision to equal treatment of service users)³⁶ where it assesses that one or more healthcare providers or health insurers holds SMP. SMP is a concept borrowed from the

²⁷ Art. 24 Mw.

²⁸ There is further scope for intersection with the ACM's powers regarding commitment decisions under Art. 49 Mw.

²⁹ For clarification of why "samenloop" has been translated as "overlap" in this thesis, see the translation note in Appendix I.

³⁰ The concept of "overlap" is defined in different ways in connection with Dutch criminal and administrative law. For a consideration of these by reference to the Wmg definition, see Loozen (2011), supra n7.

³¹ Article 18(1) Wmg.

³² Articles 18(3) and (5) Wmg respectively.

³³ Article 18(4) Wmg.

³⁴ Article 47 Wmg.

³⁵ See in particular Loozen (2011) and Loozen (2015), both supra n7.

³⁶ Art. 18(1) (a)-(I) Wmg.

telecommunications sector,³⁷ but has been considered "loosely based" on this³⁸ and may operate differently in healthcare.³⁹

The NZa has clarified that its SMP competence may interact not only with its other rule-making powers, but also with its general tariff-setting powers. For example, where healthcare providers hold market power and there is insufficient countervailing buyer power, then general tariff-setting should address this (by means of price limits and yardstick competition), rather than widespread use of the SMP tool.⁴⁰

The original design of the SMP power in the Wmg and clarified by the NZa appears to have been intended to distinguish clearly between this and the ACM's abuse of dominance powers. For example, while both provisions assess conduct, SMP does so from a preventive (*ex ante*) approach, and abuse of dominance from a repressive (*ex post*) approach.⁴¹ In addition, differences in approach are evident in the NZa's ability to impose obligations in contrast to the ACM's ability to impose fines.⁴²

Thus far, the NZa has made little use of its SMP competence, which has led to this being described as a "remedy of last resort".⁴³ Although the NZa has received a range of complaints of SMP, it appears to have opted to address these by other means,⁴⁴ apparently in contravention of its own policy.⁴⁵ While potential SMP cases rejected by the NZa involved issues of buyer power,⁴⁶

³⁷ For a discussion of the relationship between abuse of dominance and SMP in connection with telecommunications, see Michael Harker, 'EU competition law as a tool for dealing with regulatory failure: the broadband margin squeeze cases', (2013) Journal of Business Law pp.817-841.

³⁸ Sauter (2014) supra n7.

 ³⁹ Ibid. An example being that the Dutch courts have observed that a different standard for SMP in healthcare has been applied than in the electronic communications sector.
 ⁴⁰ NZa, 'Toelichting op de beleidsregel Aanmerkelijke Marktmacht in de Zorg' ('Explanatory Notes to the Policy Rule Significant Market Power in Healthcare'), September 2010, p.9.
 ⁴¹ Ibid, p.11.

⁴² Ibid, page 10.

⁴³ Sauter (2014) supra n7.

 ⁴⁴ In its 2014 review of the NZa, AEF observed that between 2009 and 2014, "hundreds" of possible SMP cases were identified via signals, opinions or requests. Many of these were addressed informally, or in the context of other matters. AEF (2014), supra n15, p.75.
 ⁴⁵ See Callista C Meijer, 'Beleidsregel AMM in de zorg – een groeimodel' ('Policy Rule SMP in Healthcare – a Growth Model') (2007) Markt en Mededinging, nr.8.

⁴⁶ AEF (2014), supra n15, p.79.

which is consistent with the NZa's focus on seller power thus far – a policy which appears to be undergoing review.

The first case to consider SMP,⁴⁷ Menzis v Van Dalen Pharmacy, involved a complaint by health insurers (Menzis) that the Van Dalen Pharmacy refused to enter into a contract with them which involved Menzis' "preference policy".48 This refusal by Van Dalen meant that Menzis was confronted with prices which were atypical for the market,⁴⁹ which presented problems for Menzis in complying with its "duty of care" to its policyholders.⁵⁰ As a result, Menzis submitted complaints of abuse of dominance and SMP by Van Dalen to the NMa and NZa, respectively, and the NZa's SMP investigation took priority accordingly. The NZa issued two decisions, firstly⁵¹ imposing an obligation on Van Dalen to enter into a contract, and secondly⁵² requiring Van Dalen to comply with any reasonable requests by health insurers. Van Dalen appealed both decisions and requested that the Dutch Trade and Industry Appeals Tribunal (CBb) intervene to implement temporary remedies regarding these and a provisional order for penalty payment issued by the NZa when Van Dalen failed to comply with the second decision.⁵³ Ultimately the CBb declared the appeal of the first decision inadmissible and the second decision unfounded.⁵⁴

⁴⁷ A second case involving a transparency and non-discrimination obligation imposed on a collective of primary care physicians that had refused to refer patients to internet pharmacies, but which led to no further legal challenge is mentioned in Sauter (2014), supra n7.

⁴⁸ Whereby an insurer determines that only one or certain products within a specific group of medicines will be included in its basic health insurance package.

⁴⁹ M.Ph.M Wiggers and J.J.M Sluijs, 'Menzis – Apotheek Van Dalen' ('Menzis v Van Dalen Pharmacy'), (2011) Markt en Mededinging augustus 2011, nr 4.

⁵⁰ Under Art. 11 Dutch Health Insurance Act 2006 (Zvw), insurers are obliged to ensure compensation of, and access to, healthcare for their policyholders. See Appendix F – Glossary – Dutch Healthcare Sector.

 ⁵¹ In an expedited decision under Article 49 Wmg. NZa, Besluitals bedoeld in artikel 49 lid 1 van de Wmg 18 november 2009 ('Decision under Art. 49(1) Wmg of 18 November 2009').
 ⁵² NZa, Besluit 22 februari 2011, eerste toepassing van aanmerkelijke

marktmachtbevoegdheid (art.48 Wmg) ('Decision involving the first application of SMP competence under Art. 48 Wmg of 22 February 2011').

⁵³ For further discussion of the permutations of this case, see the commentary by Wiggers and Sluijs. M.Ph.M Wiggers and J.J.M Sluijs, 'Menzis – Apotheek J.D. van Dalen' ('Menzis v Van Dalen Pharmacy'), (2010) Markt en Mededinging juni 2010, nr 3. Wiggers and Sluijs (2011) supra n49. M.Ph.M Wiggers and J.J.M Sluijs, 'CBb-trilogie: Apotheek Van Dalen – NZa (en Menzis)' ('Dutch Trade and Industry Appeals Tribunal (CBb) Trilogy: Van Dalen Pharmacy v NZa (and Menzis)'), Markt en Mededinging (2012), December 2012, nr.6.

⁵⁴ CBb, ECLI:NL:CBB:2012:BW7731, 'bodemprocedure' eerste AMM-besluit NZa (art. 48 WMG), 7 juni 2012. 'Dutch Trade and Industry Appeals Tribunal (CBb),

Although criticised as a test case,⁵⁵ *Menzis-Van Dalen* nevertheless demonstrated that the fundamental distinction between NZa *ex ante* and ACM *ex post* intervention inherent in SMP and abuse of dominance (to allow for market development and sanction anticompetitive conduct, respectively) appears less clear in practice for all parties involved. Thus the health insurers initially submitted the complaint to both the NZa and the ACM, and NZa investigation took priority in accordance with Art.18 Wmg. This might simply be understood as a lack of clarity about the respective aims of SMP and abuse of dominance. However, perhaps a more convincing interpretation is that aggrieved parties are only likely to be motivated to bring a case⁵⁶ if they feel exploited or excluded – in other words, where there has been an *abuse* of SMP (dominance).⁵⁷ Therefore, purely preventive SMP regulation is burdensome for the NZa in view of the difficulty of defining markets and the need for a case-by-case approach.⁵⁸ In addition, there was scope for the ACM to intervene in connection with abuse of dominance in this case, but it did not do so.⁵⁹

It is to be noted that the NZa has recognised areas for improvement in connection with the econometric tools used to establish SMP and the need for a clearer formulation of obligations regarding vertical relationships, duty to contract and excessive prices.⁶⁰

A2. Power to intervene in the drafting of contracts (Article 45

Wmg)

The substantive content of the NZa's power to intervene in contracts under Art. 45 Wmg was set out in Chapter 3. While the potential scope for NZa intervention under Art. 45 Wmg is broad, the main use of these powers thus

ECLI:NL:CBB:2012:BW7731, 'Proceedings on the merits of the NZa's first SMP decision (Art. 48 Wmg), 7 June 2012'). For a discussion of this decision, see Wiggers and Sluijs (2012) supra n53.

 ⁵⁵ See the commentary by Wiggers and Sluijs (2010, 2011, 2012), supra n49 and n53.
 ⁵⁶ In their review of the NZa, AEF identified 25 cases in which an SMP investigation had been commenced. Of these, 1 was initiated by the NZa, and 24 resulted from complaints by providers or insurers. AEF (2014) supra n15, p.75.

⁵⁷ See Wiggers and Sluijs (2011), supran49.

⁵⁸ Ibid.

⁵⁹ For discussion on this point, see Wiggers and Sluijs (2010) supran53.

⁶⁰ NZa, 'Position paper 'Werking van het zorgstelsel" ('Operation of the Healthcare System'), April 2015.

far has been effectively to codify ACM decisions in an Electronic Networks Regulation⁶¹ which imposes mandatory access to agreements concerning the use of electronic networks to exchange patient and medication data. This would appear to suggest a useful distinction between the ACM ex post powers regarding anticompetitive agreements, and this ex ante NZa power. However, the NZa has clarified that its power to intervene under Art.45 Wmg is not restricted to general unreasonable contract terms, but is linked with general competition law by a focus on contract terms which restrict or limit competition.⁶² Consequently, the Art. 45 Wmg powers have been considered a competition power – as well as a regulatory power - for the NZa,⁶³ and halfway between a competition rule and a regulatory power.⁶⁴ Furthermore, Art. 45 Wmg may be considered to strengthen both the NZa's ex ante and ACM's ex post roles, with the implication that the threshold for NZa intervention is not lower, but different: it does not target a single restriction to set an example, but seeks to address several less serious restrictions at the same time to solve the underlying problem in a structural manner.⁶⁵ In the current transfer of NZa competition powers to the ACM, it is important to note that the Art. 45 Wmg competence remains with the NZa, thus underlining the apparently truly discrete nature of this power.

A3. Possible "overlap" between NZa and ACM powers, 2006-2015

The 2006 Cooperation Protocol clarified that "overlap" may occur with regard to the NMa and NZa producing reports, (informal) opinions, decisions, guidelines/policy rules, consultation and vision documents and regulatory

⁶¹ NZa, 'Regeling CI/NR-100.099. REGELING voorwaarden voor overeenkomsten inzake elektronische netwerken met betrekking tot zorg' ('Regulation CI/NR-100.099. Regulation on Conditions for Agreements involving Electronic Networks relating to Healthcare'). (Hereafter 'NZa Electronic Networks Regulation').

⁶² Ibid.

⁶³ José Bijkerk, Wolf Sauter, 'Een nieuwe mededingingsbevoegdheid voor de NZa? Artikel 45 Wmg over ingrijpen in de voorwaarden en de wijze van totstandkomen van overeenkomsten met betrekking tot zorg of tarieven'. ('A new competition power for the NZa? Article 45 Wmg and intervention in the conditions and formulation of agreements relating to healthcare or tariffs'),(2010) Markt en Mededinging, 13(4), pp.145-156.

⁶⁴ Sauter (2014) supra n7.

⁶⁵ Bijkerk, Sauter (2010) supra n63.

frameworks.⁶⁶ This explanation has remained intact in the subsequent Protocols. The 2006, 2010 and 2014 Protocols have also been consistent in following Art. 18(3) Wmg with regard to managing "overlap", namely, that the NZa may first apply its Wmg powers before the ACM applies its Mw powers.

The substantive scope of "overlap" – defined in Art.18(2) Wmg specifically by reference to the possible complementarity of the NZa's SMP competence and the ACM's abuse of dominance powers – was briefly reconceptualised by the 2010 Cooperation Protocol⁶⁷ as follows:

NZa power	ACM power	Source
Art. 48 Wmg (SMP)	Art. 24 Mw (Abuse of	Art. 18(2) Wmg;
	dominance)	Art. 7 2006 Cooperation
		Protocol,
		Art. 11, 2010 Cooperation
		Protocol and
		Art. 18 2014 Cooperation
		Protocol
Art. 45 Wmg	Art.6 Mw	Art. 13, 2010 Cooperation
(contract powers)	(Anticompetitive	Protocol
	agreements)	
Art. 48 Wmg (SMP)	Art. 6 Mw	Art. 12, 2010 Cooperation
	(Anticompetitive	Protocol
	agreements)	

Figure 1: Overview of the varying scope of "overlap" 2006-2015

Two particularly contentious areas of this wider definition of "overlap" purported to link the ACM's competence to apply the anticompetitive agreements provision not only with the NZa's competence to intervene in

⁶⁶ NMa, 'Protocol tussen de Nederlandse Mededingingsautori teit en de Nederlandse Zorgautoriteit over de wijze van samenwerking bij aangelegenheden van wederzijds belang' ('Protocol signed by the Dutch Competition Authority and the Dutch Healthcare Authority regarding cooperation in matters of mutual interest'), October 2006. ('2006 Cooperation Protocol'). Art.6.

⁶⁷ NMa/NZa, 'Samenwerkingsprotocol NMa-NZa' ('NMa-NZa Cooperation Protocol'), December 2010. ('2010 Cooperation Protocol').

contracts (agreements), but also with its SMP competence.⁶⁸ While the first pairing appears relatively coherent,⁶⁹ although not formally recognised as equivalent,⁷⁰ the latter appears to require substantial clarification, which is not forthcoming in the Cooperation Protocol. However, it has been considered that both provisions may offer protection against market power, thus satisfy the requirement of wider Dutch administrative law that "overlapping" powers share a focus, but not the requirement that both powers target the same behaviour.⁷¹

However, both of these additional purported areas of overlap have been removed from the 2014 Protocol, which reverts to the earlier focus on overlap between SMP and abuse of dominance.⁷² Furthermore, the NZa's Art. 45 Wmg powers appear to continue to be considered a rule-making power regarding problems that resemble cartels, without actually forming a direct equivalent to anti-cartel powers.⁷³

B. Future direction

The "separate powers" model of regulation and "overlap" in Dutch healthcare is undergoing a substantial overhaul in the transfer of the NZa's SMP powers⁷⁴ to the ACM. The transfer is intended to focus the application of competition powers with regard to the healthcare sector.⁷⁵ Furthermore, the Minister for Health, Wellbeing and Sport will retain powers to issue policy rules as the

⁶⁸ Loozen (2011) supra n7 criticises both pairings, using a wider framework of "overlap" drawn from Dutch criminal and administrative law. Against this framework, two requirements must be fulfilled in order to be able to speak of "overlap", namely that provisions must target the same conduct or have the same effect.

⁶⁹ The connection between the anticompetitive agreements provision of Art.6 Mw and NZa contract powers of Art. 45 Wmg is considered by Bijkerk and Sauter (2010) supra n63.
⁷⁰ For example, in describing the division of effort between the then NMa and NZa, it was considered that the NZa had no competence regarding the enforcement of the anticompetitive agreements provision. See ACM, *Richtsnoeren voor de zorgsector* ('Guidelines for the Healthcare Sector'), March 2010, page 13.

⁷¹ Loozen (2011) supra n7.

⁷² ACM/NZa, Samenwerkingsprotocol Autoriteit Consument en Markt en Nederlandse Zorgautoriteit ('ACM and NZa Cooperation Protocol'), December 2014. ('2014 Cooperation Protocol'). Arts. 18 and 19.

⁷³ Sauter (2014) supra n7.

⁷⁴ As will the NZa's role within the "healthcare-specific" merger test. This is discussed further in Chapter 5.

⁷⁵ Edith Schippers, 'Kabinetsreactie rapport commissie Borstlap en evaluatie Wmg en NZa'.('Cabinet response to the Borstlap and AEF reports', Letter from the Minister for Health, Wellbeing and Sport to the Chairman of the First Chamber), 2 April 2015.

"responsible Minister" (it being noted that the ACM is overseen ultimately by the Minister for Economic Affairs),⁷⁶ apparently in keeping with shared regulation in other sectors. However, the proposal that the Minister retains competence to set policy rules in connection with, for example, SMP, has been criticised on the basis that such provision is not made in postal or telecommunications legislation and that the ACM already has experience of this tool.⁷⁷

From the legislative proposal drafted to implement this transfer,⁷⁸ it appears that, where possible, NZa powers will still take priority over ACM competition law powers.⁷⁹ Furthermore, "overlap" as defined under Article 18 Wmg is redefined to refer to NZa powers under the Wmg relating to implementation of the Dutch Health Insurance Act (Zvw) or the Dutch Act on Long-Term Care (Wlz).⁸⁰

Although the amendments to Article 48 Wmg largely involve substitution of "ACM" for "NZa",⁸¹ as might be anticipated, the Explanatory Memorandum elaborates some significant refinements. For example, SMP will be established not by recourse to market definition principles of general competition law, but

⁷⁶ Schippers (2015) supra n14.

⁷⁷ Kamerstukken II, 2015-16, 34 445, 4 - Wijziging van de Wet marktordening gezondheidszorg en enkele andere wetten in verband met aanpassingen van de tarief- en prestatieregulering en het markttoezicht op het terrein van de gezondheidszorg. Nr. 4 Advies Afdeling Raad Van State en nader rapport. (Second Chamber documentation, Parliamentary Session 2015-16, 34 445, 4 - Amendments to the Wmg and other laws to apply tariff regulation and market regulation in healthcare, Document No.4, Opinion of the Dutch Council of State (Raad van State). Page 7.

⁷⁸ Kamerstukken II, 2015-16, 34 445, 2 - Wijziging van de Wet marktordening gezondheidszorg en enkele andere wetten in verband met aanpassingen van de tarief- en prestatieregulering en het markttoezicht op het terrein van de gezondheidszorg. Nr. 2 Voorstel van Wet. (Second Chamber documentation, Parliamentary Session 2015-16, 34 445, 2 - Amendments to the Wmg and other laws to apply tariff regulation and market regulation in healthcare, Document No.2, Legislative Proposal).

⁷⁹ Ibid, page 6, proposed amendments to Article 18(3) Wmg.

⁸⁰ Ibid, page 6, proposed amendments to Article 18(2) Wmg.

⁸¹ Ibid, page 8, proposed amendments to Article 48 Wmg.

by other methods designed for the healthcare sector,⁸² such as the Logit Competition Index (LOCI) and Willingness To Pay (WTP).⁸³

In addition, there are two new obligations which may be imposed under Article 48.⁸⁴ Firstly, the ACM may impose a duty to supply on a healthcare provider, whereas currently there is merely a requirement for healthcare providers to enter into contracts with insurers. Secondly, a duty on healthcare providers to allow patients to choose another provider. Thus a GP who refers patients to a specific pharmacy will be obliged to offer patients a choice of pharmacies.⁸⁵

At the time of writing (July 2016), it is envisaged that these changes will take effect as of 1 January 2017.⁸⁶

Overall, the transfer of the NZa's SMP competence to the ACM signals the end of the "separate powers" model. However, such a transfer is not as radical as may first appear, having been called for at various intervals.⁸⁷ This may suggest that the idea of "separate powers" vis-à-vis SMP in Dutch healthcare has merely been refocused, as the tension between *ex ante* SMP intervention and *ex post* abuse of dominance sanction remains, albeit in the hands of a single agency, the ACM.

⁸² Kamerstukken II, 2015-16, 34 445, 3 - Wijziging van de Wet marktordening gezondheidszorg en enkele andere wetten in verband met aanpassingen van de tarief- en prestatieregulering en het markttoezicht op het terrein van de gezondheidszorg. Nr. 3 Memorie van Toelichting. (Second Chamber documentation, Parliamentary Session 2015-16, 34 445, 3 - Amendments to the Wmg and other laws to apply tariff regulation and market regulation in healthcare, Document No.3, Explanatory Memorandum).

Para 4.3.1, page 19.

⁸³ Tools developed by the NZa and used in its assessment of mergers.

⁸⁴ Explanatory Memorandum supra n82, page 20.

⁸⁵ Ibid.

⁸⁶ As discussed by law firms, for example, Maverick, 'Wetsvoorstel overheveling taken NZa naar ACM: gemiste kans' ("Legislative proposal to transfer NZa functions to the ACM: a missed opportunity") (*Maverick-law blog,* 14 April 2016).

⁸⁷ Inter alia, by Marc Wiggers.

II. England – a "concurrent powers" model

In order to understand the "concurrent powers" shared by Monitor and the CMA, this section considers three aspects which may impact how s.72 HSCA 2012 *may* operate in practice, since these powers have yet to be used.⁸⁸

Firstly, it is useful to recall the position of the competition authority vis-à-vis healthcare prior to the HSCA 2012 and what the legislation purported to change by instituting a "concurrent powers" model.

Secondly, it is important to consider briefly the reforms of the Enterprise and Regulatory Reform Act 2013 (ERRA 13) and the Competition Act (Concurrency) Regulations 2014 (hereafter the "2014 Concurrency Regulations"), which – as regards Monitor – were also influenced by the experience of enacting the HSCA 2012.

Finally, it is useful to examine Monitor's "competition-related" powers – primarily its *ex ante* licensing authorisation regime, but also Regulation 10 governing anticompetitive behaviour of the 2013 Regulations – in order to assess whether these may impact Monitor's ability to exercise its *ex post* concurrent powers under s.72 HSCA 2012. This perhaps suggests elements of a "separate powers" model in addition to the "concurrent powers" outlined by s.72 HSCA 2012. While Monitor has explicitly recognised that it may have recourse to any of the 2013 Regulations, licence authorisation or concurrent powers in addressing a complaint in the preamble to its early cases, ⁸⁹ its practice thus far has made use of the 2013 Regulations and not its concurrent powers. It would therefore appear that any tension between whether Monitor should employ the 2013 Regulations or its concurrent powers would be determined – appropriately – by the offending behaviour in question and the *applicability* of competition law in a given case, rather than a specific policy direction.

⁸⁸ As confirmed by the CMA's Concurrency Reports of 2014, 2015 and 2016. CMA, "Baseline' annual report on concurrency – 2014', 1 April 2014, CMA24. CMA, 'Annual Report on Concurrency 2015', 1 April 2015, CMA43. CMA, 'Annual Report on Concurrency 2016', 28 April 2016, CMA54.

⁸⁹ See, inter alia, Case CCD 04/13 Commissioning Cancer Surgery Services in Greater Manchester and Cheshire and Case CCD 01/13 Commissioning of radiosurgery services.

A. The position of the competition authority vis-à-vis the healthcare sector in England before and after enactment of the HSCA 2012

Prior to enactment of HSCA 2012, the competition authority's focus was effectively reserved to the PH sector, in an apparent understanding that conduct of NHS entities was exempt by fiat from oversight by the then OFT.⁹⁰ It is uncontroversial to suggest that this "fiat" encompassed categories 1 and 2. This was underscored by the creation of the NHS Co-operation and Competition Panel (NHS CCP) and the "NHS-specific" competition regime discussed in Chapter 2. The situation of category 3 (private purchaser and public provider) appeared less clear. In 2011, the then OFT took limited enforcement action by requiring NHS FTs to desist from sharing information about their Private Patient Units (PPUs).⁹¹ This might be construed as the OFT's first intervention with regard to the NHS. However, such an interpretation fails to distinguish between the NHS (categories 1 and 2) on the one hand, and the PH sector (categories 3 and 4) on the other. This particular case clearly concerned the PH sector (category 3),⁹² as the NHS FTs operate PPUs as private providers, so is entirely consistent with the OFT's focus on the PH sector and practice at that time.

It seems obvious to suggest that the lack of competition authority intervention prior to the HSCA 2012 can be attributed to questions of the *applicability* of competition law to the English NHS. Thus possible intervention in the NHS was circumscribed by the *FENIN* judgment, which prompted the OFT to close its investigations into public sector activity for several years prior to re-engaging with the theme of opening up public sector markets.⁹³

The question therefore arises of whether (and how) s.72 HSCA 2012 changed this arrangement. S.72 HSCA 2012 provides for Monitor and the CMA to share

⁹⁰ As explained by Gaynor and Town (2012), supra n20, page 559.

⁹¹ Office of Fair Trading, 'OFT welcomes action by NHS Trusts to ensure compliance with competition law' Press Release, 71/12, 16 August 2012.

⁹² The OFT clearly included Category 3 in its delineation of the PH market. See OFT, 'Private Healthcare Market Study', OFT1396, p.13.

⁹³ For a comprehensive discussion of this change in policy, see Okeoghene Odudu, 'Why it matters – Selling competition law in the new frontier', Competition Law Insight, 10 December 2013.

concurrent powers in respect of applying EU and UK competition law to healthcare provision.

Concurrent powers – defined more accurately⁹⁴ as "co-competence"⁹⁵ or "parallel jurisdiction"⁹⁶ – are a feature of the wider UK economic regulation landscape, and have recently been subject to revision by ERRA 2013.⁹⁷ "Importing" this style of regulatory relationship into healthcare entails various implications which are discussed below, but is fundamentally problematic in view of the very questionable apparent assumption that a single, unified healthcare sector exists in England. What makes this assumption questionable is primarily the relative *applicability* of competition law to the NHS and PH sector, respectively, and the ongoing distinction drawn by the CMA despite acknowledging increasing "linkages" between the two.

This fundamental problem – of the absence of a single healthcare sector, but existence of closely interlinked NHS and PH markets – is compounded by what concurrent powers in healthcare are intended to achieve. The White Paper preceding the HSCA 2012 made a single reference to concurrent powers as explicitly linked to Monitor's duty to promote competition.⁹⁸ However, as part of its wider recommendations to remove this duty, the NHS Future Forum reconceptualised "concurrent powers" as a safeguard against competition being applied disproportionately,⁹⁹ and a mechanism to ensure sector-specific

⁹⁴ "Concurrent" in its ordinary meaning of "occurring at the same time" (Oxford English Dictionary) suggests a "separate powers" approach as outlined in this thesis.

⁹⁵ Sanchez Graells (2014) supra n8.

⁹⁶ Dunne (2014) supra n9.

⁹⁷ For a comprehensive overview of the reforms, see Dunne (2014) supra n9.

⁹⁸ One of Monitor's roles was defined thus: "Promoting competition, to ensure that competition works effectively in the interests of patients and taxpayers. Like other sectoral regulators, such as OFCOM and OFGEM, Monitor will have concurrent powers with the Office of Fair Trading to apply competition law to prevent anti-competitive behaviour". Department of Health, Equity and Excellence: Liberating the NHS, Cm7881, July 2010. Page 38.
⁹⁹ "We therefore think that the Bill should be clear that Monitor is the sector specific regulator and takes concurrent powers to the Office of Fair Trading as a safeguard against

competition being applied disproportionately." NHS Future Forum supra n1, page 30.

expertise¹⁰⁰ – a benefit of the model recognised in connection with other sectors.¹⁰¹

As the wording of s.72 HSCA 2012 remained unchanged during the passage of the Health and Social Care Bill,¹⁰² this potentially significant distinction is lost in the legislation.¹⁰³ However, it is questionable whether "concurrent powers" – essentially an institutional arrangement – can achieve such ambitious aims, whether of promoting competition or avoiding disproportionate use of competition law.

It is acknowledged that the scope of concurrent powers is defined by reference to the ring-fencing of Monitor's sectoral powers under s.74 HSCA 2012 (with regard to general duties under s.62 HSCA 2012) and s.67 HSCA 2012 (regarding the interaction between licensing and competition powers). These are considered further below in subsection D. However, the shaping of concurrent powers in English healthcare under s.72 HSCA 2012, ERRA 2013 and the 2014 Concurrency Regulations is now considered.

B. Defining the scope of concurrent powers by reference to s.72 HSCA 2012, ERRA 2013 and the 2014 Concurrency Regulations

How concurrent powers operate in English healthcare can be understood in substantive terms by reference to s.72 HSCA 2012, and in institutional terms with regard to ERRA 2013 and the 2014 Concurrency Regulations as follows.

¹⁰⁰ Hence its recommendation to "maintain the provisions to give Monitor concurrent powers with the Office of Fair Trading. Under current rules, any challenge under competition law would be for OFT to deal with. However, we think that this job would be best done by a dedicated regulator with a greater knowledge of the unique nature of healthcare, including the importance of cooperation through clinical networks and the benefits of integrating services to improve quality." NHS Future Forum, supra n1, page 11.

¹⁰¹ Tony Prosser, 'Competition, Regulators and Public Service'. Ch. 10 in eds. Barry Rodger, Angus MacCulloch, *The UK Competition Act – A New Era for UK Competition Law*, (Hart Publishing, 2000).

¹⁰² Health and Social Care HC Bill (2010-11) [132] cl 60, Health and Social Care HC Bill (2010-11) [177] cl 64, Health and Social Care HC Bill (2010-11) [221] cl 67, Health and Social Care HL Bill (2010-12) [92] cl 68, Health and Social Care HL Bill (2010-12) [119] cl 70, Health and Social Care HL Bill [132] cl 72.

¹⁰³ The Explanatory Notes to the HSCA 2012 merely outline that Monitor has concurrent powers, and what these empower Monitor to do in respect of enforcement action. Paragraph 711.

B1. S.72 HSCA 2012 – the substantive scope of concurrent powers in English healthcare

S.72 HSCA provides in essence that Monitor and the OFT (now CMA) have concurrent functions in respect of applying the UK and EU competition provisions regarding anticompetitive agreements and abuse of dominance. Of particular note is that these concurrent functions relate to these provisions in so far as they "...concern the *provision* of *health care services* in England...".¹⁰⁴ The discussion of this substantive scope in Chapter 3 concluded that the substantive focus of s.72 HSCA 2012 may actually be very narrow in practice, and possibly even limited to anticompetitive behaviour by PPUs in view of the focus on *provision*. Further support for this interpretation emerged from the difficulty of separating purchasing and providing functions in the NHS and the limited *applicability* of competition law post-*FENIN*.

Of greater relevance to the present discussion of concurrent powers is the focus of s.72 HSCA 2012 on "*healthcare services*". Whether these are interpreted widely, as encompassing the NHS and PH sectors (categories 1-4) or narrowly, as limited to the NHS (categories 1 and 2) despite the expansive wording, provides insights into the problems of "concurrent powers". These can be illustrated as follows:

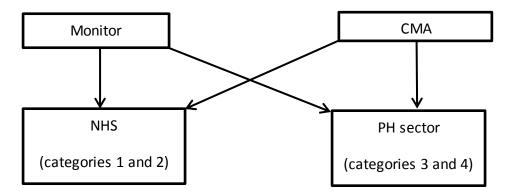


Figure 2: "Concurrent powers" under s.72 HSCA 2012 in light of a broad interpretation of "healthcare services" (as encompassing categories 1-4).

On a broad reading, in which "healthcare services" encompasses categories 1-4, "concurrent powers" can be understood as meaning that either the CMA or

¹⁰⁴ Emphasis added.

Monitor may apply competition law regardless of whether the case involves the PH sector or the NHS. Thus the CMA would be granted oversight of the NHS, and Monitor oversight of the PH sector.

Alternatively, on a narrow reading, with "healthcare services" equating to the NHS only, again either the CMA or Monitor may apply competition law under s.72 HSCA 2012 as follows:

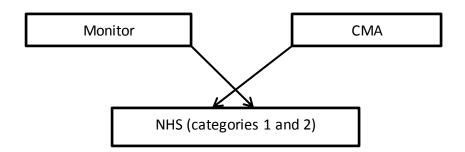


Figure 3: "Concurrent powers" under s.72 HSCA 2012 in light of a narrow interpretation of "healthcare services" (as encompassing categories 1 and 2 only).

In a departure from the pre-HSCA 2012 situation, either scenario serves to grant the CMA explicit oversight of the NHS. Indeed, this might be inferred as the overarching intention of s.72 HSCA 2012 from the White Paper onwards. Certainly there appears to be nothing in practice to suggest that the intention behind s.72 HSCA 2012 was to grant Monitor oversight of the PH sector.

Further clarification as to the scope of "concurrent powers" under s.72 HSCA 2012 is provided by the ERRA 2013 reforms and the 2014 Concurrency Regulations, and these are now considered.

B2. ERRA 2013 and the 2014 Concurrency Regulations – the

institutional scope of concurrent powers in English healthcare

While Monitor is included in some of the ERRA 2013 developments vis-à-vis concurrency, it explicitly excluded from others. For instance, Monitor is not subject to the new power for the Secretary of State to remove concurrent powers from regulators.¹⁰⁵ In addition, Monitor is not a full member of the UK

¹⁰⁵ S.52 ERRA 2013 lists OFCOM, OFGEM, OFWAT, the ORR, the Northern Ireland Authority for Utility Regulation and the CAA as the "sectoral regulators" whose concurrent powers may be removed.

Competition Network (UKCN), but attends with observer status. This is attributed to Monitor's statutory duty to prevent anti-competitive behaviour,¹⁰⁶ as distinct from the duty of other regulators to promote competition.¹⁰⁷

Some of the exceptions granted to Monitor appear to be provisional, or temporary. For example, the duty on sectoral regulators to consider whether it would be more appropriate to use their competition law powers before using their direct regulatory powers of enforcing licence conditions does not currently apply to Monitor, but the Secretary of State may extend this duty at a future date.¹⁰⁸ This is a separate matter from Monitor considering whether its concurrent powers, its licensing powers or its 2013 Regulations competence is best suited to a given case – which has been acknowledged in cases thus far ultimately assessed under the 2013 Regulations. Indeed the mere suggestion that the Secretary of State will extend this consideration requirement in the future was deemed sufficient¹⁰⁹ in the Lords' debates preceding ERRA 2013 to justify the otherwise apparent anomaly of including Monitor as one of the sectoral regulators in the CMA's new annual concurrency reports.¹¹⁰

Indeed, during the Lords Debates of the Enterprise Bill (subsequently ERRA 2013), it was recommended that Monitor be removed from the list of sectoral regulators on the grounds that the interaction between Monitor and the CMA

¹⁰⁶ Under s.62(3) HSCA 2012.

¹⁰⁷ CMA, 'Network launched to help drive competition in regulated sectors', Press Release, 3 December 2013.

¹⁰⁸ CMA (2014) supra n88, paragraph 5 and footnote 8, page 5.

¹⁰⁹ See comments by Viscount Younger of Leckie. "The Government have been clear in response to the consultation on competition reform that Monitor's explicit new duty to consider Competition Act enforcement before taking enforcement action through the provider licence provided under Schedule 14 to the Enterprise Bill will not be commenced until a future date, reflecting the unique characteristics of the health sector. Subject to this, Monitor will become part of the same concurrency regime as the other sectoral regulators. So it is right that the concurrency arrangements between the CMA and Monitor and the use of concurrent powers in the health sector should be covered by the concurrency report. This will provide greater transparency and assurance that concurrent competition powers are being used effectively and in the interests of users of healthcare services." Enterprise and Regulatory Reform Bill, HL Deb, 12 December 2012, col GC363.

¹¹⁰ S.16(7) ERRA 2013. S.16 ERRA 2013 provides that the CMA must consult sectoral regulators in preparing concurrency reports, which must include details of the CMA and/or the regulator exercising its powers under CA98 or EA02, and where a regulator has elected not to use its concurrent powers, information about the powers it has used.

would be entirely different from the latter's interaction with other sectoral regulators.¹¹¹ Furthermore, the experience of enacting the HSCA 2012 seemed to inform this cautious approach as drawing attention to possible CMA oversight of the NHS would likely prove controversial.

Of particular relevance to the present discussion are important exceptions made for Monitor in respect of cases relating to the provision of healthcare services for the *purposes of the NHS in England*¹¹² under Regulations 5 and 8 of the 2014 Concurrency Regulations. Thus Monitor is empowered to lead on such cases,¹¹³ and the CMA may not take these over.¹¹⁴ The CMA and Monitor's successor, NHS Improvement, have recently clarified the basis of case allocation which respects the limitations outlined here.¹¹⁵ This would appear to suggest that there may be other instances not affected by Regulations 5 and 8 of the 2014 Concurrency Regulations, but no further elaboration is provided.

The situation regarding concurrent powers under s.72 HSCA 2012 and Monitor's and the CMA's respective competence following Regulations 5 and 8 of the 2014 Concurrency Regulations can be illustrated as follows:

¹¹¹ See Lord Whitty's proposed Amendment 24BFA to remove Monitor from the list of regulators to be included in the CMA concurrency reports and comments. "I advise the Government, gently, not to reopen this matter – health service reform was difficult enough for them. People are settling down now to make it work but the idea that another authority might come in under this Bill and overrule a health service body trying to square off competition and co-operation would reopen huge anxieties among health service professionals, patient groups and the new commissioning body [presumably a reference to NHS England]. The Government would be wise to take it out [i.e. remove Monitor from the list of sectoral regulators included in the concurrency reports]. They can do it at this point without too much attention but if what they are proposing gets out there, they will be in serious trouble." Enterprise and Regulatory Reform Bill, HL Deb, 12 December 2012, Col GC362.

¹¹² Emphasis added.

¹¹³ Regulation 5(5), The Competition Act 1998 (Concurrency) Regulations 2014.

¹¹⁴ Regulation 8(1)(b), The Competition Act 1998 (Concurrency) Regulations 2014.

¹¹⁵ Part A – Cooperation in relation to the competition prohibitions (Competition Act 1998 and Articles 101 and 102 of the Treaty on the Functioning of the European Union), para 36, page 11. CMA and NHS Improvement, Memorandum of Understanding between the Competition and Markets Authority and NHS Improvement, 1 April 2016.

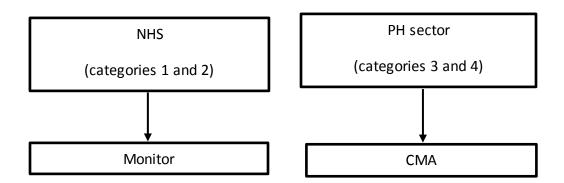


Figure 4: how concurrent powers under s.72 HSCA 2012 operate following amendments by Regulations 5 and 8 of the 2014 Concurrency Regulations.

The amendments to concurrency powers under s.72 HSCA 2012 by the 2014 Concurrency Regulations are significant for at least two reasons.

Firstly, they significantly refine the scope for CMA intervention, and in so doing, re-establish the situation which existed prior to the HSCA 2012. Thus the CMA may intervene in cases which involve the PH sector, but not the NHS in an arrangement which appears to enshrine in secondary legislation the pre-HSCA 2012 situation.

Secondly, they do nothing to clarify Monitor's position vis-à-vis the PH sector, which might be implicit from "concurrent powers" under a broad reading of "healthcare provision" of s.72 HSCA 2012 as noted above.

Rather, the amendments of the 2014 Concurrency Regulations support the view advanced during the Lords' Debates preceding ERRA 2013,¹¹⁶ namely, that concurrent powers function differently in healthcare. This is because allocation of cases is determined by other factors (notably the *applicability* of competition law) than which agency is best placed to act. Furthermore, insofar as concurrent powers have been used in other sectors, distinctions are not drawn between the markets comprising a sector. So, for example, it is not the case that the wholesale market is reserved to the competition authority and the retail market to the regulator.

¹¹⁶ See Lord Whitty's comments to this effect, supra n111.

Indeed, the practical implementation of concurrent powers under s.72 HSCA 2012 appears closer to the ordinary dictionary definition of "concurrency" in the sense of occurring at the same time, in that the NHS and PH sector both coexist and operate separately, than to "concurrency" as typically understood ("co-competence") in UK economic regulation.

In light of this convoluted institutional arrangement and the lack of clarity regarding the extent of applicability of competition law, it is unsurprising that Monitor has not yet made use of its concurrent powers.¹¹⁷

As noted above, the focus for s.72 HSCA 2012 may be restricted to activities of PPUs in practical terms in view of the *applicability* of competition law to the English NHS (discussed in Chapter 3). If this is borne out, and more cases emerge, which is a possibility in light of the removal of the private patient income cap under s.165 HSCA 2012,¹¹⁸ then the foregoing analysis leads to the conclusion that oversight of such cases would be by the CMA, consistent with the 2011 case overseen by the OFT. This is because PPUs provide healthcare for the UK-wide PH market, so would presumably not be caught by the limitation of providing healthcare services for purposes of the NHS in England under the 2014 Concurrency Regulations (which would trigger Monitor oversight).

C. Monitor's "separate", "competition-related" powers:

A final consideration in connection with Monitor's exercise of concurrent powers under s.72 HSCA 2012 arises out of its use of its regulatory tools – the Competition Oversight condition of the NHS Provider Licence and the NHS (Procurement, Patient Choice and Competition) Regulations (No.2) 2013 (hereafter "the 2013 Regulations"). In a sense, these comprise an "NHS-

¹¹⁷ Certainly the three reports available at the time of writing (July 2016) demonstrate this, with an overview of cases addressed under the 2013 Regulations being given. See CMA (2014) pages 90-93, (2015) pages 64-68 and (2016) pages 71-74, all supra n88.

¹¹⁸ The possibility that s.165 HSCA 2012 may precipitate an expansion in PPUs has been recognised by the CMA in its development of a separate test to assess PPUs as these do not meet the thresholds of general merger control. See inter alia, CMA, Private Healthcare Market Investigation Final Order, 1 October 2014. Part 2, "PPU arrangements".

specific" competition regime operating in parallel with general competition law, so may suggest a further "separate powers" model.

C1. The Competition Oversight Condition of the NHS Provider Licence

In essence, the NHS Provider Licence comprises nine General Conditions which cover areas such as the provision and publication of information, fit and proper person requirements and a requirement for providers to be registered with the Care Quality Commission (CQC).¹¹⁹ The Competition Oversight condition is part of a wider Competition Oversight condition,¹²⁰ one of several further specific conditions.¹²¹ It applies to all licence holders, whether private sector, voluntary sector or NHS FT providers. The Competition Oversight condition imposes a twofold prohibition on providers as follows:

"The Licensee shall not:

- (a) Enter into or maintain any agreement or other arrangement which has the object or which has (or would be likely to have) the effect of preventing, restricting or distorting competition in the provision of health care services for the purposes of the NHS, or
- (b) Engage in another conduct which has (or would be likely to have) the effect of preventing, restricting or distorting competition in the provision of health care services for the purposes of the NHS,

To the extent that it is against the interests of people who use health care services."¹²²

¹¹⁹ Monitor, 'The New NHS Provider Licence – Monitor's response to the statutory consultation on the new NHS provider licence'. 14 February 2013.

¹²⁰ The patient choice element is intended to protect patients' rights to choose between providers by obliging these to make information available and act in a fair way. "Choice" in this context refers to a choice of provider under the NHS Constitution or a choice conferred locally by CCGs. See Monitor (2013) supra n119, Condition 6 – Choice and Competition Conditions.

¹²¹ Others relate to pricing, integrated care, continuity of services and Foundation Trusts.

¹²² Monitor (2013), supra n119, Annex: NHS Provider Licence Standard Conditions.

Subsections (a) and (b) are clearly influenced by the anticompetitive agreements and abuse of dominance provisions of the CA98 and the TFEU. Furthermore, the condition has been interpreted as ensuring that the competition rules are applied equally across the NHS, and raising the possibility of two different competition regimes being applied.¹²³

The existence of the Competition Oversight condition offers an alternative to applying competition law insofar as anticompetitive conduct may be addressed in a theoretical example by removing a provider's licence thus effectively causing them to exit the NHS market. This may obviate any need to apply competition law, and all the cost and complexity that the latter would entail. However, it is important to note that the condition is intended to extend the spirit of competition law to all licencees, even those which may not be regarded as carrying out an "economic activity", thus "undertakings" which trigger the application of competition law. Thus the introduction of a competition oversight licence condition has been deemed to fill the potential enforcement gap under CA98,¹²⁴ apparently by extending the application of competition rules to *all* providers delivering services for the purposes of the English NHS. This appears a curious distinction to make in view of the relative clarity that competition law may apply to NHS provision¹²⁵ (as distinct from purchasing, insofar as the two may be separated). However, at the time of writing (July 2016), no action has been taken in respect of the Competition Oversight licence condition.126

¹²³ Graham (2016) supra n3.

¹²⁴ Indeed, it is important to note that the condition is intended to extend the spirit of competition law to <u>all</u> licencees, even those which may not be regarded as carrying out an "economic activity", thus "undertakings" which trigger the application of competition law. Thus the introduction of a competition oversight licence condition has been deemed to fill the potential enforcement gap under CA98. See Monitor supra n119, '6.1 Purpose of the Choice and Competition licence conditions'.

¹²⁵ For a discussion of this, see Okeoghene Odudu, 'Are State Owned Healthcare Providers That Are Funded By General Taxation Undertakings Subject To Competition Law?' [2011] ECLR 32(5), 231-241.

¹²⁶ As at 1 July 2016, 108 licences were held by "other" providers, 8 licences having been revoked on application by the licence holder pursuant to s.89(a) HSCA 2012. As at 1 July 2016, 154 licences were held by NHS FTs, with 1 revoked on the application of the licence holder pursuant to s.89(a) HSCA 2012 and 3 revoked as a result of an acquisition, meaning that the provider and licence ceased to exist. See GOV.UK, Transparency data – NHS foundation trust

C2. The 2013 Regulations

The 2013 Regulations cover a wide range of potential behaviour by NHS commissioners, although the focus, unsurprisingly, relates to procurement activity. However, Regulation 10 may have relevance to Monitor's relationship with the CMA.

Regulation 10(1) provides that commissioners must not engage in anticompetitive behaviour when commissioning services unless to do so is in the interests of people who use healthcare services. Such interests are defined in Regulation 10(1) as involving the services being provided in an integrated way, or by cooperation between the providers to improve the quality of the services.

Regulation 10(2) provides that an arrangement for providing NHS healthcare services must not include any term or condition restricting competition which is not necessary for the attainment of intended outcomes which are beneficial for NHS patients or the objective governing good procurement practice.

In contrast to Regulation 10(1), this appears to reference agreements or contracts explicitly. While the purpose of Regulation 10(2) is unclear, it might be considered to share some common features of the Dutch Healthcare Regulator's power to intervene in contracts.

Monitor has confirmed that, where a commissioner's behaviour is in patients' interests, it will not be inconsistent with the prohibition on anti-competitive behaviour of Regulation 10.¹²⁷ Monitor's analysis of whether conduct is consistent with Regulation 10 comprises assessing the effect on competition (including factors such as the number of providers affected by a commissioner's conduct and the expected duration of the conduct) and assessing benefits,

directory and register of licensed healthcare providers', last updated 19 July 2016. <<u>https://www.gov.uk/government/publications/nhs-foundation-trust-directory</u>>.

¹²⁷ Monitor, 'Substantive guidance on the Procurement, Patient Choice and Competition Regulations'. December 2013. Page 61.

which may be clinical or non-clinical.¹²⁸ Certainly, parallels may be drawn between these "benefits" and the Art. 101(3) TFEU exception.¹²⁹

As discussed in Chapter 3, Regulation 10 appears to extend the spirit of competition law to NHS Commissioners, which could serve to address the inconsistency in approach between purchasers and providers with regard to applying competition law as evidenced by cases such as FENIN.¹³⁰ It would therefore appear that Regulation 10 operates in a space where competition law may not apply, thus reducing implications for conflict between this and Monitor's concurrent powers in respect of general competition law. It has been queried whether Regulation 10(1)'s focus on patients' interests as a counterbalance to anticompetitive behaviour¹³¹ may inhibit future enforcement activity by the CMA similar to that taken by the OFT regarding PPUs¹³² as noted previously. However, this view demonstrates the limitations of trying to discuss a single, unified healthcare sector in England as it conflates not only the NHS (categories 1 and 2) and the PH sector (PPUs being an example of category 3 activity) in terms of the varying applicability of competition law, but also the respective competence of Monitor and the CMA in terms of concurrent powers as developed by the 2014 Concurrency Regulations. Nevertheless, it also raises interesting questions about how competition in the English NHS (and indeed PH sector) may develop in future and the potential influence of linkages between the two on enforcement activity under the discrete "NHS-specific" and general competition regimes.

¹²⁸ These are defined respectively, inter alia, as improvements leading to better patient outcomes and improvements resulting in a better patient experience. See Monitor (2013) supra n127, pages 62-64.

¹²⁹ Sánchez Graells (2014) supra n8.

¹³⁰ However, there is a lack of clarity about what behaviour is at issue: "anti-competitive behaviour" in Regulation 10 is defined by reference to s.64(2) HSCA 2012, which provides that "Anti-competitive behaviour" means behaviour which would (or would be likely to) prevent, restrict or distort competition and a reference to preventing anti-competitive behaviour includes a reference to eliminating or reducing the effects (or potential effects) of the behaviour.'

¹³¹ And also Monitor's general duty under s.62(3) HSCA 2012.

¹³² See Sánchez Graells (2015) supran11, pages 4-5. "One can wonder whether this type of enforcement activity will still be possible when NHS commissioners argue that the anticompetitive behaviour of healthcare providers is justified on the basis of reg.10(1) of the NHS Procurement, Patient Choice and Competition Regulations 2013, since it was carried out in the "patients' interest", measured in gualitative terms."

Regulation 10 has not been used thus far, and in contrast to the other Regulations, can only be used if Monitor receives a complaint.¹³³ Furthermore, Monitor has acknowledged in connection with Regulation 10 that if Regulations 2 and 3 (which emphasize good procurement practice) have been complied with, then other Regulations are likely to be satisfied.¹³⁴

C3. Relationship between Monitor's "competition-related" powers

and its concurrent powers

Monitor has previously considered that it has three tools at its disposal to address competition concerns, namely, its licence authorisation powers, the 2013 Regulations and its concurrent powers. At the time of writing (July 2016), only the 2013 Regulations have been used.

However, it is useful to elaborate what concerns may influence Monitor's decision to use one set of powers over another. This can be summarised as follows:

Possible combination of powers	Governed by
Competition oversight licen	sing Applicability of competition law and
condition + concurrent powers	s.67(3) HSCA 2012
Competition oversight licen	sing s.67(3) HSCA 2012
condition + Regulation 10	
Concurrent powers + Regulation	10 Applicability of competition law and
	Monitor guidance

Figure 5: Monitor's choice of powers.

In essence, a limited guidance framework is offered by the HSCA 2012. S.67(3) HSCA 2012 provides that Monitor must ignore its functions in respect of imposing and removing licence conditions¹³⁵ when exercising its competition or pricing functions. "Competition functions" relate to functions under Chapter 2 (competition), so in theory relate to Monitor's concurrent powers or its Regulation 10 powers by virtue of s.75 HSCA 2012. Such tension between

¹³³ Monitor (2013) supra n127, page 6.

¹³⁴ Ibid, page 66.

¹³⁵ Sections 111 and 113 HSCA 2012.

competition and licensing functions amounts to a "functional conflict". ¹³⁶ This would appear to describe a situation in which Monitor decides between using its power under the Competition Oversight licence condition on the one hand, and either its concurrent powers or Regulation 10 on the other. However, the question of the applicability of competition law to a given situation should not be overlooked.

In contrast to this "functional conflict", there appears to be less guidance regarding the choice between using concurrent powers and Regulation 10. As this comprises a choice between two "competition functions", it is questionable that this amounts to a need to balance "competing regulatory functions", a designation used by Monitor to describe any situation which is not a "functional conflict". ¹³⁷ Insofar as a choice between deploying the 2013 Regulations and concurrent powers is possible, this appears determined primarily by the *applicability* of competition law.

In contrast to the Dutch "separate powers" model, it is difficult to see how either the Competition Oversight licence condition or Regulation 10 may have a detrimental impact on Monitor's concurrent powers. This is because these two powers operate in a space where the scope to actually apply competition law to the English NHS is in question, as discussed previously. Certainly, there appears to be less scope either for "overlap" between the 2013 Regulations and general competition law, and no formal framework for the former to take precedence over the latter. For example, a complaint brought under the 2013 Regulations may deal with issues of competitive neutrality and patient choice

¹³⁶ See further on this point, Monitor, 'Functional conflicts and balancing competing regulatory interests policy', 2 July 2015.

<<u>https://www.gov.uk/government/publications/functional-conflicts-and-balancing-competing-regulatory-interests-policy</u>>.

¹³⁷ While Monitor recognises "balancing competing regulatory interests" as a source of potential conflict, the examples it gives are wide-ranging and involve cross-over between different functions, such as "enforcement action in relation to foundation trusts" and "duties in respect of the accounts of foundation trusts". See Monitor, supra n136, para 5. In any event, Monitor appears to perceive these less as a conflict of interest and more an overlap of functions to be addressed by "legitimately and reasonably balancing potentially competing interests". (Monitor, supra 136, para 7). This is quite different from whether, for example, there can be a conflict between the 2013 Regulations and Monitor's concurrent powers under s.72 HSCA 2012. Both of these are instances of Monitor's "competition functions" and presumably complementary rather than antagonistic.

– such as whether NHS patients have been made aware of their entitlement to a choice of NHS or PH provider – which are not obviously addressed by general competition law. This is in contrast to the high degree of complementarity evident in the NZa's SMP competence and the ACM's abuse of dominance powers.

The relative breadth of Monitor's "competition-related" powers suggest that it would not be surprising if these are deployed in preference to general competition law, perhaps reflecting the experience of other sectors. This is interesting in view of the suggestion that the Secretary of State may seek to extend the requirement to Monitor in the future of using its general competition law powers rather than its regulatory tools as noted above in connection with the ERRA 2013 reforms. However, it is difficult to see how this can operate in practice in view of questions concerning *application*, if not *applicability* of competition law.

4.4. Factors influencing the relationship between regulator and competition authority

Having outlined the "separate powers" and "concurrent powers" models in operation in the Netherlands and England, it is useful to consider two further factors which may influence the relationship between regulator and competition authority with regard to applying competition law.

Firstly, the focus of both the NZa and Monitor on patients as this may suggest a different approach to the ACM and CMA being motivated by enhancing consumer welfare commonly understood as the purpose of competition law.

Secondly, the relationship between the regulator and government as a common concern is that the former is insufficiently independent of the latter. This may present concerns insofar as there may be scope for the Minister for health to influence the approach of the competition authority as well. This is perhaps more evident in the Netherlands in view of the Minister for Health, Wellbeing and Sport setting policy direction which may affect how the ACM uses its new competition powers in healthcare cases. However, provision is 162

now made for NHS England (in lieu of the Department of Health), Monitor and the CMA to work together.

I. The regulator's focus on patients

A. The Netherlands: the NZa's "separate powers" and the "general consumer interest"

The NZa's explicit focus on patients to motivated its activities finds expression in the requirement for it to prioritise the "general consumer interest" under Art.3(4) Wmg. Although it has been queried whether the general consumer interest constitutes a source of legitimacy for regulatory intervention,¹³⁸ this section asks whether the NZa's focus on patients may impact the "separate powers" model underpinning the relationship between the NZa and ACM between 2006 and 2015.

This question is answered first by examining the "general consumer interest" in more detail, then by relating this to the NZa's powers relating to SMP and the drafting of agreements, and finally by considering the effect of the current transfer of SMP to the ACM.

A1. Overview of the "general consumer interest" under Article 3(4)

Wmg

The "general consumer interest" in Dutch healthcare relates to a general body of consumers and long-term interests, thus operates as a means to ensure that the market mechanism works effectively.¹³⁹ The "general consumer interest" comprises the healthcare values of accessibility, affordability and quality, which are defined in specific terms. "Affordability" has both micro and macro dimensions, relating to affordable basic insurance and a lack of reduction in purchasing power or dramatic increase in public spending,¹⁴⁰ respectively.

¹³⁸ Wolf Sauter, 'Is the general consumer interest a source of legitimacy for healthcare regulation? An analysis of the Dutch experience' [2009] 2-3 European Journal of Consumer Law 419-434.

¹³⁹ Thus has been related to the market failure rationale for regulation. See Sauter (2009) supra n138.

¹⁴⁰ NZa, 'Visiedocument: (In) het belang van de consument' ('Vision Document: (In) the general consumer interest') (November 2007). Section 2.1.

"Accessibility" distinguishes physical and financial aspects, ¹⁴¹ namely access to the right care within a reasonable distance and period of time, based on norms regarding waiting time for non-emergency care and that ability to pay is no barrier to receiving medical care, respectively. "Quality" in connection with the NZa (as distinct from the quality regulator, the IGZ) relates to the proper functioning of markets. These values are further underpinned by freedom of choice and transparent information.

There is potential for tension in at least two ways with regard to the overarching values and NZa regulation.¹⁴² Firstly, it may be necessary to clarify where tradeoffs between affordability, accessibility and quality are necessary, or acceptable. In establishing a hierarchy between the three, the Minister for Health, Wellbeing and Sport at the time of the 2006 reforms, suggested that in the event of conflict, quality is to be given the highest priority.¹⁴³ The second scope for tension lies in the possibility of a divergence between the "dual identity" of patients on the one hand, and insured parties on the other. This is illustrated quite well by the rejection of a Bill to amend Art.13 Zvw precipitating a near collapse of the Dutch Liberal/Labour coalition government in December 2014¹⁴⁴ discussed in Chapter 2. Art.13 Zvw operates to mitigate the limited choice of providers available to patients with cheaper "benefits in kind" policies.¹⁴⁵ While its removal may have led to lower premia, which would be an obvious benefit to insured parties and be in keeping with the overall aim of competition in Dutch healthcare of reducing costs, precluding choice of provider may have negative impacts on a patient's health outcomes, a consideration apparently instrumental in the voting down of the proposal.

¹⁴¹ Ibid.

¹⁴² Sauter (2009) supra n138.

 ¹⁴³ (eds) R.D. Friele, 'Evaluatie Wet marktordening gezondheidszorg' ('Assessment of the Dutch Healthcare (Market Regulation) Act 2006 (Wmg)') (Den Haag, ZonMw, 2009).
 ¹⁴⁴ Discussed briefly in Chapter 2, but see also, for example, Bloomberg, 'Dutch disease spreads in Europe as party allegiances break down'

<<u>http://www.bloomberg.com/news/articles/2015-02-01/dutch-disease-spreads-in-europe-as-party-allegiances-break-down</u>>and EUObserver, 'Dutch PM misses EU summit to save coalition'.<<u>https://euobserver.com/news/126994</u>>.

¹⁴⁵ By requiring insurers to offer some degree of compensation if a patient chooses (subsequent) treatment with a provider with no contract with the insurance company.

In respect of the NZa's "separate powers", it is interesting to note how the "public interests" of quality, affordability and accessibility appear to have constituted a framework used by the NZa in its assessment process, particularly with regard to proportionality.¹⁴⁶

A2. The NZa's "separate powers" and the "general consumer interest" framework

The NZa's SMP competence and the "general consumer interest"

In connection with its SMP competence, the NZa has clarified that it will only intervene when the consumer interest will be promoted as a result, suggesting a lesser focus on exclusionary than exploitative conduct.¹⁴⁷ However, the ultimate effects of both types of conduct for public interests are thought to often be similar, namely:¹⁴⁸

Accessibility	Access for individual consumers may be seriously restricted or,	
	in the most serious cases, completely debarred.	
Affordability	Excluding competitors and/or exploiting consumers may result	
	in prices higher than those which would have emerged in a	
	(sufficiently) competitive market. Consequences regarding	
	affordability may affect either the individual consumer (for	
	example, regarding individual payments, excesses or non-	
	insured care) or society as a whole. If the latter, these may be	
	consequences for the premia consumers pay for health	
	insurance.	
Quality	Parties which exclude competitors and/or have so much seller	
	power that the market is not sufficiently competitive are no	
	longer responsive to competitive pressures to maintain or	
	increase quality.	

Figure 6: Overview of the "general consumer interest" in light of exclusionary and exploitative behaviour.

 ¹⁴⁶ For example, in connection with expedited SMP investigations under Article 49 Wmg. See NZa (2010) supra n40, section 3.7.
 ¹⁴⁷ Ibid, p.28.

¹⁴⁸ Ibid, p.29.

Furthermore, in imposing SMP obligations, the NZa is required to describe the extent to which the actual or potential contact is expected to lead to consequences for market relations and (consequently) public interests.¹⁴⁹

In connection with the *Menzis – Van Dalen Pharmacy* case discussed above, the public interests of accessibility, affordability and quality played a part in satisfying requirements for an expedited investigation,¹⁵⁰ and "advantages within the meaning of public interests" was deemed a criterion for judging the reasonableness of a contract.¹⁵¹ Furthermore, affordability formed a particular focus in justifying the use of preference policies¹⁵² and the imposition of the SMP obligation.¹⁵³

The NZa's contract powers and the "general consumer interest"

As regards the NZa's Article 45 Wmg contract powers, here too the "general consumer interest" has been recognised as paramount.¹⁵⁴ Furthermore, the NZa's Regulation on Agreements concerning healthcare-related electronic networks states that it serves the public interests of quality, accessibility and affordability¹⁵⁵ under Art.3(4) Wmg in two ways.

Firstly, by promoting competition which benefits consumers, for example through increasing freedom of choice (such as being able to choose new providers, or more options with existing providers) and thereby also in the sense of affordability.

¹⁴⁹ Ibid.

¹⁵⁰ See NZa Article 49 Decision, supra n51, paragraph 39. This is in accordance with the requirements set out in the policy guidance in respect of Article 49 Wmg, NZa (2010) supra n40, Section 3.7.

¹⁵¹ NZa Art. 48 Wmg Decision, supra n52, para 180.

¹⁵² For example, in the recognition that preference policies, as a type of selective purchasing, may be beneficial for consumers and have a positive effect on affordability of healthcare. However, these positive effects can only be realised by health insurers if a pharmacist agrees to cooperate with the preference policy. See NZa Article 49 Decision, supra n51, paras 75 and 76.

¹⁵³ On the basis that not imposing the obligation would mean that positive effects on affordability would not be obtained. See NZa Article 49 Decision, supra n51, para 98, and NZa Article 48 Decision, supra n52, paras 234-237.

¹⁵⁴ See NZa, 'Toelichting Toepassing artikel 45 Wmg' ('Explanatory Notes regarding the application of Art. 45 Wmg'), December 2009, Section 3.5, p.13.

¹⁵⁵ NZa Electronic Networks Regulation supra n61, page 3.

Secondly, from a healthcare perspective, by the advantages of electronic networks in healthcare in the meaning of quality offering greater access for healthcare providers and thus for consumers who direct their healthcare requests/demands to them.

The Electronic Networks Regulation also clarifies that healthcare providers having access to patient data (such as diagnoses and X-ray results) and medication data can be important for patient safety, and that managing prescriptions and appointments online by reference to data connected to waiting times is directly in patients' interests (in terms of accessibility), and particularly important for their healthcare.¹⁵⁶ An implication of this is that there can be benefits to patients which may go beyond NZa compliance with Art. 3(4) Wmg. Such wide-ranging benefits may suggest – at least in connection with healthcare provider access to electronic networks and online services for patients – that the consistent approach envisaged by the Regulation may address the tension outlined above and produce benefits for patients on the one hand, and insured parties on the other.

A3. Effect of the "general consumer interest" on the "separate powers" model

The effect of the "general consumer interest" on the "separate powers" model varies based on the extent to which the respective powers of the NZa and ACM are indeed separate.

Thus in connection with the NZa's SMP competence, in view of its relationship with the ACM's abuse of dominance powers, the "general consumer interest" may add little to a standard competition assessment based on the effects of exclusionary and exploitative conduct for public interests as outlined above. However, insofar as a general competition assessment may achieve different outcomes, the "general consumer interest" appears to offer a mechanism to draw on non-competition matters and use these to balance the NZa's approach

¹⁵⁶ Ibid, page 11.

to, for example, sanctions in the healthcare sector as suggested by the examples above.

In contrast, the relationship between the NZa's contracts power and the ACM's anticompetitive agreements power is markedly less clear. We have seen that the NZa's power can offer a useful consolidation of ACM decision-making practice, as evidenced by the Electronic Networks Regulation. However, the justification of benefits in the "general consumer interest" do not extend beyond what the ACM could offer.

B. England: the "concurrent powers" model and Monitor's focus on patients

While s.74 HSCA 2012 requires Monitor to disregard its general duties (and thus its focus on patients) when using its concurrent powers, these may nevertheless influence its approach in at least two ways.

Firstly, the elaboration of Monitor's focus on patients under s.62 HSCA 2012 reinforces the inconsistency elsewhere in referencing "healthcare" (potentially categories 1-4) and the NHS (exclusively categories 1 and 2). However, this nevertheless reflects the complexity of the English system which permits patients to switch between the NHS and PH sectors. Building on this latter aspect in particular, a further consideration is that patients in England enjoy a "dual identity" as patients and taxpayers and their interests may vary according to these.

Secondly, there is a potentially significant divergence in approach in that Monitor does not have a duty to promote competition, but rather focuses on preventing anticompetitive behaviour where this is not in the interests of patients.¹⁵⁷

These aspects are now considered further.

¹⁵⁷ S.62(3) HSCA 2012.

B1. Monitor's duty and the different "types" of patient in England

S.62(1) HSCA 2012 places a main general duty on Monitor to protect and promote the interests of people who use health care services by promoting provision of healthcare services which (a) is economic, efficient and effective, and (b) maintains or improves the quality of the services. This is elaborated further, with "protect" meaning that Monitor will act to ensure that the interests of people who use health services are not diminished, whilst "promote" is intended to mean furthering their interests.¹⁵⁸

The reference to "healthcare services" appears to extend beyond the NHS, as it has the meaning given under s.64(3) HSCA 2012, namely:

"[...] all forms of health care provided for individuals, whether relating to physical or mental health [...]; and [...] it does not matter if a health care service is also an adult social care service".

This would appear to suggest that Monitor's duty under s.62(1) HSCA 2012 is owed to <u>all</u> patients in England, whether accessing NHS or PH services. Indeed, it appears to be possible for a single patient to move between the two sectors subject to Department of Health and NHS England rules¹⁵⁹ intended to avoid NHS resources being used to subsidise private healthcare in keeping with the principles of the NHS. However, these do not preclude patients from paying for additional private healthcare while continuing to receive care from the NHS.¹⁶⁰ Furthermore, a patient who commences treatment which would have been routinely commissioned by NHS England on a private basis can, at any stage, request to transfer to complete the treatment within the NHS.¹⁶¹ The emphasis is therefore on keeping NHS and private treatment as separate as possible, so that the treatments are parallel and "co-funding" is avoided as this is not permitted. "Co-funding"¹⁶² relates to any arrangement under which the cost of

¹⁵⁸ Explanatory Notes to the HSCA 2012, para 666.

 ¹⁵⁹ Department of Health, 'Guidance on NHS patients who wish to pay for additional private care', 23 March 2009. NHS Commissioning Board (now NHS England), 'Commissioning Policy: Defining the boundaries between NHS and Private Healthcare'. April 2013. Ref: NHSCB/CP/12.
 ¹⁶⁰ Department of Health (2009), supra n159.

¹⁶¹ NHS England (2013), supra n159.

¹⁶² As distinct from "co-payment", which is permitted in limited circumstances. "Co-payment" refers to Regulations requiring patients to make a contribution to the overall cost of NHS

an episode of care within the NHS is part-funded by an NHS commissioner and part-funded privately by the patient.¹⁶³ This may lead to a scenario in which a patient receives a combination of drugs, only some of which are funded by the NHS. In such instances, the patient must fund all the drugs, but may apply to NHS England under the individual funding request process for the funding of the whole treatment on the grounds that the patient has exceptional circumstances.¹⁶⁴¹⁶⁵

Against this background of complex interactions between the PH sector and the English NHS, it is perhaps unsurprising that Monitor's general duty should be couched in the broad, even unwieldy, terms of "people who use healthcare services".

However, Monitor's duty under s.62(1) HSCA 2012 is effectively confined to NHS patients (categories 1 and 2), which would be consistent with its approach in practice thus far. This narrow interpretation highlights a discrepancy in connection with the "dual identity" of patients and taxpayers. This is particularly notable when contrasted with NHS England's approach, as evidenced by, for example, Simon Stevens' exhortation to "think like a patient, act like a taxpayer". ¹⁶⁶ In view of Monitor's commitment to the NHS as a taxation-funded service free at the point of delivery¹⁶⁷ and its close partnership with NHS England, the failure to couch its general duty in terms of "patients and taxpayers" in the HSCA 2012 appears overlooked, even remiss. This is particularly so when recalling that competition within the English NHS

commissioned care, so typically refers to charges for prescriptions, dental and optical treatment. NHS England (2013) supra n159.

 ¹⁶³ Ibid, p.13. A further distinction appears to be drawn between NHS/private healthcare co-funding as outlined here, which is permitted, and co-funding within the NHS, which is not.
 ¹⁶⁴ Ibid, p.9.

¹⁶⁵ It is perhaps worth noting in this regard that in connection with personal injury claims, there is no requirement for claimants to seek NHS treatment in order for their expenses to be assessed as "reasonable" (s.2(4) Law Reform (Personal Injuries) Act 1948). However, Eagle v Chambers (No.2) [2004] EWCA Civ 1033 suggests that it is not possible to recover damages for the cost of future private treatment if the evidence shows that the claimant would instead obtain treatment via the NHS.

¹⁶⁶ Simon Stevens (CEO of NHS England) speech, 1 April 2014.

¹⁶⁷ Monitor, 'Monitor's Strategy 2014-17 – Helping to redesign healthcare provision in England'.

predominantly takes the form of competition *for* the market, thus commissioning exercises linked with securing value for money for taxpayers.

Certainly there is precedent in Ofcom's dual duty to consumers and citizens¹⁶⁸ to have justified Monitor adopting a similar "dual identity" approach. Indeed, similar to Ofcom, Monitor too can be described as having a broad remit of functions, which include having regard to the likely future demand for health services,¹⁶⁹ enabling the integration of NHS services to improve quality or reduce inequalities,¹⁷⁰ and securing that people who use healthcare services and other members of the public are involved to an appropriate degree in decisions that Monitor makes about the exercise of its functions.¹⁷¹

However, the lack of explicit reference to taxpayers may be explained by two factors.

On the one hand, the concession made in the implementation of the HSCA 2012 to focus on quality, not on price. This may prompt an inference that competition on quality is something patients may be responsive to (in light of the information asymmetry between patients and providers), whereas taxpayers may favour competition on price insofar as this can achieve value for money. However, the extent to which taxpayers are sensitive to price with regard to healthcare provision is perhaps questionable.

On the other hand, the interests of taxpayers and patients may align to such a degree that the distinction becomes superfluous. It has, after all, been suggested that, with regard to the delivery of public services, the preferences of a state's citizens in their role as taxpayers are unlikely to be very different from their preference in their role as users.¹⁷² It may be the case that a good public service is simultaneously responsive to users' needs and accountable to taxpayers, however interests may differ with regard to geographical distribution such that taxpayers in one part of the country subsidize public

¹⁶⁸ As discussed in Prosser (2006) supra n24.

¹⁶⁹ S.62(2) HSCA 2012.

¹⁷⁰ Ss.62(4) and (5) HSCA 2012.

¹⁷¹ S.62(7) HSCA 2012.

¹⁷²Julian Le Grand, 'The Other Invisible Hand – Delivering Public Services Through Choice and Competition'. Princeton University Press, 2007.

service users in another.¹⁷³ This has been recognised as a very real concern regarding the "postcode lottery" allocation of drugs.¹⁷⁴

Against this background, it becomes necessary to draw a clearer distinction between competition as a mechanism to improve NHS care (which is in the interests of both taxpayers and patients, given that the former seem likely to benefit from the NHS at some stage in their lives, if not within a single treatment episode) and competition between the NHS and the PH sectors (which might serve the interests of patients where they can alternate between the two). Monitor's focus might be understood as making market mechanisms work with regard to the former (both in terms of competition *for* and *in* the market). However, the explicit focus on "people who use healthcare services" – as distinct from taxpayers - suggests a concern for the latter.

This dual identity of patient/taxpayer is ultimately helpful – and appears thus far largely overlooked – in understanding how competition works within the NHS and consequently Monitor's focus with regard to this. So, to borrow NHS England terminology, while "acting like a patient" may appear to equate patients with consumers as a demand-driven impetus as per the Dutch system, "thinking like a taxpayer" suggests a form of constraint, most obviously in the form of accountability for securing value for money as associated with public procurement rules. The latter is essential in view of the apparent ongoing commitment to keeping the NHS as a taxation-funded service which nevertheless seeks to incorporate elements of competition.

B2. Monitor's duty and its concurrent powers

Monitor's duty under s.62(1) HSCA 2012 is further defined by s.62(3), which provides that

¹⁷³ Ibid.

¹⁷⁴ For a discussion of rationing within the NHS, see John Meadowcroft, 'Patients, Politics and Power: Government Failure and the Politicization of UK Health Care'. Journal of Medicine and Philosophy, (2008) 33:427-444.

"Monitor must exercise its functions with a view to preventing anti-competitive behaviour in the provision of healthcare services for the purposes of the NHS which is against the interests of people who use such services".

It is important to note that "anticompetitive behaviour" is defined specifically under s.64(2) HSCA 2012 as

"[...] behaviour which would (or would be likely to) prevent, restrict or distort competition and a reference to preventing anti-competitive behaviour includes a reference to eliminating or reducing the effects (or potential effects) of the behaviour".

As this clearly borrows from the terminology of general competition law, it might be inferred that "anticompetitive behaviour" will be defined by reference to "anticompetitive agreements" in a manner reminiscent of SMP being defined by reference to abuse of dominance in the Netherlands. Certainly an example given in the Explanatory Notes to the HSCA 2012 would appear to support this:

"[...] if providers colluded to fix prices or to restrict the range of services available to commissioners (e.g. to restrict provision of care in patients' homes rather than in a clinic or hospital setting), against the interests of patients, then such behaviour may be anti-competitive."¹⁷⁵

It will be recalled that the "healthcare services" of s.62(1) might be deemed to encompass categories 1-4 and its users both NHS and private patients. In contrast, s.62(3) is clearly circumscribed to the English NHS ("the provision of healthcare services for the purposes of the NHS") and NHS patients ("people who use such services"), thus categories 1 and 2. Perhaps unsurprisingly, the s.62(3) qualification was added to the Health and Social Care Bill following the NHS Future Forum's report,¹⁷⁶ so can be understood as part of the wider enterprise to refocus competition vis-à-vis the English NHS prior to enactment of the HSCA 2012.

¹⁷⁵ Explanatory Notes to the HSCA 2012, para 667.

¹⁷⁶ Health and Social Care, HC Bill (2010-12), [221] cl 58(3).

As previously recognised, categories 1 and 2 represent an area of English healthcare where the *applicability* of competition law is ambiguous or unlikely, in view of *FENIN* and the possibility that NHS bodies comprise single economic entities, so involve relationships to which competition law cannot attach.¹⁷⁷ In view of this, and the elaboration of the concurrency arrangements between Monitor and the CMA outlined above, it is difficult to see what s.62(3) HSCA 2012 adds in general, and to the relationship between Monitor and the CMA in particular.

As regards Monitor and the CMA's concurrent powers under s.72 HSCA 2012, s.62(3) is only problematic if it were to lead to Monitor taking a different approach to the CMA in applying general competition law (which presupposes that this is clearly applicable). However, a safeguard against this is offered by s.74 HSCA 2012.

S.74 HSCA 2012 provides that Monitor's general duties under s.62 do not apply in relation to anything done by Monitor in the carrying out of its functions by virtue of s.72.¹⁷⁸ However, where Monitor exercises its concurrent powers under s.72 HSCA 2012, it may nevertheless have regard to any of the matters in respect of which a duty is imposed by s.62 if it is a matter to which the CMA is entitled to have regard.¹⁷⁹ This appears to prompt two questions: firstly, whether there are different areas of interest to Monitor and the CMA, and secondly, whether Monitor's duty to prevent anticompetitive behaviour which is not in patients' interests under s.62(3) is consistent with exceptions to general competition law.

The first is answered to a limited extent by the Explanatory Notes to the HSCA 2012:¹⁸⁰

"[...]whilst Monitor and the [CMA] may both have regard to patients' interests in relation to the provision of healthcare services for the purposes of the NHS,

¹⁷⁷ See Okeoghene Odudu, 'Competition Law and the National Health Service' (*Competition Bulletin: Competition Law Views from Blackstone Chambers*, 12 October 2012).

¹⁷⁸ S.74(2) HSCA 2012.

¹⁷⁹ S.74(3) HSCA 2012.

¹⁸⁰ Explanatory Notes to the HSCA 2012, para 721.

the [CMA] would not always have regard to considerations relating to promoting research into matters relevant to the NHS."

The second question has been considered in terms of a comparison and contrast of Monitor's approach to the prohibition on anticompetitive behaviour of the 2013 Regulations¹⁸¹ with approaches to applying Article 101(3) TFEU.¹⁸² That analysis concludes that Monitor must ensure that it takes a strict approach in determining "patients' interests", but that there is no fundamental inconsistency between the 2013 Regulations and EU economic law.

In view of this, a more appropriate reading of s.62(3) HSCA 2012 is that it comprises a further element of an "NHS-specific" competition regime which operates in the space where the applicability of general competition law is ambiguous following *FENIN*.

B3. Effect of Monitor's duty on the "concurrent powers" model

Overall, Monitor's duty under s.62(1) as elaborated further by s.62(3) HSCA 2012 has little impact on the concurrent powers model insofar as it does not affect the CMA's application of competition law, particularly in view of the safeguard afforded by s.74 HSCA 2012, which should ensure a consistent approach. However, the elaboration of Monitor's duty serves to reinforce the development of "concurrent powers" as entailing the ongoing distinction between the NHS and the PH sectors, which in turn raises questions about the purpose of s.74 HSCA 2012. The ongoing uncertainty about the extent of the *applicability* of competition law to the English NHS and the "healthcare-specific" style of concurrency to develop from the 2014 Concurrency Regulations, suggest that the purpose of s.74 HSCA 2012 as a safeguard to ensure consistent application of competition law by the CMA and Monitor becomes highly questionable, if not redundant.

¹⁸¹ Similarly defined by reference to s.64(2) HSCA 2012.

¹⁸² See Sánchez Graells (2014) supran8 and (2015) supran11.

II. The role of government in connection with the relationship between the regulator and competition authority

As noted in the elaboration of the thesis discussion frameworks above, the relationship between the regulator and competition authority may also be affected by the evolving role of government oversight in the development of competition in the Dutch and English healthcare sectors.

A. The Netherlands: the "separate powers" model and the NZa's and ACM's relationships with the Minister for Health, Wellbeing and Sport

As suggested by the discussion of the relationship between the NZa and ACM in light of the "continuum" framework above, it might be anticipated that the role of the Minister is reduced.

The relationship between the NZa and ACM may also be (at least indirectly) influenced by the relationship of either agency with the Minister for Health, Wellbeing and Sport. Certainly Ministerial intervention in the developing competition reforms in the Netherlands has been deemed a recurrent feature.¹⁸³ The forms which Ministerial intervention has taken encompass changes to legislation to introduce the "healthcare-specific" merger test¹⁸⁴ as well as calls for a reduction in the variety of insurance policies offered to aid patient choice.¹⁸⁵

The effects of the relationship between the Minister for Health, Wellbeing and Sport and the NZa on the "separate powers" model suggest a link with any relationship the Minister may have with the ACM as well. It is important to note that this is currently subject to change with the transfer of NZa competition

¹⁸³ Sauter (2014), supra n7.

¹⁸⁴ Discussed in Chapter 5.

¹⁸⁵ Ministerie van Volksgezondheid, Welzijn en Sport, 'Schippers wil minder verschillende zorgpolissen', Nieuwsbericht, 30 juni 2015. (Ministry of Health, Wellbeing and Sport, 'Minister calls for fewer types of policy', Press Release, 30 June 2015).

powers to the ACM. While it is essential to consider the two relationships separately, it is first useful to consider the status of the NZa and ACM.

The NZa and ACM are both Autonomous Administrative Agencies (ZBOs),¹⁸⁶ an administrative form shared by other sectoral regulators in the Netherlands.¹⁸⁷ In general terms, this status confers a relationship with government which sees the relevant Minister issue general policy direction while the regulator is responsible for day-to-day implementation of the policy. Thus the ACM is subject to oversight by the Minister for Economic Affairs, but the Minister may only intervene in ACM practice in limited circumstances.¹⁸⁸ An apparently critical feature of the transfer of SMP to the ACM is that, with regard to healthcare, the ACM will effectively be implementing policy set by the Minister for Health, Wellbeing and Sport. This arrangement can be found in other sectors (such as transport), so is not novel as such, but as noted previously,¹⁸⁹ concerns have been raised about its proposed development in healthcare.

A1. The relationship between the NZa and the Minister for Health,

Wellbeing and Sport

Between 2006 and 2015, various links between the NZa and Minister were established which have a bearing on the development of competition in the Dutch healthcare sector. Perhaps most notable is the requirement for the two to cooperate with regard to setting tariffs, with the NZa making recommendations to the Minister regarding which hospital service prices can be liberalised.

¹⁸⁶ Zelfsbestuurorganen (ZBOs).

¹⁸⁷ However, there has been a reduction in the creation of ZBOs as the preferred legal and administrative form for new regulators. This has been explained by the ZBO model being criticised as not offering a satisfactory answer to the inherent tension between the necessary "independence" (of the regulator) and "Ministerial responsibility" (for the regulator). For further discussion, see Margot Aelen, 'Beginselen van goed toezicht: het onafhankelijkheidsbeginsel' ('Principles of good regulation: the principle of independence') Tijdschrift voor Toezicht (2015), Aflevering 2.

¹⁸⁸ An example being to overturn an ACM decision to block a merger. For further discussion, see Annetje Ottow, *Market & Competition Authorities – Good Agency Principles* (Oxford University Press 2015) pages 114-117.

¹⁸⁹ See page 144 and supra n77.

A further aspect can be found in the clarification by the Explanatory Memorandum to the Wmg that the Dutch government is, and remains, responsible for oversight of public interests in healthcare.¹⁹⁰ Prior to the 2006 reforms and institution of a demand-driven system, the government was influential in motivating providers and insurers to merge or achieve growths in scale.¹⁹¹ However, change was deemed necessary to incentivise providers and insurers to accept their roles in a marketplace, but that this could not be achieved overnight, with the recognition of "competition where possible, regulation where necessary".¹⁹²

However, perhaps of most relevance to the present discussion is Ministerial intervention which has changed the competition law framework in one way or another. An obvious example is in the amendment of the Wmg to incorporate the "healthcare-specific" merger test for the NZa which took effect in January 2014. This is discussed in detail in Chapter 5, but is considered briefly here as it might be construed as a Ministerial response to the perceived problem of the ACM not blocking any hospital mergers under general merger control between 2006 and 2014. If this interpretation is accepted, then the current transfer of NZa competition powers to the ACM might be viewed in the same light – namely, as a response to a perceived problem.

A2. The relationship between the ACM and the Minister for Health, Wellbeing and Sport

Between 2006 and 2015, there appeared to be no explicit framework for the Minister for Health, Wellbeing and Sport to influence the ACM's practice in healthcare since the ACM is overseen by the Minister for Economic Affairs. Indeed, the extent to which the relationship between the NZa and the Minister

¹⁹⁰ Kamerstukken II, 2004-05, 30 186, 3 - Regels inzake marktordening, doelmatigheid en beheerste kostenontwikkeling op het gebied van de gezondheidszorg (Wet marktordening gezondheidszorg), Nr.3 Memorie van Toelichting. (Second Chamber documentation, Parliamentary Session 2005-06, 30 186, 3 (Explanatory Memorandum) – Rules governing market organisation, efficiency and managed cost development in healthcare (Dutch Healthcare (Market Regulation) Act 2006 (Wmg)). Page 2.

¹⁹¹ Ibid. Page 2-3.

¹⁹² Ibid. Page 3.

proved influential for the perceived lack of competition cases in this period might be questionable.

While the current transfer of powers to the ACM entails additional functions and responsibilities, it appears not to modify the substantive scope of competition law. How the new arrangements evolve in practice obviously remains to be seen. However, it is notable that senior figures in the ACM have already expressed reservations about what the new SMP powers can achieve, namely that the transfer of powers would not necessarily lead to *more* intervention on the basis of sector-specific regulation.¹⁹³ This is because the ACM has consistently (and correctly) taken the view that it can only intervene where it establishes a breach of the competition rules.

Overall, Ministerial intervention has had an indirect effect on the "separate powers" model. It remains to be seen how scope for Ministerial intervention may affect any residual tension between *ex ante* and *ex post* powers inherent in the ACM's competence to take action in connection with SMP or abuse of dominance, respectively.

B. England: the "concurrent powers" model and Monitor's relationship with the Secretary of State for Health

The relationship between Monitor and the Secretary of State for Health, in contrast to the situation in the Netherlands, has received comparatively little attention. Perhaps most notably it has been suggested that the wider HSCA 2012 reforms raise constitutional concerns by making the Secretary of State for Health's relationship with the NHS more complex, by creating opaque networks of non-statutory bodies which may influence decision-making and (especially in relation to competition) by "juridifying" policy choices – such as private provision of NHS services – as matters of law.¹⁹⁴

¹⁹³ ACM, Spreekpunten Henk Don bij rondetafelgesprek 'kwaliteitloont' in de Tweede Kamer op 17 april 2015. ('Points for discussion by Henk Don at the "Quality Pays" round table discussion in the Second Chamber 17 April 2015').

¹⁹⁴ ACL Davies, 'This Time, It's For Real' [2013] M.L.R. 76(3), 564-588.

In order to understand the relationship between Monitor and the Secretary of State for Health with regard to competition and Monitor's relationship with the CMA in applying competition law, it is necessary to look both beyond and behind the competition provisions of the HSCA 2012 to the new agencies created by the HSCA 2012 and the ongoing influence of the pre-HSCA 2012 NHS competition regime.

As regards the wider HSCA 2012 reforms of the roles of the Secretary of State for Health and the Department of Health, two elements are of particular note to the present discussion: the establishment of NHS England and the new mechanisms for modifying licence conditions and determining the NHS tariff.

B1. The establishment of NHS England

Section 9 HSCA 2012 amends the National Health Service Act 2006 to incorporate the functions of the NHS Commissioning Board (now renamed NHS England). Section 1H(2) NHS Act 2006 now provides that NHS England, concurrently with the Secretary of State, is under a duty¹⁹⁵ - subject to limited exceptions¹⁹⁶ - to continue the promotion in England of a comprehensive health service designed to secure improvement –

- (a) In the physical and mental health of the people of England, and
- (b) In the prevention, diagnosis and treatment of illness.

In essence, although it is unclear how "concurrently" is to be interpreted in this context, this provision appears to serve to limit Secretary of State oversight with regarding to promoting a comprehensive health service in England. The Explanatory Notes to the HSCA 2012 clarify that NHS England's duty to promote a comprehensive health service would not apply to those services falling within the public health functions of the Secretary of State or local authorities.¹⁹⁷ Certainly NHS England appears to interpret its remit in expansive terms:

¹⁹⁵ Section 1(1) National Health Service Act 2006.

¹⁹⁶ Namely, "...the part of the health service that is provided in pursuance of the public health functions of the Secretary of State or local authorities", which is beyond the scope of the present discussion.

¹⁹⁷ Explanatory Notes to the Health and Social Care Act 2012, para 97.

"NHS England leads the National Health Service (NHS) in England. We set the priorities and direction of the NHS and encourage and inform the national debate to improve health and care."¹⁹⁸

NHS England has outlined the role of the Secretary of State for Health as follows:

"The Secretary of State has overall responsibility for the work of the Department of Health (DH). DH provides strategic leadership for public health, the NHS and social care in England."¹⁹⁹

Nevertheless, it is NHS England which has devised a "strategic vision" for the NHS in the form of the NHS Five Year Forward View (NHS FYFV),²⁰⁰ in partnership with other bodies (including Monitor and the NHS Trust Development Authority), while acknowledging the need for consensus and input from government.

Limited oversight by the Secretary of State might be inferred by annual publication of "the Mandate", which sets out the ambitions which the government wants NHS England to achieve,²⁰¹ and reaffirms the government's commitment to an NHS built on the guiding principles that access to healthcare is based on need and not the ability to pay, and that services are comprehensive and available to all.²⁰² The Mandate makes a single reference to competition as an example of how NHS England will need to balance different ways of ensuring local and national delivery. Limited reference to competition was made in the 2013-2015 and 2015-2016 Mandates as a means to achieving better quality,²⁰³ but this has been removed in the current version.

¹⁹⁸ NHS England website, supra n18.

¹⁹⁹ NHS England, 'Understanding the New NHS – A guide for everyone working and training within the NHS', page 8, 'Structure of the NHS in England'.<<u>https://www.england.nhs.uk/wp-content/uploads/2014/06/simple-nhs-guide.pdf</u>>.

²⁰⁰ NHS England website, supra n18.

²⁰¹ Department of Health, 'The Mandate – A Mandate from the Government to the NHS Commissioning Board: April 2013 – March 2015' November 2013.

²⁰² Department of Health, 'The Government's Mandate to NHS England for 2016-2017', January 2016. Para 1.1.

²⁰³ See paragraphs 6.4 of both Department of Health, 2013-2015 Mandate, supra n201 and 'The Mandate – A Mandate from the Government to the NHS England: April 2015 – March 2016', December 2015. "The objectives in this mandate can only be realised through local

B2. Post-HSCA 2012 system of referral of decisions regarding licence modifications and the NHS tariff to the CMA

The HSCA 2012 provides a role for the CMA in respect of decisions regarding licence modifications. Where Monitor gives notice of a proposal to include or modify a special condition in a licence and this is rejected by the applicant or licence holder, s.101(2) HSCA 2012 provides that Monitor can refer to the CMA to investigate and report on whether any matters relating to the (proposed) provision of a healthcare service for the purposes of the NHS by the applicant or licence holder concerned specified in the reference (may) operate against the public interest. The Explanatory Notes clarify that the CMA's focus must be on the public interest, so could not consider references in terms of the impact on competition as an end in itself.²⁰⁴ Furthermore, s.101(6) HSCA 2012 provides that the CMA must have regard to the matters in respect of which Monitor has duties under s.62. Although no further clarification is offered by the Explanatory Notes, this might be construed as meaning that the CMA must have regard to Monitor's duty to balance anticompetitive behaviour with patient interests under s.62(3) HSCA 2012. However, there has been no recourse to this mechanism at the time of writing (July 2016).

The HSCA 2012 also introduces a new system for determining the NHS tariff. This is important because the NHS tariff has been instrumental in facilitating conditions for competition with regard to the NHS, such as "payment by results" to incentivise NHS providers and as a benchmark for private and voluntary sector providers to adhere to, thus effectively creating a market for "NHS provision".

Prior to the HSCA 2012, the NHS tariff was determined by the Department of Health. However, the HSCA 2012 sets out a mechanism whereby Monitor must publish a "national tariff" document specifying, inter alia, certain healthcare services which are or may be provided for the purposes of the NHS and the

empowerment. The Board's role in the new system will require it to consider how best to balance different ways of enabling local and national delivery. These may include [...] the transformative effect of information and transparency, enabling patients to make fully informed decisions, and encouraging competition between peers for better quality". ²⁰⁴ Explanatory Notes to the HSCA 2012, para 798.

method used for determining the national prices of those services.²⁰⁵ Prior to publication of the national tariff, Monitor must consult on its proposals by sending a notice outlining the proposed healthcare services and method(s) used to determine prices to each CCG and relevant provider and such other persons as it considers appropriate.²⁰⁶ This notice must comprise, inter alia, the healthcare services to be included and the method(s) used to determine prices, both of which are subject to agreement between Monitor and NHS England.²⁰⁷ If the consultation reveals objections which exceed certain thresholds determined separately for CCGs and providers,²⁰⁸ then Monitor may not publish the tariff and must refer it for CMA review of whether the method proposed is appropriate.²⁰⁹²¹⁰ This review function of the CMA is not one of its general purposes under the Competition Act 1998, but is governed by the HSCA 2012.²¹¹ Thus far, references to the 2015-16 tariff were raised, but apparently resolved by NHS England and Monitor offering providers a choice between an "enhanced tariff option" and a "default tariff rollover", 212 thus no recourse to CMA review was deemed necessary.

What emerges from the foregoing is a complicated picture in which the relationship between Monitor and the CMA is not only dependent upon it

²⁰⁵ Section 116 HSCA 2012.

²⁰⁶ Section 118 HSCA 2012.

²⁰⁷ Section 118(7) and (8) HSCA 2012.

²⁰⁸ Expressed as the "objection percentage" in s.120(2) HSCA 2012. S.120(3)(a) defines this for CCGs as the proportion of CCGs or relevant providers who objected to the proposed method. S.120(3)(b) defines this as the "share of supply percentage" of relevant providers who objected to the proposed method, weighted according to their share of supply in England of such services as may be prescribed.

²⁰⁹ S.120(1)(b) HSCA 2012 specifies the Competition Commission and s.120(4) HSCA 2012.

²¹⁰ Further guidance is provided by Competition Commission, National Tariff Methodology Reference Rules under the Health and Social Care Act 2012: Guide. February 2014. CC22.

 $^{^{211}}$ S.120(5) HSCA 2012. Schedule 12 HSCA 2012 sets out the procedure on a reference under s.120 HSCA 2012.

²¹² See, inter alia, NHS National Tariff Payment System 2015-2016 Engagement Documents <<u>https://www.gov.uk/government/consultations/nhs-national-tariff-payment-system-</u>

<u>201516-engagement-documents</u>>. Simon Stevens and David Bennett, Letter to Chief Executives of providers of NHS-funded care, 18 February 2015. <<u>https://www.england.nhs.uk/wp-content/uploads/2015/02/tariff-arrangmnts-2015-16nhs-activity.pdf</u>>.

sharing concurrent powers under s.72 HSCA 2012, although a distinction is drawn between these and the separate roles considered above.²¹³

4.5. Conclusions

This chapter has reviewed the relationship between the new healthcare regulator and the competition authority in the Netherlands and England to attempt to clarify how intervention by the former may affect the application of general competition law by the latter. This is necessary as the underlying institutional relationship may offer some measure of explanation for the absence of competition cases in both countries and, more widely, the potential success of the competition reforms to both the Dutch and English healthcare systems.

By considering the relationship between the two agencies in general terms through the lenses of the three thesis discussion frameworks, this chapter established that there are significant changes to the role of the Minister in both countries which may influence the relationship between the regulator and the competition authority. While this means that it is still possible to speak of the "macro" level despite the reduced role of government, this section established that the conception of movement along a continuum away from government responsibility to competition authority oversight is by no means clear. Furthermore, the differing approaches taken – from the ongoing involvement of the Minister for Health, Wellbeing and Sport as regards policy direction for the ACM in light of the current transfer of power in the Netherlands, to the effective removal of input by the Secretary of State for Health with the creation of NHS England – suggest that the picture is increasingly complex and perhaps counterintuitively so, in view of the respective scope for competition in Bismarck and Beveridge systems. The differing relationships also suggest

²¹³ However, a distinction is drawn between the concurrent powers shared by the CMA and NHS Improvement and "the functions of the CMA in its separate role of considering references related to proposed action by NHS Improvement under healthcare sector legislation, for example in relation to setting the national tariff for healthcare services." CMA, NHS Improvement (2016), supra n115.

movement between the "competition-centric" and "healthcare-centric" approaches.

This chapter also examined the extent of the "separate powers" and "concurrent powers" models. This enabled an understanding of the potential limitations of each model – for example, that the "separate powers" model may represent in essence the tension between *ex ante* and *ex post* intervention, but not offer a resolution of this, despite the removal of "separate" powers with the transfer of SMP competence to the ACM.

Perhaps most significantly, the chapter demonstrated that the "concurrent powers" granted to Monitor and the CMA under s.72 HSCA 2012 operate in a very different way to other sectors in view of the distinction between the NHS and PH sectors and the consequent *applicability* of competition law. Indeed, the actual relationship between the CMA and Monitor which has developed from the HSCA 2012, the ERRA 2013 reforms and the 2014 Concurrency Regulations represents "concurrency" as a concept closer to the literal dictionary definition of [powers] existing at the same time, rather than the "cocompetence" intended as per other sectors. The recent establishment of NHS Improvement and development of a Memorandum of Understanding with the CMA in theory offered an opportunity to revisit this institutional framework. However, the reluctance to have recourse to primary legislation following the experience of enacting the HSCA 2012 appears to suggest that the current framework is increasingly entrenched. The connection between the "concurrent powers" under s.72 HSCA 2012 and "healthcare provision" underscores again the fact that it remains difficult, and even impractical, to speak of "healthcare" as a single sector in England. While other sectors may comprise various markets, the distinction between the NHS and the PH sector is pronounced to such an extent that it is difficult to speak of concurrent powers since Monitor's expertise is effectively reserved to the NHS (a position reinforced as much by the ERRA 2013 and the 2014 Concurrency Regulations as by the HSCA 2012), and the CMA's to the PH sector. This appears to undermine the argument typically advanced in favour of concurrent powers of the benefits of sector-specific expertise both in assessing competition cases and also in

185

terms of reputation which may facilitate the development of competition policy in a sector. Both – and particularly the latter – appear to have obvious relevance to healthcare. However, the extent to which knowledge of the NHS can be imputed from the CMA's experience of the PH sector is questionable. These are two very distinctive markets for different reasons: the NHS due to its commitment to universal coverage, and the supplementary nature of the PH sector which brings it closer to "standard" markets, which is unusual for healthcare (at least in Europe).

The chapter also examined two factors which may prove influential in shaping the relationship between the regulator and competition authority in England and the Netherlands, namely, the focus of the regulator on patients and the evolving role of government in connection with this relationship.

Examination of the regulators' focus on patients was intended to indicate whether any significant discrepancy existed between this and the competition authority's motivation to enhance consumer welfare by applying competition law, as this may have implications for whether and how competition law is applied. With regard to the Netherlands, the chapter examined the NZa's focus as encapsulated in its duty to promote the "general consumer interest", understood in terms of the values of accessibility, affordability and quality commonly associated with healthcare provision. This provided a framework for grounding the NZa's decisions using its "separate powers", and the chapter found that as this is not automatically replicated in the ACM's assessment criteria, there may be a need to include these by other means, such as policy directions. In England, Monitor's general duty to protect and promote the interests of people who use healthcare services under s.62(1) HSCA 2012 was examined and found to reinforce still further the potential scope for distinction between NHS and private patients. This – along with the qualification of s.62(3) - appears to support further the view advanced in this chapter that "concurrency" in connection with regulating English healthcare takes on a different meaning in the absence of a single, unified sector. This section examined the implications of this new style of concurrency for potential competition cases and found that the situation which existed prior to the enactment of the HSCA 2012 – namely, that the CMA would take enforcement action only in connection with the PH sector – may well continue.

In its last section, the chapter considered the evolving role of the government and how this may impact the relationship between the competition authority and regulator with regard to applying competition law. Here too we see counterintuitive developments. In the Netherlands, where the applicability of competition law is considerably less in question, it may be the case that the Minister intervenes to try and direct how the ACM responds. In England, the creation of NHS England marks a significant turning-point, and raises questions about the operation of Monitor (and now NHS Improvement) despite being at least nominally independent of the Department of Health. In light of the perhaps limited applicability of competition law, it seems reasonable to query the role of the CMA. This chapter has found that, even where the CMA has limited scope to apply competition law, it has other functions in connection with competition in the NHS, namely effectively as an arbitrator in resolving disputes regarding the setting of the NHS tariff by NHS England and Monitor. This creation of semi-independent bodies, coupled with a reduced role for the Secretary of State for Health clearly offers a potentially rich area for future research.

Finally, the original motivation for the research question of this chapter came from criticisms made in both England and the Netherlands, that the power to apply general competition law should be the exclusive preserve of the competition authority. Indeed, this is taking place in the Netherlands with the current transfer of SMP competence to the ACM, although it remains to be seen whether further policy directions may serve to complicate the picture of a competition authority applying general competition law. Certainly the idea that general competition law is applied by a single agency has the merit of simplicity, and suggests as much a "competition-centric" approach as a "healthcarecentric" approach. In England, the concerns surrounding the enactment of the HSCA 2012 suggest that sole oversight of the NHS by the CMA is problematic, over and above questions of the applicability of competition law to the NHS considered in Chapter 3. This may suffice to explain the effective obviation of CMA oversight of the NHS by the 2014 Concurrency Regulations. Consequently, the common "solution" of transferring the regulator's competition powers to the competition authority should be treated with caution.

Chapter 5

What can "healthcare-specific" merger control achieve in Dutch and English healthcare?

Contents

5.1. Introduction	
5.2. Thesis discussion frameworks and the discussions of this chapter	
I. The "healthcare structure" – macro, meso and micro levels	
II. The continuum between healthcare provision as a public service overs government and a competitive marketplace overseen by a competition authority	
III. A "competition-centric" or "healthcare-centric" approach	
5.3. What is "healthcare-specific" merger control and how does it relate to merger control?	-
I. Overview of UK and Dutch general merger control	200
A. Market definition and hospital mergers	
B. Dutch general merger control and hospital merger cases	201
C. UK general merger control and hospital merger cases in England.	205
II. Jurisdictional aspects	207
A. The Netherlands	207
A1. Lower turnover thresholds	207
A2. The "healthcare-specific" merger test and merger effects report	209
B. England	210
B1. The requirement for a "relevant merger situation" - NHS Trusts and N FTs	
B2. The requirement for a "relevant merger situation" - PPUs	219
C. Relationship between the jurisdictional aspects and general merge control 220	şer
III. Substantive assessment aspects	223
A. The Netherlands	223
A1. Additional assessment criteria for the ACM	223
A2. NZa Opinions, 2006-2015	224
B. England	225
B1. Monitor's advisory function under s.79(5) HSCA 2012	225

C. Relationship between the "substantive assessment aspects" and general merger control		
5.4. What is "healthcare-specific" merger control intended to achieve?2	228	
I. "Selling" competition reforms and engaging with the healthcare sector2	229	
II. Ensuring appropriate oversight of mergers in a sector in transition2	231	
III. Counteracting the limitations of a competition-based test	232	
IV. Elaborating the appropriate place of merger control in a sector heavily dependent upon cooperative relationships	234	
5.5. Conclusions – what can "healthcare-specific" merger control achieve in Dutch		
and English healthcare?		

5.1. Introduction

In contrast to the preceding discussions of Dutch and English experiences of applying competition law to healthcare and the associated interactions between the competition authority and healthcare regulator, the applicability of general merger control to hospital mergers and the exclusive competence of the competition authority are not in doubt in either country. A further contrast is seen in hospital mergers representing a comparatively active area in terms of the number of cases: six in England subsequent to the HSCA 2012 reforms¹ and fifteen between 2012 and 2014 in the Netherlands.² Indeed, merger activity has been considered a logical response to the opening up of Dutch hospital markets³ as previously unregulated markets strive for efficiency. Although the HSCA 2012 reforms are still unfolding, this may also prove to be the case in England as the NHS increasingly operates within a financially straitened environment. Certainly, episodes of "merger mania" – albeit assessed under an "NHS-specific" merger test - have accompanied previous NHS reform. The most notable example being merger as a mechanism to implement successive government policy (between 2004 and approximately 2014) to "upgrade" NHS

¹ For an overview, see Andrew Taylor, 'Competing over health – What's next for the National Health Service in England?', Competition Law Insight, 16 February 2016.

² This marks an increase on the nine hospital mergers assessed between 2004 and 2011. Ron Kemp, Marie-Louise Leijh-Smit and Krijn Schep, 'Concentratietoezicht ACM in de

ziekenhuissector – Inzichtin en reflectie op de praktijk', ('ACM merger control in the hospital sector – insights into and reflections on practice') Markt en Mededinging Juli 2015 Nr. 3.

³ Marcel Canoy and Wolf Sauter, 'Out of control? Hospital mergers in the Netherlands and the public interest' [2010] E.C.L.R. 31(9), 377.

Trusts to NHS Foundation Trust (NHS FT) status in a process subsequently named the "NHS FT pipeline". Thus "political drivers" may also play a part – at least in England – alongside economic and clinical drivers for hospital mergers.⁴

However, applying general control to hospital mergers⁵ in both the Netherlands and England has proved difficult, even contentious, in light of tensions, inter alia, between mergers and promoting competition⁶ and, more generally, the ability of a competition test to accommodate "healthcare-specific" concerns. The transitional nature of the healthcare markets in both countries complicates the picture further. For example, the gradual liberalisation of hospital service prices and encouragement of selective contracting by health insurers in the Netherlands proved instrumental in the ACM's approval of the *Tilburg Hospitals* merger,⁷ a decision which has attracted criticism. In England, the distinctive nature of the NHS raised questions about the use of general merger control and varying perceptions of merger benefits within the NHS and by the CMA⁸ when the latter blocked the *Bournemouth-Poole* merger,⁹ the first to be assessed under the HSCA 2012 reforms. However, subsequent NHS FT mergers have

⁴ Economic/financial drivers have been defined as encompassing economic gains, reduced management costs through economies of scale and scope and reduced operating costs arising from rationalisation of service provision. Client care/clinical quality drivers typically refer to improvements in clinical quality, whether by means of increased effectiveness of higher volume activity of specialised units, higher quality medical training or the capacity to retain and recruit staff more effectively. See Marco Cereste, Neil Doherty, Cheryl Travers, 'An investigation into the level and impact of merger activity amongst hospitals in the UK's National Health Service', Journal of Health Organization and Management, [2003] Vol. 17, No.1, 6.

⁵ As distinct from mergers involving, for example, health insurers or pharmaceutical companies, which attract less sensitivity.

⁶ On this point, see Canoy and Sauter (2010) supra n3.

⁷ ACM, Case 7295/402 TweeSteden Ziekenhuis – St Elisabeth Ziekenhuis. ('TweeSteden Hospital – St Elisabeth Hospital') ('Tilburg Hospitals merger').

⁸ See, for example, Fod Barnes, 'Competition law and patient choice in the NHS: help or hindrance?' (*Oxera Agenda*, January 2014).

⁹ CMA, Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust / Poole Hospital NHS Foundation Trust Merger Inquiry (CC). 17 October 2013.

been approved both at Phase I (*Heatherwood-Frimley Park* and *Chelsea-West Middx*)¹⁰ and Phase II (*Ashford – Royal Surrey*).¹¹

In view of this, it is not surprising that a range of modifications to general merger control have been introduced in both countries. These can be described collectively as "healthcare-specific" merger control, and this can be understood further as comprising both "jurisdictional" and "substantive assessment" aspects which have been introduced both prior, and subsequent to, the application of general merger control in relation to the 2006 and HSCA 2012 reforms. These form the focus of this chapter, but in overview, comprise the following:

¹⁰ For example, CMA, Case Reference ME/6432-14, Anticipated acquisition of Heatherwood and Wexham Park Hospitals NHS Foundation Trust by Frimley Park Hospital NHS Foundation Trust, 3 June 2014. CMA, Case Reference ME/6481-14, Anticipated acquisition by Chelsea and Westminster NHS Foundation Trust of West Middlesex University NHS Trust, 19 January 2015. ¹¹ CMA, Ashford and St Peter's and Royal Surrey County A report on the anticipated merger of Ashford and St Peter's Hospitals NHS Foundation Trust and Royal Surrey County Hospital NHS Foundation Trust, 16 September 2015 (Phase II decision).

	Jurisdictional aspects	Substantive assessment aspects
The	- Temporary lower	- Temporary additional
Netherlands	turnover	assessment criteria;
	thresholds;	- NZa Opinions.
	- "Healthcare-	
	specific" merger	
	test.	
England	- S.79 HSCA 2012 –	- Monitor advisory
	focus on NHS FTs;	function under s.79(5)
	- Alternative	HSCA 2012.
	organizational	
	forms for NHS	
	Trusts	
	("Transactions	
	pipeline");	
	- "NHS-specific"	
	merger test ("NHS	
	FT pipeline");	
	- New test for	
	Private Patient	
	Units (PPUs).	

Figure 1: Overview of "healthcare-specific" merger control.

These modifications are affected by the ongoing wider developments regarding competition in healthcare in both countries. Thus the current refocusing of the ACM's powers in connection with healthcare includes the transfer of the "healthcare-specific" merger test to the ACM from the NZa, and the refocusing of how public interests are to be incorporated in the merger assessment process. In England, the development of a new test for PPUs arises from concerns of an expansion in these as a result of s.165 HSCA 2012 removing the private patient income cap, and alternative organizational structures for NHS Trusts is clearly linked to the development of new care models with the NHS Five Year Forward View.

This chapter therefore provides a timely assessment of what "healthcarespecific" merger control can achieve by reference to the development of the aforementioned modifications. These might be considered to respond to general concerns about hospital mergers,¹² typically relating to increased costs, as well as specific concerns about apparent preference for merger over other forms of cooperation in view of the relative clarity of merger assessment arising from widespread merger approval vis-à-vis perceived uncertainty regarding the anticompetitive agreements provisions.¹³ Widespread merger approval has proved a particular concern in the Netherlands prior to the blocking of the *Albert Schweitzer Hospital – Rivas Care Group* merger¹⁴ in July 2015.

The chapter is structured as follows.

Section 2 outlines the three thesis discussion frameworks in relation to general merger control and "healthcare-specific" merger control.

Section 3 asks what "healthcare-specific" merger control is and how it relates to general merger control. This enables discussion in overview of the constituent aspects outlined above and illustrated in Appendices J and K. A brief overview of market definition and general merger control is followed by overviews of cases discussed in this chapter, namely, the *Zeeland Hospitals*, *Tilburg Hospitals* and *Albert Schweitzer Hospital – Rivas Care Group* mergers in the Netherlands, and the *Bournemouth-Poole* and *Ashford – Royal Surrey* NHS FT mergers in England.

¹² It has been established in both countries that merged entities can exceed the optimal hospital size. Canoy and Sauter (2010) (supra n3) refer to OECD data to conclude that the size of Dutch hospitals is above the EU average. This is also a concern in England, see Anita Charlesworth, 'Size may not be everything: reviewing hospital mergers' (*Nuffield Trust Blog Post*, 24 February 2012). In addition, government-mandated mergers in England have been deemed to produce no more benefit than those arising between private hospitals. Martin Gaynor, Mauro Laudicella, Carol Propper, 'Can governments do it better? Merger mania and hospital outcomes in the English NHS' [2012] Journal of Health Economics Volume 31, Issue 3, May 2012, 528.

¹³ On this point, see R.J.P. Jansen, 'Samenwerken of fuseren in de zorg?' ('Collaborating or merging in healthcare?'), Markt & Mededinging 2013 nr.2, E. Loozen, M. Varkevisser and E. Schut, 'Beoordeling ziekenhuisfusies door ACM: staat de consument wel echt centraal?' ('Are consumers really at the centre of the ACM's hospital merger decisions?'), Markt & Mededinging 2014 nr.01, Andrew Taylor, When does an alliance become a merger? (*NHS Competition Regulation*, 14 July 2015).

¹⁴ ACM, Zaak 14.0982.24/Stichting Albert Schweitzer Ziekenhuis – Stichting Rivas Zorggroep. ('Albert Schweitzer Hospital – Rivas Care Group merger').

Section 4 develops consideration of the individual aspects by asking what "healthcare-specific" merger control *is intended* to achieve.

Section 5 draws on the previous sections to conclude and assess what "healthcare-specific" merger control *can* achieve in Dutch and English healthcare.

5.2. Thesis discussion frameworks and the discussions of this chapter

I. The "healthcare structure" – macro, meso and micro levels

While the focus of this chapter is on modifications made to general merger control as it is applied to hospital mergers, thus providers (micro level), the other levels of the "healthcare structure" are also engaged to varying degrees.

The meso level of purchasing activity is engaged to only a limited degree in the discussions of this chapter, for instance in the countervailing buyer power of health insurers being a factor which enabled the ACM to approve the *Tilburg Hospitals* merger.

The macro level is more evident in the Dutch system in the changing relationship between the ACM and NZa regarding merger control, particularly with the current transfer of the "healthcare-specific" merger test to the ACM. The role of the Minister for Health, Wellbeing and Sport is noted in connection with setting policy direction. In England, the macro level can be seen in the roles of Monitor and the NHS Trust Development Authority (NHS TDA) (now NHS Improvement) – and not explicitly the Secretary of State for Health - in assessing and approving mergers between NHS Trusts in the context of the "NHS FT pipeline". However, the transition period surrounding the *Bournemouth-Poole* merger was marked by calls for Ministerial intervention in, and reconsideration of, NHS merger assessment.¹⁵ The macro level is also highly

¹⁵ See Kiran Desai, 'Public Hospital Mergers: a case for broader considerations than competition law?' [2013] E.C.L.R. 2013, 34(12), 646-653 and Paul Corrigan and Andrew Taylor,

important since policy direction has provided a motivation for mergers – notably, the successive government policy for NHS Trusts to achieve NHS FT status. Indeed, this approach to "directing" hospital mergers might also be inferred in the "Transactions pipeline" and varied organizational forms in light of the new care models developing with the NHS Five Year Forward View. Furthermore, policy influence may be emerging in Monitor's assessment of "relevant customer benefits" in the HSCA 2012 regime for mergers involving NHS FTs as these have been linked to current government policy of achieving a "seven day NHS" in the *Ashford - Royal Surrey* merger.

II. The continuum between healthcare provision as a public service overseen by government and a competitive marketplace overseen by a competition authority

The "continuum" framework has most relevance to this chapter and is developed further here.

The application of general merger control by a competition authority may represent the end point of the continuum, and amendments/modifications may merely represent points along the continuum as the end point of healthcare as a market amenable to oversight exclusively by general competition rules has not yet been reached. Insofar as modifications are geared towards achieving this end point, they might be described as "prospective" in nature. There is an implication that modifications to general merger control are not necessary beyond a transition phase as healthcare can fundamentally be regarded as a market like any other. In other words, in this conception the emphasis is on the healthcare sector to adapt its ways of working to accommodate general merger control.

Alternatively, the application of general merger control might be seen instead as marking a change of direction, and so modifications might be described as "reactive" in nature. This view suggests that modifications are not necessarily

^{&#}x27;The CMA can improve the NHS merger regime: here's how', Health Service Journal, 26 March 2014.

mere temporary mechanisms to facilitate an ultimate application of general merger control, but rather represent necessary (however temporary) accommodations of the specificities of the healthcare sector. In this conception there is an implication that it is general merger control which needs to adapt, not the healthcare sector.

The modifications discussed in this chapter relate to these "prospective" and "reactive" conceptions as follows.

The temporary nature of the lower turnover thresholds and additional assessment criteria introduced in the Netherlands might lead to designation as "prospective" in nature. However, the 2006 reforms follow a brief period (from 2004)¹⁶ in which general merger control was applied to hospital mergers with no modifications, so these modifications might be considered "reactive". With regard to modifications in England, the "NHS-specific" merger test used to assess mergers between NHS Trusts wishing to achieve NHS FT status might similarly be designated "prospective".

As regards "reactive" modifications in the Netherlands, these comprise the "healthcare-specific" merger test and NZa Opinions since they respond to the perceived problem of widespread merger approval (between 2006 and 2015) and the transition to a new system with the 2006 reforms, respectively. In England, tests conducted in accordance with the "Transactions" pipeline might be interpreted as an acknowledgement that not all NHS Trusts will achieve NHS FT status, and be amenable to scrutiny under general merger control by virtue of s.79 HSCA 2012, thus "reactive". Similarly, the new test envisaged for PPUs is "reactive" in that it responds to the problem of these not meeting criteria for assessment under general merger control. However, insofar as the test anticipates an expansion in PPUs following the removal of the private patient

¹⁶ The then NMa concluded only in 2003 that competition was possible between hospitals and other providers of hospital care on the grounds that these had sufficient freedom to determine the quantity, composition, form and quality of the care they provide. See NMa, 'Concurrentie in de Ziekenhuissector', Visiedocument 3128/55, Den Haag, januari 2004. ('Competition in the hospital sector' Vision Document 3128/55. The Hague, January 2004), Para 119.

income cap by the HSCA 2012, the test might equally be designated "prospective".

The advisory functions of the NZa (between 2006 and 2015) and Monitor are harder to classify. On the one hand, these are "prospective" in that they (along with other factors) may influence the ACM or CMA's decision, but do not affect the test applied, hence cannot be "reactive". However, on the other hand, these advisory functions *could* be characterised as "reactive" as they can be construed as a necessary response to the application of general merger control (or rather, the nominal applicability pre-HSCA 2012 in England) with no modifications in the move towards a new system in both countries, as part of the wider 2006 reforms in the Netherlands and HSCA 2012 reforms in England.

III. A "competition-centric" or "healthcare-centric" approach

The two approaches are evidenced by the views that "healthcare-specific" modifications to hospital merger assessment are either necessary or not.

A "competition-centric" approach may suggest that modifications and regulator input are an unnecessary complication to general merger control. Thus the current refocusing of the ACM's powers regarding merger control – such as the removal of NZa Opinions, and transfer of the "healthcare-specific" merger test to the ACM - might be seen in this light, although it has already been suggested that the real issue is how the ACM applies general merger control, and a moratorium on hospital mergers may be a necessary step to address this.¹⁷

In contrast, a "healthcare-centric" approach suggests that general merger control may not be sufficient to assess hospital mergers in view of the organizational structures and non-economic concerns involved. Thus it may be necessary – even desirable – to have modifications of the general test, regulator

¹⁷ E.M.H. Loozen, 'Wijziging regelgeving markttoezicht in de zorg' ('Changes to legislation governing market regulation in healthcare'), Instituut Beleid & Management Gezondheidszorg, Erasmus University Rotterdam, November 2015.

input and even separate tests. This approach is clearly evident in England in view of the different tests for NHS Trusts, NHS FTs and now PPUs.

Insofar as it is possible to draw links between the second and third frameworks, the "competition-centric" approach might be linked to the "prospective" amendments and the "healthcare-centric" approach to "reactive" amendments.

5.3. What is "healthcare-specific" merger control and how does it relate to general merger control?

This section examines the operation of Dutch and UK general merger control and the modifications made which might collectively comprise "healthcarespecific" merger control in order to understand how the two are related and may complement each other. This can be understood in terms of modifications relating to "jurisdictional aspects" (that is, clarification of which arrangements are subject to general merger control) and "substantive assessment aspects", or attempts to incorporate wider, typically non-economic concerns which may not otherwise be given much attention in general merger control.

The "healthcare-specific" modifications in the Netherlands include lower turnover thresholds and a "healthcare-specific" merger test with a "merger effects" report, which might be linked to questions of jurisdiction. Further elements are additional criteria for the ACM to consider in its assessment and the NZa Opinions between 2006 and 2015, which might be related to the assessment process. In England, the modifications include a role for Monitor to identify "relevant customer benefits" under s.79(5) HSCA 2012 as part of the CMA's merger assessment, thus a substantive assessment aspect. However, modifications are more prominent in terms of jurisdictional aspects in view of different tests being developed for NHS Trusts and Private Patient Units (PPUs) in addition to the application of general merger control to NHS FTs by s.79 HSCA 2012.

An overview of how "healthcare-specific" merger control relates to general merger control is set out diagrammatically in Appendices J (the Netherlands) 199

and K (England) and is examined below following a brief overview of general merger control.

I. Overview of UK and Dutch general merger control

A. Market definition and hospital mergers

Common to substantive merger assessment in both countries is, of course, market definition, and this can prove outcome-determinative in hospital merger cases.¹⁸ However, this is an element characterised by different approaches in the two systems. For example, the "hypothetical monopolist" test has been rejected in the Netherlands, but the CMA continues to use it as a guide in defining both product and geographic markets in NHS mergers.¹⁹ Furthermore, the approaches to geographic market definition differ, with the development of modern econometric methods applicable to Dutch hospital markets relying on patient willingness to travel, or time-elasticities as a proxy for price substitution.²⁰ In England, the CMA distinguishes the PH and NHS sectors and has clarified that the relevant geographic market may be based on the location of providers and will be informed by an assessment of the willingness of patients to travel for consultation or treatment (the "catchment area").²¹ Finally, there are different approaches to defining product markets which reflect the two systems. In the Netherlands, the ACM typically

¹⁸ As seen in a range of US hospital merger decisions, and also the *Hilversum-Gooi Noord* merger, where a wider market based on patient willingness to travel was established at Phase II, thus led the ACM to grant a licence and permit the merger to proceed. For discussion of this case, see Johan Van de Gronden and Erika Szyszczak, 'Introducing competition principles into healthcare through EU law and policy: a case study of the Netherlands' [2014] Medical Law Review, Vol. 22, No.2, 157.

¹⁹ See, for example, Ashford – Royal Surrey (supra n11), para 5.51.

²⁰ See Marco Varkevisser, Cory Capps, Frederick Schut, "Defining Hospital Markets for Antitrust Enforcement: New Approaches and their Applicability to the Netherlands", [2008] Health Economics, Policy and Law, Vol.3 Issue 1. Also, Marco Varkevisser and Frederik Schut, "The Impact of Geographic Market Definition on the Stringency of Hospital Merger Control in Germany and the Netherlands" [2012] Health Economics, Policy and Law, 7, 363-381. ²¹ CMA, CMA guidance on the review of NHS mergers, 31 July 2014, CMA29, para 6.40. This follows the OFT's use of catchment areas in the Bournemouth-Poole merger case. OFT, ME/5351/12, Anticipated Merger between The Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust and Poole Hospital NHS Foundation Trust, 7 February 2013. Para 47.

distinguishes "inpatient" and "outpatient" general hospital care²² from separate markets for highly specialist care which may be offered only by providers with a licence under the Special Medical Procedures Act (WBMV) or by university hospitals.²³ However, the ACM may focus on specialties where these would result in different consequences for a merger than an assessment based on markets for general hospital care. In England, the CMA's approach to product market definition now encompasses both the NHS and PH sector and is based on specialty.²⁴

Although these aspects do not always feature in discussions of other elements of "healthcare-specific" merger control, how measurement tools are interpreted in the context of general merger control is pertinent. For example, the interpretation of GP referral data has been considered significant to the outcome of the recent *Ashford – Royal Surrey* merger. However, the premise that the NHS FTs/Trusts with the most referrals represent the main competitors appears misleading, and the CMA's focus on random variation of patient choices problematic.²⁵

B. Dutch general merger control and hospital merger cases

In the Netherlands, the general merger control regime is set out in the Dutch Competition Act (Mw)²⁶ and is heavily influenced by the EU Merger Regulation (EUMR).

Jurisdiction is established by a requirement for "undertakings",²⁷ satisfaction of a turnover test and degree of transfer of control to distinguish notifiable

²² A similar approach to that taken in the United States. For discussions of how the Dutch approach to defining product markets has developed, see Varkevisser et al (2008) and (2012) supra n20.

²³ For further discussion, see Kemp et al. (2015) supra n2.

²⁴ Based on CMA (2014) supra n21, paras 6.37-6.39.

²⁵ For discussions of this, see Andrew Taylor, 'Is clearance for hospital mergers about to get easier?' (*Nuffield Trust Blog*, 10 September 2015). Also Andrew Taylor, 'Using patient referrals to analyse hospital competition' (*NHS Competition Regulation*, 26 November 2015).
²⁶ Article 26-49 Mw.

²⁷ Defined as "economic activities" by reference to competition law. Case C-41/90 Klaus Höfner and Fritz Elser v Macrotron GmbH [1991]I-1979 and elaborated as "offering goods or services on a market" in Case C-35/96 Commission v Italy [1998] ECR I-3851.

mergers²⁸ from collaborations subject to a self-assessment regime.²⁹ Dutch general merger control also comprises a two-phase assessment. Phase I is a mandatory "notification" phase³⁰ intended to establish whether a merger leads to a significant impediment to effective competition (SIEC) on the Dutch market or part of it by creating or strengthening an economically dominant position. Where the ACM determines that there is no SIEC, the merger can be approved. However, where the ACM finds a SIEC, a licence is required for the merger, and a Phase II assessment is undertaken, unless the merger parties propose "remedies" to offset the SIEC.³¹ Phase II is a "licence authorisation" phase involving an in-depth investigation of the SIEC which results either in the merger being blocked, or the granting of a licence to enable the merger to proceed. This section considers two merger cases approved at Phase II (the *Zeeland Hospitals* and *Tilburg Hospitals* mergers), as well as the sole blocked merger between the Albert Schweitzer Hospital and Rivas Care Group.

The Zeeland Hospitals case³² involved a merger between the sole direct competitors in the remote Zeeland province which resulted in a market share of over 80% and was finally³³ approved in 2009. Approval followed a Phase II assessment subject to remedies to implement an efficiency defence advanced by the merging parties. After a SIEC was established at Phase I, the hospitals claimed that the merger was necessary to ensure an adequate level of quality regarding the provision of even basic care. This argument was underscored by

²⁸ Dutch general merger control distinguishes between three types of notifiable "concentration": merger, takeover and joint venture. See ACM, *Richtsnoeren voor de zorgsector* ('Guidelines for the healthcare sector), March 2010, para 5.1.
²⁹ See ACM, 'Assessing mergers and collaborations in hospital care', 27 September 2013.
³⁰ It is prohibited for undertakings to operate as a merged undertaking prior to approval by the ACM. This is referred to as "gun-jumping" and comprises premature implementation of a

notifiable merger or breach of the anticompetitive agreements provision (Art. 6 Mw) for mergers regardless of whether they are notifiable. See ACM (2010) supra n28, para 5.2.3. ³¹ This option of avoiding a Phase II assessment has proved successful in some merger cases involving home care organisations. For example, ACM, Case No. 5206 Stichting Pantein – Stichting Thuiszorg Brabant Noord-Oost, cited in ACM (2010) supra n28, para 5.3.1. ³² Discussed further by Wolf Sauter, 'Experiences from the Netherlands; The Application of Competition Rules in Health Care' in Johan Van de Gronden, Erika Szyszczak, Ulla Neergaard, Markus Krajewski (eds), *Health Care and EU Law* (TMC Asser Press, 2011) and Van de Gronden and Szyszczak (2014) supra n18.

³³ The merger was officially notified in 2005 (under case 5196) but was withdrawn after a Phase II assessment was deemed necessary. The merger was notified a second time in 2008 under case 6424/427.

the quality regulator (the IGZ), although the NZa was more sceptical in its Opinion. The ACM initially took the view that the conditions for a successful efficiency defence had not been satisfied because the claimed benefits were not verifiable, nor was it clear that these would be passed on to patients. However, on the authority of the IGZ, the ACM accepted that the benefits were merger-specific. This proved critical as the ACM then proposed a range of behavioural remedies (a price cap, commitments regarding the claimed quality improvements and the opening-up of the collective agreement between the hospitals and their consultants so the latter could compete with the merged entity) to implement the efficiency defence. This approach by the ACM is notable not only for being the first of its kind, but has been described as "unique" by both economists and lawyers³⁴ and creative³⁵ in its use of the efficiency defence.

The 2012 *Tilburg Hospitals* case³⁶ involved a merger of two hospitals in the city of Tilburg in the south of the Netherlands with a predicted combined market share of 70-80% and price increases of 25-33%. The ACM ultimately cleared this merger at Phase II subject to a voluntary price cap on the grounds that wider changes in the sector – namely that government subsidy to support insurer and hospital purchasing decisions due to be withdrawn from January 2015 – would be sufficient to correct any SIEC. The price cap was therefore intended to provide some protection against the anticipated price increase in the transition period from 2015-2016. It is surprising to note that the ACM itself³⁷ contended that the price cap neither constitutes a "remedy" in the sense of the Remedies Guidelines 2007,³⁸ nor a condition or restriction in accordance with Art.41(4) Mw, which provides that a licence may be issued subject to restrictions, or with conditions attached to it. In addition, the ACM acknowledged in a press release

³⁷ ACM, Case 7295/402 supra n7, Bijlage 3, Prijsplafond. ('Appendix 3, Price Cap').

³⁴ Specifically Marc Wiggers, *De NMa en de NZa in de curatieve zorgsector. Een toetsing aan het Europees mededingingsrecht* ('The NMa and the NZa in the curative healthcare sector – an assessment against EU competition law') Kluwer 2013 and Varkevisser et al. (2008) supra n20.
³⁵ By, inter alia, Canoy and Sauter (2010) supra n3 and Van de Gronden and Szyszczak (2014) supra n18.

³⁶ Discussed by Edith Loozen, Marco Varkevisser, Frederik Schut, 'Dutch Authority for Consumers and Markets fails to meet the standard of proof in recent hospital merger decisions'. [2014] E.C.L.R., 35(1),16.

³⁸ ACM, 'Richtsnoeren Remedies 2007' ('Remedies Guidelines 2007') 21 September 2007.

that it is powerless to enforce this behavioural remedy.³⁹ This approach was strongly criticised as an inappropriate use of remedies, which, together with inconclusive market definitions, suggest it is incomprehensible that the merger was cleared.⁴⁰

The 2015 proposed Albert Schweitzer Hospital – Rivas Care Group merger is notable for being the first hospital merger to be blocked by the ACM. The Albert Schweitzer Hospital in Dordrecht operates in the field of inpatient and outpatient general hospital care and specialist hospital care. Rivas Care Group comprises a hospital, an outpatient clinic and several care facilities including residential care and nursing homes, home care services, and maternal and child health centres near Rotterdam. At Phase I the ACM established that the merging parties were each other's main competitors, thus competitive pressure would be removed by the merger, and this could not be offset by the health insurers' buyer power.⁴¹ This finding was consolidated by arguments advanced by health insurers and patient organizations that the hospitals had not demonstrated the benefits of the merger. The ACM considered that the Phase II investigation should examine three aspects: the extent of the relevant geographic market, the competitive pressure exerted by the surrounding hospitals and the possible benefits of the proposed merger.⁴² The ACM established that the geographic market had been correctly determined at Phase I,⁴³ and the merged entity would hold market shares of 70-80% on the markets for inpatient and outpatient general hospital care. Ultimately the ACM concluded that the merger would result in the removal of a considerable amount of competitive pressure and that scope for patients or health insurers to discipline the merged entity by, respectively, voting with their feet and

³⁹ ACM, 'Regierol zorgverzekeraar cruciaal bij toestaan ziekenhuisfusies', ('Leading role of health insurers critical in approving hospital mergers') 7 December 2012.

⁴⁰ Loozen et al. (2014) supra n36.

⁴¹ ACM, Further investigation needed into merger between hospitals, Press release 18 March 2014.

⁴² ACM, supra n14, para 2.

⁴³ Ibid, paras 59-60.

choosing other hospitals or negotiate favourable prices and quality, was limited.⁴⁴ As a result, the ACM declined to issue a merger licence in July 2015.⁴⁵

Overall, the foregoing illustrates how the ACM's assessment includes factors such as the position of affected undertakings on the relevant market, the position of other operators on the market, the independence of suppliers from the proposed merged entity and the possibilities for new entry.⁴⁶ However, critiques of ACM decisions also focus specifically on how the ACM interprets elements of general merger control. For instance, it has been suggested that if the merging hospitals hold a market share of 50%, this is sufficient proof of a SIEC⁴⁷ (in line with the EU presumption of dominance). However, this has been criticised on the basis that market share may not of itself indicate dominance, nor equate to a SIEC, but nevertheless may provide a starting-point for the ACM's assessment.⁴⁸ This kind of critique is interesting because it sets a framework for discussion separate from the "healthcare-specific" merger control by suggesting that the real problem is with how general merger control is applied by the competition authority, as distinct from any perceived problem with the general test as such.⁴⁹

C. UK general merger control and hospital merger cases in

England

In England, the UK general merger control regime of the Enterprise Act 2002 (EA02) comprises a system of voluntary notification and a two-stage assessment overseen by the CMA. Its jurisdiction is determined by a "relevant merger situation" comprising two or more "enterprises" which cease to be

⁴⁴ ACM, ACM prohibits proposed merger between two Dutch hospital groups, Press Release, 15 July 2015.

⁴⁵ In August 2015 the chairman of the board of directors of the Albert Schweitzer Hospital indicated his intention to appeal against the finding. Zorgvisie, 'Albert Schweitzer and Rivas vechten fusieverbod aan' ('Albert Schweitzer Hospital and Rivas Care Group fight merger ban').

⁴⁶ ACM (2010) supra n28, Section 5.3.1, para 134.

⁴⁷ Loozen et al. (2014), supra n13.

⁴⁸ Kemp et al (2015) supra n2.

⁴⁹ For an overview of this perspective, see Loozen (2015) supra n17.

distinct and satisfy either the turnover⁵⁰ or "share of supply" test.⁵¹ Cases involving NHS FTs post-HSCA 2012 have satisfied the turnover threshold test.⁵² Phase I assessment determines whether the relevant merger situation may lead, or has led to a Substantial Lessening of Competition (SLC). A merger must pass from Phase I to Phase II assessment unless no SLC is established at Phase I, or an exception applies.⁵³ The most relevant exception for hospital mergers is the identification of "relevant customer benefits" pertaining to reductions in price or improvements in quality⁵⁴ in view of Monitor's advisory role in establishing these under s.79(5) HSCA 2012. Phase II involves an indepth investigation of whether the SLC can be mitigated, for example by the CMA determining relevant customer benefits. Following HSCA 2012, two NHS FT mergers have proceeded to Phase II assessment, with one being blocked (*Bournemouth-Poole*) and one approved (*Ashford-Royal Surrey*).

The *Bournemouth-Poole* case involved a 2:1 merger to monopoly of two closest geographical competitors in the south of England.⁵⁵ The parties articulated the view that the merger would achieve economies of scale, improved consultant cover, realized synergies and greater financial resilience for both NHS FTs. Ultimately the Competition Commission (CC) established the proposed merger would lead to an SLC in 19 elective inpatient services, 33 outpatient services, maternity services and private cardiology services. The CC concluded that the parties had identified no "relevant customer benefits" which could offset the SLC. The CC blocked the merger but took the further step of requiring the

⁵⁰ S.23(1)(b) EA02 provides that the value of the turnover in the UK of the enterprise being taken over must exceed £70 million.

⁵¹ The CMA's approach involves a flexible definition: "The share of supply can relate to any reasonable description of goods and services". CMA (2014) supra n21, para 5.17.

⁵² Bournemouth-Poole, Heatherwood-Frimley Park, Chelsea-West Middx., Ashford-Royal Surrey. The turnover of a business contributed to a proposed joint venture similarly satisfied the turnover threshold test in OFT, 'Anticipated pathology joint venture between University College London Hospitals NHS Foundation Trust, Royal Free London NHS Foundation Trust and the Doctors Laboratory Limited'. ME/6094/13.

⁵³ S.22 EA02. The CMA has acknowledged the possibility that the "de minimis" exception may be relevant. CMA (2014) supra n21, para 7.29.

⁵⁴ As defined under s.30(1)(a) EA02.

⁵⁵ Discussed, inter alia, by Rosie Curran, Simon Albert, It seemed like a good idea at the time: the application of competition law to the health sector in England, [2014] ECLR 35(9), 419-424.

parties not to merge for ten years.⁵⁶ The case has been considered a difficult test case, but as offering useful lessons regarding, inter alia, the difficulty of advancing failing firm arguments in the NHS context where providers do not exit the market in any conventional sense, but rather change organizational form to ensure continuity of service.⁵⁷

The Ashford-Royal Surrey case involved a proposed merger of hospitals in Surrey, near London. The merger was considered by the parties to be the most effective way of ensuring that they could continue to deliver high-quality services to patients amid financial and capacity-related challenges. At Phase I the CMA established that the merger could result in reduced quality and less scope for patient choice in several elective specialty services, so referred it for an in-depth investigation. At Phase II the CMA inquiry group approved the merger, having established that there would be sufficient competition and choice for patients in the area due to the presence of a number of nearby hospitals as credible alternatives.

The influence of Monitor's identification of "relevant customer benefits" in both cases is considered below in connection with "substantive assessment aspects".

II. Jurisdictional aspects

A. The Netherlands

The jurisdictional aspects of Dutch "healthcare-specific" merger control comprise two elements – lower turnover thresholds and a "healthcare-specific" merger test.

A1. Lower turnover thresholds

Lower turnover thresholds were introduced initially between 2008 and 2013,⁵⁸ but retained until 2018. A review in 2012 established that the ACM had

⁵⁶ Ibid.

⁵⁷ Ibid.

⁵⁸ A Decree of 6 December 2007 instituted temporary measures extending the applicability of merger control to healthcare providers. These measures took the form of lower turnover thresholds for mergers between undertakings in the healthcare sector between 2008 and

examined twice as many mergers, and that a considerable number of mergers which (potentially) raised competition concerns were caught by the notification obligation.⁵⁹

The relationship between the general merger control thresholds of Article 29(1) Mw and the lower thresholds⁶⁰ can be illustrated as follows:

	General merger	Healthcare merger
	control	control
Combined global	Must exceed €113,45	Must exceed €55
turnover of all	million.	million.
undertakings in the		
previous calendar year		
Individual turnover in	Must exceed €30	Must exceed €10
the Netherlands of at	million.	million.
least two of the		
undertakings concerned		
in the previous calendar		
year		

Figure 2: Lower turnover thresholds applicable to Dutch healthcare mergers 2008-2018.

In addition, a further "care turnover threshold" of ξ 5.5million was introduced. This has proved effective in avoiding notification of mergers not intended to be covered by the lower thresholds.⁶¹

^{2013.} Besluit van 6 december 2007, houdende tijdelijke verruiming van het toepassingsbereik van het concentratietoezicht op ondernemingen die zorg verlenen. (Decree of 6 December 2007 instituting temporary measures regarding the applicability of merger control to healthcare providers).

⁵⁹ Explanatory Note to the Decree of 19 October 2012 extending the 2007 Decree. Besluit van 19 oktober 2012, houdende wijziging van het Besluit tijdelijke verruiming van het toepassingsbereik van het concentratietoezicht op ondernemingen die zorg verlenen in verband met een verlenging van het besluit. (Decree of 19 October 2012 extending the Decree instituting temporary measures regarding the applicability of merger control to undertakings providing care in connection with extending the Decree).

⁶⁰ Article 29(3) Dutch Competition Act 1998 (Mw) provides that turnover thresholds may be reduced for particular categories of undertakings for a specified period of time.
⁶¹ Ibid.

Whether – and how – these thresholds will be affected by the 2015 reforms appears unclear at present.

A2. The "healthcare-specific" merger test and merger effects report

The core element of this test, introduced in January 2014, comprised a prohibition⁶² on consummating any merger involving healthcare providers without prior approval by the NZa. This effectively meant an additional stage prior to, and distinct from, the competition test conducted by the ACM. The prohibition did not apply to healthcare providers which provide care to fewer than fifty people,⁶³ and an exemption may have applied in exceptional circumstances (such as the imminent insolvency of a provider which would otherwise be saved by a merger).⁶⁴

In order to avoid the prohibition, healthcare providers wishing to enter into a merger were obliged to apply to the NZa for approval and submit a "merger effects" report. This was intended to demonstrate that the merger parties had considered the following aspects as a minimum:65

- a. The aims of the merger;
- b. The reasons for merging;
- c. The structure of the envisaged merged entity of healthcare provider(s);
- d. The financial consequences of the merger for the healthcare provider(s);
- e. The consequences of the merger for healthcare provision to clients;
- f. The risks which the merger may entail for quality and accessibility of care and the ways in which these risks can be managed;
- g. The ways in which stakeholders have been consulted about the proposed merger and how their contribution has been dealt with;

⁶² Art. 49a(1) Wmg.

⁶³ Art. 49a(3)Wmg.

⁶⁴ Explanatory Notes cited in CT Dekker and JG Sijmons, 'Continuïteit van zorg en zorgspecifieke fusietoetsing' ('Continuity of healthcare and healthcare-specific merger assessment'). [2013] Tijdschrift voor Gezondheidsrecht, Aflevering 2. 65 Art.49b(2) Wmg.

h. The ways and timeframe in which the merger will be implemented.

The NZa was able to withhold approval under the "healthcare-specific" merger test in two circumstances: firstly, if "stakeholders" (such as patients and staff) had not been adequately consulted,⁶⁶ and secondly, if continuity of critical care (as defined by statute) was endangered by the proposed merger.⁶⁷

Following the 2015 reforms, this "healthcare-specific" merger test will now be implemented by the ACM and will apply to mergers which involve undertakings directly or indirectly involved in the provision of care with specific turnover thresholds of \notin 7000000 and \notin 500000 in the preceding calendar year.⁶⁸ Significantly, it is now intended that the "healthcare-specific" merger test should coincide with the initial notification phase of general merger assessment.⁶⁹ The "merger effects report" is amended to emphasise that parties must demonstrate that they have considered other forms of collaboration and state why a merger has been chosen in preference to these.⁷⁰ The ACM may – similarly to the NZa - withhold its approval if critical care is endangered by the proposed merger or if clients and stakeholders have not been appropriately consulted and their views given due consideration.⁷¹

B. England

The modifications which comprise the "jurisdictional aspects" are separate scrutiny for NHS Trusts (via the NHS FT and transactions "pipelines") and PPUs.

⁶⁶ Art. 49(c)(2)(a) Wmg.

⁶⁷ Art. 49(c)(2)(b) Wmg.

⁶⁸ Proposed amendments - Art. 49a(1)(a) and (b) Wmg - provide that one of the merger parties must have a turnover of at least €7000,000 and the other(s) a turnover of at least €500,000 in the Netherlands. Kamerstukken II, 2015-16, 34 445, 2 - Wijziging van de Wet marktordening gezondheidszorg en enkele andere wetten in verband met aanpassingen van de tarief- en prestatieregulering en het markttoezicht op het terrein van de gezondheidszorg. Nr. 2 Voorstel van Wet. (Second Chamber documentation, Parliamentary Session 2015-16, 34 445, 2 - Amendments to the Wmg and other laws to apply tariff regulation and market regulation in healthcare, Document No.2, Legislative Proposal). Page 9.

⁶⁹ Kamerstukken II, 2015-16, 34 445, 3 - Wijziging van de Wet marktordening gezondheidszorg en enkele andere wetten in verband met aanpassingen van de tarief- en prestatieregulering en het markttoezicht op het terrein van de gezondheidszorg. Nr. 3 Memorie van Toelichting. (Second Chamber documentation, Parliamentary Session 2015-16, 34 445, 3 - Amendments to the Wmg and other laws to apply tariff regulation and market regulation in healthcare, Document No.3, Explanatory Memorandum). Para 4.3.2, page 22.

⁷⁰ Proposed amendments – Art.49b Wmg Legislative Proposal, supra n68.

⁷¹ Proposed amendments – Art. 49d Wmg. Legislative Proposal, supra n68.

An underlying intention of s.79 HSCA 2012 was to create "a single regime for merger control, which avoids duplication of the roles of Monitor and the OFT and eliminates risk of double-jeopardy".⁷² Thus s.79 HSCA 2012 clarifies that general merger control applies to NHS FTs, and there is no longer a grey area in which these may be subject both to the EA02 test and an "NHS-specific" merger test conducted by the NHS CCP prior to the HSCA 2012. Whether this desire to create a single merger control regime was merely a reflection of the policy in operation at the time (and is now being discontinued) for NHS Trusts to achieve NHS FT status is unclear. Certainly, as it has now been recognised that not all NHS Trusts will achieve NHS FT status via the "NHS FT pipeline", the creation of the "Transactions pipeline" suggests that alternative organizational forms are being pursued in connection with the new care models of the NHS Five Year Forward View.

It is important to note that, perhaps surprisingly, the (primary) jurisdictional requirement for an "enterprise",⁷³ has not proved decisive in separate scrutiny of NHS Trusts and PPUs. Thus NHS FTs,⁷⁴ NHS Trusts (despite their less autonomous status)⁷⁵ and PPUs are all deemed "enterprises" and no comparable discussion of any implications of providing services "free for the patient at the point of delivery" has emerged in connection with merger

⁷² Health and Social Care Act 2012 Explanatory Notes, Section 79 – Mergers involving NHS foundation trusts, para 740.

⁷³ S.79(6) HSCA 2012 provides that the definitions of Part 3 EA02 apply. S.129 EA02 defines an "enterprise" as the activities, or part of the activities, of a business, and a "business" as including a professional practice and any other undertaking which is carried on for gain or reward or which is an undertaking in the course of which goods or services are supplied otherwise than free of charge.

⁷⁴ Although s.79 HSCA 2012 is typically advanced as authority for NHS FTs being "enterprises" in all four cases discussed in this chapter, this was clarified further in the *Bournemouth-Poole* merger. Thus an NHS FT is an "enterprise" on the grounds that it provides clinical services for gain or reward, has a substantial amount of financial and corporate autonomy to manage its finances and can retain and benefit from surplus generated from income received from commissioning for the provision of clinical services. This appears uncontroversial, as does the further determining factor that regulation of FTs did not prevent providers from maintaining sufficient scope of autonomy to make organisational, financial and other operational decisions with a substantial impact on the sector. See OFT, ME/5351/12, supra n21, paragraphs 4.1-4.3.

⁷⁵ The logic for considering NHS FTs to be "enterprises" as articulated in the Bournemouth-Poole merger decision (supra 21, paras 4.1-4.3) appears to have informed CMA guidance that NHS Trusts are similarly considered to be "enterprises". See CMA (2014) supra n21, para 5.19, footnote 36.

control⁷⁶ as has been found in connection with the *applicability* of competition law.⁷⁷

Rather, it is the (secondary) jurisdictional threshold of a requirement for a "relevant merger situation" which appears to prompt the need for separate scrutiny for NHS Trusts and PPUs. This is discussed as follows, but in overview, the applicability of the EA02 test can be summarised as follows:

Merger Parties	Test used	Oversight
"Enterprise" (e.g. PH	EA02	CMA and Monitor
provider) + NHS FT		
NHS FT + NHS FT	EA02	CMA and Monitor
NHS FT + NHS Trust	EA02	CMA and Monitor
NHS Trust + NHS Trust	Scrutiny in the context	Monitor and the Trust
	of the NHS FT or	Development Authority
	"transactions" pipeline.	(now NHS
		Improvement)

Figure 3: Overview of the applicability of the EA02 to NHS mergers.

B1. The requirement for a "relevant merger situation" - NHS Trusts and NHS FTs

The requirement for a "relevant merger situation", namely the change in control necessary for two or more enterprises to cease to be distinct, serves to draw a distinction between how NHS Trusts and NHS FTs are viewed vis-à-vis general merger control.

⁷⁶ This is because, since commissioning organisations procure and pay a consideration for the provision of such services depending on the number of patients that are treated, NHS FTs have the incentive to re-invest such income to attract patients. See Bournemouth-Poole merger decision, supra n21, para 4.1. Indeed, CMA guidance clarifies that "enterprises" in healthcare can comprise entire organisations, such as NHS FTs or NHS Trusts controlling hospitals, ambulance services, mental health services, community services and individual services or specialties. The CMA emphasizes a case-by-case approach, but distinguishes NHS mergers by considering what is necessary to operate the relevant service or clinical specialty. See CMA (2014) supra n21, paras 5.3 and 5.4. So, for example, it is not always necessary for the transaction to include the transfer of an NHS contract (governing the supply of goods and services to the NHS), if the acquiring provider is already able to supply the services without requiring the NHS contract to transfer and acquires staff and assets.

⁷⁷ This is a separate point to the perceived possible need for a different test for NHS mergers discussed by Desai (2013) and Corrigan and Taylor (2014), both supra n15.

As regards NHS FTs, s.79(1) HSCA 2012 provides that there are two instances where two or more enterprises cease to be distinct. Firstly, where the activities of two or more NHS FTs cease to be distinct activities.⁷⁸ This appears straightforward and has been illustrated by recent mergers between FTs such as *Heatherwood-Frimley Park, Chelsea –West Middx, Ashford - Royal Surrey.* Secondly, where the activities or one or more NHS FTs and the activities of one or more businesses cease to be distinct activities.⁷⁹ This would appear to apply to mergers between NHS FTs and NHS Trusts,⁸⁰ or between NHS FTs and PH providers under arrangements for PH providers to deliver NHS services in category 2.⁸¹

In contrast, a merger involving two or more NHS Trusts has been deemed by the CMA as not implying the requisite change in control since the resulting entity would remain overseen ultimately by the Secretary of State for Health.⁸² A distinction is increasingly being drawn between NHS Trusts which are able to achieve NHS FT status (in line with successive government policy between 2004 and approximately 2014) and those which are not, so are facing alternative organizational arrangements involving private providers which may still fail to satisfy the "change in control" requirement for a "relevant merger situation". This distinction is reflected in two different kinds of assessment named the "NHS FT pipeline" and the "Transactions pipeline", respectively. These are now considered.

The NHS FT pipeline

This is the more established of the two "pipelines" and has developed over the course of the New Labour reforms to give effect to successive government policy since 2004 for all NHS Trusts to achieve NHS FT status. The use of this

⁷⁸ S.79(2) HSCA 2012.

⁷⁹ S.79(3) HSCA 2012. S.79(4) HSCA 2012 clarifies that the references to "activities" include a reference to part of an NHS FT's or a business' activities.

⁸⁰ Which, prior to HSCA 2012, appear to have been scrutinised under the "NHS-specific" merger test only, regardless of the potential to be subject to EA02. See, for example, NHS CCP, Merger of Bexley Care Trust with Oxleas NHS Foundation Trust and South London Healthcare Trust, February 2010.

⁸¹ Such arrangements were within the scope of the NHS Co-operation and Competition Panel (NHS CCP), Merger Guidelines, 25 October 2010, at para 4.10.

⁸² CMA (2014) supra n21, para 5.7.

"NHS-specific" test to "upgrade" NHS Trusts to NHS FT status was made explicit in individual cases, for example,

"The merger was arranged within the broader policy context that requires the majority of NHS trusts to become NHS foundation trusts by April 2014."⁸³

Between 2009 and 2013 the NHS Co-operation and Competition Panel (NHS CCP) reviewed mergers between NHS Trusts and NHS FTs and produced recommendations regarding approval for the Secretary of State for Health or Monitor, who respectively had exclusive competence to approve mergers involving NHS Trusts and NHS FTs.

The NHS CCP's Merger Guidelines were based on Principle 10 of the NHS Principles and Rules for Cooperation and Competition (NHS PRCC) which provided that:

"Mergers, including vertical integration, between providers are permissible where there remains sufficient choice and competition or where they are otherwise in patients' and taxpayers' interests, for example because they will deliver significant improvements in the quality of care."

The NHS CCP adopted a wide definition of "merger", but explicitly excluded mergers between commissioners.⁸⁴

The substantive content of the NHS CCP's assessment broadly reflected general merger control, comprising a two-phase test to establish whether a proposed merger was consistent with the provisions about patient choice and competition of the NHS PRCC. It was established that the test comprised a "cost-benefit analysis" in which potential benefits such as improved clinical outcomes, better services or greater efficiency were weighed against any possible adverse effects on patients and/or taxpayers (including both financial

 ⁸³ For example, NHS CCP, 'Proposed merger of Royal Free London Foundation Trust with Barnet and Chase Farm Hospitals NHS Trust', Final Report 13 August 2013, para 29.
 ⁸⁴ NHS CCP (2010) supra n81, para 4.9.

and non-financial impacts) arising from a loss of patient choice or competition.⁸⁵

However, there are at least two points of note⁸⁶ regarding overlap and divergence between the NHS CCP and EA02 regimes.

Firstly, although the NHS CCP regime was nominally a voluntary regime, in practice all NHS mergers were examined prior to consummation.⁸⁷

Secondly, the NHS CCP's jurisdictional thresholds operated in a different manner, focusing on the revenue of the combined entity in the last financial year, with different thresholds for different sectors:⁸⁸

- £70 million in the case of acute and mental health trusts;
- £35 million in the case of community service providers; or
- £15 million in the case of primary care providers.

Concurrent with the implementation of the HSCA 2012, ultimate decisionmaking powers were transferred from the Secretary of State for Health to the then newly-established NHS TDA,⁸⁹ although the former has apparently continued its involvement in merger approval.⁹⁰ Prior to the NHS TDA's involvement, it had been envisaged that Monitor would adopt a similar approach to the NHS CCP's under the NHS PRCC.⁹¹

More recently, there appears to be a move away from the "NHS FT pipeline" as Care Quality Commission (CQC) ratings now represent a better indicator of

⁸⁵ Ibid, Para 6.3.

⁸⁶ A third being the NHS CCP's rejection of a "share of supply" test to establish jurisdiction on the grounds that existing turnovers were easier and simpler to apply. NHS Co-operation and Competition Panel, 'Mergers Response to Consultation Document', 04 October 2010. Para 48. ⁸⁷ Desai (2013) supra n15.

⁸⁸ NHS CCP (2010) supra n81, para 4.20.

⁸⁹ Under Direction 4(g)(iii)(bb) of the National Health Service Trust Development Authority Directions.

<<u>https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/175350/N</u> TDA_Directions_2013.pdf>.

⁹⁰ See, for example, NHS TDA, The acquisition of Barnet and Chase Farm Hospitals NHS Trust by the Royal Free London NHS Foundation Trust, July 2014.

⁹¹ Monitor, Briefing Note 'The respective roles of Monitor, the Office of Fair Trading and the Competition Commission in relation to mergers involving NHS trusts and NHS foundation trusts' 17 October 2013.

quality than FT status,⁹² and a growing acceptance that not all NHS Trusts are able to achieve NHS FT status.⁹³ It is recognised that, from a general competition perspective, there may be a tension between a policy for NHS Trusts to achieve NHS FT status (with the implication of government-mandated widespread merger approval) and resisting consolidation.⁹⁴ However, the extent to which this tension holds in connection with the distinctive nature of the English NHS is questionable in view of the reluctance to engage with the concept of provider exit⁹⁵ and the need to ensure universal provision. Certainly a more logical interpretation of the apparent refocusing (even discontinuation) of the NHS FT pipeline arises from the explanation of ensuring universal service rather than a desire to resist consolidation.⁹⁶ However, had all NHS Trusts achieved NHS FT status, resisting consolidation may well have become a more evident concern as these are now subject to the general merger control regime by virtue of s.79 HSCA 2012.

⁹² The Secretary of State for Health, Jeremy Hunt, has expressed the view that CQC ratings are a better indicator of success for NHS providers. See Crispin Dowler, 'Exclusive Hunt Interview: CQC ratings have replaced Foundation Trust status as a definition of success', Health Service Journal, 9 September 2015. David Bennett (former CEO of Monitor) and Simon Stevens (CEO NHS England) have both recently called for the "Foundation Trust pipeline" (of NHS Trusts seeking to achieve FT status, typically via merger) to be discontinued. See Crispin Dowler, 'Bennett calls for freeze of Foundation Trust pipeline', Health Service Journal, 5 November 2015. Chris Ham, 'Simon Stevens' vision for the NHS: welcome but challenging to deliver' (The King's Fund blog, 14 October 2015).

⁹³ As acknowledged by Simon Stevens, CEO of NHS England, in comments to Health Select Committee on 21 July 2015 in response to Question 36. "Increasingly, for many providers the foundation trust/NHS trust distinction is a distinction without a difference, and, frankly, lying behind that, exactly as you say, is that the kinds of tests that were being set by Monitor for becoming an FT are unlikely to be met by some of those institutions despite the fact that we are going to continue to need them to provide valued and important local services. One of the tasks for the newly paired Monitor and TDA will be to answer the exam question you have just set, which is, "Let's not kid ourselves that, for some of these institutions, they are on a path to FT status, because they're not, but we need them, so what is the right way of recognising their governance and ensuring that in concert with other parts of the health service locally they have a future that works?" We have to stop pretending that everybody is going to meet the current set of FT tests, and instead just get real about the circumstances facing different parts of the country."

⁹⁴ Certainly it has been considered that government-mandated mergers produce no more benefit than other mergers. See Gaynor et al (2012) supra n12.

⁹⁵ Indeed, a further tension might be inferred from Monitor's development of a failure regime as acknowledged by the former OFT, and the development of a "success regime" to ensure provider sustainability in the context of the NHS Five Year Forward View.

⁹⁶ See comments by Simon Stevens, supra n93.

The Transactions pipeline

Since 2013, oversight of NHS Trusts includes assessment by the NHS TDA against annual accountability frameworks.⁹⁷ These allow for two broad options for ensuring NHS Trust sustainability: application for NHS FT status, or one of a range of transactions.

With regard to ensuring the sustainability of NHS Trusts, the NHS TDA has recognised six types of transaction as follows:⁹⁸

⁹⁷ NHS TDA, 'Delivering High Quality Care for Patients – The Accountability Framework for NHS Trust Boards', April 2013. NHS TDA, 'Delivering for Patients – The 2014/15 Accountability Framework for NHS Trust Boards', 31 March 2014. NHS TDA, 'Delivering for Patients – The 2015/16 Accountability Framework for NHS Trust Boards', 2 April 2015.

⁹⁸ Adapted from NHS TDA Accountability Frameworks 2013 (page 85), 2014-15 (pages 1-2) and 2015-2016 (pages 35-36) (all supra n97).

Description	Oversight
These are "statutory mergers" and	NHS TDA
take place when two NHS Trusts	
come together to form a new,	
merged entity.	
When an NHS FT "takes over" the	CMA and Monitor
running of assets previously owned	(EA02)
by an NHS Trust.	
A much larger NHS Trust could "take	NHS TDA
over" a much smaller NHS Trust,	
retaining the identity of the larger	
NHS Trust.	
A long-term contract or franchise	NHS TDA
could be awarded to the private	
sector to run services previously	
delivered by an NHS Trust. (An	
example would be the Circle-	
Hinchingbrooke arrangement).	
A short-term contract could be	NHS TDA
awarded to another NHS organisation	
or to the private sector to run an NHS	
facility.	
An NHS Trust could decide to sell	NHS TDA
assets it owns to another	
organisation, yet remain viable as an	
NHS Trust.	
An NHS Trust could decide to split its	NHS TDA
assets into two or more parts, with	
each part representing a viable	
solution.	
	These are "statutory mergers" and take place when two NHS Trusts come together to form a new, merged entity. When an NHS FT "takes over" the running of assets previously owned by an NHS Trust. A much larger NHS Trust could "take over" a much smaller NHS Trust, retaining the identity of the larger NHS Trust. A long-term contract or franchise could be awarded to the private sector to run services previously delivered by an NHS Trust. (An example would be the Circle- Hinchingbrooke arrangement). A short-term contract could be awarded to another NHS organisation or to the private sector to run an NHS facility. An NHS Trust could decide to sell assets it owns to another organisation, yet remain viable as an NHS Trust. An NHS Trust could decide to split its assets into two or more parts, with each part representing a viable

Figure 4: Types of "Transaction" available to ensure NHS Trust sustainability.

Monitor similarly recognises various forms of "transactions", ⁹⁹ and has further clarified that the regulatory framework governing transactions involving NHS FTs comprises competition review of mergers by the CMA and risk assessment of transactions by Monitor.¹⁰⁰

The development of the "transactions" pipeline has coincided to a certain extent with the start of implementing new care models as part of the NHS Five Year Forward View. It appears that Monitor has a role in approving these new care models, apparently by reference to its Foundation Trust assessment process. A recent example¹⁰¹ is the integrated care organisation, Torbay and South Devon Foundation Trust, which emerged out of the acquisition of community provider Torbay and Southern Devon Health and Care Trust by South Devon Healthcare Foundation Trust.¹⁰²

B2. The requirement for a "relevant merger situation" - PPUs

The new test for PPUs proposed by the CMA is mentioned briefly here because it appears motivated by the prospect of an expansion in PPUs following the removal of the private patient income cap by s.165 HSCA 2012.¹⁰³ Furthermore, the new test marks a first modification of the EA02 regime for the private healthcare (PH) sector, and intended to target primarily scope for individual PH providers to consolidate their market share by operating PPUs,¹⁰⁴ as opposed

⁹⁹ Including those which should be reported under the threshold set out in Monitor's "Risk assessment framework" (including most mergers or acquisitions as well as larger capital investment projects), statutory transactions (mergers or acquisitions involving one or more NHS FTs, separations and dissolutions of NHS FTs as defined by ss.56-57A NHS Act 2006 as amended by HSCA 2012) and transactions which could be reviewed by the CMA under EA 02. Page 7.

¹⁰⁰ Ibid, page 8.

¹⁰¹ It is unclear why such a restructuring was not subject to the EA02 regime since the creation of a NHS FT would presumably include the requisite change in control.

¹⁰² Monitor, 'Patients in South Devon set to get integrated care after hospital acquisition', Press Release, 1 October 2015.

¹⁰³ CMA, Private Healthcare Market Investigation Final Report, 2 April 2014, para 11.249. ¹⁰⁴ The CMA found that an adverse effect on competition could arise in connection with PPUs on the PH market because PH providers can benefit from NHS infrastructure and the possibility of partnership with an NHS Trust to manage a PPU offers a low-risk means of market entry for private hospital operators. Ibid, paras 11.249-11.252.

to NHS FTs operating PPUs,¹⁰⁵ although the latter may still be included since a PPU is defined as:

"...a facility within a national health service [site] providing inpatient, day-case patient or outpatient privately-funded healthcare services to private patients; such units may be separate units dedicated to private patients or be facilities within a main national health service site which are made available to private patients either on a dedicated or non-dedicated basis".¹⁰⁶

In jurisdictional terms, a new test is necessary because previous PPU arrangements – such as commercial leasing, the use of (but not title to) equipment and the secondment of support staff (as opposed to transfer of employees),¹⁰⁷ or use of an NHS FT name on the branding and promotion of PPU facilities¹⁰⁸ - had not previously constituted a "relevant merger situation". The new test therefore comprises a jurisdictional threshold of "PPU arrangement" and assessment involving "relevant customer benefits" based on market investigation criteria. At the time of writing (July 2016), the test has not been used.

C. Relationship between the jurisdictional aspects and general merger control

How the jurisdictional aspects of "healthcare-specific" merger control complement general merger control appears to both extend and narrow the oversight of the ACM and CMA and accordingly the range of mergers assessed.

For example, the lower turnover thresholds and separate "care turnover" threshold in the Netherlands have the function of *extending* the ACM's oversight in terms of the number of hospital mergers examined. This is an important consideration in view of healthcare as a sector in transition, but,

¹⁰⁵ The CMA established that of the 83 dedicated PPUs in the UK, 74 are managed in-house by the NHS and 9 are managed by private hospital groups. Ibid, para 2.28.

¹⁰⁶ CMA, Private Healthcare Market Investigation Final Order, 1 October 2014.

¹⁰⁷ All established in ME/2524/06 Award of management contract to provide private inpatient bone marrow transplants and sarcoma cancer treatments at UCLH NHS FT to HCA International Limited.

¹⁰⁸ As considered in ME/5641/12 Anticipated lease by HCA International Limited of premises from Guy's and St Thomas' NHS FT, para 17.

albeit with the benefit of hindsight, may have contributed to the problem of widespread hospital merger approval.

In England, the delineation of general merger scope by s.79 HSCA 2012 to mergers involving NHS FTs and the new PPU test may extend the scope of CMA oversight, if not the range of mergers examined.

The new PPU test clearly extends the scope for CMA oversight by introducing a new threshold of "PPU arrangement" which is not dependent upon a change in control. This appears to enable the CMA to scrutinise any new NHS FT PPUs which arise as a result of removing the private patient income cap, thus extending oversight of NHS FTs acting as private providers on the PH market. However, the CMA's overarching concern in its PH Market Investigation was to avoid further consolidation of, and distortions of competition by PH providers acquiring PPUs. This would appear to suggest that the intended scope behind the new test is narrower than first appear. However, the permutations between PPUs operated by NHS FTs and those operated by PH providers may be less clear-cut in practice, so merits further research if these develop as anticipated.

S.79 HSCA 2012 extends the scope for CMA oversight by making explicit the applicability of general merger control to the NHS. This is because a merger between an NHS Trust and a NHS FT seems likely to be caught on the grounds that the requirement for "enterprises" is satisfied and there presumably is sufficient change in control for a "relevant merger situation" insofar as the resulting entity is likely to be an NHS FT, thus no longer subject to Secretary of State control.

However, s.79 HSCA 2012 may limit the scope for CMA oversight by referencing mergers involving NHS FTs, thereby avoiding oversight of emerging arrangements in connection with the "transactions pipeline" or the new care models. These arrangements clearly involve "enterprises" in the form of private companies and NHS Trusts. However, whether they entail the requisite change in control necessary for a "relevant merger situation" remains unclear unless

221

the resulting body remains subject to Secretary of State control, so avoidance of CMA oversight is then not associated with s.79 HSCA 2012.

In the Netherlands, the "healthcare-specific" merger test, with its requirement for submission of a "merger effects" report and the option for the NZa to prohibit a proposed merger which endangered the provision of critical care, would appear to operate potentially to reduce the ACM's oversight of hospital mergers. In other words, the "healthcare-specific" merger test would appear to serve as a filter for Dutch general merger control. This is a notable feature in view of the system of mandatory notification.¹⁰⁹ It is interesting to note that the refocusing of the "healthcare-specific" merger test with the 2015 reforms sees the "merger effects" report being retained, and a new requirement for parties apparently to justify a merger over other forms of collaboration. This may serve to refocus the jurisdiction of general merger control by a filter which not only may reduce the number of notified mergers, but distinguishes other forms of collaboration. An example of this can be seen in recent questions regarding the applicability of general merger control to Specialist Partnerships (Maatschappen). These are partnerships of medical specialists across different hospitals and regions and questions have been raised as to how best to manage any resulting competition concerns.¹¹⁰ As regards merger control, the question arose of whether the Specialist Partnership was a separate entity from a hospital. The ACM clarified that it regards partnerships and hospitals as forming

¹⁰⁹ This would presumably serve to increase the number of mergers examined by the ACM, and in which the main "filter" available to the ACM appears to be the establishment of a SIEC leading to a dominant position. In view of the complexities surrounding market definition for hospitals and establishing "dominance" in a healthcare context, this is a significant hurdle. The ACM has recently reiterated that it can only take action where there are instances of market power from a competition perspective, which only emerges in a limited number of cases. See ACM, 'Position Paper Autoriteit Consument en Markt Rondetafelgesprek "Kwaliteit loont" ('ACM Position Paper on the "Quality Pays" roundtable discussion'). 17 April 2015. ¹¹⁰ See, for example, Marco Varkevisser et al., 'Instellingsoverstijgende maatschappen: Huidige ontwikkelingen, mogelijke gevolgen en de aanpak van eventuele mededingingsproblemen. Eindrapport'. ('Cross-institution partnerships: current developments, possible consequences and managing potential competition problems. Final Report'). IMBG, Erasmus Universiteit Rotterdam. Maart 2013. Edith Loozen,'Mededingingstoezicht op maatschappen van zorgaanbieders: welke rol is weggelegd voor ACM respectievelijk NZa?' ('Competition regulation of healthcare provider partnerships: what roles do the ACM and NZa play?') [2013] Tijdschrift voor Gezondheidsrecht (37) 7.

a single undertaking, subject to as yet unclarified exceptions.¹¹¹ Consequently, if the specialist partnership of one hospital merges with another partnership from another hospital, the ACM does not consider this as a merger between two independent undertakings, but as cooperation between the two hospitals regarding the same specialty. The formation of specialist partnerships at city or region level are therefore considered by the ACM to be agreements between hospitals which must be examined under the anticompetitive agreements provisions (Art. 6 Mw).¹¹²

III. Substantive assessment aspects

A. The Netherlands

The "assessment aspects" comprise additional assessment criteria for the ACM and NZa Opinions.

A1. Additional assessment criteria for the ACM

In 2013, new Policy Rules clarifying "healthcare-specific" criteria for the ACM to consider in assessments of mergers between healthcare providers where the combined market share exceeds 35% were introduced regarding mergers between healthcare providers and health insurers, respectively.¹¹³ These are in force until 1 January 2018.¹¹⁴ In essence, the ACM must consider four factors:¹¹⁵ the transparency of care quality, clients' travel behaviour or willingness to travel, possibilities for entry by other healthcare providers, and the ways in

¹¹¹ ACM, 'ACM-lijn maatschappen en ziekenhuizen' ('ACM guidance on healthcare provider partnerships and hospitals'), 6 June 2013.

¹¹² Ibid.

¹¹³ Beleidsregel van de Minister van Economische Zaken van 5 juli 2013, nr. WJZ/13118300, houdende bijzondere regels betreffende concentraties van zorgaanbieders en zorgverzekeraars. (Policy Rule by the Minister for Economic Affairs of 5 July 2013, No. WJZ/13118300, setting out special rules governing mergers of healthcare providers and health insurers). Article 3 of these rules is concerned with mergers between health insurers, but this is beyond the scope of this chapter.

¹¹⁴ The 2013 Policy Rules consolidate the 2009 Policy Rules which were repealed on 16 July 2013 and were addressed specifically to healthcare providers but remain broadly unchanged in substantive terms. Beleidsregel van de Minister van Economische Zaken van 1 september 2009, nr. WJZ/9145416, houdende bijzondere regels betreffende concentraties van zorgaanbieders. (Policy Rule by the Minister for Economic Affairs of 1 September 2009, No. WJZ/9145416, setting out special rules governing mergers of healthcare providers).
¹¹⁵ Article 2(1) 2009 Policy Rules, supra n113.

which healthcare purchasers¹¹⁶ can influence client choice. These criteria may influence the definition of relevant markets as well as reflect the consequences of a merger for competition.¹¹⁷ In addition, the ACM must request an Opinion from the "client councils" of the healthcare provider most affected by the merger regarding the relevant market(s).¹¹⁸ It is currently unclear how the 2015 reforms of the ACM's competition powers may affect the 2013 Policy Rules.

A2. NZa Opinions, 2006-2015

The requirement for the ACM to consult the NZa during the merger assessment and for the NZa to provide a non-binding Opinion at either or both stages of the merger review process was set out in soft law documentation such as the ACM's Guidelines for the Healthcare Sector¹¹⁹ and the NZa-ACM Cooperation Protocols.¹²⁰ The NZa's duty to prioritise the "general consumer interest",¹²¹ defined in terms of affordability, accessibility and quality, formed the basis for its Opinions, although it was obliged to follow the advice of the quality regulator (IGZ) in its assessments of quality.¹²² In addition, the NZa developed two econometric methods – the Option Demand Method (ODM) and the Logit Competition Index method (LOCI) with the ACM to assess possible post-merger price increases.¹²³ These two models are used to assess whether a merger may result in price increases in the markets for inpatient and outpatient care, and

¹¹⁶ "Healthcare purchasers" can refer to health insurers in the "cure" sector, regional "care agencies" in the "care" sector or municipalities.

¹¹⁷ Explanatory Notes to the 2013 Policy Rules supra n113.

¹¹⁸ Article 2(2) 2009 Policy Rules, supra n113.

¹¹⁹ ACM (2010) supra n28.

¹²⁰NMa, 'Protocol tussen de Nederlandse Mededingingsautoriteit en de Nederlandse Zorgautoriteit over de wijze van samenwerking bij aangelegenheden van wederzijds belang' ('Protocol signed by the Dutch Competition Authority and the Dutch Healthcare Authority regarding cooperation in matters of mutual interest'), October 2006. NMa/NZa, 'Samenwerkingsprotocol NMa-NZa' ('NMa-NZa Cooperation Protocol'), December 2010.

ACM/NZa, Samenwerkingsprotocol Autoriteit Consument en Markt en Nederlandse Zorgautoriteit ('ACM and NZa Cooperation Protocol'), December 2014.

 $^{^{121}}$ Article 3(4) Wmg. See also ACM (2010) supra n28, section 5.3.3.

¹²² Article 19 Wmg.

¹²³ The ODM is related to the insurance aspects of hospital care by translating patient willingness to pay (WTP) into the inclusion of a hospital in the contracted care offer of health insurers. LOCI is an index which characterises the competitiveness of a hospital between 0 (monopoly) and 1 (perfect competition) as determined by the overlap of products/services provided by health insurers in different segments. As described in, for example, the NZa Opinion in the Tilburg Hospitals case. NZa, Zienswijze vergunningsaanvraag Stichting TweeSteden ziekenhuis en Stichting St. Elisabeth ziekenhuis, Juli 2012. (NZa, Opinion on the licence request in the Tilburg Hospitals merger, July 2012).

informed the "affordability" aspect of the NZa Opinions. Furthermore, changes in the sector have led to the inclusion of other factors in NZa Opinions, such as selective contracting. While the "healthcare-specific" merger test introduced in January 2014 was referenced in some NZa Opinions, it appears that the test was intended to replace the NZa's Opinions.¹²⁴ However, the NZa provided an Opinion in the 2015 *Albert Schweitzer Hospital – Rivas Care Group* merger, although it is unclear how its assessment of possible price increases influenced the ACM's decision to block this merger as the latter considered that these did not necessarily reflect the extent of underlying competitive tension between the parties.¹²⁵

Among the 2015 reforms of the "healthcare-specific" merger test, it is intended that the ACM may examine a proposed merger in the light of criteria to be determined by Ministerial Decrees regarding the protection of public interests in healthcare.¹²⁶ However, it is intended that these would apply where, as a result of a merger, there are insufficient alternatives for specific types of care or a health insurer is unable to fulfil its duty of care obligations.¹²⁷ The proposals allow for the possibility, and not the obligation of setting further criteria as this recourse would only be employed if general merger control fails to safeguard public interests.¹²⁸

B. England

B1. Monitor's advisory function under s.79(5) HSCA 2012

Monitor's advisory function under s.79(5) HSCA 2012 to identify "relevant customer benefits" appears, at least *prima facie*, to be capable of complementing CMA assessments, since this mechanism exists in the wider context of the EA02 test.

¹²⁴ Wolf Sauter, 'Sectorspecifiek mededingingsrecht en fusietoetsing' ('Sector-specific competition law and merger control'), Regel Maat 2013 (28) 2.

¹²⁵ See ACM Decision supra n14, paras 79-82.

¹²⁶ Explanatory Memorandum supra n69, para 5.3.2, page 23.

¹²⁷ Ibid.

¹²⁸ Ibid.

However, Monitor's identification of "relevant customer benefits" is reserved to input at Phase I, and appears not to have been outcome-determinative of either of the two Phase II decisions thus far.

In the Bournemouth-Poole merger, although Monitor emphasized the relevant customer benefit associated with reconfiguring maternity services at Phase I, this was not submitted by the parties to the Phase II assessment. Ultimately the then Competition Commission (CC) concluded that the merger would result in an SLC in 55 services and found no relevant customer benefits. The CC also rejected the parties' proposed behavioural remedy of assessing quality which might be affected by the SLCs by using the metric of the Friends and Family Test (FFT).¹²⁹ Having considered that partial divestiture would not provide a feasible structural remedy as the services affected by the SLCs were not easily divisible, the CC concluded that prohibition was the only proportionate remedy that would address the SLCs and adverse effects that it established. However, it would be unfair to consider Monitor's input into this merger as indicative of its approach. It is acknowledged that this merger provided a difficult test case, not least as a 2-to-1 merger to monopoly would always encounter tough scrutiny from the competition authorities.¹³⁰ Furthermore, this was compounded by the wider changes in the sector at the time,¹³¹ namely enactment of the HSCA 2012 with all the changes this entailed, such as the change between the NHS CCP and Monitor as well as refocused substantive tests.

In the *Ashford-Royal Surrey* merger, Monitor identified potential relevant patient benefits in respect of increased access to consultants (via the introduction of weekend ward rounds and out-of-hours consultant rota) across

¹²⁹ The FFT was implemented in April 2013 and asks patients to rate the likelihood of their recommending a ward/service etc. to friends and family if they needed similar treatment. <<u>http://www.nhs.uk/NHSEngland/AboutNHSservices/Pages/nhs-friends-and-family-test.aspx</u>>.

¹³⁰ Curran and Albert (2014), supra n55.

¹³¹ For a comprehensive analysis of this based on interviews with groups involved in the merger, see Emma Spencelayh and Jennifer Dixon, 'Mergers in the NHS – Lessons from the decision to block the proposed merger of hospitals in Bournemouth and Poole', The Health Foundation Policy Analysis, December 2014.

gastroenterology, stroke and interventional radiology.¹³² However, the CMA did not consider that these were sufficient to offset the SLC it identified at Phase I, thus did not obviate the need for a Phase II assessment.¹³³ Nevertheless, these relevant customer benefits serve to highlight the role that government policy may continue to play in NHS merger decisions. At Phase II the CMA considered Monitor's advice in connection with "the requirement for seven-day services", following the establishment of the NHS Services Seven Days a Week Forum in February 2013 to consider how NHS services can be improved to provide a more responsive and patient-centred service across the seven-day week.¹³⁴ This would appear to suggest that current government policy to provide a "seven day NHS" is finding reflection in CMA assessment. In the Phase II decision, the CMA also paid attention to Monitor's assessment of the merging parties in its capacity as NHS FT regulator.

C. Relationship between the "substantive assessment aspects" and general merger control

How the substantive assessment aspects complement general merger control is largely related to the (limited) scope for the latter to accommodate noncompetition concerns.

This is evidenced primarily by the inclusion of NZa Opinions in the Netherlands and Monitor's advisory role regarding "relevant customer benefits" under s.79(5) HSCA 2012.

With regard to NZa Opinions, while the ACM has acknowledged these and the NZa's econometric assessments, this arises out of a period of tension following the *Zeeland Hospitals* merger discussed above. How public interests will be incorporated into merger assessment following the current reforms is unclear. However, it appears that these may be incorporated less routinely and less

¹³² Monitor, Monitor's advice to the Competition and Markets Authority on the merger benefits of the proposed merger of Ashford and St Peter's Hospitals NHS Foundation Trust and Royal Surrey County Hospital NHS Foundation Trust. March 2015.

¹³³ CMA, ME/6511/14 Anticipated Merger of Ashford and St Peter's Hospitals NHS Foundation Trust and Royal Surrey County Hospital NHS Foundation Trust, 12 March 2015. (Phase I decision). Paragraphs 24-33.

¹³⁴ CMA supra n11, paragraphs 4.18-4.23.

explicitly in view of the anticipation that general merger control will accommodate public interests as a rule as noted above.¹³⁵ Whether this will result in a "creative" – as opposed to a "strict" – interpretation of Dutch general merger control remains to be seen. However, this underscoring of the potential flexibility of Dutch general merger control suggests a willingness to engage with the criticism that what is at fault is not the underlying substantive test, but the interpretation and implementation of this.¹³⁶

Monitor's advisory function under s.79(5) HSCA 2012 might also be construed as an attempt to incorporate public interests, albeit within the confines of "relevant customer benefits".¹³⁷ However, the references to the development of a seven-day NHS within the context of the Ashford-Royal Surrey merger case suggests that relevant customer benefits may equally serve as a means of advancing policy, so these will be interpreted in a more flexible way.

5.4. What is "healthcare-specific" merger control intended to achieve?

Having examined in overview the constituent elements of "healthcare-specific" merger control, it is useful to consider what purposes these serve, or what they are intended to achieve. To this end, various conceptions are possible, but at least four issues can be identified in connection with the application of general merger control to hospital mergers. These range from the introduction of competition reforms via counteracting the limitations of a competition-based test to considering the role of merger control in a sector heavily dependent upon different types of agreement and cooperative relationships as follows.

¹³⁵ See supra n126.

¹³⁶ A view elaborated by Loozen (2015), supra n17.

¹³⁷ Mary Guy, 'Monitor's Advice to the OFT and the New Healthcare Regulation' (*Competition Policy Blog*, 20 February 2013) and 'The Meaning of 'Relevant Customer Benefits' in the Context of Health Care: Monitor's Advice and the Competition Commission's Response' (*Competition Policy Blog*, 28 October 2013).

I. "Selling" competition reforms and engaging with the healthcare sector

In moving away from healthcare provision as a public service overseen by government to a market-based system overseen by a competition authority, it has been acknowledged that success of such reforms will depend largely on public perception,¹³⁸ which in turn relies on perception of the reforms by the healthcare sector. Thus there is a need for broader efforts to "sell" competition¹³⁹ and engage with healthcare providers involved in the implementation of the reforms. In terms of "healthcare-specific" merger control, the role of the regulators in both countries and the Dutch "healthcare-specific" merger test seem particularly relevant.

Underpinning the competition reforms in both the Netherlands and England has been the incorporation of the NZa's and Monitor's advisory functions into merger assessment. As approving or blocking a merger is the exclusive preserve of the ACM or CMA, it is necessary to have a clearly-defined role for the NZa and Monitor.

The relationship between the ACM, NZa and quality regulator (IGZ) can be illustrated as follows, with white arrows denoting the lack of statutory consultation requirement:

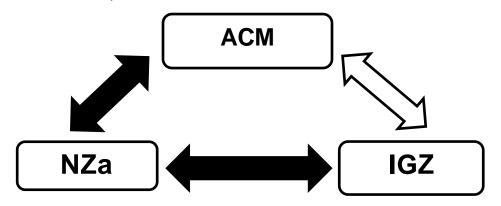


Figure 5: The institutional relationship between the ACM, NZa and IGZ in healthcare merger assessment, 2006-2015.

¹³⁸ Sauter (2011), supra n32.

¹³⁹ On this point in connection with wider public service reform in England, see Okeoghene Odudu, 'Why it matters: Selling competition law in the new frontier', [2013] Competition Law Insight, 10 December 2013.

While this framework appeared to afford the NZa a defined role within merger assessment, this was challenged in the context of the *Zeeland Hospitals* merger, as the ACM appeared to give greater weight to the IGZ's advice, effectively sidelining the NZa's Opinion. This led to the purpose of the NZa being questioned.¹⁴⁰

In England, it is interesting to note that Monitor's function within NHS FT merger assessment was only incorporated by the final debates prior to enactment of the HSCA 2012, in stark contrast to modifications of its other roles which are largely attributable to the NHS Future Forum's recommendations in refocusing competition. Nevertheless, inclusion of a function for Monitor may be considered to be motivated by the same intention of facilitating the transfer between an "NHS-specific" and general merger control regime. Monitor being assigned a pre-existing function within general merger control (identifying "relevant customer benefits" exceptions), rather than a new role related to, but independent of the EA02 test strengthens this.

It seems uncontroversial to suggest that the "merger effects" report of the Dutch "healthcare-specific" merger test serves an important function in engaging with healthcare providers, as well as facilitating communication between these and the competition authority. The NZa's ability to prohibit a merger on the basis that stakeholders have not been adequately consulted appears to reinforce this. Although not a category of "healthcare-specific" merger control in England, emphasis on considering merger effects can be inferred from the significant efforts made by the CMA, Monitor and competition lawyers to bridge any communication gap between the CMA and the NHS, particularly following the *Bournemouth-Poole* merger. This is evident in the range of publications by the agencies and in the trade press outlining the merger control process and assessment criteria.¹⁴¹

¹⁴⁰ Yvonne Maasdam, Jan-Koen Sluijs, 'Wie van de drie is de echte marktmeester in de zorg: de IGZ, de NMa of toch de NZa?' ('Who is the real market umpire in healthcare? The IGZ, the NMa or actually the NZa?') (2009), Actualiteiten Mededingingsrecht.

¹⁴¹ See, for example, David Bennett, 'Monitor's plan for a better merger regime', Health Service Journal, 23 January 2014. Gerard Hanratty, 'Heatherwood-Frimley Park shows the way through merger process', Health Service Journal, 26 June 2014. Temi Akinrinade, Joanna

II. Ensuring appropriate oversight of mergers in a sector in transition

Dutch experience of uncertainty regarding the potential for hospitals to raise competition concerns in the period 1998-2004 coupled with an ongoing move towards the 2006 reforms suggests that the timing of the application of general merger control appears critical. Indeed, it has been suggested that the lack of application of general merger control amounted to a "regulatory holiday" creating market distortions with the implication that these were subsequently aggravated by ongoing merger approval.¹⁴²

This would appear to suggest that there is a need for "healthcare-specific" amendments which are both "prospective" as well as "reactive" to the application of general merger control. Many of the elements of "healthcare-specific" merger control are "reactive", such as the introduction of lower turnover thresholds in the Netherlands. However, the development of the "NHS-specific" test in England might be deemed "prospective", at least with the benefit of hindsight¹⁴³ as the application of general merger control seems a logical step for NHS Trusts which have attained NHS FT status and are consequently independent of government oversight. Whether the PPU test can be deemed "prospective" is questionable. While it appears to anticipate an expansion of PPUs, it also can be construed as a "reaction" to PPUs being found not to qualify for Phase I assessment thus far.¹⁴⁴

Christoforou, Emily Clark, 'How to navigate a competition review to get trust merger approval', Health Service Journal 14 October 2014.

¹⁴² Canoy and Sauter (2010) supra n3.

¹⁴³ Whether competition in the NHS would have developed along the same lines as the HSCA 2012 reforms in the absence of the coalition government is a moot point. While the HSCA 2012 reforms build on previous New Labour reforms, they have also been criticised for taking earlier reforms in a wrong direction. See comments by the former Secretary of State for Health Alan Milburn in Tom Gash and Theo Roos, 'Choice and competition in public services: learning from history', Institute for Government, August 2012.

¹⁴⁴ OFT ME/2524/06 supra n107 and OFT ME/5641/12 supra n108.

III. Counteracting the limitations of a competition-based test

This offers a healthcare perspective on the wider issue of the flexibility of general competition law to accommodate public interest concerns.¹⁴⁵ More specifically, the issue is the importance of making healthcare values of affordability, accessibility and quality "sufficiently operational" for competition authorities to handle.¹⁴⁶ In other words, how to apply effectively a standard test to the healthcare sector, characterised by atypical consumers and (at least in England) a move away from competition on price.

This "operationalisation" is demonstrated in part by the additional criteria for the ACM, but mainly by the incorporation of regulator advice into the merger assessment process. Both are now considered.

In a sense, an intention of the additional assessment criteria is to understand aspects of patient behaviour – such as willingness to travel further for specialist rather than basic care, and responding to greater availability of information about quality¹⁴⁷ – which may not otherwise be reflected in the competition test of Dutch general merger control. In essence, the 2013 Policy Rules can be seen very much as a reflection of a sector in transition. There is an acknowledged need for the ACM's decision-making process to be as transparent as possible as developments such as the change in classification of hospital services may influence elements such as market definition which are fundamental to the merger control process.¹⁴⁸

As regards the regulator's role, in England, Monitor's duty to advise on "relevant customer benefits" is a model of regulator input found in other sectors,¹⁴⁹ but is now developing in a healthcare context. As noted above in

¹⁴⁵ On this wider point in connection with mergers, see David Reader, 'Accommodating Public Interest Considerations in Domestic Merger Control: Empirical Insights', CCP Working Paper 16-3, and more generally relating to competition law, Christopher Townley, 'Article 81 EC and Public Policy', Hart 2009.

¹⁴⁶ Canoy and Sauter (2010) supra n3. This "operationalisation" has been identified as a lesson in the context of it being crucial to employ merger control.

¹⁴⁷ Explanatory Notes to the 2013 Policy Rules supra n113.
¹⁴⁸ Ibid.

¹⁴⁹ For example, Ofwat considers relevant customer benefits in the context of comparative competition and mergers in the water sector, and a similarly formal process is in place for

connection with the *Ashford-Royal Surrey* merger, these may appear to offer a means to comply with government policy for the NHS.

In the Netherlands, the focus of the NZa's Opinions in merger cases was on the "general consumer interest",¹⁵⁰ which refers to long-term interests,¹⁵¹ so can be distinguished from the interests of individual consumers or healthcare providers. The NZa interpreted this in terms of the wider public interests of affordability, accessibility and quality. These have been further defined in connection with healthcare. For example, "accessibility" can be understood in terms of physical and financial accessibility. The former acknowledges access to the right care within a reasonable distance and time period, based on norms regarding waiting time for elective care. The latter provides that ability to pay is no barrier to receiving medical care. "Affordability" can be considered both at a micro level (relating to affordable basic insurance) and macro level (relating to lack of reduction of purchasing power or a dramatic increase in public spending).¹⁵² The "quality" dimension of the NZa's Opinions was previously focused on the transparency of quality and whether markets worked well presumably in complement to IGZ assessments regarding the medical quality of healthcare, whereas more recent NZa Opinions included a section on "quality" devoted to the IGZ's advice.153

The 2015 reforms include a potentially significant refocusing of how public interests may be incorporated, with the suggestion that recourse to Ministerial Decrees may be had only where general merger control proves insufficient. While the ACM has acknowledged that affordability and accessibility of

Ofcom to produce a report at Phase I regarding media mergers. However, other sectoral regulators may also be consulted in merger assessment accordingly. ¹⁵⁰ Art.3(4) Wmg.

¹⁵¹ Wolf Sauter, 'Is the general consumer interest a source of legitimacy for healthcare regulation? An analysis of the Dutch experience', European Journal of Consumer Law 2-3/2009.

¹⁵² NZa, 'Visiedocument: (In) het belang van de consument' ('Vision Document: (In) the general consumer interest') (November 2007). Section 2.1.

¹⁵³ See, for example, NZa (2012) supra n123.

healthcare comprise part of its competition assessment, an in-depth analysis of the effects of a merger on the *quality* of the healthcare provided does not.¹⁵⁴

IV. Elaborating the appropriate place of merger control in a sector heavily dependent upon cooperative relationships

The creation of the "NHS-specific" test, the "Transactions" pipeline and PPU test in England reinforce the existence of different forms of cooperation within the hospital sector. Recognising that such arrangements may not fall within the scope of general merger control raises the question of whether the anticompetitive agreements provisions are triggered instead.¹⁵⁵ It has been suggested – albeit in view of the widespread merger approval by the ACM - that navigating merger control is a more attractive proposition to healthcare providers than confronting the relative uncertainty of the anticompetitive agreements provisions.¹⁵⁶ As mergers represent a more definitive form of "consolidation" than other types of cooperation,¹⁵⁷ this appears not only counterintuitive, but also counterproductive if such perceptions were to lead to mergers in lieu of less involved forms of cooperation.

¹⁵⁴ ACM, 'Position paper Autoriteit Consument en Markt. Rondetafelgesprek fusietoets zorginstellingen', ('ACM Position Paper on the roundtable discussion of the healthcare institution merger test'), 29 June 2015.

¹⁵⁵ This is perhaps more likely in the Netherlands, where both merger control and the anticompetitive agreements provision (Art.6 Mw) are addressed to "undertakings" by the Dutch Competition Act. In England, although NHS FTs and NHS Trusts are indeed "enterprises" for the purposes of EA02, their respective status as "undertakings" for the purposes of the Chapter I prohibition of CA98 is less clearif an NHS FT and NHS Trust were to enter into a potentially anticompetitive agreement. See Okeoghene Odudu, 'Competition Law and the National Health Service' (*Competition Bulletin: Competition Law Views from Blackstone Chambers*, October 2012).

¹⁵⁶ Jansen (2013) and Taylor (2015), both supra n13.

¹⁵⁷ In England, the "Dalton Review" of organisational reforms which accompanied the NHS Five Year Forward View and the development of the "transactions" pipeline identified three levels of organisational form: Collaborative (comprising Federations and Joint Ventures), Contractual (comprising service level chains and management contracts) and Consolidation (comprising integrated care organisations, multi-site trusts and multi-service chains or Foundation-Groups). David Dalton, Examining new options and opportunities for providers of NHS care, December 2014. Page 18.

5.5. Conclusions – what can "healthcare-specific" merger control achieve in Dutch and English healthcare?

This chapter has examined the question of what "healthcare-specific" merger control *can* achieve in Dutch and English healthcare by reference to the elements which it comprises, how it complements general merger control as applied to hospital mergers in both countries and what is *intended* to achieve.

The deliberately broad definition of "healthcare-specific" merger control has demonstrated that there are elements which enable general merger control to accommodate aspects which it may not typically consider.

Consideration of what "healthcare-specific" merger control is *intended* to achieve offers a framework against which what it *can* achieve might be evaluated. Thus the intention for the ACM to examine a greater number of hospital mergers has been achieved by the introduction of lower turnover thresholds and the "care turnover" threshold. Similarly, intentions to improve engagement with hospitals have been achieved as a result of the "merger effects report", particularly in view of the criticism that the "healthcare-specific" merger test is merely procedural, not substantive in nature.¹⁵⁸ Equally, the inclusion of Monitor and the NZa in the general merger assessment processes appears to have satisfied the intention of facilitating the move away from government to competition authority oversight. This seems to be the case particularly in the Netherlands, in view of the 2015 reforms.

Perhaps the most important – and unifying – example of what "healthcarespecific" merger control is both *intended* to, and can *actually achieve* is the recognition that general merger control may be unsuitable as a mechanism for evaluating all organizational forms or cooperative relationships. This is illustrated by the distinction the ACM draws between "mergers" and "collaborations" in respect of, for example, Specialist Partnerships in the Netherlands as noted above. This distinction is strengthened by the

¹⁵⁸ See Sauter (2013) supra n124 and E.M.H. Loozen, 'Inrichting van meervoudig toezicht op marktwerking' ('Introduction of multisector regulation of competition'), RegelMaat 2013 (28)
2.

requirement for parties to justify the choice of a merger under the 2015 reforms. However, defining of the limits of general merger control is evidenced most strongly by the creation of "NHS-specific" and PPU tests in England, as these serve to reinforce the threshold filter of a "relevant merger situation" based on degree of change in control rather than "enterprises".

Of course, what "healthcare-specific" merger control can achieve can also produce distinctions from what may have been intended. For example, although some of the "healthcare-specific" amendments may have been intended to counter widespread merger approval, it is difficult to claim that the blocking of the Albert Schweitzer Hospital – Rivas Care Group merger in 2015 is solely attributable to "healthcare-specific" amendments as distinct from the finding of a SIEC under Dutch general merger control which could not be offset by countervailing buyer power and market conditions. However, this is not to suggest that "healthcare-specific" merger control is somehow distinct from general merger control - in an assessment of the ACM's practice, the "healthcare-specific" elements are also included.¹⁵⁹ In a similar vein, if government policy is continuing to influence NHS mergers, as evidenced by the focus on a seven-day NHS in connection with the Ashford – Royal Surrey merger, then it is questionable whether Monitor's advice regarding "relevant customer benefits" under s.79(5) HSCA 2012 adds anything to the CMA assessment at Phase II which appears to examine the wider policy context anyway. However, although Monitor's input may contribute little in substantive terms, its presence is significant in terms of perception of how NHS mergers are treated by the CMA.

A further example of what "healthcare-specific" merger control can achieve lies in raising awareness of differences in healthcare and consequently of potential limitations in developing competition in the sector.

The 2015 reforms in the Netherlands may prove instructive in this regard. It will be recalled that the NZa's role vis-à-vis Opinions and the "healthcare-specific" merger test is being removed. This has the effect of streamlining general

¹⁵⁹ Kemp et al (2015) supra n2.

merger control assessment as prospective merging parties will only deal with one agency – the ACM – thus saving time and money, as well as avoiding confusion about the NZa's role.¹⁶⁰ It appears that consideration of healthcare values of affordability, accessibility and quality will be incorporated by other means, questioning the NZa's role in merger assessment in the first place, over and above "selling" competition reforms. Furthermore, the "healthcarespecific" merger test is to be refocused in terms of whom it is addressed to, and with regard to some of the considerations for the "merger effects" report. This suggests that the experience of the NZa's inclusion in merger assessments has produced lessons which have been heeded.

It may appear, in the round, that an effect of these reforms is to re-focus, as much as simplify the general merger control procedure. However, this appears to suggest that elements of "healthcare-specific" merger control in the Netherlands have proved needlessly complicated. However, while "healthcarespecific" merger control may not have counteracted the problem of widespread merger approval, it has nevertheless served a useful function with regard to how competition in Dutch healthcare may be perceived. It has therefore provided a basis on which the 2015 reforms can build.

With regard to "healthcare-specific" merger control in England, a less complicated picture emerges in which general merger control appears comparatively unencumbered by regulator intervention as the "relevant customer benefits" exception, although not widely used in other sectors, is already incorporated into the test of EA02, and appears merely "refocused" to involve Monitor.

¹⁶⁰ The latter being criticised by the Borstlap and AEF reports discussed in Chapter 2. Andersson Elffers Felix (in samenwerking met Radicand Economics and Tilburg Law and Economics Center (TILEC)), 'Ordening en Toezicht in de zorg: Evaluatie van de Wet marktordening gezondheidszorg (Wmg) en de Nederlandse Zorgautoriteit (NZa)', (AEF in cooperation with Radicand Economics and TILEC, 'Oversight and regulation in healthcare: Assessment of the Dutch Healthcare (Market Regulation) Act 2006 (Wmg) and the Dutch Healthcare Authority (NZa)') September 2014. H Borstlap, PFM van der Meer Mohr, LJE Smits, 'Het rapport van de onderzoekscommissie intern functioneren NZa', 2 September 2014. ('Report of the investigation committee on the internal operation of the NZa'), 2 September 2014.

It remains to be seen how Monitor and the NHS TDA's incorporation into NHS Improvement will affect merger control. However, this may not mark a significant change in approach. This is partly due to the reticence of the government to engage with active promotion of competition following the experience of enacting HSCA 2012. Indeed, the CEOs of NHS Improvement have already indicated an ambivalence about competition and mergers.¹⁶¹ However, more compelling in this regard is the structure of NHS Improvement itself, which is not created by statute, so Monitor will continue to exist as a statutory authority with responsibility for enforcing competition rules in the NHS¹⁶² – which presumably includes its s.79(5) HSCA 2012 function.

The foregoing suggests that there are indeed limits to what "healthcarespecific" merger control can achieve. However this, in turn, highlights limitations of applying general merger control to a sector in transition, therefore at least marks an important developmental stage.

¹⁶¹ See comments by Ed Smith to the Health Select Committee on 19 January 2016 in response to Question 33 regarding the balance between putting contracts out to tender with use of public money, "It is important in the short term that we absolutely focus on the key issues. The key issues are getting the money right in the system. The reports from the King's Fund and others have shown in the past that mergers and other forms of integration have not necessarily achieved benefit. [...] There are examples of where competition has not worked, but, equally, there are good examples of where competition does work."

Chapter 6

Conclusions

Contents

6.1. Overview of findings chapter-by-chapter and thesis contributions:240
I. Chapter 3 – How does applying competition law impact healthcare provision in the Netherlands and England?
II. Chapter 4 – How should the new sectoral regulators for healthcare work with the competition authorities in applying competition law?
III. Chapter 5 – What can "healthcare-specific" merger control achieve in Dutch andEnglish healthcare?
6.2. Conclusions by thesis discussion framework243
I. The "healthcare structure" – macro, meso and micro levels243
A. The macro level – state intervention243
B. The meso level – healthcare purchasers245
C. The microlevel – healthcare providers246
II. The "continuum" between healthcare as a public service overseen by government and a market-based system overseen by a competition authority247
III. A "competition-centric" or "healthcare-centric" approach249
6.3. Broader conclusions by theme and policy recommendations:251
I. General observations arising from examination of the Dutch experience251
II. The relationship between the EU competition law framework and the emergent national competition policies in healthcare253
III. The limits of importing regulatory structures from other sectors in connection with developing competition in healthcare256
IV. The need for modifications to general law to accommodate the specificities of the healthcare sector
V. The need to understand and acknowledge the interactions between the NHS and PH sector in England and the absence of a single, unified "healthcare" sector258
6.4. Future directions of research arising from the thesis

6.1. Overview of findings chapter-by-chapter and thesis contributions

In general terms, this thesis has examined the applicability and application of competition law to Dutch and English healthcare, the relationship between the new healthcare regulators and competition authorities in so doing, and the modifications made to general merger control as applied to hospital mergers. In particular, it has sought to contribute to understanding how the general law may be applied and where exemptions and modifications are deemed necessary. This is important in view of the need to establish a workable competition policy in healthcare. A competition policy might be defined as comprising both general law (competition law and merger control), regulatory rules and the various actors which have input into assessments (typically the competition authority and healthcare regulator, although the quality regulator may also have a role). This thesis has attempted to outline what competition policy in healthcare looks like by reference to the Dutch and English experiences, which encompass the broad Bismarck and Beveridge typologies.

Over the course of writing this thesis and presenting initial research findings to a wide range of audiences¹ in the UK and abroad,² it has become apparent that competition in healthcare is a theme of interest beyond a niche aspect of either competition or health law. However, it is impossible to divorce competition in healthcare entirely from either general competition policy or understandings of healthcare system organisation: it relies heavily on both. Therefore a competition policy for healthcare cannot exist in isolation. However, the wideranging events which have occurred in the past four years have affected the concept of a competition policy for healthcare to varying degrees. For example,

¹ Including both academic and non-academic audiences. Academic audiences include the Health Law and Policy Research Group "Old Markets New Markets" workshop at the University of Sheffield, Social Justice 2014 workshop at the London School of Economics (LSE) and Tilburg Law and Economics Center (TILEC) as well as the Centre for Competition Policy (CCP) at UEA. Non-academic audiences include the Dutch Healthcare Authority (NZa), the Authority for Consumers and Markets (ACM) and PolicyBristol event as well as discussions with members of Monitor (now NHS Improvement) and the Competition and Markets Authority (CMA).

² Including the Antitrust Law and Healthcare workshop at the European University Institute in Florence in November 2014.

the creation of the ACM and the CMA may be perceived as having little, if any, impact on the development of competition in healthcare beyond this potentially being treated as less of a priority for larger agencies.³ Although the proposed repeal of the HSCA 2012 pledged by the Labour, Green and Liberal Democrat parties ahead of the UK general election in 2015 failed to materialise, perhaps the main impact this could have had would be to simplify competition policy vis-à-vis the NHS and left intact the general competition regime. In contrast, the vote in the recent UK referendum to leave the EU could seem in theory to have the reverse effect: of removing the EU competition law framework and leaving the HSCA 2012 intact.

In addition to contributing to contemporary discussions of competition in healthcare, the research in this thesis offers a contribution to various types of literature as follows.

I. Chapter 3 – How does applying competition law impact healthcare provision in the Netherlands and England?

The discussions of the applicability and application of competition law in Chapter 3 add to existing considerations of the applicability of EU competition law (outlined in the Introduction) by offering an insight into what potential "Euro-national competition rules for healthcare"⁴ may look like and how these may operate. Interestingly, based on the research in Chapter 3, there may be common ground associated with "healthcare", regardless of system model, such as access to electronic networks and professional associations.⁵ However, there are also aspects specific to individual countries which will raise particular questions. These include healthcare intermediaries and specialist partnerships in the Netherlands, and CCGs in England. Chapter 3 has also illustrated the significance of the distinction between the NHS and PH sector in England, and in particular the need to distinguish between private providers delivering NHS

³ Although it is recognised that the ACM incorporates the former Dutch Consumer Authority, and its advice also includes healthcare-related issues.

⁴ Johan Van de Gronden, 'The Treaty Provisions on Competition and Health Care' in Johan Willem van de Gronden, Erika Szyszczak, Ulla Neergaard, Markus Krajewski (eds), *Health Care and EU Law* (TMC Asser Press 2011).

⁵ Which may, of course, also be found in other sectors.

services (category 2) and NHS providers delivering PH services via PPUs (category 3). While category 2 activity still remains a grey area as regards the *extent* of the applicability of competition law, category 3 is clearer in this regard as the former OFT took (albeit limited) enforcement action against NHS FTs in respect of sharing information about their PPUs. Insofar as the removal of the private patient income cap may result in an expansion of PPUs operated by NHS FTs, it is conceivable that similar action by the CMA may be necessary as NHS FTs engage with competition law in their capacity as private providers.

II. Chapter 4 – How should the new sectoral regulators for healthcare work with the competition authorities in applying competition law?

The examination in Chapter 4 of the relationships between the competition authority and healthcare regulator in the Netherlands and England adds to a growing literature which considers economic regulation in healthcare. By examining the NZa and Monitor (as opposed to a healthcare regulator and another sectoral regulator), the research in Chapter 4 offers an initial in-depth assessment of aspects prominent in, if not unique to, healthcare, namely the focus on patients (and their dual identity as insurance policyholders and taxpayers in the Netherlands and England, respectively) and the evolving Ministerial intervention in light of the establishment of the healthcare regulators. Chapter 4 also contributes to recent literature⁶ to set out an in-depth consideration of the distinctive take on "concurrent powers" of s.72 HSCA 2012 as refocused by the 2014 Concurrency Regulations and relate this to the framework of the applicability of competition law to the NHS and the underlying distinction between this and the PH sector.

⁶ Albert Sánchez Graells, 'Monitor and the Competition and Markets Authority' (2014) University of Leicester School of Law Research Paper No.14-32.

III. Chapter 5 – What can "healthcare-specific" merger control achieve in Dutch and English healthcare?

The examination of "healthcare-specific" modifications to general merger control in the Netherlands and England offers a further dimension of originality to contribute to more general considerations of competition reforms in both countries which include merger control as one aspect among several. The chapter also provides a significant contribution as it focuses on the law – in contrast to the wider (health) economic literature which considers the development of "healthcare-specific" econometric tests,⁷ or policy-related literature examining the experience of mergers in the NHS.⁸

6.2. Conclusions by thesis discussion framework

I. The "healthcare structure" – macro, meso and micro levels

By considering the developments flowing from primarily sections 72 and 79 HSCA 2012, there appears to be most impact at the macro level of state intervention. However, the other two levels – meso and micro, relating respectively to purchasers and providers – have also been engaged.

A. The macro level – state intervention

The macro level of state intervention has been engaged throughout the discussions of this thesis in various ways.

With regard to the *applicability* of competition law (discussed in Chapter 3), the macro level is engaged by the distinction drawn between instances where the state is not subject (in respect of acts of imperium), and where it may be deemed to be carrying out economic activities, thus an "undertaking". The macro level was further engaged in connection with the potential tension

⁷ Most notably emanating in the Netherlands – see Marco Varkevisser and Frederik Schut, 'The impact of geographic market definition on the stringency of hospital merger control in Germany and the Netherlands' [2012] 7(3) Health Economics, Policy and Law 363-381.

⁸ Emma Spencelayh and Jennifer Dixon, 'Mergers in the NHS – Lessons from the decision to block the proposed merger of hospitals in Bournemouth and Poole', The Health Foundation Policy Analysis, December 2014.

between EU and Member State interaction, in light of the subsidiarity principle in relation to Article 168(7) TFEU and concerns about divergent national interpretations of EU competition law leading to "Euro-national competition rules for healthcare" as noted previously.

However, the most notable changes in state intervention can be seen in the evolving role of the government vis-à-vis the competition authority and healthcare regulator in both countries. Indeed, an important conclusion from the preceding discussions is that it may not be possible to separate entirely Ministerial intervention in healthcare from the oversight by independent agencies. Thus, as a result of the HSCA 2012 and 2006 reforms, the macro level has evolved to now comprise all three: the Minister, the healthcare regulator and the competition authority. The ongoing influence of the Minister, however, appears subject to counterintuitive developments in the two countries. In the Netherlands the applicability of competition law (to purchasers and providers) has been relatively clear, and this has been combined with – initially – a clearer framework for the relationship between competition authority and healthcare regulator, and subsequently greater competence accruing to the competition authority. However, despite this, it appears that Ministerial oversight and power to set policy direction for healthcare will merely transfer from the NZa to the ACM. This appears surprising as lesser Ministerial intervention might have been anticipated in these circumstances. In contrast, the HSCA 2012 reforms have seen a notable transfer of competence from the Secretary of State for Health to NHS England, against a backdrop of a relative lack of clarity concerning the extent of the applicability of competition law, so greater Ministerial intervention may have been anticipated.

Indeed, the focus of the macro level in light of the discussions of this thesis is on the relationship and interaction between the three – the Minister, competition authority and healthcare regulator. The scope for convoluted interactions between the three have been illustrated in the discussions of Chapter 5 concerning the development of differing assessment aspects of merger control. Furthermore, a significant finding has been that government intervention may still be experienced, even if this is not explicit, as evidenced by the apparent linking of "relevant consumer benefits" and the "seven day NHS" policy. Discussions in Chapter 4 of the choice of competition authorityregulator relationship model – separate or concurrent powers – also highlight this focus of the macro level. A significant finding of Chapter 4 was that the combination of concurrent powers under s.72 HSCA 2012, as tempered by the ERRA 2013 and 2014 Concurrency Regulations reforms appears to have served to replicate the pre-HSCA 2012 situation whereby the CMA has oversight over the PH sector (categories 3 and 4), and Monitor (admittedly as distinct from the Department of Health) power to intervene regarding the NHS (categories 1 and 2).

Overall, it can be concluded that Ministerial intervention in the competition reforms in both countries is still ongoing, but the extent of its visibility may vary. This is particularly true in England, where NHS England has responsibility for setting strategic vision for the NHS. In terms of further research, it may be interesting to examine the extent to which NHS Improvement (formerly Monitor) and NHS England are independent of the Department of Health, and what Ministerial oversight of the ACM means in practical terms as the effects of the transfer of competence unfolds in the Netherlands.

B. The meso level – healthcare purchasers

The meso level has been engaged to a significantly lesser extent in this thesis. Indeed its particular relevance might be associated with questions of applicability of competition law in view of the conflation of purchasing and providing functions in CCGs and the elaboration of national frameworks in the form of Article 122 Dutch Health Insurance Act (Zvw) and the prohibition on anticompetitive behaviour by NHS Commissioners of Regulation 10 of the National Health Service (Procurement, Patient Choice and Competition) Regulations (No.2) 2013. However, it appears in both countries that taking action against healthcare purchasers has not been a priority for the competition authorities thus far. This is perhaps surprising in the Netherlands in view of the undoubted consolidation of the health insurance market. In England, the 2013 Regulations appear to provide a framework for developing the NHS market further. Indeed, an area for future research may be the ongoing reconfiguration of CCGs in view of mergers of these. However, a current focus is developing on avoiding conflicts of interest where healthcare providers are also purchasers, and an alignment of the 2013 Regulations with procurement rules.⁹

C. The micro level – healthcare providers

The micro level has been engaged at various points across the thesis. In discussions of the applicability of competition law in Chapter 3, it was established that while healthcare providers (as distinct from purchasers) are typically subject to competition law, the experience in England appears influenced by the legacy of the FENIN judgment as CMA guidance to private practitioners relates exclusively to their work in the PH sector (categories 3 and 4), and not that performed for the purposes of the NHS (categories 1 and 2). This suggests an ongoing distinction between the NHS and PH sector which also permeates the respective oversight of Monitor and the CMA. These findings in essence that there is no single, unified healthcare sector in England, but two very closely related markets - coupled with an endorsement of the view that the FENIN legacy is evident in the ultimate purpose of healthcare provision (i.e. based on clinical need, not the ability to pay) as opposed to a distinction purchasing and providing functions,¹⁰enable understanding between discussion to move beyond questions of whether public providers are subject to competition law.11 Indeed, this interpretation potentially identifies a jurisdictional gap whereby private providers delivering services for the purposes of the NHS (category 2) may not be subject to competition law. Although scope for certain aspects of anticompetitive behaviour (such as price-

⁹ See Albert Sánchez Graells, 'Conflicts of interest in healthcare: NHS procurement rules must be clarified', University of Bristol and PolicyBristol Policy Briefing 31/2016.

¹⁰ As articulated by Tony Prosser, 'EU competition law and public services' in Elias Mossialos, Govin Permanand, Rita Baeten, Tamara Hervey (eds), *Health Systems Governance in Europe: The Role of European Union Law and Policy* (CUP 2010), and Nina Boeger and Tony Prosser, 'United Kingdom', Chapter 18 in Markus Krajewski, Ulla Neergaard, Johan Van de Gronden (eds), *The Changing Legal Framework for Services of General Interest in Europe – Between Competition and Solidarity*, (TMC Asser Press, 2009). Graham has also acknowledged that the extent of the applicability of competition law to the English NHS is limited. See Cosmo Graham, 'UK: The Concurrent Enforcement by Regulators of Competition Law and Sector-Specific Regulation'. (2016) Journal of European Competition Law and Practice (Advance Access published 26 May 2016).

¹¹ Clarification of this point is summarised well by Odudu. See Okeoghene Odudu, 'Are Stateowned healthcare providers undertakings subject to competition law?' [2011] 32(5) European Competition Law Review 231-241.

fixing) may be circumscribed by the existence of the NHS tariff, this is concerning in view of the perception that private providers may seek to exploit the NHS. However, such an eventuality may be mitigated to a certain extent by the framework offered by the 2013 Regulations.

Healthcare providers have also provided a focus for the modifications to general merger control discussed in Chapter 5. The modifications surveyed in the thesis have demonstrated that not all types of cooperation may meet the thresholds of general merger control. In addition, the consideration that the relative straightforwardness of general merger control (coupled with widespread approval of hospital mergers in the Netherlands) may have led healthcare providers to merge, rather than seek alternative forms of cooperation and risk falling foul of the anticompetitive agreements provisions has been re-emphasized by the discussions of this thesis. Furthermore, the distinction between the NHS and PH sector appears underscored by the CMA's proposal of a separate test for Private Patient Units (PPUs) in light of the potential expansion of these following the removal of the private patient income cap by s.165 HSCA 2012. While the focus of the test is to avoid further distortions of the PH market, there is a need to assess the impact of any potential expansion on the NHS as well.

II. The "continuum" between healthcare as a public service overseen by government and a market-based system overseen by a competition authority

As acknowledged previously,¹² a binary distinction between a solidarity-based system and a competition-based system is unhelpful in light of the political necessity of a gradual, or even partial introduction of competition.¹³ Therefore the purpose of the "continuum" framework linking the two was to assess the extent to which the 2006 and HSCA 2012 reforms marked movement from

¹² See Chapter 3, pages 76-77, footnote 19.

¹³ Wolf Sauter, 'Services of general economic interest and universal service obligations as an EU law framework for curative health care' TILEC Discussion Paper 29, Tilburg University (2007).

oversight by government to oversight by the competition authority. This might also be conceptualised as testing whether Littlechild's consideration of UK economic regulation as "holding the fort" pending the arrival of competition may fare differently in healthcare than in other sectors, where it has been acknowledged that, over the past thirty years, regulation has assumed a more permanent than temporary character.

In essence, discussions of this thesis have demonstrated that establishing the applicability of general law (whether competition rules or merger control) and thus the entitlement of the competition authority to exercise oversight over healthcare, does not equate in practice to reaching the end point of the continuum. This is demonstrated in the Netherlands by Ministerial oversight of policy direction in healthcare apparently transferring to the ACM with the current transfer of NZa competition powers. In England, this is demonstrated by distinctions drawn between the NHS and PH sector (inter alia by the CMA) and the restrictions placed on the CMA by the 2014 Concurrency Regulations. Rather, perhaps unsurprisingly, what we are seeing with the 2006 and HSCA 2012 reforms is a change in direction away from the (mythical) end point of the continuum. This change in direction recognises competition as an important aspect of healthcare system modernisation, but is not capable of simplifying healthcare system organisation in isolation from wider political concerns and intervention.

As noted in Chapter 4,¹⁴ the "continuum" may operate differently in healthcare to other liberalised sectors which have undergone a sequence of "privatisationregulation-liberalisation". In light of the HSCA 2012 reforms, the sequence is refocused thus: regulation (by Monitor) – liberalisation (insofar as this describes the commitment to competitive neutrality for private and voluntary sector providers delivering NHS services) – privatisation. However, the sequence may in practice not extend beyond liberalisation, since experiments with private ownership have been limited to franchising arrangements (as seen with Circle's temporary management of an NHS hospital). It remains to be seen

¹⁴ See Chapter 4, page 135.

how this develops in light of the new care models of the NHS Five Year Forward View.

It was suggested in Chapter 5 that the continuum framework has most relevance to the "healthcare-specific" modifications introduced in the Netherlands and England. These were grouped as either "prospective" (typically intended to be temporary) in nature or "reactive" to the application of general merger control. The "prospective" modifications included the temporary lower turnover thresholds and assessment criteria in the Netherlands and the "NHS FT pipeline" in England. The "reactive" modifications included the "healthcare-specific" merger test and NZa Opinions in the Netherlands, and the "Transactions pipeline" and new PPU test in England.

However, the mere existence of "reactive" modifications supports further the view that we are experiencing a change in direction, rather than merely reaching an end point of the competition authority applying general law.

III. A "competition-centric" or "healthcare-centric" approach

In essence, a "competition-centric" approach suggests that healthcare is no different to other sectors with the implication that the general law and oversight by the competition authority is sufficient to deliver benefits of healthcare modernisation. Conversely, a "healthcare-centric" approach suggests that healthcare is different, and a more nuanced approach which takes account of the specificities of the sector is needed for competition to help deliver benefits of healthcare modernisation. These two approaches¹⁵ have been juxtaposed in this thesis to provide a framework for assessing the 2006 and HSCA 2012 reforms as follows.

Chapter 3 discussions regarding the applicability of competition law are necessary for either approach. This is because the framework is more concerned with the interpretation of competition law – whether it can

¹⁵ Which draw on a wider literature in which opinions are polarised as to whether healthcare as a sector merits special treatment or not regarding competition reforms. For an example developed in a law context, see Edith Loozen, 'Public healthcare interests require strict competition enforcement' [2015] 119(7) Health Policy 882-888.

accommodate values such as affordability, accessibility and quality¹⁶ - rather than the mechanisms of establishing applicability as such. Thus the consideration that competition law is capable of accommodating specific concerns of the public sector¹⁷ has relevance to either approach as suggesting that competition law can (extend to) accommodate healthcare values.

Chapter 4 suggested that the "separate powers" model of the Netherlands is related more closely to a "healthcare-centric" approach which recognises the distinctive nature of healthcare. Furthermore, the current transfer of NZa powers to the ACM may not change this view insofar as the tension between ex ante and ex post intervention can be construed as giving effect to the distinctive nature of healthcare. In contrast, the "concurrent powers" model in operation in England may fit within either approach. As concurrent powers are found in other sectors, this style of relationship appears to fit the "competitioncentric" approach in light of the implication that healthcare is not different. However, recognition that concurrent powers may operate differently in healthcare¹⁸ (in view of the absence of a single, unified healthcare sector) and effective elaboration of this by the 2014 Concurrency Regulations (restricting CMA oversight effectively to the PH sector) suggests that healthcare *is* different, thus the concurrent powers of s.72 HSCA 2012 fit with a "healthcarecentric" approach.

In Chapter 5, the two approaches were linked explicitly with the views that "healthcare-specific" modifications to hospital merger assessment are either necessary or not. Thus the current transfer of NZa powers to the ACM might be construed as a "competition-centric" approach, indicating that modifications and regulator input amounted to little more than a diversion. A separate issue relating to this approach is the consideration that the real problem lies in how the ACM applies general merger control to hospital mergers, and not the

¹⁶ Van de Gronden (2011) supra n4.

¹⁷ Tony Prosser, *The Limits of Competition Law* (OUP 2005), p.24.

¹⁸ See Lord Whitty's comments in the context of the Lords Debates of ERRA 2013. Chapter 4, at footnote 111, page 152.

underlying substantive test.¹⁹ Conversely, the idea that general merger control may prove insufficient to assess hospital mergers in view of the organisational structures and non-economic concerns raised clearly underpins a "healthcare-centric" approach. This explains the need for – and desirability of – separate tests for NHS Trusts, NHS FTs and PPUs in England.

Overall, "healthcare-centric" can be seen as the dominant approach emerging from both the 2006 and HSCA 2012 reforms. This can be evidenced by the predominance of the National Health Service (Procurement, Patient Choice and Competition) Regulations (No.2) 2013 as regards enforcement action in England, and the refocusing of the healthcare-specific merger test in the Netherlands to include a requirement to consider whether forms of cooperation other than merger may be best suited to working arrangements in healthcare.

6.3. Broader conclusions by theme and policy recommendations:

I. General observations arising from examination of the Dutch experience

This thesis has examined the competition provisions of the HSCA 2012 by reference to the Dutch experience of applying identical, or very similar provisions (in respect of competition law and merger control, respectively) and establishing an equivalent regulatory framework with defined a relationship between the competition authority and healthcare regulator.

The most striking aspect of examining the Dutch experience has been the flexibility demonstrated in implementing reform and apparent willingness to review developments and engage with different approaches, even where this may involve enacting new legislation. This is demonstrated by the independent assessments of the NZa, renewed Cooperation Protocols between the NZa and

¹⁹ E.M.H. Loozen, 'Wijziging regelgeving markttoezicht in de zorg' ('Changes to legislation governing market regulation in healthcare'), Instituut Beleid & Management Gezondheidszorg, Erasmus University Rotterdam, November 2015.

ACM, the temporary nature of lower turnover thresholds in merger control and the current streamlining of competition oversight by transferring the NZa's powers relating to SMP and merger control to the ACM. A further notable aspect has been Ministerial commitment to making the 2006 reforms work even if Ministerial intervention is less than desirable from the perspective of independent agencies.

This appears in stark contrast to the dogged, even blind, commitment to enacting the HSCA 2012 in England despite ongoing and widespread opposition and with concessions made with apparently little consideration of the consequences. Examples of the latter can be seen in the retention of concurrent powers (while removing Monitor's duty to promote competition and recasting it as a "sectoral" rather than an "economic" regulator) and the decision to put the NHS Principles and Rules for Cooperation and Competition (NHS PRCC) on a statutory footing in response to the NHS Future Forum report. This situation has unsurprisingly led to the criticism that "we are left with some pretty unworkable ideas in primary legislation".²⁰ The lack of willingness on the part of the coalition government (primarily) but also the Conservative government (following the 2015 UK general election) to revisit the issue of competition in healthcare has been demonstrated by the Lords Debates in connection with the Enterprise and Regulatory Reform Act 2013 (ERRA 2013) and, perhaps most notably, by the creation of NHS Improvement as an agency apparently with no legal status beyond that of Monitor and the NHS Trust Development Authority. In light of the determination needed to enact the HSCA 2012, there has been notably little endorsement of, or support for, the resulting competition regime by the Secretary of State for Health. This may not be surprising in view of the purpose of the HSCA 2012 reforms, inter alia, the creation of NHS England and emphasis on its relationship with NHS Improvement. However, perception is also important, and an apparent lack of interest has led to suggestions that NHS Improvement's days as a sectoral

²⁰ Kieran Walshe, 'Queen's Speech: We can't avoid legislation for ever', Health Service Journal, 28 May 2015.

regulator may be numbered,²¹ following criticism by the previous CEO of Monitor.²²

A further consideration is that the 2006 reforms in the Netherlands follow a period of approximately 20 years of incremental reform in transforming a system of state-funded sickness funds covering the majority of the population and an additional private health insurance system to a single private health insurance scheme. While the HSCA 2012 reforms similarly follow incremental forms from the NHS internal market via the New Labour reforms, the extent to which these are intended to result in a significant system change (presumably to an insurance-based system)²³ is unclear. Certainly the concessions made in respect of the HSCA 2012 and commitment to the NHS as a taxation-funded service suggest that such a transition is by no means straightforward and will have to accommodate political concerns in the same way that the NHS internal market is a modified version of "managed competition" and even the concessions made by Aneurin Bevan (for example regarding consultant work in private practice) to implement the NHS.

II. The relationship between the EU competition law framework and the emergent national competition policies in healthcare

It is well-established that the EU courts have drawn a distinction between healthcare providers and purchasers with only the former being subject to competition law. This can be explained in part by the view that buyer power is inherently less anticompetitive than selling power, particularly where resulting benefits are passed on to consumers.²⁴ Certainly this is more persuasive than an apparent unwillingness to recognise providing and purchasing as the two

²¹ Andrew Taylor, 'Competing over health – What's next for the National Health Service in England?', Competition Law Insight, 16 February 2016.

²² Crispin Dowler, 'Bennett: Government 'micromanagement' creating 'dependency mindset' among leaders' Health Service Journal, 5 November 2015.

²³ Lucy Reynolds and Martin McKee, 'Opening the oyster: the 2010-11 NHS reforms in England' [2012] 12(2) Clinical Medicine 128-32.

²⁴ See Wolf Sauter, Public Services in EU Law, (CUP 2015), page 119. Sauter notes that he has not come across this view being articulated as a possible defence of the more restrictive view under the competition rules. However, such a "defence" might be inferred from comments by Advocate General Maduro in *FENIN*. See Chapter 3, page 106 at footnote 156.

constituent elements of an economic activity. Nevertheless, this apparent imbalance and focus on provider competition²⁵ persists in the EU law framework, and calls²⁶ for further clarification at EU level of this framework, and how exceptions may operate are to be welcomed.

Chapter 3 demonstrated how this distinction is being addressed at a national level in the Netherlands and England. In essence, the Dutch government enacted Article 122 Dutch Health Insurance Act (Zvw) to ensure that the private health insurers are subject to at least Dutch, if not EU competition law. Furthermore, the ACM has thus far been reluctant to address concerns about buyer power.²⁷ In England, it seems that the *FENIN* legacy pertains²⁸ based on a simplistic²⁹ interpretation which distinguishes between purchasers and providers. However, as with the Netherlands, it appears that such a distinction has been deemed undesirable by the apparent attempt to mitigate this with the prohibition on anticompetitive behaviour by commissioners in Regulation 10 of the National Health Service (Procurement, Patient Choice and Competition) Regulations (No.2) 2013. In Chapter 3 it was noted that this is curious in view of the evident distinction between the differing models of competition in the two countries. Whereas the "managed competition" model in the Netherlands relies on competition between health insurers as much as between healthcare providers (and indeed between the two), the separation of purchasing and providing functions (the "NHS internal market model") in England is a modified version of this which relies on provider competition only. Thus patients in England typically cannot choose a different NHS commissioner, but if dissatisfied with the service received, may opt for treatment in the PH sector instead.

²⁵ As evidenced by European Commission, Expert Panel on Effective Ways of Investing in Health (EXPH), 'Competition among health care providers in the European Union – Investigating Policy Options', 17 February 2015.

²⁶ For example by Johan van de Gronden and Erika Szyszczak, 'Introducing Competition Principles into Health Care Through EU Law and Policy: A Case Study of the Netherlands' [2014] 22(2) Medical Law Review 238-254.

²⁷ See Wolf Sauter, 'The balance between competition law and regulation in Dutch healthcare markets' (2014) TILEC Discussion Paper, DP 2014-041.

²⁸ S.72 HSCA 2012 explicitly references "healthcare providers".

²⁹ Further on this point see Prosser (2010) and Boeger and Prosser (2009), both supra n10, as well as the GC judgment in *FENIN*.

In view of this justifiable distinction, and the exceedingly narrow scope in practice for Regulation 10 to be applied, it is recommended that Regulation 10 be removed, or at least declared inapplicable. However, the same effect may be achieved by the apparent absence of intention to use this Regulation.

More generally, it is recommended that the CMA re-evaluate their interpretation of *FENIN*, and clarify their understanding of the relationship between the NHS and PH sector in light of their guidance to private practitioners applying only to their PH sector work (category 4) and not their NHS work (category 2). This is necessary because this approach by the CMA – a presumed enforcement priority being the PH sector - appears to be explained more by alternative interpretations of *FENIN* based on the ultimate end purpose of the purchase (that is, to provide healthcare services for the NHS, which can equate to providing healthcare services based on clinical need, not the ability to pay), not the purchaser/provider distinction. On the face of it, this may leave a jurisdictional gap with regard to potential anticompetitive behaviour by private providers delivering NHS services (category 2), so further clarification by the CMA is to be welcomed.

It is recognised that the CMA's capacity to take action with the concurrent powers of s.72 HSCA 2012 in individual cases regarding NHS provision is constrained by Regulations 5 and 8 of the Concurrency Regulations 2014. However, this is a different matter to more general guidance about its interpretation of *FENIN*, or joint guidance with NHS Improvement regarding private providers and/or the constraints on potential anticompetitive behaviour resulting from structures such as the NHS tariff (limiting scope for price-fixing) or the NHS Provider Licence. This could complement general CMA guidance, for example regarding bid-rigging in the public sector which can be linked to the NHS.³⁰ In this regard, the UK legislature should explore further the protection which may be afforded by the Services of General Economic Interest (SGEI) exception and develop a public service obligation as necessary in order

³⁰ Sarah Calkin, 'CMA warning over public sector bid rigging', Health Service Journal, 21 June 2016.

to give effect to the apparent ongoing commitment to keeping the NHS as a taxation-funded service free at the point of delivery.³¹

III. The limits of importing regulatory structures from other sectors in connection with developing competition in healthcare

Chapter 4 demonstrated the difficulty of practical implementation of the granting of concurrent powers to Monitor and the CMA under s.72 HSCA 2012 following the 2014 Concurrency Regulations. While the exercise of the concurrent powers is complicated by the lack of clarity about the extent of the applicability of competition law to the NHS, there are also problems with the choice of concurrent powers - better understood as "co-competence" - as a means of enforcement. In Chapter 4 the effect of the 2014 Concurrency Regulations vis-à-vis s.72 HSCA 2012 was effectively to reinstate the pre-HSCA 2012 situation whereby the CMA exercises oversight over the PH sector (categories 3 and 4) and Monitor (albeit in lieu of the Department of Health) oversight over the NHS (categories 1 and 2) via the 2013 Regulations (in lieu of the NHS Principles and Rules for Cooperation and Competition). Furthermore, this gives a new dimension to "concurrency" not found in other sectors - an analogy was drawn with the hypothetical situation of the competition authority exercising oversight over the wholesale energy market and the regulator oversight over the retail energy market.

In view of this very different conception of "concurrency" vis-à-vis healthcare, it is tempting to recommend that this model be abandoned in favour of a recognition that the CMA and NHS Improvement serve very different functions, but cooperate where appropriate – effectively that NHS Improvement's role should comprise an advisory function with regard to applying competition law as it does in connection with merger control under s.79 HSCA 2012. This is a different dimension to recommending that NHS Improvement's powers be transferred to the CMA.³² The obvious drawback to this recommendation,

³¹ As articulated in the context of the NHS Mandate and acknowledged by Monitor, 'Monitor's Strategy 2014-17 – Helping to redesign healthcare provision in England'.

³² Made by Sánchez Graells (2014) supra n6.

however, is the political sensitivity likely to ensue from the realisation that the CMA may exercise oversight over the NHS.³³ However, this may prove less incendiary in the event of clarifications by the CMA and NHS Improvement that competition cases may be the exception, not the rule, and that the main oversight of the NHS and addressing of anticompetitive behaviour would occur in the context of the NHS Provider Licence by NHS Improvement. Certainly such an approach appears to have been tacitly acknowledged in NHS Improvement's duty to use its competition law powers ahead of its regulatory powers being delayed until a (thus far apparently unspecified) future date.³⁴

Insofar as healthcare may serve as an example of how competition may work which may be replicated in other sectors such as education,³⁵ there is a need to understand that concurrent powers work differently and that this needs to be acknowledged explicitly by the CMA in its Annual Concurrency Reports beyond the statement that no cases involving concurrent powers have been brought thus far.

IV. The need for modifications to general law to accommodate the specificities of the healthcare sector

Chapter 5 explored the modifications made to merger control in the Netherlands and England. One of the notable aspects of the chapter was that parties (typically hospitals, but also other healthcare providers) may seek to merge rather than explore other forms of collaboration on the basis that merger control is clear and thus easier to navigate than the relative uncertainty of the anticompetitive agreements provisions. This is being addressed in the Netherlands by the new requirement in the "healthcare-specific" merger test for parties to justify why merger has been chosen over other forms of collaboration. There appears to be a similar need for clarity about different

³³ A point elaborated by Lord Whitty in the Lords debates of the ERRA 2013. See supra n18.

³⁴ See Viscount Younger of Leckie's comments in the Lords debates of ERRA 2013. See Chapter 4, page 152, footnote 109.

³⁵ Where there is a similar distinction between state and private education combined with greater private sector involvement in the state sector. Also, tentative parallels may already be drawn between the experience of NHS FTs and the encouragement of schools to apply for Academy status.

forms of collaboration in the NHS, particularly in view of the "Transactions pipeline" and the new care models emerging from the NHS Five Year Forward View. A similar requirement to openly justify the choice of a particular type of collaboration can therefore be recommended.

V. The need to understand and acknowledge the interactions between the NHS and PH sector in England and the absence of a single, unified "healthcare" sector

This thesis has demonstrated the problems of the apparently inconsistent use of the word "healthcare" (as compared and contrasted with provisions specifically governing the NHS) by reference mainly to the applicability of competition law and the interaction between Monitor and the CMA.

While this may seem a minor point, it entails significant considerations. Most notably, that there is no single, unified "healthcare" sector in England which may be amenable to competition reforms and the application of competition law. Rather, there are two increasingly interlinked markets of the NHS and PH sector which behave in fundamentally different ways. The NHS is still – correctly – referred to as a "quasi-market"³⁶ which serves to justify the existence of separate regimes such as the 2013 Regulations. The PH sector resembles a standard market, yet the supplementary nature of private medical insurance represents an anomaly as a healthcare market (at least among European healthcare systems) insofar as it does not engage with questions of universal coverage.

What is curious about the use of the word "healthcare" in the HSCA 2012 is that it offers scope for interpretation which acknowledges the coexistence of the NHS and PH sectors, but ultimately fails to address the distinctions between these. As the underlying intention of the HSCA 2012 appears to have been NHS reform, it appears curious that "healthcare" – as opposed to "NHS" – should be used at all.

³⁶ See Sánchez Graells (2016) supran9.

While the reluctance to review the HSCA 2012 or propose new legislation pertains, it is recommended that clarification of the distinction between, and coexistence of, the NHS and PH sectors be implemented by other means – for example, by further comment by the CMA and NHS Improvement as suggested above.

6.4. Future directions of research arising from the thesis

The research questions of this thesis have examined – broadly – the applicability and application of competition law to Dutch and English healthcare, the relationship between the competition authority and healthcare regulator in both countries and modifications to general law. However, there are related aspects which have not been included, for reasons of space and the thesis' specific focus on sections 72 and 79 HSCA 2012. In addition, there are aspects mentioned in the thesis which merit closer consideration. Four future directions can be identified and are now considered.

The state aid rules and the Services of General Economic Interest (SGEI) exception.

Due to the explicit focus on sections 72 and 79 HSCA 2012, this thesis examined competition law in a relatively narrow sense – as comprising merger control and the provisions governing anticompetitive agreements and abuse of dominance. However, how the state aid rules and SGEI exception may operate with regard to the English NHS has been identified as an area in need of further research. Furthermore, the latter is a recurrent theme as evidenced by two recent Private Members' Bills. The NHS Reinstatement Bill purported to classify the NHS as a Service of General Interest, but failed to progress beyond a second reading. The National Health Service (Amended Duties and Powers) Bill referenced the SGEI exception. While this progressed to Committee stage, it was discontinued following protracted discussions which demonstrated the difficulty of trying to apply concepts such as solidarity and the *Altmark* exception to the English NHS. There is therefore a need for practitioners and academics to engage more openly with this area of law in a manner similar to

discussions focused on the HSCA 2012 reforms (which did not engage with this). Further research may explore, for example, the limits of the SGEI exception with regard to the NHS, since, by its nature as an exception, this appears limited.

Patient choice and the three categories of English healthcare

In the assertion that there is no single, unified healthcare sector in England, this thesis has started to engage with the complexities of the relationship between the English NHS and the private healthcare sector which have been in evidence since 1948. These range from the contentious issues of "NHS pay-beds" via Department of Health rules on "co-funding" to acknowledgement of increasing linkages between the two by the CMA in its 2014 Private Healthcare Market Investigation. Chapter 4 outlined how it has become possible to speak of three categories of "English patient" – NHS, private medical insurance and self-pay – as well as the dual identity of patients and taxpayers vis-à-vis the NHS. Subsequent research could develop these themes further by exploring the extent to which these three categories of patient may combine and the implications this may have, inter alia, for competition reforms of the NHS which typically seek to exploit the competitive tension between the NHS and private healthcare sectors.

The interaction between general competition law (specifically s.72 HSCA 2012) and the 2013 Regulations

Reference was made in Chapters 3 and 4 to the 2013 Regulations as a regulatory regime in relation to general competition law. Further research is needed into the 2013 Regulations as a self-contained competition regime and the extent to which these relate to general competition law (as similar analysis regarding the relationship with the public procurement rules has already been conducted).

The transition from government to regulator oversight of the NHS

Chapter 4's examination of the interaction between the competition authority and regulator in applying competition law included a consideration of the evolving role of the Minister regarding healthcare provision. This benefits from further examination – particularly the English experience of establishing NHS England and NHS Improvement. Although this changing landscape raises questions regarding the future direction of competition policy, other aspects come into play, such as the public law implications of accountability.

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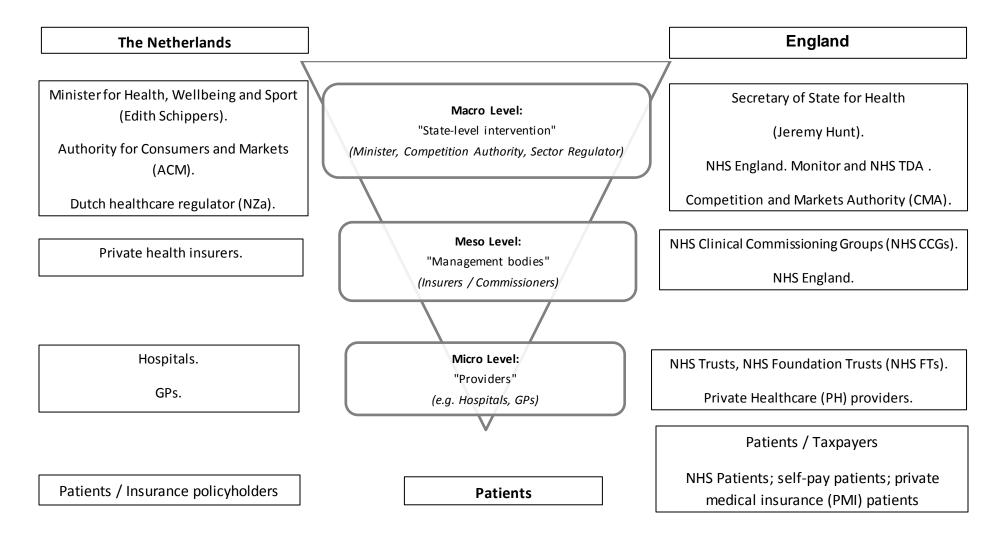
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Appendices

Contents
Appendicesi
Appendix A - Discussion Framework (1): The "healthcare structure" – Actorsiii
Appendix B – Thesis Discussion Framework (1):iv
The "healthcare structure" – chapter overviewiv
Appendix C - The Netherlands – perspective in overviewv
I. The Dutch "healthcare triangle"v
II. Overview of themes and provisions in connection with Dutch healthcare:
Appendix D - England – perspective in overviewvii
I. The four categories of English healthcarevii
II. Overview of themes and provisions in connection with English healthcareviii
Appendix E - Thesis Timelineix
Appendix F – Glossary - Dutch Healthcare Sectorxi
Appendix G – Glossary - English Healthcare Sector xvii
Appendix H - Thesis Acronyms and Abbreviationsxxvii
Appendix I - A note on terminology and translationsxxix
Appendix J – Chapter 5 - Overview of relationship between "healthcare-specific" merger control and general merger control in the Netherlands, 2006 - 2015xxxii
Appendix K – Chapter 5 - Overview of relationship between "healthcare-specific" merger control and general merger control in Englandxxxiii
Appendix L - Table of Casesxxxiv
Appendix M - Table of Legislationxxxix
Appendix N – Official Documents xlvi
Appendix O – May 2015 Blog Postliii
Competition Policy Blog
https://competitionpolicy.wordpress.com/2015/05/05/what-could-repeal-of-the- health-and-social-care-act-2012-mean-for-the-application-of-competition-law-and-the- english-nhs/
What could repeal of the Health and Social Care Act 2012 mean for the application of competition law and the English NHS?

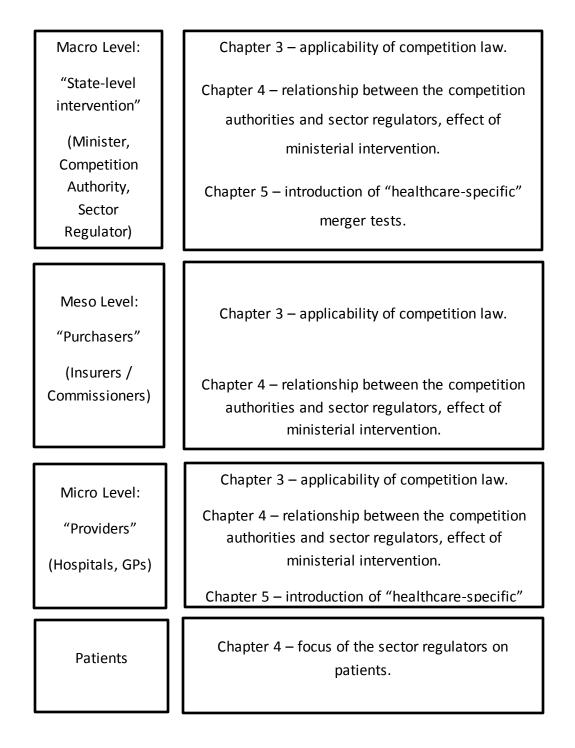
Appendix P – February 2013 blog post	lx
Monitor's Advice to the OFT and the New Healthcare Regulation	lx
Appendix Q – October 2013 Blog Post	lxiii
The Meaning of 'Relevant Customer Benefits' in the Context of Health Ca	are: Monitor's
Advice and the Competition Commission's Response	lxiii
Appendix R – Medical Law Review Article	lxvi

Appendix A - Discussion Framework (1): The "healthcare structure" – Actors



Appendix B – Thesis Discussion Framework (1):

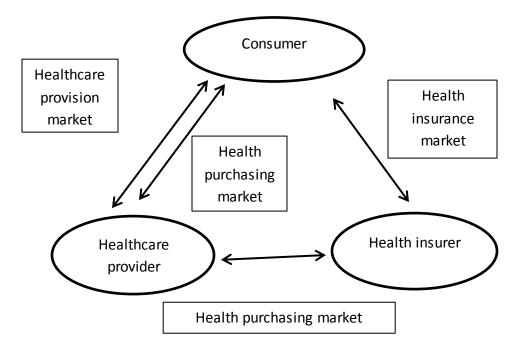
The "healthcare structure" – chapter overview



Appendix C - The Netherlands – perspective in overview

I. The Dutch "healthcare triangle"

The interaction between patients, healthcare providers and health insurers which give effect to the introduction of mandatory private health insurance has been described as a "healthcare triangle"¹ and is illustrated as follows:



The operation of the "triangle" is discussed in Chapter 2, but has relevance to the substantive discussions of Chapters 3, 4 and 5, as the three parties – patients, providers and insurers are discussed throughout.

¹ See, inter alia, Wolf Sauter, 'Is the general consumer interest a source of legitimacy for healthcare regulation? An analysis of the Dutch experience' (2009) European Journal of Consumer Law 2-3/2009.

II. Overview of themes and provisions in connection with Dutch healthcare:

Chapter	Themes and provisions considered
Chapter 3 – Competition Law	 Applicability of the Dutch Competition Act (Mw) and Articles 101 and 102 TFEU; Effect of AOK Bundesverband judgment and enactment of Article 122 Dutch Health Insurance Act 2006 (Zvw).
Chapter 4 – Relationship between the healthcare regulator and competition authority	 NZa's competition powers relating to Significant Market Power (SMP) and contract terms – Articles 45 and 48 Dutch Healthcare (Market Regulation) Act 2006 (Wmg). Concept of "overlap" (samenloop) between the NZa's SMP competence and the ACM's abuse of dominance competence - Art. 18 Wmg. Elaboration of this by the "Cooperation Protocols" signed by the ACM and NZa in 2006, 2010 and 2015. Proposed transfer of NZa competition powers to the ACM 2015-2016.
Chapter 5 – Merger control	 Application of Dutch general merger control (Mw) . Modifications to this: NZa's opinions, lower turnover thresholds, additional "healthcare-specific" assessment criteria. Introduction of a "healthcare-specific" merger test in 2014. Transfer of the NZa's merger powers to the ACM, 2015-2016.

Appendix D - England – perspective in overview

I. The four categories of English healthcare

	N	HS	Private Heal	thcare (PH)
The Four Categories of English Healthcare	Category 1 Public Funding + Public Provision	Category 2 Public Funding + Private Provision	Category 3 Private Funding + Public Provision	Category 4 Private Funding + Private Provision
Examples discussed in this thesis	NHS Trusts NHS Foundation Trusts (NHS FTs).	NHS Concordat arrangements, Independent Sector Treatment Centres (ISTCs).	NHS Private Patient Units (NHS PPUs)	Private ophthalmologists
Oversight bodies	Monitor, NHS TDA, NHS England, Competition and Markets Authority (CMA)	Monitor, NHS England Competition and Markets Authority (CMA)	Competition and Markets Authority (CMA)	

II. Overview of themes and provisions in connection with English healthcare

Chapter	Themes and Provisions considered
Chapter 3 – Competition Law	 Applicability of the Competition Act 1998 (CA98) and Articles 101 and 102 TFEU; Effect of <i>FENIN</i> judgment and enactment of s.72 Health and Social Care Act 2012 (HSCA 2012).
Chapter 4 – Relationship between the healthcare regulator and competition authority	 Monitor's competition powers – Competition Oversight condition of the NHS Provider Licence, Regulation 10 (prohibition on anticompetitive behaviour) of the National Health Service (Procurement, Patient Choice and Competition) Regulations (No.2) 2013, concurrent powers to apply general competition law of s.72 HSCA 2012.
	 Development of the concept of "concurrent powers" under s.72 HSCA 2012 in the English healthcare context by the wider concurrency reforms of the Enterprise and Regulatory Reform Act 2013 (ERRA 13) and specifically the Competition Act 1998 (Concurrency) Regulations 2014.
Chapter 5 – Merger control	 Application of UK general merger control of the Enterprise Act 2002 (EA02) as extended to NHS Foundation Trusts (NHS FTs) by s.79 HSCA 2012. Development of separate scrutiny for NHS Trusts (the NHS FT and Transactions pipelines) and Private Patient Units (PPUs). Incorporation of a role for Monitor to identify "relevant customer benefits" under s.79(5) HSCA 2012.

Appendix E - Thesis Timeline

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2014	14 Introduction of the "healthcare-specific" merger test in the	
	Netherlands	
2015	2015 Transfer of NZa competition powers to the ACM.	
2016	April: Establishment of NHS Improvement (Monitor and NHS TDA).	

Appendix F – Glossary - Dutch Healthcare Sector

"A" Segment (also known as the "regulated segment")¹

Refers to hospital service prices which are still subject to the tariff set by the Dutch Healthcare Authority (NZa).

AEF Report

Refers to the independent review of the Dutch Healthcare Authority (NZa) published by the Andersson Elffers Felix consultancy in September 2014 - 'Oversight and regulation in healthcare: Assessment of the Dutch Healthcare (Market Regulation) Act 2006 (Wmg) and the Dutch Healthcare Authority (NZa)') – see Bibliography.

Article 13 Dutch Health Insurance Act 2006 (Zvw)

Article 13 Zvw mitigates the restriction on patient choice of health insurer in benefits-in-kind policies by providing that the patient is entitled to level of compensation (determined by the insurer) even if they choose a provider which has no contract with the insurer.

Article 122 Dutch Health Insurance Act 2006 (Zvw)

Article 122 Zvw provides that Dutch health insurers are "undertakings" for the purposes of the Dutch Competition Act (Mw), even if they are not "undertakings" for the purposes of EU competition law.

Authority for Consumers and Markets (ACM)

Agency established in 2013 which comprises the former Dutch telecommunications regulator (OPTA), Dutch Competition Authority (NMa) and Consumer Authority. Discussed in the context of its competition authority functions in this thesis.

Autonomous Administrative Agency (zelfsbestuurorgaan (ZBO))

¹ See NZa, 'Stand van de zorgmarkten 2015', (NZa Annual Report 2015), page 48.

Regulatory model for various Dutch economic regulators, including the Dutch Authority for Consumers and Markets (ACM) and the Dutch Healthcare Authority (NZa).

"B" Segment (also known as the "liberalised segment")

Refers to hospital service prices which are no longer subject to the tariff set by the Dutch Healthcare Authority (NZa), as distinct from the "A" Segment. Approximately 70% of hospital service prices have been "liberalised".²

Basic package of health insurance (basispakket)

Refers to the mandatory private health insurance which adults living and working in the Netherlands must take out (subject to limited exceptions). The range of services included in the basic package may vary, but typically includes GP care, hospitalisation, specialist mental health care, and physiotherapy for people with chronic illnesses.³ The basic package is to be distinguished from supplementary insurance.

Benefits-in-kind policy (naturapolis)

One of generally three policy types offered by Dutch health insurers. Benefitsin-kind policies restrict a patient's choice of providers to those with whom the insurer has contracts, so are less expensive than a reimbursement policy. This limitation of benefits-in-kind policies is mitigated to a certain extent by Article 122 Dutch Health Insurance Act 2006.

Boer & Croon Report

Refers to an early assessment of the NZa by the consultancy Boer & Croon in 2009 – see Bibliography.

Borstlap Report

² Ibid.

³ See Ministry of Public Health, Wellbeing and Sport (VWS), 'Healthcare in the Netherlands', January 2016, pages 7-8. <<u>file:///C:/Users/Home/Downloads/healthcare-in-the-netherlands.pdf</u>>.

An independent report into the NZa's operation prompted by the suicide of Arthur Gotleib, an NZa employee in 2014. The investigation conducted by the Borstlap Committee is wide-ranging, but the aspects relevant to this thesis focus on the relationship between the NZa and the Minister for Health, Wellbeing and Sport.

Combination policy (combinatiepolis)

Combines aspects of both a benefits-in-kind policy and a reimbursement policy which vary according to type of healthcare.

District Court of Rotterdam (Rechtbank (Rb) Rotterdam)

Appeal Court of first instance for ACM decisions. The appeal judgments of the District Court of Rotterdam may be appealed to the Dutch Trade and Industry Appeals Tribunal.

Dutch Competition Authority (Nederlandse Mededingingsautoriteit (NMa))

Agency established by the Dutch Competition Act (Mw) and in existence between 1998 and 2013, before being subsumed into the Authority for Consumers and Markets (ACM).

Dutch Healthcare Authority (Nederlandse Zorgautoriteit (NZa))

Agency established by the Dutch Healthcare (Market Regulation) Act 2006 (Wmg), inter alia to develop and have oversight over markets. Economic regulator for healthcare.

Dutch Healthcare Inspectorate (Inspectie voor Gezondheidszorg (IGZ))

Dutch quality regulator which can work with the Authority for Consumers and Markets (ACM) and thee Dutch Healthcare Authority (NZa) by, for example, providing advice on quality issues in competition assessments.

Dutch Trade and Industry Appeals Tribunal (College voor Beroep (CBb))

Higher appeal court for decisions by the ACM where appeals have been determined at first instance by the Rotterdam District Court.

General Consumer Interest (consumentenbelang)

The Dutch Healthcare Authority (NZa) has a duty to consider the general consumer interest in its activities under Article 3(4) Dutch Healthcare (Market Regulation) Act 2006 (Wmg). Although not defined in statute, the NZa has defined the "general consumer interest" in terms of healthcare values of accessibility, affordability and quality. See further the discussions in Chapter 4.

Healthcare provider partnerships (Maatschappen)

Regional specialist partnerships comprise a group of consultants with a particular specialism.

"Healthcare-specific" merger test (zorgspecifieke fusietoets)

Introduced in January 2014, the "healthcare-specific" merger test comprised an initial procedural assessment of a proposed merger by the NZa prior to substantive assessment under general merger control by the ACM. The test comprised two elements: a requirement for the merging parties to submit a "merger effects" report demonstrating consideration of specific aspects, such as the financial consequences of the merger and consultation of relevant stakeholders. The second aspect allows the NZa to block a merger proposal if it is likely to endanger critical care. This test has been transferred to the ACM, and partially reformulated to include a requirement on merging parties to explain why merger, as distinct from other forms of collaboration, has been selected.

Insurers' duty of care (zorgplicht)

Article 11 Dutch Health Insurance Act 2006 (Zvw) places a duty of care on health insurers to ensure delivery and compensation of care as defined by Article 10 Zvw (including general medical care, dental care and pharmaceutical care). The NZa has interpreted the duty of care as meaning not only the content and extent of care, but also the quality, timely availability and accessibility of insured care.⁴

Insurers' preference policy (preferentiebeleid)

The preference policy means that an insurer indicates that only one or certain products within a specific group of medicines will be covered by its basic health insurance.⁵

Logit Competition Index method (LOCI)

Econometric method used by the NZa to assess affordability of healthcare as part of its duty to consider the general consumer interest. The LOCI method models hospital care by determining competition between healthcare providers by the overlap between products offered by different healthcare providers in different segments. The competition position of each hospital is assessed according to an index between 0 (representing a monopoly) and 1 (perfect competition).⁶

Option Demand Method (ODM)

Econometric method used by the NZa to assess affordability of healthcare as part of its duty to consider the general consumer interest. The ODM translates patient preferences into willingness to pay (WTP), which is seen as a yardstick for negotiating power with regard to prices which hospitals can charge insurers.⁷

Overlap (samenloop)

⁴ NZa, Beleidsregel TH/BR-018 Toezichtkader zorgplicht zorgverzekeraars Zvw (Policy Rule TH/BR-018 Regulatory Framework for the Health Insurers' Duty of Care under the Zvw') December 2014. Page 5.

⁵ Juridisch-Economisch Lexicon – The Legal and Economic Lexicon. Online edition. Wolters Kluwer.

⁶ For further information, see the NZa's Opinion in the Tilburg Hospitals case. NZa, Zienswijze vergunningsaanvraag Stichting Tweesteden ziekenhuis en Stichting St. Elisabeth ziekenhuis, Juli 2012.

⁷ Ibid.

Defined by Art. 18(3) Wmg as the "overlap" between the NZa's SMP competence and the ACM's abuse of dominance powers – discussed in Chapter 4. See also Note on Terminology and Translation (Appendix I).

Reimbursement policy (restitutiepolis)

Health insurance policy which allows patients a greater choice of provider than a benefits-in-kind policy, and is more expensive.

Appendix G – Glossary - English Healthcare Sector

"Any Qualified Provider" / "Any Willing Provider" policy

The "Any Willing Provider" policy was introduced for elective services in 2008 to give effect to patient choice policies whereby NHS patients would have a choice of private or NHS providers. This initiative was subsequently rebranded "Any Qualified Provider" to highlight the requirement that certain service standards must be met and the providers open to regulation by the Care Quality Commission.¹

Clinical Commissioning Groups (CCGs)

Section 11 HSCA 2012 inserts section 1I National Health Service Act 2006 to establish bodies corporate known as Clinical Commissioning Groups (CCGs). CCGs are clinically-led bodies responsible for the planning and commissioning (purchasing) of healthcare services for their local area. There are now 209 CCGs in England.² CCGs replaced *Primary Care Trusts* (PCTs) on 1 April 2013 and so are successors to the *GP Fundholding Initiative* (GPFI).

Competition Oversight condition

One of two Choice and Competition Conditions of the *NHS Provider Licence* which allow Monitor to protect and promote patients' interests by supporting patient choice of provider and, where it is in the interests of patients, preventing anti-competitive behaviour.³ The two conditions apply to all licence holders. The Competition Oversight condition provides that:

"The Licensee shall not:

(a) enter into or maintain any agreement or other arrangement which has the object or which has (or would be likely to have) the effect of preventing,

 $^{^{1}}$ Office of Health Economics (OHE), 'Competition in the NHS', January 2012. Page 17.

² NHS Clinical Commissioners, "About CCGs". <<u>http://www.nhscc.org/ccgs/</u>>.

³ Monitor, The New NHS Provider Licence, 14 February 2013, page 3. <<u>https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/285008/T</u> <u>oPublishLicenceDoc14February.pdf</u>>.

restricting or distorting competition in the provision of health care services for the purposes of the NHS, or

(b) engage in any other conduct which has (or would be likely to have) the effect of preventing, restricting or distorting competition in the provision of health care services for the purposes of the NHS, to the extent that it is against the interests of people who use health care services."⁴

Concordat

Refers to the Concordat signed between the NHS and the Independent Health Authority (IHA) in 2000. Unveiled as part of the NHS Plan, the Concordat was intended to offer a framework for private, voluntary sector and NHS providers to work together and encourage cooperative working initially with regard to elective care, critical care and intermediate care.⁵ For the purposes of this thesis, Concordat arrangements offer examples of activity in category 2.

General Practitioner (GP) Fundholding Initiative (GPFI)

Introduced by the NHS and Community Care Act 1990, the GPFI comprised a voluntary scheme for GP practices to apply to become budget-holders, and purchase elective care for patients from NHS Trusts. Operated in parallel to, but was distinct from, the NHS Internal Market. Superseded by *Primary Care Trusts* (PCTs) and latterly *Clinical Commissioning Groups* (CCGs).

Independent Sector Treatment Centre (ISTC)

ISTCs are private sector-owned clinics contracted to treat NHS patients and set up in 2003 following the establishment of treatment centres in the context of the *NHS Plan* under New Labour. For the purposes of this thesis, ISTCs provide an example of category 2 activity.

⁴ Monitor, Annexe – NHS Provider Licence Standard Conditions, page 22. <u>https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/285009/Annex_NHS_provider_licence_conditions_20120207.pdf</u>.

⁵ NHS, The NHS Plan – A Plan for Investment, A Plan for Reform, July 2000. Para 11.7
<<u>http://1nj5ms2lli5hdggbe3mm7ms5.wpengine.netdna-cdn.com/files/2010/03/pnsuk1.pdf</u>>.

Monitor

Comprises the independent regulator of *NHS Foundation Trusts* (NHS FTs), established in 2004 by the Health and Social Care (Community Health and Standards) Act 2003, which continues to exist under section 61 HSCA 2012 and assumes further duties under section 62 HSCA 2012 in its capacity as the sector regulator for healthcare in England.

As of 1 April 2016, Monitor has become one of the constituent elements of *NHS Improvement* along with the *NHS Trust Development Authority* (NHS TDA).

National Health Service (Procurement, Patient Choice and Competition) Regulations (No.2) 2013 (SI 2013 No.500)

Regulations enacted under section 75 HSCA 2012 (hence also known as the "section 75 Regulations") which repeal and replace an original set of Regulations (SI 2013 No.257) following controversy surrounding Regulations 5 and 10 in respect of procurement activity and anticompetitive behaviour. The 2013 Regulations are addressed to "relevant bodies" – mainly CCGs and NHS England. They comprise one of Monitor's three "competition powers" – the others being the Competition Oversight condition of the NHS Provider Licence and concurrent powers shared with the CMA under section 72 HSCA 2012.

New care models

These are set out and developed within the context of the *NHS Five Year Forward View*. They emphasize integrated models of care and include Multispeciality Community Providers (MCPs), Primary and Acute Care Systems (PACS), urgent and emergency care networks and viable smaller hospitals.

NHS "amenity bed"

A facility available to <u>NHS patients</u> who wish to pay for the privacy of a single en-suite room. In existence since the inception of the NHS in 1948 and still advertised by NHS hospitals and private hospitals. Not to be confused with *NHS pay-beds*, and latterly *Private Patient Units (PPUs)*.

NHS Commissioning Board (NHS CB)

An autonomous agency established by section 9 HSCA 2012 which inserts section 1H to the National Health Service Act 2006 and subsequently renamed NHS England. See *NHS England*.

NHS Co-operation and Competition Panel (NHS CCP)

A non-statutory body within the Department of Health which existed between 2009 and 2013. It examined behaviour of NHS bodies in light of the Principles and Rules of Cooperation and Competition (NHS PRCC) and assessed mergers involving NHS Trusts between 2009 and 2013 and made recommendations to the Secretary of State for Health. The NHS CCP was incorporated into Monitor as the Co-operation and Competition Directorate following the HSCA 2012 reforms.

NHS Constitution

Sections 1 and 2 Health Act 2009 make provision for regard to be had to the NHS Constitution, a document which sets out (non-actionable) rights for patients, public and staff.⁶ All NHS bodies and private and third sector providers supplying NHS services are required to take account of the Constitution in their decisions and actions. The NHS Constitution helps give effect to New Labour choice policies by "enshrining" a right to choose GP and other providers in defined circumstances. These rights are given further effect by the rules on patient choice found in the *National Health Service (Procurement, Patient Choice and Competition) Regulations (No.2) 2013*.

NHS England

NHS England (originally known as the *NHS Commissioning Board*) leads the NHS in England by setting the priorities and direction for the NHS. (<u>https://www.england.nhs.uk/about/</u>).

NHS England has functions in respect of specialist commissioning and supporting *clinical commissioning groups* (CCGs) as well as devising and implementing the *NHS Five Year Forward View* (NHS FYFV).

⁶ <u>https://www.gov.uk/government/publications/the-nhs-constitution-for-england.</u>

Simon Stevens is CEO of NHS England and is accountable to Parliament for over £100 billion of annual Health Service funding. (https://www.england.nhs.uk/about/whos-who/).

NHS England is governed by a range of frameworks, including the NHS Mandate and the NHS Constitution. (<u>https://www.england.nhs.uk/about/gov/</u>).

NHS Five Year Forward View (NHS FYFV)

The NHS Five Year Forward View was published on 23 October 2014 and sets out "a new shared vision for the future of the NHS based around the new models of care".

It was developed by the partner organisations that deliver and oversee health and care services including the Care Quality Commission (CQC), Public Health England and NHS Improvement.

(https://www.england.nhs.uk/ourwork/futurenhs/)

NHS Foundation Trusts (NHS FTs)

Public benefit corporations authorised to provide goods and services for the purposes of the health service in England and established by Part I, Health and Social Care (Community Health and Standards) Act 2003.⁷ NHS FTs have been subject to the oversight of an independent regulator, Monitor, since 2004.

In contrast to NHS Trusts, NHS FTs are able to retain and re-invest a surplus.

NHS Trusts have been able to apply to Monitor for NHS FT status authorisation with the support of the Secretary of State for Health under successive government policy since 2004. This process has subsequently been termed the "NHS FT pipeline" and is discussed in Chapter 5.

NB - Like NHS Trusts, NHS FTs are not trusts in the legal sense.⁸

⁷ Repealed by National Health Service (Consequential Provisions) Act 2006 c. 43 <u>Sch.4</u> para.1 (March 1, 2007).

⁸ ACL Davies, 'Foundation hospitals: a new approach to accountability and autonomy in the public services?', Public Law 2004.

NHS Future Forum

An independent group set up in order to "pause, listen and reflect" on the content of the Health and Social Care Bill and launched on 6 April 2011.⁹ The Forum made a series of recommendations on the future for NHS modernisation, including a specific "Choice and Competition" report published in June 2011.

NHS Improvement

Since 1 April 2016 NHS Improvement is the operational name of the nonstatutory body which oversees *NHS Trusts, NHS Foundation Trusts (NHS FTs)* and private providers who deliver services for the NHS.

NHS Improvement comprises, inter alia, Monitor and the NHS Trust Development Authority (NHS TDA). (<u>https://improvement.nhs.uk/about-us/who-we-are/</u>).

NHS Improvement leadership includes Jim Mackey (CEO) and Ed Smith (Chairman of the Board) (<u>https://improvement.nhs.uk/about-us/leadership/</u>).

NHS Internal Market

Elaborated by the Conservative government White Paper, Working for Patients, and established by the National Health Service And Community Care Act 1990 and inspired by the "managed competition" model of Alain Enthoven. Introduced the "purchaser/provider" split by separating the purchasing functions of District Health Authorities (DHAs) and creating the new secondary care provider category of NHS Trusts, a status which hospitals and other providers were allowed to apply for.

Relationships between DHAs and NHS Trusts were governed by "NHS contracts", which clarified the services provided by NHS Trusts and what the DHAs would pay.

⁹ <<u>https://www.gov.uk/government/publications/nhs-future-forum-recommendations-to-government-on-nhs-modernisation</u>>.

The NHS Internal Market was overseen by the Department of Health and Secretary of State for Health (via the NHS Executive), and nominally subject to a separate, "NHS-specific", competition regime comprising rules regarding collusion and mergers - See NHS Executive, "The Operation of the NHS Internal Market: Local Freedoms, National Responsibilities".

Although New Labour distanced itself from the concept of the "NHS Internal Market", it retained the quasi-market model and the core element of the "purchaser/provider split".

NHS Mandate

A document published annually since 2014 which sets out the Government's direction and ambitions for the NHS.

(https://www.gov.uk/government/publications/nhs-mandate-2015-to-2016).

NHS "pay-bed"

A facility within NHS hospitals available to <u>private</u> patients. Now largely superseded by *Private Patient Units (PPUs)*. Cf "NHS amenity beds".

NHS Principles and Rules of Competition and Cooperation (NHS PRCC)

A non-statutory set of rules governing behaviour by NHS providers and purchasers between 2007 and approximately 2013 following the HSCA 2012 reforms. The NHS PRCC included provisions which related to anticompetitive agreements (Principle 5?), abuse of dominance/unilateral conduct (Principle 6) and merger control (Principle 10). In response to the NHS Future Forum report during the passage off the HSCA 2012, the coalition government undertook to put the NHS PRCC on a statutory footing to demonstrate that it did not intend to extend the application of competition law. The NHS PRCC thus formed the basis for the National Health Service (Procurement, Patient Choice and Competition) Regulations (No.2) 2013 (SI 2013 No.500).

NHS Provider Licence

The "main tool"¹⁰ for Monitor to regulate providers (NHS FTs as well as private and voluntary sector providers) of NHS services in the regulatory framework established by the HSCA 2012 reforms. The NHS Provider Licence comprises a range of general licence conditions applicable to all licence holders, requiring that directors be "fit and proper" as well as governing obligations in connection with pricing, choice and competition and supporting continuity of service. For the purposes of this thesis, the focus is on the *Competition Oversight condition*.

As at 30 June 2016, 155 NHS FTs¹¹ and 108 "other providers"¹² (i.e. private or voluntary sector providers) hold an NHS Provider Licence.

NHS Tariff (also known as the "National Tariff")

Section 116 HSCA 2012 provides that Monitor is to publish a document known as the "national tariff" which specifies, inter alia, which healthcare services are or may be provided for the purposes of the NHS, the method used for determining the national prices of those services and the national price of each service. The NHS Tariff is relevant to this thesis as it enables competition in connection with *Payment by Results (PbR)* and represents one of the lesserknown HSCA 2012 reforms as Monitor, NHS England and the CMA may be involved in setting the tariff, a function previously performed by the Department of Health. This aspect is considered in Chapter 4.

NHS Trusts

Established by sections 5-11 of the NHS and Community Care Act 1990.

NB – NHS Trusts are not trusts in the legal sense.¹³

¹⁰ Monitor, The New NHS Provider Licence, 14 February 2013, page 1.
<<u>https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/285008/T</u>
<u>oPublishLicenceDoc14February.pdf</u>>.

¹¹ Based on a total of 158, with 2 licences ceasing to exist following acquisition of providers and 1 being withdrawn at the request of the licence holder pursuant to s.89(a) HSCA 2012. Data updated at 1 May 2016. <u>https://www.gov.uk/government/publications/nhs-foundation-trust-directory</u>.

¹² Based on a total of 112, with 8 licences being withdrawn at the request of the licence holder pursuant to s.89(a) HSCA 2012. Data updated at 1 April 2016. https://www.gov.uk/government/publications/nhs-foundation-trust-directory.

¹³ Davies (2004), supra n8.

NHS Trust Development Authority (NHS TDA)

Established as part of the HSCA 2012 to provide support, oversight and governance to NHS Trusts. Since 1 April 2016 a constituent element of *NHS Improvement* along with *Monitor*.

Payment by Results (PbR)

Activity-based funding of NHS hospital services in England introduced progressively from 2003/4. Under PbR, hospitals are paid a fixed national price per patient treated (inpatient spell, outpatient attendance, A&E attendance), for both emergency and elective cases.¹⁴

Primary Care Trusts (PCTs)

Administrative bodies created by the NHS Plan 2000 with responsibility for commissioning primary, community and secondary healthcare services as successors to the GP Fundholding Initiative abolished by New Labour in 1997. PCTs were abolished by the HSCA 2012, and their work is now performed by Clinical Commissioning Groups (CCGs).

Private Healthcare (PH) sector/market

Described by the Competition and Markets Authority (CMA) as comprising private medical insurance (PMI) providers and private healthcare providers (PPUs whether operated by NHS FTs or PH companies, as well as private hospitals, clinics etc.). Refers to categories 3 and 4 of the "four categories of English healthcare" in this thesis.

Private Medical Insurance (PMI)

Refers to supplementary private health insurance available in the UK, and forms part of the private healthcare (PH) market.

¹⁴ For further information, see OHE (2012), supra n1, page 17. Also Louise Marshall, Anita Charlesworth, Jeremy Hurst, 'The NHS payment system: evolving policy and emerging evidence' Nuffield Trust Research Report February 2014.

<<u>http://www.nuffieldtrust.org.uk/sites/files/nuffield/publication/140220_nhs_payment_rese</u> arch_report.pdf>

Private Patient Income cap

Section 15 Health and Social Care (Community Health and Standards) Act 2003 introduced an authorisation to restrict the total income of NHS Foundation Trusts from charges imposed in respect of goods and services provided to patients other than patients being provided with goods and services for the purposes of the NHS. This restriction, known as the Private Patient Income (PPI) cap, was subject to modifications by subsequent acts (such as section 44 Health Act 2009 regarding the income made by mental health trusts) and was repealed by section 165 HSCA 2012.

Private Patient Unit (PPU)

Defined by the CMA as

"...a facility within a national health service [site] providing inpatient, day-case patient or outpatient privately-funded healthcare services to private patients; such units may be separate units dedicated to private patients or be facilities within a main national health service site which are made available to private patients either on a dedicated or non-dedicated basis".¹⁵

PPUs are to be distinguished from services provided to NHS patients in return for payment, such as *NHS amenity beds*.

PPUs are considered part of the PH sector, and for the purposes of this thesis serve to underscore the distinction between NHS FTs operating in the PH sector (category 3), and private providers delivering NHS services (category 2). This has implications for the applicability of general competition law and merger control and associated oversight, thus are considered in Chapters 3, 4 and 5.

¹⁵ CMA, Private Healthcare Market Investigation, Final Order, 1 October 2014. Page 3.

Appendix H - Thesis Acronyms and Abbreviations

Acronym /	Explanation
Abbreviation	
ACM	Dutch Authority for Consumers and Markets (Autoriteit
	<i>consument en markten</i>) – incorporated the former Dutch
	Competition Authority (Nederlandse
	Mededingingsautoriteit (NMa)), the Dutch telecoms
	regulator (Onafhankelijke Post en Telecommunicatie
	Autoriteit (OPTA)) and the Dutch Consumer Authority
	(Consumentenautoriteit)).
AQP	Any Qualified Provider
CA 98	Competition Act 1998
СС	Competition Commission (incorporated into the CMA as of
	1 st April 2014)
CCG	Clinical Commissioning Group
СМА	Competition and Markets Authority – replaced the OFT and
	CC in April 2014
CQC	Care Quality Commission
CVZ	Dutch Health Insurance Board (College voor
	Zorgverzekeringen) – incorporated into the Dutch National
	Healthcare Institute (Zorginstituut Nederland) since 1 April
	2014.
DHA	District Health Authority (NHS purchaser at the time of the
	NHS Internal Market)
EA 02	Enterprise Act 2002
ERRA 2013	Enterprise and Regulatory Reform Act 2013
EXPH	European Commission Expert Panel on Effective Ways of
	Investing in Health
HSCA 2012	Health and Social Care Act 2012
IGZ	Dutch healthcare quality regulator (Inspectie voor de
	Gezondheidszorg)
IHA	Independent Health Authority
ISTC	Independent Sector Treatment Centre
LHV	Dutch GPs' Association (Landelijke Huisartsenvereniging)
LVE	Dutch Association of Emergency Psychologists (Landelijke
	Vereniging van Eerstelijnspsychologen)
LOCI	Logit Competition Index method – econometric test used by
	the NZa. See Appendix F.
Mw	Dutch Competition Act (Mededingingswet)
NHS	National Health Service
NHS CCP	NHS Cooperation and Competition Panel
NHS FFT	NHS Friends and Family Test
NHS FT	NHS Foundation Trust
NHS FYFV	NHS Five Year Forward View
NHS PCT	NHS Primary Care Trust
NHS PRCC	NHS Principles and Rules for Cooperation and Competition

NHS TDA	NHS Trust Development Authority
NIP	Dutch Institute of Psychologists (<i>Nederlands Instituut van</i>
	Psychologen)
NMa	Former Dutch Competition Authority (<i>Nederlandse</i>
	Mededingingsautoriteit - incorporated into the ACM as of
	1 st April 2013)
NVP	Dutch Psychotherapy Association (Nederlandse Vereniging
	voor Psychotherapie)
NVVP	Dutch Association of Independent Psychotherapists
	(Nederlandse Vereniging van Vrijgevestigde
	Psychotherapeuten)
NZa	Dutch Healthcare Regulator (Nederlandse Zorgautoriteit)
ODM	Option Demand Method – econometric test used by the
	NZa. See Appendix F.
OFT	Office of Fair Trading (incorporated into the CMA as of 1 st
	April 2014)
OHE	Office of Health Economics
ΟΡΤΑ	Dutch independent post and telecommunications regulator
	(Onafhankelijke Post en Telecommunicatie Autoriteit), now
	subsumed into the ACM.
PH	Private Healthcare sector (UK)
PMI	Private Medical Insurance (UK)
PPU	Private Patient Unit (UK)
PSO	Public service obligation
RES	Risk Equalisation Scheme
SGI	Service of General Interest
SGEI	Service of General Economic Interest
SIEC	Significant Impediment to Effective Competition
SLC	Substantial Lessening of Competition
SMP	Significant Market Power
SSGI	Social Service of General Interest
SSNIP	Small but Significant and Non-transitory Increase in Price
TFEU	Treaty on the Functioning of the European Union
Whc	Dutch Consumer Protection (Enforcement) Act (Wet
	handhaving consumentenbescherming)
WIz	Dutch Long-Term Care Act (Wet langdurige zorg)
Wmg	Dutch Healthcare (Market Regulation) Act 2006 (Wet
	marktordening gezondheidszorg)
WTG	Dutch Healthcare Tariffs Act (Wet tarieven
	gezondheidszorg)
ZBO	Dutch autonomous administrative agency
	(zelfbestuursorgaan)
Zfw	Dutch Sickness Funds Act (Ziekenfondswet)
Zvw	Dutch Health Insurance Act (Zorgverzekeringswet)

Appendix I - A note on terminology and translations

1. <u>Referencing Dutch legal documents:</u>

This thesis contains a range of references to Dutch draft legislation and associated documents (such as Explanatory Memoranda, Opinions by the Dutch Council of State etc.). These have been referenced according to a Dutch referencing system¹ with necessary clarifications of the nature of the document provided in the translation.

Thus the format used is the following:

Kamerstukken II, 2004-05, 30186, 3, page X

This is explained as follows:

"Kamerstukken II" refers to the fact the documentation emanates from the Second Chamber.

"2004-05" refers to the parliamentary session.

"30186" refers to the document subject matter – for example, the development of the Dutch Healthcare (Market Regulation) Act 2006 (Wmg).

"3" refers to the document number. The documents referred to in this thesis are the following:

Number	Document
2	Legislative proposal
3	Explanatory Memorandum
4	Opinion of the Dutch Council of State

¹ Leidraad voor juridische auteurs, (Zevende druk, Kluwer 2013). (Guidance for legal authors, 7th edition).

2. <u>Use of Dutch acronyms:</u>

This thesis contains a range of references to Dutch agencies and legislation. The names/titles of these have been rendered in English, with the related Dutch acronym retained – for example, *Dutch Competition Act 1998 (Mw 1998)*, and *Dutch healthcare regulator (NZa)*. The Dutch names/titles are included in full in the Abbreviations list in Appendix H, which is arranged alphabetically by acronym, and includes the Dutch title as well – for example, *NZa – Nederlandse Zorgautoriteit – Dutch healthcare regulator*.

It is to be noted that other literature in this area may adopt a similar approach, or may create acronyms based on the English translation – for example, *Dutch Competition Act (DCA)*.² A further variation is to retain the Dutch acronym and title alongside the English translation in the main text – for example, *Dutch Competition Act (Mededingingswet, Mw*).³

It is useful for readers to be aware that both approaches exist. However, as a matter of good translation practice, it was decided in this thesis to use English translations for the purposes of comprehension and the official Dutch acronyms to facilitate further research in this area.

3. <u>"Concurrency" and "Samenloop":</u>

Chapter 4 is concerned with the relationship between the economic regulators for healthcare and the competition authorities and draws on the concepts of *"concurrent powers"* and *"samenloop"* in England (the UK) and the Netherlands, respectively.

"Samenloop" broadly refers to a situation in which <u>different</u> rules may be used to address the same conduct.⁴ In this thesis, the focus is on the specific instance

² See, for example, Edith M.H. Loozen, 'Public healthcare interests require strict competition enforcement'. Journal of Health Policy (2015) Volume 119, Issue 7, pages 882-888.
 ³ See, for example, Johan van de Gronden and Erika Szyszczak, 'Introducing Competition Principles into Health Care Through EU Law and Policy: A Case Study of the Netherlands' [2014] 22(2) Medical Law Review 238-254.

⁴ The concept of "samenloop" has been elaborated in the context of Dutch criminal and administrative law. For a discussion of this in the context of the ACM and NZa, see Edith M.H. Loozen, 'NMa en NZa: houd je bij je leest! Een analyse van de mededingings bevoegdheden of the Dutch healthcare regulator's *ex ante* powers and the Dutch Authority for Consumers and Markets' *ex post* powers as defined in the Dutch Healthcare (Market Regulation) Act 2006 (Wmg).

In many circumstances, it would be perfectly acceptable and accurate to translate "*samenloop*" as "*concurrent*", particularly in view of the general dictionary definition:

"Existing, happening or done at the same time" [...]⁵

However, when discussing aspects of UK economic regulation, "concurrency" takes on the meaning of the competition authority and the economic regulator applying the <u>same</u> rules (applying general competition law). This situation is arguably better described as the agencies being "co-competent".⁶ As the English nomenclature proves problematic in this comparative analysis, "samenloop" has therefore been translated as "overlap".

4. <u>"Inpatient", "Outpatient" and "klinisch", "niet-klinisch":</u>

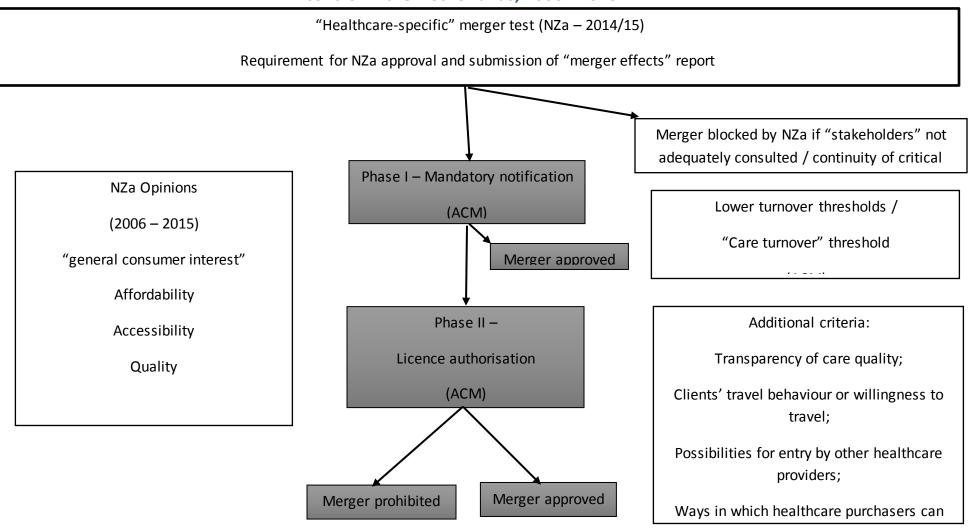
The Dutch terms "klinisch" and "niet-klinisch", when related to hospital treatment, relate to where a patient is treated. They have therefore been translated as "inpatient" and "outpatient" since a literal rendering, "clinical" and "non-clinical", arguably raises comparisons with types of treatment which relate more to the distinction in UK healthcare between health and social care.

van beide toezichthouders aan de hand van het Samenwerkingsprotocol NMa-NZa 2010', Tijdschrift voor Toezicht (2011) 4, 22-5-47.

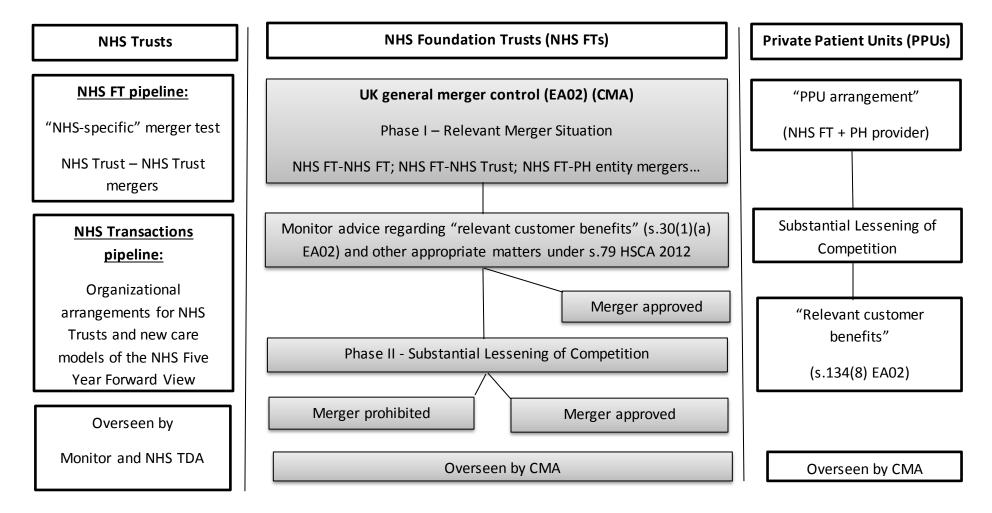
⁵ <<u>http://www.oxforddictionaries.com/definition/english/concurrent></u>.

⁶ A term used by Albert Sánchez Graells to describe the relationship between Monitor and the Competition and Markets Authority (CMA). See Albert Sánchez Graells, 'Monitor and the Competition and Markets Authority' (2014) University of Leicester School of Law Research Paper No.14-32.

Appendix J – Chapter 5 - Overview of relationship between "healthcare-specific" merger control and general merger control in the Netherlands, 2006 - 2015



Appendix K – Chapter 5 - Overview of relationship between "healthcare-specific" merger control and general merger control in England



Appendix L - Table of Cases

1. <u>EU</u>

Case C-41/90 Klaus Höfner and Fritz Elser v Macrotron GmbH [1991] I-1979.

Case C-62/86 AKZO Chemie BV v Commission [1991] ECR I-3359.

Joined cases C-159/91 and C-160/91 Poucet & Pistre [1993] ECR I-00637.

Case C-35/96 Commission v Italy [1998] ECR I-3851.

Case C-67/94, Albany International v Stichting Bedrijfspensioenfonds Textielindustrie [1999] ECR I-5751.

Joined Cases C-180/98 to C-184/98, Pavel Pavlov et al Stichting Pensioenfonds Medische Specialisten [2000] ECR I-6451.

Case C-475-99, Ambulanz Glöckner [2001] ECR I-8089.

Case C-309/99 JCJ Wouters, JW Savelbergh and Price Waterhouse Belastingadviseurs BV v Algemene Raad van de Nederlandse Orde van Advocaten (Wouters) [2002] ECR I-1577.

Joined Cases C-264/01, C-306-01 and C-355/01, *AOK Bundesverband* [2004] ECR I-2493.

Case C-205/03, FENIN [2006] ECR I-6295. (Also, Opinion of AG Maduro).

Case C-519/04P David Meca-Medina and Igor Majcen v Commission (Meca-Medina) [2006] ECR I-6991.

2. The Netherlands

ACM (NMa) cases

Case no. 2501 Dienstapotheek Assen (Assen Out-of-Hours Pharmacy) 21 June 2004.

Case no. 3022-205 Stichting Automatisering Gezondheidszorg Breda (Breda Foundation for Computerising Healthcare) 15 November 2004.

Case no. 5196 Ziekenhuis Walcheren – Stichting Oosterscheldeziekenhuizen, (Zeeland Hospitals merger) 18 November 2005.

Case no. 5851, Thuiszorg 't Gooi (Home Care Het Gooi), 19 September 2008.

Case no. 6108, Thuiszorg Kennemerland (Home Care Kennemerland), 19 September 2008.

Case no. 3309, NIP, LVE, NVP, NVVP (Dutch Psychologists' Associations) 17 March 2009.

Case no. 6424/427 Ziekenhuis Walcheren –Oosterscheldeziekenhuizen, (Zeeland Hospitals merger) 25 March 2009.

Case no. 6888/435 (LHV) (Dutch GPs' Association) 30 December 2011.

Case no. 7295/402 TweeSteden Ziekenhuis – St Elisabeth Ziekenhuis. ('TweeSteden Hospital – St Elisabeth Hospital') ('Tilburg Hospitals merger') 2 November 2012.

Case no. 6888_1/510 (LHV) (Dutch GPs' Association) 3 February 2014.

Case no. 14.0982.24/Stichting Albert Schweitzer Ziekenhuis – Stichting Rivas Zorggroep. ('Albert Schweitzer Hospital – Rivas Care Group merger') 22 July 2015.

NZa cases, Opinion and Regulation

NZa, 'Besluit van de Raad van Bestuur van de Nederlandse Zorgautoriteit als bedoeld in artikel 49 lid 1 van de Wet Marktordening Gezondheidszorg', 18 November 2009 (Decision under Art. 49(1) Wmg of 18 November 2009). NZa, 'Regeling CI/NR-100.099. REGELING voorwaarden voor overeenkomsten inzake elektronische netwerken met betrekking tot zorg', December 2009. ('Regulation CI/NR-100.099. Regulation on Conditions for Agreements involving Electronic Networks relating to healthcare').

NZa, Besluit 22 februari 2011, eerste toepassing van aanmerkelijke marktmachtbevoegdheid (art.48 Wmg). ('Decision involving the first application of SMP competence under Art. 48 Wmg of 22 February 2011').

NZa, Zienswijze vergunningsaanvraag Stichting Tweesteden ziekenhuis en Stichting St. Elisabeth ziekenhuis, Juli 2012. ('Opinion regarding the licence request in the Tilburg Hospitals merger' July 2012).

Dutch Trade and Industry Appeals Tribunal (CBb) case

ECLI:NL:CBB:2012:BW7731 'bodemprocedure' eerste AMM-besluit NZa (Art. 48 Wmg) ('Proceedings on the merits of the NZa's first SMP decision (Art. 48 Wmg)'). 7 June 2012.

3. England (UK)

Competition Appeals Tribunal (CAT)

Case 1006/2/1/01 BetterCare Group Limited v Director General of Fair Trading [2002] CAT 6, [2002] Comp.A.R.229.

Competition and Markets Authority (CMA) (in chronological order)

Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust / Poole Hospital NHS Foundation Trust Merger Inquiry (CC). 17 October 2013.

Private Healthcare Market Investigation Final Report, April 2014.

ME/6432-14, Anticipated acquisition of Heatherwood and Wexham Park Hospitals NHS Foundation Trust by Frimley Park Hospital NHS Foundation Trust, 3 June 2014.

Private Healthcare Market Investigation Final Order, October 2014.

ME/6481-14, Anticipated acquisition by Chelsea and Westminster NHS Foundation Trust of West Middlesex University NHS Trust, 19 January 2015.

ME/6511/14 Anticipated Merger of Ashford and St Peter's Hospitals NHS Foundation Trust and Royal Surrey County Hospital NHS Foundation Trust, 12 March 2015. (Phase I decision).

CE/9784-13, Private Ophthalmology: investigation into anti-competitive information exchange and pricing agreements. Infringement decision 20 August 2015.

CMA, Ashford and St Peter's and Royal Surrey County A report on the anticipated merger of Ashford and St Peter's Hospitals NHS Foundation Trust and Royal Surrey County Hospital NHS Foundation Trust, 16 September 2015 (Phase II decision).

Monitor / NHS Trust Development Authority (NHS TDA) (NHS Improvement) CCD 01/13 Commissioning of radiosurgery services.

CCD 04/13 Commissioning Cancer Surgery Services in Greater Manchester and Cheshire.

NHS TDA, The acquisition of Barnet and Chase Farm Hospitals NHS Trust by the Royal Free London NHS Foundation Trust, July 2014.

Monitor's advice to the Competition and Markets Authority on the merger benefits of the proposed merger of Ashford and St Peter's Hospitals NHS Foundation Trust and Royal Surrey County Hospital NHS Foundation Trust. March 2015.

NHS Cooperation and Competition Panel (NHS CCP)

Merger of Bexley Care Trust with Oxleas NHS Foundation Trust and South London Healthcare Trust, February 2010.

Proposed merger of Royal Free London Foundation Trust with Barnet and Chase Farm Hospitals NHS Trust, Final Report 13 August 2013.

Office of Fair Trading (OFT)

OFT Decision: Anaesthetists' groups, No. 15/04/2003. 14 April 2003.

ME/2524/06 Award of management contract to provide private in-patient bone marrow transplants and sarcoma cancer treatments at UCLH NHS FT to HCA International Limited. 12 October 2006.

OFT, Dentistry – an OFT Market Study, May 2012, OFT1414.

'OFT welcomes action by NHS Trusts to ensure compliance with competition law' Press Release, 71/12, 16 August 2012.

ME/5641/12 Anticipated lease by HCA International Limited of premises from Guy's and St Thomas' NHS FT. 7 November 2012.

ME/5351/12, Anticipated Merger between The Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust and Poole Hospital NHS Foundation Trust, 7 February 2013.

ME/6094/13 Anticipated pathology joint venture between University College London Hospitals NHS Foundation Trust, Royal Free London NHS Foundation Trust and the Doctors Laboratory Limited. 22 November 2013.

Other cases

R v North and East Devon HA Ex p.Coughlan [2000] 2 WLR 622

Eagle v Chambers (No.2) [2004] EWCA Civ 1033

R (on the application of Grogan) v Bexley NHS Care Trust [2006] EWHC 44 (Admin).

xxxviii

Appendix M - Table of Legislation

1. <u>EU</u>

Treaty on the Functioning of the European Union (TFEU)

Article 101

Article 102

Article 168(7)

Article 345 TFEU (ex Art.295 TEC)

Council Regulation (EC) No. 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty

Article 3(1)

Article 3(2)

Article 3(3)

2. The Netherlands

Legislative Proposals and associated documentation

Preceding the Dutch Health Insurance Act 2006 (Zvw):

Kamerstukken II, 2003-04, 29 763, 3 - Regeling van een sociale verzekering voor geneeskundige zorg ten behoeve van de gehele bevolking (Zorgverzekeringswet). Nr.3, Memorie van Toelichting. (Second Chamber documentation, Parliamentary Session 2003-04, 29 763, 3 (Explanatory Memorandum) - Regulation of social insurance for curative care for the whole population (Dutch Health Insurance Act 2006 (Zvw)).

Preceding the Dutch Healthcare (Market Regulation) Act 2006 (Wmg):

Kamerstukken II, 2004-05, 30 186, 3 - Regels inzake marktordening, doelmatigheid en beheerste kostenontwikkeling op het gebied van de xxxix gezondheidszorg (Wet marktordening gezondheidszorg), Nr.3 Memorie van Toelichting. (Second Chamber documentation, Parliamentary Session 2005-06, 30 186, 3 (Explanatory Memorandum) – Rules governing market organisation, efficiency and managed cost development in healthcare (Dutch Healthcare (Market Regulation) Act 2006 (Wmg)).

Current proposals to amend the Wmg to implement the transfer of competence from the NZa to the ACM:

Kamerstukken II, 2015-16, 34 445, 2 - Wijziging van de Wet marktordening gezondheidszorg en enkele andere wetten in verband met aanpassingen van de tarief- en prestatieregulering en het markttoezicht op het terrain van de gezondheidszorg. Nr. 2 Voorstel van Wet. (Second Chamber documentation, Parliamentary Session 2015-16, 34 445, 2 - Amendments to the Wmg and other laws to apply tariff regulation and market regulation in healthcare, Document No.2, Legislative Proposal).

Proposed amendments to Article 18(3) Wmg.
Proposed amendments to Article 18(2) Wmg.
Proposed amendments to Article 48 Wmg.
Proposed amendments to Article 49(1)(a) and (b) Wmg.
Proposed amendments to Article 49b Wmg.
Proposed amendments to Article 49d Wmg.

Kamerstukken II, 2015-16, 34 445, 3 - Wijziging van de Wet marktordening gezondheidszorg en enkele andere wetten in verband met aanpassingen van de tarief- en prestatieregulering en het markttoezicht op het terrain van de gezondheidszorg. Nr. 3 Memorie van Toelichting. (Second Chamber documentation, Parliamentary Session 2015-16, 34 445, 3 - Amendments to the Wmg and other laws to apply tariff regulation and market regulation in healthcare, Document No.3, Explanatory Memorandum).

Kamerstukken II, 2015-16, 34 445, 4 - Wijziging van de Wet marktordening gezondheidszorg en enkele andere wetten in verband met aanpassingen van

de tarief- en prestatieregulering en het markttoezicht op het terrain van de gezondheidszorg. Nr. 4 Advies Afdeling Raad Van State en nader rapport. (Second Chamber documentation, Parliamentary Session 2015-16, 34 445, 4 - Amendments to the Wmg and other laws to apply tariff regulation and market regulation in healthcare, Document No.4, Opinion of the Dutch Council of State (Raad van State).

Dutch Competition Act 1998 – Mededingingswet 1998 (Mw)

Article 1(f) Mw

Article 6

Article 24

Article 29(1)

Article 29(3)

Article 41(4)

Article 49

Dutch Healthcare (Market Regulation) Act 2006 – Wet marktordening gezondheidszorg 2006 (Wmg)

Article 3(4)

Article 17

Article 18

Article 18(1)(a)-(l)

Article 18(2)

Article 18(3)

Article 18(4)

Article 18(5)

Article 19

Article 45

Article 47

Article 48

Article 49

Article 49(1)

Article 49a(1)

Article 49a(3)

Article 49b(2)

Article 49c(2)(a)

Article 49c(2)(b)

Dutch Health Insurance Act 2006 – Zorgverzekeringswet 2006 (Zvw)

Article 11

Article 13

Article 122

3. England

Bills and associated documentation

Health and Social Care | HC Bill 2010-11| [132]

Health and Social Care | HC Bill 2010-11| [177]

Health and Social Care | HC Bill 2010-12 [221]

Health and Social Care | HC Bill 2010-12 [321]

Health and Social Care | HL Bill 2010-12 [92]

Health and Social Care | HL Bill 2010-12 [[119]

Health and Social Care | HL Bill 2010-12 [132]

National Health Service (Amended Duties and Powers) | HC Bill 2014-15 | [18]

National Health Service | HC Bill 2015-16 | [37]

<u>Hansard</u>

HC Deb, 24 February 2009, Col. 66WH

HL Deb, 12 December 2012, Cols. GC362 and GC363

Competition Act 1998 (CA98)

Section 2 (Chapter I prohibition)

Section 18 (Chapter II prohibition)

Enterprise Act 2002 (EA02)

Section 22

Section 23(1)(b)

Section 30(1)(a)

Section 129

Enterprise and Regulatory Reform Act 2013 (ERRA 2013)

Section 16

Section 16(7)

Section 52

Health and Social Care Act 2012 (HSCA 2012)

Section 9

Section 23

Section 26

Section 62, 62(1), 62(2), 62(3), 62(4), 62(5), 62(7)

Section 64(2), 64(3) Section 67, 67(3) Section 72 Section 73 Section 74, 74(2), 74(3) Section 75 Section 76 Section 77 Section 78 Section 79, 79(1), 79(2), 79(3), 79(4), 79(5), 79(6) Section 89(a) Section 101(2), 101(6) Section 111 Section 113 Section 116 Section 118, 118(7), 118(8) Section 120, 120(1)(b), 120(2), 120(3)(a), 120(3)(b), 120(4), 120(5), Section 150 Section 165 Schedule 12

Explanatory Notes to the HSCA 2012: Paragraphs 97, 666, 667, 711, 721, 740 and 798.

Law Reform (Personal Injuries) Act 1948

Section 2(4)

National Health Service Act 2006

Section 1(1) Section 1H(2) Section 56

Section 57A

The Competition Act 1998 (Concurrency) Regulations 2014

Regulation 5(5) and Regulation 8(1)(b)

Appendix N – Official Documents

The Netherlands

Policy Documents

Beleidsregel van de Minister van Economische Zaken van 1 september 2009, nr. WJZ/9145416, houdende bijzondere regels betreffende concentraties van zorgaanbieders. (Policy Rule by the Minister for Economic Affairs of 1 September 2009, No. WJZ/9145416, setting out special rules governing healthcare provider mergers).

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Appendix O – May 2015 Blog Post

Competition Policy Blog

https://competitionpolicy.wordpress.com/2015/05/05/what-could-repealof-the-health-and-social-care-act-2012-mean-for-the-application-ofcompetition-law-and-the-english-nhs/

What could repeal of the Health and Social Care Act 2012 mean for the application of competition law and the English NHS?

(By Mary Guy) In view of the significant opposition to the competition provisions of the Health and Social Care Act 2012 (HSCA 2012), it is unsurprising that several parties are explicitly proposing repeal in their 2015 UK election manifestos. Repeal of the HSCA 2012 appears to offer a neat shorthand for disapplying competition law with regard to the English NHS. But how do the competition provisions of the HSCA 2012 relate to the application of competition law, and what would repealing them actually achieve? This blog post explores these two questions by specific reference to s.72 HSCA 2012, so "competition law" is defined as the anticompetitive agreements and abuse of dominance provisions.[1]

What the parties are proposing

- The Liberal Democrats propose not only to repeal any parts of the HSCA 2012 which make NHS services vulnerable to forced privatisation through international agreements on free markets in goods and services, but also to end the role of the Competition and Markets Authority (CMA) in health, making it clear that the needs of patients, fairness and access always come ahead of competition.[2]
- The Labour Party proposes to repeal the HSCA 2012, scrap the competition regime and restore proper democratic accountability for the NHS.[3]

 The Green Party proposes to repeal the HSCA 2012 and introduce an NHS Reinstatement Bill to, inter alia, abolish competition and the purchaserprovider split and restore the obligation upon the government to provide a comprehensive health service.[4]

In contrast, *any* explicit reference to the HSCA 2012 is conspicuous by its absence in both the Conservatives' and UKIP's manifestos.

What does s.72 HSCA 2012 do?

S.72 HSCA 2012 provides that Monitor, the new sector regulator for healthcare, has concurrent powers with the CMA[5] to apply the provisions of UK and EU competition law.[6] Examples suggested by Monitor of where these rules have relevance include instances where providers agree not to compete for particular patients or services, and where a major hospital might only provide a certain service to GPs if a high proportion of patients are referred to it.[7]

It is to be noted that s.72 does not make competition law *applicable* as such. This is determined by the existence of an "undertaking", defined as an "economic activity"[8] which involves "offering goods or services on a market".[9] While there has been some doubt about whether the English NHS satisfies these requirements with regard to both providing and purchasing activities,[10] there is a growing consensus suggesting on balance that it does.[11] This view appears supported by New Labour reforms in establishing NHS Foundation Trusts with greater financial autonomy, and increased private sector involvement in providing NHS services.

Therefore s.72 merely defines the interaction between Monitor and the CMA regarding the enforcement of competition law. The relationship between the two agencies is based on "concurrent" powers whereby either may apply competition law – influenced by the model of other UK regulators. The experience of this arrangement in other sectors has suggested that regulators opt to use regulatory tools rather than their concurrent competition law powers. Obviously it remains to be seen whether this would be reflected in connection with the NHS, but it is certainly not inconceivable. Monitor has

already considered its provider licence – which includes a specific "Choice and Competition" condition – not only as its new main tool for regulating providers of NHS services,[12] but also as alternative to its concurrent competition law function.[13]

While the lack of use of concurrent competition functions by certain regulators may be addressed to a certain extent by the Secretary of State's new removal power under the Enterprise and Regulatory Reform Act 2013 (ERRA 2013),[14] Monitor is excluded from this. Consequently, either Monitor or the CMA remains competent to apply competition law, and provision exists for determining which is to act in a specific case.[15] However, Monitor's position is strengthened in that it may only be directed to transfer cases to the CMA if these are not principally concerned with matters relating to the provision of healthcare services for the purposes of the NHS in England.[16]

A further dimension to the practical implementation of the concurrency arrangements between Monitor and the CMA results from concessions made in connection with the HSCA 2012. The original intention of the White Paper was for Monitor to have a duty to promote competition.[17] However, following the "listening exercise" conducted during the passage of the Health and Social Care Bill, the NHS Future Forum proposed, inter alia, the removal of this duty as a safeguard against the misuse of competition.[18] In addition, Monitor's general duties under s.62 HSCA 2012 effectively require it to balance anticompetitive behaviour with patients' interests,[19] which appears to give further effect to the NHS Future Forum's proposal.

What emerges from the above is a picture of a competition regime which may – perversely – actually be more appealing to those sceptical about the role of competition in the English NHS than to those actively in favour of it. Certainly questions have been raised about Monitor's ability to act as an effective cocompetent competition authority in light of the combined HSCA 2012 and ERRA 2013 reforms.[20]

What would repeal of s.72 HSCA 2012 actually achieve?

Repeal may potentially have very different repercussions for two related, but distinct, aspects: the relationship between Monitor and the CMA, and the applicability of competition law.

With regard to the relationship between Monitor and the CMA, repeal may have a significant impact as the effect would presumably be to transfer competition law enforcement powers to the CMA. Indeed, such transfer has been recommended[21] as a response to Monitor's perhaps ambivalent status. So repeal may conceivably pave the way for more active enforcement of NHSrelated competition issues in light of the CMA's commitment to promoting competition – potentially in contrast to the OFT's previous apparent reluctance to pursue cases involving the NHS.[22]

As regards the actual *applicability* of competition law, repeal of the HSCA 2012 provisions appears to have little effect – as s.72 does not operate to initiate this. The Green Party's proposal of an NHS Reinstatement Bill[23] and the Liberal Democrats' proposal of removing the CMA's role in health perhaps hint at one option for dis-applying competition law. This would involve establishing the English NHS effectively as a "non-economic" activity,[24] which apparently may only be achieved by a significant reversal of developments (including creation of Foundation Trusts) in the NHS of at least the past decade. [25] While this may theoretically be possible, the logistics of attempting this should not be underestimated.

Perhaps a more feasible option regarding the dis-application of competition law may be to explore what the EU law exception for Services of General Economic Interest (SGEI) can offer.[26] This was raised in debates preceding the HSCA 2012[27] and a recent Private Member's Bill,[28] but a serious discussion has yet to be had. Clarifying the scope of the SGEI exception vis-à-vis the English NHS may well facilitate a more appropriate application of competition law. That – again perversely – may serve the interests of both those for and against competition in the English NHS.

[1] Other provisions of Chapter 2 HSCA 2012, such as sections 75 and 79 HSCA 2012 relate to functions in connection with merger control and procurement respectively and are beyond the scope of this post.

[2] Liberal Democrats, Manifesto 2015, "Stronger Economy. Fairer Society. Opportunity for Everyone", p.73.

[3] The Labour Party, "Britain Can Be Better", The Labour Party Manifesto 2015,p. 35.

[4] The Green Party, "For the Common Good – General Election Manifesto 2015", p.31.

[5] A function consolidated by a duty on both agencies to cooperate under section 80 HSCA 2012.

[6] The Chapter I and II prohibitions of the Competition Act 1998 and Articles 101 and 102 of the Treaty on the Functioning of the European Union, respectively.

[7] Monitor, 'Choice and Competition: hypothetical scenarios for NHS providers', 12 September 2014.

[8] Case C-41/90 Klaus Höfner and Fritz Elser v Macrotron GmbH [1991] I-1979.

[9] Case C-35/96 Commission v Italy [1998] ECR I-3851.

[10] With doubt relating more to purchasing activities to support healthcare provision free at the point of delivery in light of Case C-205/03P Federación Española de Empresas de Tecnología Sanitaria (FENIN) v Commission.

[11] For discussion on this point, see O Odudu, 'Are State-Owned Healthcare Providers that are funded by General Taxation Subject To Competition Law?', ECLR 2011, 32(5), 231-241 and B Collins, 'Procurement and Competition Rules – Can the NHS be exempted?'. The King's Fund Briefing, March

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[12] Monitor, 'The NHS Provider Licence', 14 February 2013. Foreword by David Bennett, Chairman and Chief Executive of Monitor.

[13] Monitor, 'Guidance on application of the Competition Act 1998 in the healthcare sector: guidance for providers', 12 September 2014.

[14] S.52, Enterprise and Regulatory Reform Act 2013 (ERRA 2013). For a discussion of this, and related reforms, see N Dunne, 'Recasting Competition Concurrency under the Enterprise and Regulatory Reform Act 2013'. (2014) 77(2) MLR 254-276.

[15] See Regulation 4, the Competition Act 1998 (Concurrency) Regulations 2014.

[16] Regulation 8(1)(b), the Competition Act 1998 (Concurrency) Regulations2014.

[17] Department of Health, "Equity and Excellence: Liberating the NHS", page5.

[18] NHS Future Forum, 'Choice and Competition – Delivering Real Choice – A Report from the NHS Future Forum'. Page 9.

[19] Ss.62(1) and (3) HSCA 2012.

[20] For a critical view of both aspects, see A Sánchez Graells, 'Monitor and the Competition and Markets Authority'. University of Leicester School of Law Research Paper No.14-32.

[21] Ibid.

[22] The most notable instance recently being its acceptance of voluntary commitments by NHS hospitals to desist from sharing commercially sensitive data about Private Patient Unit (PPU) prices. OFT Press Release, 'OFT welcomes

lviii

action by NHS Trusts to ensure compliance with competition law'.http://webarchive.nationalarchives.gov.uk/20140402142426/http:/www. oft.gov.uk/news-and-updates/press/2012/71-12

[23] Possibly in continuation of the cross-party NHS Bill tabled by the Green MP Caroline Lucas and apparently suspended after a first vote with the end of the fixed-term parliament in March 2015.

[24] Or "Service of General Interest" in EU law terminology.

[25] See Collins (n11).

[26] A complex area of law which raises various questions about EU and Member State competence, particularly with regard to healthcare in view of Art. 168(7) TFEU.

[27] See T Powell: Health and Social Care Bill: Summary of Lords Committee and Report Stages. Standard Note: SN/SP/6252. 26 March 2012

[28] The NHS (Amended Duties and Powers) Bill tabled by the Labour MP Clive Efford and discontinued following a protracted discussion amongst Conservative MPs about the concept of solidarity at the Committee Stage in March 2015, having received a vote of 241 to 18 in favour of a second reading in November 2014 (http://www.publications.parliament.uk/pa/cm201415/cmhansrd/cm141121/

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lix

Appendix P – February 2013 blog post

Competition Policy Blog

https://competitionpolicy.wordpress.com/2013/02/20/monitors-advice-tothe-oft-and-the-new-healthcare-regulation/

Monitor's Advice to the OFT and the New Healthcare Regulation

(by Mary Guy)[1] On 11 February, Monitor (the UK's independent regulator of NHS foundation trusts) published its advice to the Office of Fair Trading (OFT) regarding the anticipated merger of Poole Hospital NHS Foundation Trust and The Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust (hereafter "the Dorset FT merger"). This is the first NHS merger to be assessed on competition grounds under the Enterprise Act 2002 (EA02) merger provisions as implemented by the Health and Social Care Act 2012 (HSCA 2012). It has been referred by the OFT to the Competition Commission (CC), which will produce its final report by June 24, 2013.

A notable departure from the two-phase assessment of mergers by the NHS Cooperation and Competition Panel (NHS CCP) is already in evidence. Monitor's role in the new process involves advising the OFT of "relevant customer benefits" (i.e. lower prices, higher quality or greater choice of goods or services – as defined by s.30(1)(a) EA 02) and such other matters as it deems relevant to the merger. These actions amount to statutory obligations by virtue of s.79(5) HSCA 2012.

Within the wider merger assessment process, the identification of "relevant customer benefits" is significant for two reasons. Firstly, if the OFT decides that these benefits are such as to outweigh the effects of lessened competition results of the merger, this amounts to an exception to the general rule of its obligation to refer mergers to the CC (s.22(2)(b) EA02). Secondly, if the CC establishes that the merger is likely to result in a significant lessening of competition, it will consider possible remedies, taking into account any relevant customer benefits.

With regard to the current Dorset FT merger, Monitor established that it is looking for two aspects with regard to relevant customer benefits: a real improvement in quality of services to patients (or value for money) and clinical benefits (i.e. improvements in health outcomes or patient experience). Monitor found these with regard to improved quality of service accruing from the reconfiguration of maternity and cardiology services. It rejected the more economic benefits submitted by the parties, namely, delivery of financial savings through economies of scale, improved scope of services and enhanced ability to raise capital.

However, identification of these relevant customer benefits was insufficient to prevent the OFT from referring the Dorset FT merger to the CC, and it remains unknown whether or not the CC will consider these in its final assessment.

What is clear from Monitor's advice is that it has interpreted its obligations under s.79(5) HSCA 2012 narrowly in this case – and relied on its purported lack of statutory power to defend this approach. For example, it clarifies that it did not consider alternative options to address local challenges, something which perhaps undermines the requirement that relevant customer benefits be merger-specific (i.e. unobtainable by other means). In addition, it does not consider whether hospital mergers are appropriate.

This suggests that Monitor's advice is based on s.79(5)(a) HSCA 2012 exclusively. S.79(5)(b) HSCA 2012, with its emphasis on "such other matters as Monitor considers appropriate", is not only potentially wide in its scope, but also arguably unclear in its purpose. It may be used in an attempt to cover what may be termed "public interests", given the apparent inability of the EA02 to recognise the political sensitivities attached to the NHS. However, the consideration of "patient and taxpayer benefits" in NHS CCP assessments served the purpose of providing a remedy to reduced competition and choice. Under the new system, this may be achieved by considering relevant customer benefits. This is evidenced by Monitor highlighting the reduction in cardiology patient transfers as a relevant customer benefit because it amounts to

lxi

associated cost savings for taxpayers and commissioners. Indeed, this is the only reference to "taxpayers" in the advice.

Alternatively, the potential breadth of s.79(5)(b) HSCA 2012 may provide scope for Monitor to develop and expand its relationship with other agencies. While its advice in the current case acknowledges consultation with members of the NHS CCP and Clinical Reference Group, there is also statutory provision available for Monitor to cooperate with the Care Quality Commission (CQC) under ss.288 and 289 HSCA 2012. Development of a healthcare regulator's role by virtue of such relationships has already been seen in The Netherlands.

Based on the Dorset FT merger case to date, it may be concluded that Monitor's role in the new NHS FT merger assessment is limited to consideration of relevant customer benefits, which may not play a decisive role in the CC's final decision. However, in contrast to other sector regulators, Monitor's position is strengthened by its mutual statutory obligations vis-à-vis the OFT. It will be interesting to see what recognition Monitor ultimately receives from the CC this summer.

^[1] Bruce Lyons was not involved in the editing of this blog post because he has acted as an adviser to Monitor in the past.

Appendix Q – October 2013 Blog Post

Competition Policy Blog

https://competitionpolicy.wordpress.com/2013/10/28/the-meaning-ofrelevant-customer-benefits-in-the-context-of-health-care-monitors-adviceand-the-competition-commissions-response/

The Meaning of 'Relevant Customer Benefits' in the Context of Health Care: Monitor's Advice and the Competition Commission's Response

(by Mary Guy)[1] On 17 October, the Competition Commission (CC)blocked the proposed merger between Poole Hospital NHS Foundation Trust and The Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust (hereafter "the Dorset FT merger"), the first to be assessed under the regime for Foundation Trusts (FTs) established by the Health and Social Care Act 2012 (HSCA 2012). This new regime sees Monitor providing advice regarding "relevant customer benefits" to the OFT, which – along with the CC – has exclusive competence to determine mergers between NHS FTs. The case suggests that a higher standard of 'relevant customer benefits' is applied in the context of mergers in health care.

What is interesting about the CC's decision is how "relevant customer benefits" can be interpreted in the healthcare sector and – in response to an earlier post – how Monitor's advice has been received by the CC and, by implication, what this may tell us about the role and perception of healthcare regulators more generally. These aspects are also relevant to wider legal and economic discussions about whether and how healthcare can be treated as a special case with regard to mergers.[2]

s.30(1)(a) Enterprise Act 2002 defines "relevant customer benefits" as lower prices, higher quality or greater choice of goods or services. This arguably proves problematic in relation to healthcare, where competition on price has been rejected in a desire to avoid a "race to the bottom" as regards quality. Furthermore, quality itself is extremely difficult to define in any meaningful and quantifiable sense in relation to healthcare. In the Dorset FTs merger case, the parties submitted a range of proposed benefits (e.g. improvements in quality and increased consultant coverage across a range of services) which were mainly rejected by Monitor. Revisions of these (including the benefits to maternity services which Monitor had approved) by the parties were ultimately rejected by the CC as insufficient to offset significant lessening of competition in no fewer than 55 areas. This suggests that a high barrier has been set for establishing benefits in healthcare mergers, consistent with the interpretation of the Explanatory Notes to the EA02, namely that "relevant customer benefits" are to be construed narrowly. Any inference that this may be relaxed in healthcare cases – e.g. by the suggestion in the Explanatory Notes to the HSCA 2012 that such benefits could be interpreted in terms of the likely costs and benefits to patients which would arise from a merger (thus reflecting the merger test terminology of Monitor's predecessor, the NHS Competition and Cooperation Panel (NHS CCP)) – appears not to be borne out. The threshold has arguably been further heightened by the CC's clarification of "customers" ultimately as patients, as opposed to commissioners (CCGs), or shareholders (in view of the status of FTs as public benefit corporations under s.43 NHS Act 2006).

Monitor's advisory role has been restricted in this case to assessing "relevant customer benefits" under s.79(5)(a) HSCA 2012, as opposed to its power to comment on such other matters as it considers appropriate under s.79(5)(b) HSCA 2012. However, it appears that the CC has given considerable attention to Monitor's advice, which is to be welcomed in terms of the legitimacy this lends to Monitor in its new role as economic regulator for healthcare. The CC's decision also draws to a perhaps surprising extent on the experience of Monitor's predecessor, the NHS CCP. For example, the CC considered guidance arising from the NHS CCP's report on the operation of the "any willing provider model for the provision of routine elective care", the NHS CCP's approach to assessing the failure of NHS hospitals as part of their assessment of mergers and NHS CCP empirical studies. This apparent support for the approach taken by the healthcare regulator (firstly the NHS CCP and secondly Monitor) was strengthened by the CC, OFT and Monitor issuing a joint statement at the same time as the CC's decision, emphasising the three agencies' commitment to ensuring that patients' interests are at the heart of assessing public hospital mergers.

The decision to block the Dorset FTs merger has – predictably – been both welcomed and criticised. Indeed, blocking this merger may appear controversial in terms of the costs and time incurred in the decision process, or based on empirical literature suggesting that healthcare mergers can be beneficial. However, there has been little to suggest that general conclusions may be drawn for future cases: rather, if anything, the CC's decision appears to reveal a system very much in transition. On the one hand, a characteristic favouring of structural over behavioural remedies was seen in the CC's unequivocal rejection of the merger parties' proposal of a modified NHS friends and family test. However, on the other hand, the decision – and related publications – reveal that a clear requirement to benefit patients (as opposed to other defined groups of consumers or customers) is paramount, which arguably promotes not only the interests of a healthcare regulator, but perhaps also the wider public. While this decision is therefore to be welcomed

for its narrow interpretation of "relevant customer benefits" and for the weight it accords to the regulator's expertise, it will be interesting to see whether future healthcare merger cases confirm the CC's approach, or apply a more flexible interpretation of "relevant customer benefits" on a case-by-case basis.

[1] Edited by Andreas Stephan

[2] This is an issue which has been developed further in The Netherlands, where a healthcare-specific merger test considered to strengthen the input of the healthcare regulator into the pure competition-based general merger assessment has been designed.

Appendix R – Medical Law Review Article

See attached file.

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