

# **Developing a national strategy for combating counterfeit medicines**

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# *Abstract*

## **Background**

Counterfeit medicines pose a worldwide problem to governments, pharmaceutical companies and patients, meaning a systemic and comprehensive approach needs to be adopted by medicines regulatory agencies. The UK's Medicines and Health Regulatory Agency (MHRA) was one of the first national agencies to develop and implement a strategy to combat counterfeit medicines. Exploring this experience from different perspectives provides an opportunity to build knowledge and inform others considering adopting a similar approach.

## **Aims**

The aim of this research is to describe and investigate the key components in developing an anti-counterfeit medicines strategy in the UK; through describing and examining agency and stakeholder views on its development, implementation and evaluation and the roles of pharmacists and GPs within this.

## **Methods**

A mixed method qualitative and quantitative research design was used which comprised four separate studies. Two semi-structured interview studies of MHRA and stakeholders participants were undertaken alongside two postal survey studies of community pharmacists and GPs.

## **Findings**

The significant risk to patients resulting from counterfeit medicines underpinned the decision to develop and implement a national strategy. Stakeholders have an important role in the development of the strategy and in its implementation by securing the supply chain, sharing information, educating others, being vigilant and reporting suspicions.

Pharmacists and GPs reported limited experience of counterfeit medicines. Whilst GPs reported receiving no related education or training, pharmacists frequently reported supply practices which did not align with current guidance.

## **Conclusion**

There was agreement that in order to effectively combat counterfeit medicines a national strategy was required. Stakeholders from the pharmaceutical industry, regulatory bodies, medical and pharmacy professions were seen to have an important role in both its drafting and implementation. Pharmacists and GPs mainly believed that they had a role in combating counterfeit medicines however it was identified that they required better underpinning education and training. The research findings provide a framework of evidence-based guidance for developing an anti-counterfeit medicines strategy.

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# *List of abbreviations*

AIDS	Acquired Immune Deficiency Syndrome
ASOP	Alliance for Safe Online Pharmacies
BMA	British Medical Association
CCGs	clinical commissioning groups
DDA	Dispensing Doctors Association
EMA	European Medicines Agency
ETA	Euskadi Ta Askatasuna
EU	The European Union
FDA	US-Food and Drug Administration
GMC	General Medical Council
GPhC	General Pharmaceutical Council
GPs	General Practitioners
HIV/AIDS	Human Immunodeficiency virus/Acquired Immune Deficiency Syndrome
HMA-WGEO	Heads of Medicines Agencies Working Group of Enforcement Officers
HSCIC	Health & Social Care Information Centre
IE&S	Inspection, Enforcement and Standards division
IMPACT	International Medical Products Anti-Counterfeiting Taskforce
INTERPOL	The International Criminal Police Organization
IRA	Irish Republican Army
MAS	Mobile Authentication Service
MHRA	The UK's Medicines and Healthcare Products Regulatory Agency
NAFDAC	National Agency for Food and Drug Administration and Control
NHS	UK National Health Service
NPA	National Pharmacy Association
OTCs	Over The Counter medicines
PDA	Pharmacists Defence Association
PFIPC	Permanent Forum of International Pharmaceutical Crime
PhRMA	Pharmaceutical Research and Manufacturers of America
POMs	Prescription Only Medicines
PSI	Pharmaceutical Security Institute
PSI	Pharmaceutical Security Industry
RAS	Rapid Alert System
RCGP	Royal College of General Practitioners

RFID	Radio Frequency Identification
RPS	Royal Pharmaceutical Society
RPSGB	Royal Pharmaceutical Society of Great Britain
SPSS	Statistical Package for the Social Sciences
UEA	University of East Anglia
UK	The United Kingdom
USA	The United States of America
US	United States
VRMM	Vigilance and Risk Management of Medicines division
WCO	World Customs Organization
WHO	World Health Organization
WHPA	World Health Professions Alliance



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*To my father*

*I wish you were here to see this moment of my life*

*May Allah have mercy upon his soul and grant him the highest level in Paradise.*

# *Chapter 1*

## *Introduction to the Research Project*

## 1.1 Introduction

This thesis and the research reported herein concerns the phenomenon ‘counterfeit medicines’. More specifically, it focuses on how a national medicines regulatory agency drafts, implements and evaluates an anti-counterfeit medicines strategy by working with its stakeholders and relevant groups of health professionals. The aim of this introductory chapter is to identify the research topic and state the problem that has prompted the research, and describe the contribution to knowledge the research makes. The chapter finishes with an outline of the structure of the thesis.

## 1.2 Research problem

The counterfeiting of medicines is a worldwide problem affecting countries around the globe and medicines of all kinds. The World Health Organization (WHO) defines a counterfeit medicine as, “*one which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products, and counterfeit products may include products with the correct ingredients, wrong ingredients, without active ingredients, with insufficient quantity of active ingredient or with fake packaging*” (1). Counterfeit medicines impose major challenges on national and international health and medicines regulatory agencies which need to adopt a systematic and harmonized approach to match and combat the global scale of the issue. Without decisive action counterfeit medicines would continue to pose a significant risk to public health including causing death. Many reports have shown an increase in the trading of counterfeit medicines as more criminals have been attracted to the activity. Counterfeit medicines have been seen in the pharmaceutical supply chain and are increasing being sold online which represents another challenge (2-10).

The increasing supply of counterfeit medicines has a range of serious consequences for different stakeholders. For the users of counterfeit medicines, the general public, the most serious consequences are health and treatment related. Counterfeiters are known to use potentially injurious materials in their production and can be contaminated with toxic chemicals. These medicines can include no active ingredients, incorrect active ingredients or the wrong concentration of the correct active ingredient. Each of these

scenarios could lead to treatment failure, illness and even death. A significant amount of evidence is available to confirm the risk to the public of counterfeit medicines (10-17).

Pharmaceutical companies also face a range of adverse consequences from the counterfeit medicines phenomenon. The pharmaceutical supply chain is both complex and long with medicines passing through multiple transactions meaning that there are a number of points at which counterfeit medicines can enter the supply chain and find their way to end users. The main consequences for suppliers of legitimate medicines, are that their profits are affected when counterfeit medicines secure market share at their expense, and their reputation can be damaged as ineffective or dangerous medicines are confused in the minds of users with medicines from legitimate suppliers, particularly when the counterfeiters are deliberately seeking to replicate branded medicines. The overall consequences in financial and reputational terms are, however, difficult to quantify (12, 17, 18).

The third set of negative consequences from counterfeit medicines are those faced by governments, their agencies and the public health system. It is a clear duty of government to protect the public health and counterfeit medicines represent a clear risk to this health. The legitimate supply chain represents a valuable source of taxation revenue while the illegal trade in counterfeits does not make such a contribution. Another financial consequence for governments is the possibility that legitimate suppliers will charge public health systems more for their medicines to compensate for the impact of counterfeiting. For governments in developing countries there is a danger that legitimate pharmaceutical companies will be deterred from supplying to countries perceived to be high risk in terms of counterfeiting (12, 19-22).

The implementation of effective approaches to combating counterfeit medicines is a matter of great importance for any country. The Medicines and Healthcare products Regulatory Agency (MHRA) strategy implemented in the United Kingdom (UK) is one of the first such approaches to combating counterfeit medicines at a national level and could form a template for other countries. There are, however, certain gaps in knowledge concerning the development, implementation and evaluation of the MHRA's strategy, which this research seeks to fill.

## **1.3 The Research Context**

The research context for this study is a complex one in which multiple actors are engaged. Criminals are manufacturing and distributing counterfeit medical products in all parts of the world; pharmaceutical companies, law enforcement agencies, healthcare professionals and medicines regulatory agencies are engaged in combating this illicit trade. The key components for this research are the regulatory agency, the regulatory agencies stakeholders and the healthcare professionals. This is because it is these actors whose views can best inform an investigation into the development, implementation and evaluation of an anti-counterfeit medicines strategy.

The medicine supply chain starts from the pharmaceutical companies via the wholesalers and distributors before the medicines are supplied to patients by their pharmacists. Therefore, counterfeit medicines have an impact on all the stakeholders involved in the medicines supply chain (1, 6, 11, 12, 20, 23). Many national and international medicines regulatory agencies such as the WHO and the MHRA alongside many non-profit organizations like the Pharmaceutical Security Institute (PSI) have realized the danger of counterfeit medicines (5, 13, 24). In response they have allocated significant resources to the prevention and combating of counterfeit medicines at both national and international levels, as with the MHRA's Anti-counterfeiting Strategy 2007-2010 (25). Responsibilities and resources for combating counterfeit medicines are usually given to national medicines regulatory authorities who then decide how best to address the problem. Within some countries this has been undertaken by the development of national strategies in order to ensure that the approach is holistic, efficient and involves all stakeholders. The UK is considered to be at the forefront of strategy development an implication of being one of the first countries to develop such a strategy. Many of the activities undertaken with the resources have shared similar features: communicating with the public to improve their education and awareness of the topic; communicating with frontline health professionals (pharmacists and general practitioners (GPs)); and collaborating with stakeholders and other national and international agencies (12, 19, 20, 24-30). Therefore, the views of those stakeholders on the methods needed to tackle counterfeit medicines as well as the knowledge and the views of pharmacists and GPs would assist the medicines regulatory agencies in organizing its activities for combating counterfeit medicines.

In order to develop such activities, it is important for the national medicines regulatory agency's decision-makers to understand the drafting, implementation and evaluation processes involved as each of these stages are likely to strongly influence the efficacy of the strategy. Such decision-makers also need to understand the possible outcomes of these activities and methods evaluating their outcomes (vital for the development of future strategies) and to be clear about the role of the agency's stakeholders, including frontline health professionals (pharmacists and GPs). This research therefore investigates current practice in the United Kingdom (UK) with respect to combating counterfeit medicines in order to fill gaps in knowledge of certain aspects of developing, implementing and evaluating a national anti-counterfeit medicines strategy in order to inform future practice in these processes in any country where such a strategy is being contemplated.

## **1.4 Contribution of the Research**

This research aims to fill a number of gaps in the knowledge of the views and perceptions of key actors involved in the process of drafting, implementing and evaluating an anti-counterfeit medicines strategy. These gaps include how different stakeholders perceive their own roles and those of others in this process and in the overall effort to combat the counterfeit medicines problem. Furthermore, having enhanced our understanding of the process the research aimed to provide findings which could provide evidence to underpin a guidance framework which could be used by decision-makers at national medicines regulatory agencies to assist in their strategy development. The guidance framework would include recommendations based on the findings of this research project covering a wide range of issues related to the process such as identifying the various stakeholders, what their roles are, how they communicate and what their current perceptions, views and behaviours are in combating counterfeit medicines. While this research was conducted entirely within the UK context, its findings are expected to have some generalisability to other countries given the global nature of the counterfeit medicines trade.

## 1.5 Structure of the thesis

**Chapter two: Literature Review** – The thesis starts with a literature review to enable the reader to understand the concepts relevant to understand the problem of counterfeit medicines by examining how counterfeit medicines are defined and what issues may affect the range and choice of definition, presenting statistics on counterfeit medicines and their different sources; and examining their effects on public health, on society and on the economy. The factors involved in trading in counterfeit medicines will be addressed to include availability of counterfeit medicines through the internet. The impact of counterfeit medicines on the pharmaceutical industry, on governments (regulatory bodies and healthcare providers), and on patients will also be considered together with the efforts worldwide to combat counterfeit medicines. The chapter will conclude by identifying the gap in knowledge about combating counterfeit medicines which informs the rationale for conducting this research and stating the related aims and objectives of this research.

**Chapter Three: Research Methodology** – This chapter will detail and justify the research methodology that was used to conduct the current research discussing the underlying research approach, then justifying the choice of mixed method approach (qualitative and quantitative methods) for this research.

**Chapter Four: The MHRA perspective on developing an anti-counterfeit medicines strategy** – This chapter presents the first empirical study of the research project which examines the views of employees of a national medicines regulatory agency about an anti-counterfeit medicines strategy in order to gain an understanding of the process from drafting to evaluating of such strategy from the position of regulators. Through using semi-structured interviews with MHRA participants, this study explores their views on developing and implementing such a strategy; the role of the agency's stakeholders and frontline health professionals (pharmacists and GPs) in combating counterfeit medicines; and the outcomes they might be expected from such strategy and about methods could be used to evaluate those outcomes.

**Chapter Five: MHRA stakeholders' perspectives on developing an anti-counterfeit medicines strategy** – This chapter presents the second empirical study intended to widen the understanding of the process of developing such strategy throughout gaining the



views of the agency's stakeholders in the area of anti-counterfeit medicines strategy. Using findings from semi-structured interviews with the participants from different MHRA stakeholder groups, this chapter aims to delineate agency stakeholders' views on the agency stakeholders' roles in developing and implementing such a strategy; the role of frontline health professionals (pharmacists and GPs) in combating counterfeit medicines; and the outcomes that they would be expected from such a strategy and the methods could be used to evaluate those outcomes.

**Chapter Six:** *Community pharmacists' views of their role in combating counterfeit medicines* – This chapter presents the third empirical study which aims to identify the current practice and views of community pharmacists in England in the area of counterfeit medicines. Using a survey study, this chapter explores findings about community pharmacists' experience, knowledge and practices in relation to issues raised by counterfeit medicines, their views on the role of pharmacists in combating counterfeit medicines and their views on the communication methods used by a medicine regulatory agency.

**Chapter Seven:** *General Practitioners' views on their role in combating counterfeit medicines* – This chapter presents the final empirical study in this thesis to explore the views of general practitioners in England about counterfeit medicines. Using a survey study, this chapter investigates the general practitioners' experience, knowledge and practices about counterfeit medicines as well as their views on the role of GPs in combating counterfeit medicines and their views on the methods of communication used by a medicine regulatory agency.

**Chapter Eight:** *General Discussion and Conclusion* – This chapter presents a wider evaluative consideration of the nature and implications of how far the study findings have been able to address the gaps in understanding relating to the process of developing an anti-counterfeit medicines strategy, what these studies' findings have told us about stakeholders' views on the nature of the development process and factors influencing that process and its outcomes and what the implications of those findings may be for those people who may be involved in anti-counterfeit medicines strategy development in the UK and elsewhere. The research conclusions are summarised, evaluating the quality and appropriateness of the research design is evaluated as is the robustness of the research findings and their contribution to the wider field of research.

A set of recommendations aimed primarily at those likely to be involved in strategy development in the future is presented in the form of a guidance framework linked to specific study findings. The chapter ends by presenting the research limitations and recommendation for possible future research in this field.



# *Chapter 2*

## *Literature Review*

## **2.1 Introduction**

The literature review is a pathway toward setting the objectives for the current exploratory research as it identifies which areas needed to be explored by revealing gaps in knowledge and empirical investigation and revealing what the current research could add to the existing knowledge corpus. The research objectives are presented at the end of this chapter. The literature review also evaluates the nature and scale of the counterfeit medicines problem to provide context for the chapters to come. In addition to this, the researcher anticipated limitations in the literature, in particular with regard to empirical and other academic studies, mainly due to the borderless and criminal nature of supplying counterfeit medicines. A reliance on global non-governmental organizations (NGOs) for prevalence statistics and the problematic nature of such data was also foreseen in advance. The review, which was updated continually during the data collection, data analysis and synthesis phases of the study, was therefore also an opportunity to test these assumptions. The literature review aimed to gain a better understanding of how and why counterfeit medicines may pose problems to governments, stakeholders and the public. This chapter starts by seeking to establish what the term “counterfeit medicines” may mean, which meaning will be useful in this study, and present evidence about extent, type and the seriousness of the problems they may pose. It will also aim to identify the sources of counterfeit medicines and describe how they can affect patients and consumers. Counterfeit medicines supplied via the internet as well as the normal supply chain will be also explored. It will then describe factors involved in combating counterfeit medicines, to include the technologies now available to support this. The consequences of counterfeit medicines for pharmaceutical industries, patients and consumers and governmental organizations and what efforts have been made to address these by different organizations will be highlighted. The chapter will end by identifying the aim and the objectives of this thesis.

Counterfeiting has its origins as an ancient criminal activity which was probably first used when currency in the form of coins and notes was introduced. Today counterfeiting is pervasive throughout all areas of manufacturing, its form and focus depending on its potential value to the counterfeiters. In the twentieth century items such as handbags, watches, and perfumes where the false use of brands could return high profit to the counterfeiters is widespread across the globe. By the end of the

twentieth century, products which risked public health were identified as part of the counterfeiting culture. Such products have included pharmaceutical products, toys, cigarettes and spare parts for aircrafts and cars. However, counterfeit medicines pose a particularly serious danger, as they are strongly implicated in direct harms to public health, sometimes causing death. The counterfeiting of pharmaceuticals differs from other types of products because the counterfeiters attempt to imitate the physical packaging or appearance of the medicine being targeted, without consideration of the contents, which are naturally assumed to be effective by purchasers for the conditions they are designed to treat. Counterfeit pharmaceuticals often contain the ingredients of an entirely different drug, or the same drug in a different quantity or mixture. They may have no active ingredients at all and some may be contaminated by unidentified but potentially dangerous chemicals (either added in ignorance or resulting from poor sterilization practices) (11, 31, 32).

In 1958, at the Conference of Experts on the Rational Use of Drugs, the World Health Organization (WHO) drew attention for the first time to counterfeit medicines as an important global issue. As apparent from counterfeit products seized, the counterfeiters do not differentiate between brand-innovated medicines or generic medicines. Counterfeiters target a wide variety of pharmaceutical products, from lifestyle to life-saving medicines, including biological products. However, case reports have shown that some medicines are more often counterfeited than others, and that these are characterized by high prices and high levels of consumption (4, 19, 20, 33, 34).

Counterfeit medicines do not only affect developing and also less-developed countries (although the incidences of counterfeit medicines in these countries are very high), they also affect developed countries. Many health organizations in developed nations, such as the US Food and Drug Administration (US-FDA), the European Medicines Agency (EMA) and the UK Medicines and Healthcare Products Regulatory Agency (MHRA), have reported incidences of counterfeit medicines (8, 35). The MHRA considers counterfeit medicines a “*major public health issue*” (23). According to the WHO, in its report published in 2006, counterfeit medicines are becoming “*a global public health crisis*” (36).

## 2.2 Counterfeit Medicines: Understanding the Problem

### 2.2.1 Counterfeit medicines: Definitions

The words “counterfeit”, “fake” and “falsified” are all used in the pharmaceutical industry to refer to copies of genuine medicines. These terms are used to describe medicines that appear very similar to an original brand or generic medicine but are manufactured by an unauthorized entity. The objective of the counterfeiter is to produce a product that is very similar to the genuine product in its outer package, and its substance (colour, shape and size), and might also have a similar bar code. The sophistication of this procedure makes it, in some cases, very difficult to distinguish a real medicine from a counterfeit one. All types of pharmaceutical products can be counterfeited, from lifestyle medicines (which are the most common in developed countries), such as erectile dysfunction medication (Viagra™), anti-obesity medication (Alli™) and many others; to the lifesaving medicines (which are the most common in developing and less-developed countries), such as anti-malaria tablets, HIV/AIDS medicines and others. Biological medicines are also been counterfeited (2, 4, 9, 10, 12, 33).

Defining counterfeit medicines has been the subject of much international debate. It has been considered that lack of a standardized definition for such medicines has become an obstacle in combating the counterfeit medicines (2, 7). Mackey and Liang (2011), highlighted that the key challenge in standardizing a definition is possible interference with the definition of intellectual property with respect to copyright and trademarks (2). A further challenge is that not all countries have adequate legislation for dealing with drug counterfeiting (37).

The WHO defines a counterfeit medicine as, “*one which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products, and counterfeit products may include products with the correct ingredients, wrong ingredients, without active ingredients, with insufficient quantity of active ingredient or with fake packaging*” (1). This is the most common definition used worldwide (7). According to Attaran et al. (2011), the WHO definition is particularly useful because it includes the clear phrase “deliberately

and fraudulently mislabelled” (27). Through this phrase, the WHO has emphasized the principle of intent as a key aspect of “counterfeit”; its definition also clarifies that this activity is “fraudulent”, and that counterfeiting can never be accidental.

However, some countries use their own particular definition to describe counterfeit medicines. For instance, the US Food and Drug Administration (US FDA) defines counterfeit medicines as, *“those sold under a product name without proper authorization, where the identity of the source of the drug is knowingly and intentionally mislabelled in a way that suggests that it is the authentic approved product. This definition can apply to brand name products, generic products, or the bulk ingredients used to make the drug product. Counterfeit drugs under this definition may include products without the active ingredient, with an insufficient quantity of the active ingredient, with the wrong active ingredient, or with packaging that falsely suggests the drug was manufactured by the FDA-approved manufacturer”* (38). Many other countries are now using the US FDA definition (4).

Likewise, the MHRA in the UK applies the definition in the EU Falsified Medicines Directive, which is “Any medicinal product with a false representation of: a) its identity, including its packaging, and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients; b) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or c) its history, including the records and documents relating to the distribution channels used” (39).

All those definitions are trying to address similar meanings which is about purposefully copying a genuine medicine. For the purpose of this thesis, the definition of counterfeit medicines as given by the WHO will be used as it is the most common definition used worldwide.

### **2.2.2 Counterfeit medicines: Statistical evidence of extent**

According to the WHO, the exact figures for the quantity and volume of counterfeit medicines in the supply chain, are difficult to determine. There are many reasons for this; the WHO receives information on counterfeit medicines from various sources



including medicine regulatory agencies, authorized manufacturing companies, independent studies and many others. Also, there is no standard methodology used in the studies publishing the statistics on counterfeit medicines, and many of these studies have been conducted only in specific periods of time and specific locations, and therefore only offer snapshots of the problem. Therefore, the figures that been published regarding the counterfeit medicines problem could be seen as the “*tip of the iceberg*” for a major worldwide problem (1, 40, 41).

The WHO has, nonetheless, estimated that counterfeit medicines worldwide may constitute as much as 10% of all pharmaceutical production. However, this figure should be treated with caution because it can be misleading, according to the International Medical Products Anti-Counterfeiting Taskforce (IMPACT). The WHO has estimated that while less than 1% of medicines in developed countries are counterfeited, in some developing and less-developed countries, it may reach 60% (1, 7, 13, 42). The European Commission estimated that counterfeit medicines represent 5-7% of the medicines circulated in the EU, and may be as high as 15% (23). Furthermore, the Centres for Disease Control and Prevention (USA) has estimated the percentage of counterfeit medicines in the developed world is between 1% and 10%, and could be 30% in countries in Africa, Asia and Latin America (14). In Southeast Asia, 53% of anti-malarial medicines are estimated to be counterfeited. Also, 31% of TB medicines are estimated to be counterfeited in Botswana (3). In 2004, it was estimated that 40 to 50% of all medicines in Nigeria were counterfeited (43). Counterfeit medicine seizures by custom officials within the European Union increased 384% between 2005 and 2006, with a further 51% increase in 2007; detentions increased by 118% in 2008 (44). Counterfeit cases were discovered in 89 countries in 2005, while in 2004 they had been found in only 67 countries (3).

The US FDA in line with the WHO has estimated that counterfeit medicines represent 10% of the global pharmaceutical market; but that only 1% or less are sold in the US market (45). In Asian countries, between 5 and 10% of all medicines are counterfeited according to the International Federation of Pharmaceutical Manufacturers' Associations (10). In Russia, 12% of medicines are reported to be counterfeit but in the Ukraine it is 40% (19). The counterfeit figures in Brazil are between 5 and 7% of all medicines, based on data from the Brazilian Health Ministry (10). The WHO has

estimated that more than 20% of the pharmaceuticals in the former Soviet Republic are counterfeit (11). The WHO estimated in 2005 that the counterfeit medicines sold worldwide could be worth \$35 billion (15). Also, the Centre for Medicines in the Public Interest (USA) expected that the value of counterfeiting was going to reach \$75 billion by 2010, with an annual average growth of 13% (3, 42).

The WHO estimated that 70% of counterfeit medicines contained no active pharmaceutical ingredients (or incorrect ingredients). Also, between 10% and 15% of these counterfeit medicines contained contaminants (9). Another report published in 2005 by the WHO covered counterfeit medicines from 20 countries, finding that an active ingredient was missing from the product in 60% of the 325 cases studied. This study found that only 4% of counterfeit medicines contained the same quantity and quality of medication as their genuine counterparts (46).

The statistics on counterfeit medicines are based on estimates; an accurate estimation of counterfeit medicines is both problematic and complex owing to the lack of reliable research and standardized methodology. Some authors have asserted that the figures for national or international counterfeiting are little more than informed guesswork. The reports on counterfeit medicine figures published by the WHO (10% of world trade is counterfeit), or IMPACT (10–30% depending on area) are not based on any large-scale published scientific data (47). Most research into counterfeit medicines has employed the technique of “convenience sampling”, arguing that comprehensive studies are not feasible in practice (48), which will have biased the output results from these studies. Newton et al. (2009), argued that many currently published articles that have studied the quality of medicines have suffered from weakness on its sampling and reporting methods which could have affected the accuracy of the results (49). All of the above figures have a major limitation; counterfeit medicines are manufactured in secret and represent an area of criminal activity, making exact calculations of these figures largely impossible. The collection and collation of the data used to arrive at these figures are not standardized or uniform across the world because many countries do not have the resources needed for such an exercise (7, 50). As Outtersson and Smith (2006) stated, “*empirical, reliable and transparent statistics about drug counterfeiting are virtually non-existent*” (51). Much of the evidence published in many reports is merely gleaned from citations i.e. the findings are circular and there is much duplication (51). For

example, the US FDA uses WHO data for worldwide counterfeit medicines, and European bodies use WHO data but also WHO citations from the US FDA reports (51). However, the US-FDA and the WHO both take the view that the published statistics cannot be relied upon because they might be inaccurate; the only matter on which there is agreement is that the penetration of this criminal activity varies considerably between countries (52). All these data and reports indicate that the sources of counterfeit medicines are widely distributed across the world, contributing to their global impact.

### **2.2.3 Counterfeit medicines: Sources**

For various reasons identifying the sources of counterfeit medicines on a global basis is extremely difficult (10). The WHO states that 30% of countries have no drug regulation or only a limited capacity that is hardly adequate. This may be due to a lack of financial/human resources or may reflect a lack of policy priority; in any case this opens the door to counterfeiters, allowing them to work freely, as described by Enyindaa and Tolliverb (43, 53). Another reason for the inability to identify the source of counterfeit medicines is the lack of reporting to the WHO by national governments and pharmaceuticals companies as those reports might affect their image. Another difficulty is that counterfeit medicines generally pass through many countries before reaching their ultimate destination; this represents a serious challenge for anti-counterfeit authorities in pursuit of counterfeiters. Indeed, it has been estimated that counterfeit drugs may be bought and sold as many as thirty times before reaching an end consumer. A final reason is that the ingredients for a counterfeit medication may be produced in one country, formulated into tablets or capsules in another country, packaged in a third country, and then shipped through other countries to its final destination (3, 7, 12, 42, 54).

Many powerful and far-reaching criminal organizations have been identified as involved in counterfeit medicine activities, including the Russian mafia, Mexican gangs, Chinese Triads and Colombian drug cartels. Those with experience in the field say that these organized networks are capable of producing items that are almost indistinguishable from the genuine product. There is also some documented evidence that terrorist

organizations are or have been involved in counterfeit medicines activities, such as the IRA (Irish Republican Army), and ETA (Euskadi Ta Askatasuna) (2, 16, 36).

Most counterfeit medicines are produced in the Third World or developing countries. Many researchers and enforcement bodies consider that the largest source of counterfeit medicines is China (both active ingredients and finished products); in fact, in 2003 China's government closed down 1,300 illegal pharmaceutical factories and investigated cases worth \$57 million. The WHO published a study which showed that in more than 50% of documented cases, the counterfeited medicines in question had been produced in China, Vietnam and the Philippines. India has also become a major source of counterfeit medicines; some figures estimate that 35% of the world's counterfeit medicines come from India, making it the new leader in the market. Pakistan and Nigeria as well as Asian countries outside China are also becoming sources of counterfeit medicines. Latin America (especially Mexico) has become a major player, and now represents an important source for counterfeit medicines. Russia and the former Soviet Union countries are also becoming highly involved in counterfeit activities (3, 8, 10, 15, 16, 35, 47, 48, 55, 56).

Although these countries are the major sources of counterfeit medicines, there is evidence of cases of the production of counterfeit medicines in numerous other countries. According to the WHO, 14% of counterfeited medicines that have been reported were produced in the industrialized areas of Europe. For instance, an operation was discovered in the UK, which produced 500,000 counterfeited tablets daily. Also, there have been confirmed cases of counterfeit production in Spain, the USA, France, Italy and Greece (2, 8-10, 15). Governments are facing a major challenge with respect to identifying the sources of counterfeit medicines and this requires a great deal of cooperation between all countries in order to tackle these sources.

#### **2.2.4 Counterfeit medicines: their effects**

The particular dangers associated with counterfeit medicines come from the counterfeiters' use of whatever materials are available to copy their target medicine's appearance, regardless of the potentially injurious effects of those materials. Thus,

counterfeit pharmaceuticals often contain the wrong or no active ingredients, or they may be contaminated through the addition of toxic chemicals or through poor sterilization practices (11). Counterfeit medicines are dangerous and can be very harmful to public health. The effects of counterfeit medicines can be classified in three groups. Firstly, when counterfeit medicines have incorrect active pharmaceutical ingredients, the patient will not be treated for his/her illness and this may lead to more complicated cases or even death. For example, in the case of anti-malaria and HIV/AIDS medicines, the patient might die if not treated with correct doses, and the fake drug might contribute to developing drug resistance to the genuine medicines (13, 16). Secondly, serious complications can occur when a counterfeit medicine contains incorrect concentrations of the active pharmaceutical ingredients. For instance, when a cancer patient needs a precise concentration of medicine to counter the side-effects of chemotherapy, if that patient is not administered the correct dose, he or she could die (10). The third effect of counterfeit medicines is when counterfeiters add materials (that might be toxic) to a counterfeit medicine, merely to make it look like the genuine article; they may use polluted water, toxic yellow road paint, floor wax and boric acid (which is used to kill cockroaches) (14, 17).

There are numerous reports from health organizations and news sources regarding injuries and deaths of patients that are linked to the consumption of counterfeit medicines. According to the WHO, counterfeits purportedly treating AIDS, bacterial infections, cancer, fungal infections, high cholesterol and tuberculosis have been documented. In 1995, for example, over 50,000 people were inoculated with fake meningitis vaccines in Nigeria, possibly resulting in the deaths of 2,500 children (12). In 2006, a US cancer patient died in Missouri after using counterfeit medicines (Procrit<sup>®</sup>) to reduce the symptoms of chemotherapy (15). Also in the USA, 62 people died in 2008 from taking a counterfeit of heparin, which had come from China (12). In China, the estimation for deaths due to counterfeit medicines has reached 192,000 cases (45). In 1998, it was reported that 400 children in Haiti, Nigeria, and Bangladesh died after ingesting counterfeit paracetamol (acetaminophen) syrup that was made using diethylene glycol (7). In addition, the estimate for death worldwide caused by counterfeit anti-malarial and anti-TB medicines is 700,000 (12). In 2005, more than 1,000 were hospitalized in Russia due to counterfeit medicines (23). There are also many reports of patient deaths from medicines bought online in the USA, New Zealand

and Canada (2). In 1998, there were 200 cases of unwanted pregnancies for women who used counterfeit contraceptive pills in Brazil (15).

The effects of counterfeit medicines can be generally summed up as increasing morbidity and mortality, adverse effects, therapeutic failure, inaccurate reports of drug resistance due to substandard medicines and a rise in drug-resistant pathogens. These cases indicate that a key difference between most other counterfeit goods and counterfeit medicines is that the use of the latter leads to especially serious public health dangers. A further deleterious health effect arises when consumers find that the drugs they are taking or have been prescribed are less than effective; then they can understandably lose confidence even in the genuine product which might lead to consumers to seek treatment from traditional medicines (23, 31). The dangers associated with counterfeit medicines place a great responsibility on governments to protect the public, something which requires a systemic approach.

### **2.2.5 Counterfeit medicines and the Internet**

One type of service which has recently greatly increased is online pharmacy and this is due to their convenience and the offer of a wide range of products as well as anonymity to the purchaser. Consumers can now buy their medication at any time of the day and from anywhere in the world. For disabled patients and those living in rural areas, online pharmacies provide direct-to-door delivery. Online medicines are frequently more affordable than those purchased from retail pharmacies which incur greater overheads. Finally, online pharmacies can provide consumers with a great deal of information about the drugs and their actions, which can enable them to make an informed decision (57-62).

However, online pharmacies also have some significant drawbacks for consumers. In most cases, the consumer cannot be sure whether or not the online pharmacy is legitimate. The quality of online products is also a cause for concern; it is difficult to determine whether drugs purchased online are counterfeit, unapproved or illegal. Most of the time, online pharmacies sell their medicines without a valid prescription, and they

may ask for and hold a great deal of personal information. In many cases, online pharmacies market products with false or misleading health claims (58-60, 63).

Internet pharmacies afford an excellent opportunity for counterfeiters to distribute their counterfeit medicines in the global market. It is very difficult for government agencies to correctly identify online pharmacy websites and then to find counterfeit products (64). Gallagher and Chapman (2010), classified online pharmacies into three groups which are the legitimate sites within its country, sites registered in other countries, and illegitimate sites (57). Legitimate sites are authorized and regulated by the local government. For example, in the UK, online pharmacies must register with the General Pharmaceutical Council (GPhC) (65). The second group of sites are online pharmacies that are not registered in the local jurisdiction but might be registered in other country and may sell medicines following consultation (questionnaire or telephone interview) (57). The final group of websites are online pharmacies that are not regulated in any country and sell medicines without prescription or consultation; these are the most unsafe websites, and their location cannot usually be identified. These sites are generally designed in an attractive manner and many of them try to appear to represent well-known pharmacies, perhaps in Canada or the UK, However, the study conducted by Gallagher and Chapman (2010) and its three-fold classification was reliant on the location information published by the websites themselves which we know may not be reliable. According to the US FDA, online pharmacies are often comprised of multiple related sites and links. The WHO reported that many internet pharmacies do not reveal their real-world address (60, 66, 67).

The WHO estimated that almost 50% of medicines purchased over the Internet are counterfeit (1). A report published by the US FDA and the US Customs claimed that 88% of online medicine shipments to US patients are counterfeit. In addition, the US FDA has estimated that medicines purchased from online pharmacies are worth \$1 billion a year, and this figure is expected to rise (42). A report for the US FDA claimed that of the 11,000 internet pharmacy sites that claimed to be Canadian, only 1,009 (1.95%) actually sold prescription drug products, and that of those 1,009 websites, only 214 were registered to a Canadian entity (11). A study conducted by the US FDA in 2005 found that 85% of online pharmacies claiming to be Canadian in origin actually were from other countries (14).

Both the US FDA and the MHRA have published warnings about the dangers of unwittingly purchasing counterfeit medicines from online pharmacies (62). A survey conducted by the UK MHRA that covered 2,076 UK adults found that over 14% of consumers had been able to purchase prescription-only medicines (i.e. without a valid prescription) (44). Another study showed that 78% of UK GPs believed that patients put themselves in harm's way by buying from online pharmacies (44). In Europe, 20% of consumers of medicines declared that they bought from the Internet (2).

The dangers of online pharmacies were dramatically revealed in an operation organized and coordinated by INTERPOL, called Operation Pangea which occurred every year. The main objective of those operations is to tackle illegal online trading in counterfeit medicines. In those operations, INTERPOL worked with the World Customs Organization (WCO), the Permanent Forum of International Pharmaceutical Crime (PFIPC), the Heads of Medicines Agencies Working Group of Enforcement Officers (HMA WGEO), the Pharmaceutical Security Industry (PSI) and the electronic payments industry. In the last of these operations (Pangea VII) 113 countries and 198 agencies participated in the operation. The results were that more than 11,800 illegal websites were identified, 9.6 million fake and illicit medicines seized (such as slimming pills, cancer medication, erectile dysfunction pills, cough and cold medication), which were worth \$32 million; also, 1,249 investigations were launched, and 434 arrests were made (68).

In conclusion, it is not easy to investigate the legitimacy of online pharmacies as the task is very complex and resource intensive. Until now, there is no international legislation dedicated to regulating online pharmacies. Therefore, governments will need to educate their consumers of the safe method for buying medicines from online sources (14, 59, 60, 63). Also, governments need to work together to stop the sale of counterfeit medicines online and need to put in place effective education activities informing both public and healthcare professionals about the danger of counterfeit medicines.



## **2.2.6 Counterfeit medicines and the supply chain**

To understand how counterfeit medicines reach patients and consumers, it is important to highlight the various processes through which the medicines are transported from the pharmaceutical manufacturing companies to the destination market. In the ideal scenario of medicines supply chains, the pharmaceutical manufacturing companies ship their medicines directly to their main wholesalers. These wholesalers then distribute the medicines directly to hospitals or retail pharmacies, which then dispense these medicines to patients or sell them to consumers. However, in the real world, the pharmaceutical supply chain is both complex and long. Medicines pass through multiple transactions, going back and forth, before reaching the supply point. The risk of counterfeit medicines reaching patients and consumers increases with the increasing complexity of the supply chain (27, 43, 69).

To counteract the risk of the counterfeit medicines penetrating the supply chain, many major pharmaceutical manufacturing companies have started to distribute their products through a “closed” pharmaceutical distribution system, in which both manufacture and wholesale are conducted in a wholly transparent and highly-scrutinized supply chain. This process is designed to track the transit of medicines all the way to the destination. The objective of this is to reduce the risk of counterfeit medicines reaching patients and consumers. This closed pharmaceutical supply chain is monitored by regulatory agencies such as the MHRA. These agencies seek to secure the supply chain in order to prevent counterfeit medicines from entering. Therefore, this makes it more difficult to obtain medicines that have not passed through the approved framework; by increasing these types and levels of control, incidences of counterfeiting should be reduced. However, not infrequently, medicines can travel a much more circuitous route before reaching the pharmacies or hospitals. For example, wholesalers may sell their medicines to other wholesalers to cover temporary shortages or to reduce overstocked items, or they may send them to other smaller companies for repackaging (to change the medicines from bulk to unit-of-use containers). Thus, it is common in the pharmaceutical supply chain for medicines to pass through several transactions before reaching their destination. This variety of transaction activities affords an opportunity for counterfeiters to introduce their fake products into the supply chain. Another key threat in terms of counterfeits entering the medicine supply chain is related to parallel

imports and to the risk of confusion that arises from this kind of trade. This practice is legal in many countries, for example, a European wholesaler may buy and then import medicines from another European country at a low price, and then resell them back to that country at a higher price in order to profit from fluctuations in market demand. However, the speculator is allowed, within certain limits, to redesign the packaging in order to make the medicines more attractive to the target market, and this may result in confusion on the part of the purchasing entity; it is here that counterfeit medicines may be introduced into the destination market. (8, 26, 32, 34, 43, 69). Therefore, all parties involved in the medicines supply chain would have duties to combat counterfeit medicines and government needs to work closely with these parties.

### **2.2.7 Motivations for trading in counterfeit medicines**

The increasing trade in counterfeit medicines all over the world is driven by a number of key motivations, which reflect the reasons for counterfeiters starting in the first place. However, it is an uncommon motive for the counterfeiter to intentionally harm people which is very rare. An example of an exception was in the USA in 1982, when Tylenol™ was contaminated with poison by an unknown person, which resulted in seven deaths (8).

The most important motivations underpinning trading in counterfeit medicines is that huge economic benefits are to be gained (2, 11, 12, 14). The production of counterfeit medicines requires little capital and simple equipment; therefore, counterfeiters can generate considerable profits by producing at a low cost and then selling at a price commensurate with genuine medicines. Some authors have estimated that the profit margin can reach 2,000% of production cost, which goes some way to explaining the estimated value of worldwide counterfeit medicines as being \$75 billion (in 2010). For criminal organizations, trading in counterfeit medicines has become an alternative to trafficking in narcotics due to their high profitability (9, 14).

An additional motivation that accelerates the trade in counterfeit medicines is the very low risk of getting caught. This could be due to the nature of the product; the medicine is ingested and the packaging is discarded. Thus, the active (or otherwise) ingredients

are metabolized in the body, and are consequently difficult to identify at a later date, especially if the patient has ingested numerous other substances as part of normal treatment. This means that any evidence of counterfeiting is, on the one hand, destroyed as refuse, and on the other, converted into other chemical compounds and dispersed (10, 11, 20). Some healthcare professionals (physicians and nurses) as well as some patients have little doubt that a significant amount of therapeutic failure might be because of counterfeit medicines, although this is very difficult to substantiate. Therefore, it is important that healthcare professionals generally, in assessing treatment failure or iatrogenic illness, consider the possibility of the presence of counterfeit medicines. Also, it is important to educate healthcare providers (physicians, nurses and pharmacists) and patients more widely about the existence, effects and means to avoid counterfeit medicines (3, 12).

Another motivating factor is in the low penalties for trading in counterfeit medicines which permit counterfeiters to go about their trade with little fear. For example, in the USA, selling counterfeit trademark goods such as handbags may result in the dealer being sentenced to up to 10 years in prison, yet trading in counterfeit medicines has only been subject to up to 3 years in prison. However, this has begun to change: for instance, in November 2007, the Chinese State Food and Drug Administration introduced severe penalties for trading in counterfeit medicines, which could mean life imprisonment or even the death penalty. Also, the Council of Europe recently adopted the MEDICRIME convention, which increases the penalty for trading in counterfeit medicines. Nevertheless, there is still no international legal framework for tracking, apprehending and sentencing counterfeiters (10, 12, 27, 44, 70).

Finally, the availability of modern digital printing technologies for packaging and labelling, poverty, inadequate health facilities, corruption and the high cost of drugs (from taxes and tariffs) all increase motivations for trading in counterfeit medicines (12). All these motivating factors have contributed to increasing the supply of counterfeit medicines worldwide, which in turn has increased the risk imposed on public health. This has put the medicines regulatory agencies in a position of great responsibility for the protection of consumers.

## **2.2.8 Technologies available to help combat counterfeit medicines**

Modern technology is seen to play a crucial role in combating the actions of counterfeiters. In general, the technologies that can be used in combating counterfeit medicines can be classified into three categories: packaging or labelling; technological authentication; and data carrier identification through the supply chain. The first relates to the integrity of the outer packaging and the inner labelling or leaflets; these can carry tamper-evident features, for example, security seals, glue on perforated cartons and cartons fitted with breakage evidence devices. The second category relates to pharmaceutical products being authenticated by covert and overt technologies, such as immunoassay (biochemical markers), reactive inks, holograms, watermarks, colour-shifting inks, guilloches, fibres or threads. The third category relates to the medicine being identified at each stage of the supply chain through a data carrier (micro-chip tags). The strategy in this category of technological weapons is to serialize all medicines with unique codes to facilitate their identification (and authentication) at each stage of the supply chain (Radio-frequency Identification (RFID) is an example of this category) (10, 43, 71). All the above technologies vary in terms of cost and efficacy. However, it is essential to select the tool that is best suited to each country's level of development and it is unrealistic to expect the least developed countries to have access to the most costly technology. For example, the biggest problem is in the developing world, where resources are limited, poor control mechanisms exist, and many medicines are supplied outside conventional means. The current technologies used in combating counterfeit medicines often have fundamental defects, which affect their intended performance. This was exemplified in 2005, when a study conducted in the USA by a large US pharmaceutical wholesaler found that more than 25% of the RFID tags were unreadable (4, 11, 20).

National health and medicines regulatory agencies are facing many challenges with respect to counterfeit medicines which flags up the need for a systemic approach that could be adapted by an agency in order to combat counterfeit medicines. Also, cooperation between parties in the medicines supply chain as well as the other national health and medicines regulatory agencies are essential to combat counterfeit medicines.

## **2.3 Consequences of Counterfeit Medicines**

Many parties (stakeholders) deal with medicines along the medicines supply chain in one way or another. From a business perspective this would be the pharmaceuticals manufacturing companies (branded and generic), wholesalers and distributors. From a regulating and providing treatment perspective this would be the government (departments of health, medicines regulatory agencies and health professionals). Finally, comes the patient as end user. Counterfeit medicines would have an impact on all those stakeholders and they could cause many problems on different levels. Counterfeit medicines can inflict a great deal of harm to the pharmaceutical industry, as well as posing a significant risk to public health. In addition, counterfeit medicines can have an impact on various government bodies.

### **2.3.1 The impact of counterfeit medicines on the pharmaceutical industry**

The process of inventing, developing, testing and licensing a new medicine needs much investment on the part of pioneer pharmaceutical companies, in terms of time, manpower and money. The estimated cost to put a new product on the market in 2004 was between \$800 and \$900 million. This estimation was based on the generalization that only one product will successfully reach the market after the company has examined and tested 5,000 molecules. In addition, the process of launching an innovative product on the market is a very lengthy one and can be up to 15 years. Not all innovative products that have been released onto the market will generate profits for the pharmaceutical company as only 30% result in profits which are sufficient to cover the costs of research and development. The pharmaceutical industry is considered a very costly and high-risk business (10, 17, 21).

Counterfeit medicines have damaging effects on pharmaceutical companies. Trading in counterfeit medicines takes profits from innovative manufacturers, who must then recoup their considerable research and development costs from elsewhere. As a result of the reduced profits, innovative pharmaceutical companies may be forced to reduce investment in new medicines. Counterfeiters target generic as well as branded

medicines, and the profits of generic pharmaceutical companies will also be reduced; this will have consequences on the availability of low cost, high quality generics (12, 17, 20).

Counterfeit medicines damage the brand image and brand value of genuine medicines, and diminish their reputation in the eyes of patients. Pharmaceutical companies can have their reputation for quality compromised and they can be exposed to litigation should consumers be harmed by counterfeit versions of their medicines as the consumers do not know they used counterfeit medicines (29, 35, 55). Damage to reputation does not only affect branded medicines; the medicines of good quality generic companies also suffer from reputational damage from counterfeit medicines (8, 26). The negative impact on pharmaceutical companies caused by counterfeit medicines has led some pharmaceutical companies to cease cooperating and sharing the information they have with other stakeholders. Because accurate figures on the extent of counterfeit medicines are not available, assessing the damage to the product's brand is complex and difficult to define (12, 17, 18).

Counterfeit medicines seize market share from the genuine ones. Thus, the genuine pharmaceutical companies have to adjust their production and this can have ramifications on the supply chain. Also, genuine pharmaceutical companies have to spend a great deal of money in tracing the counterfeiters and in taking them to court (26, 72). Recently, many genuine pharmaceutical companies have begun to be more proactive and now hire investigators to trace the source of counterfeit medicines and to work with national authorities. They also now publicize their anti-counterfeiting strategies and technologies (3, 55). Sources citing the threats to pharmaceutical companies' financial strength need, however, to be balanced against the proven profitability and high profit margins of the major companies. Reports have shown that despite the rise of global counterfeiting, leading companies have been able to maintain higher average profit margins than any other sector (73). While still remaining highly profitable despite the costs of counterfeiting, the potential consequences of counterfeiting for the industry raises the need for the industry to be part of the efforts to combat counterfeit medicines and have a role in the national strategy.

### **2.3.2 The impact of counterfeit medicines on governments, regulatory bodies and healthcare providers**

The effects of counterfeit medicines are evident beyond the pharmaceutical companies and patients; they also have a significant impact on the reputation of government agencies. Patients who have had an experience with counterfeit medicines may think that the relevant regulatory authority was unable to protect them and that it is not fit for purpose and that may lead patients to seek treatment from other recourses like traditional medicines. For this reason, some governments do not publish figures on counterfeit medicines that could affect its image (12, 28).

Governments of many countries exact taxation from companies (including pharmaceutical manufacturers) in terms of percentage of profits. This also applies to wholesalers, distributors and retailers, which will be used to improve their public health systems. Counterfeit medicines bypass the regular distribution chain, and therefore a large amount of revenue that should have gone to the government and to their health systems is lost. Also, counterfeit medicines increase the costs of medicines paid for by the government (as well as by patients) because the pharmaceutical companies have to increase their prices to recoup their losses from counterfeit medicines (12, 19, 20).

Another impact of counterfeit medicines on governments would be through increasing the country's unemployment level. This could happen in two ways: pharmaceutical companies lower their number of employees due to the losses incurred from counterfeit medicines, and potential international investors tend not to invest in a country that has a counterfeit medicines problem (21, 22). Therefore, governments need to coordinate with other interested organizations including the pharmaceuticals companies in its efforts to combat counterfeit medicines.

### **2.3.3 The impact of counterfeit medicines on patients**

There are different types of impact on patients which have a more or lesser direct relation to their health and treatment. In most cases, patients take a medicine assuming that it will be genuine; therefore, patients are unlikely to suspect that any harm that may

have occurred would be caused by a counterfeit medicine. It is in this hidden way that counterfeit medicines threaten public health (26, 72). Counterfeiters are producing medicines which could cause therapeutic failure in patients. Also, in cases of infectious disease, inaccurate active ingredients can increase resistance to medicine on the part of pathogens. In these ways, counterfeit medicines contribute to the public health risk by aiding the spread of infectious diseases, and compromising the fight against them (2, 12, 28, 55).

Counterfeiters minimize the costs of production by using cheap impure ingredients, using unhygienic manufacturing processes and not following the good manufacturing practise of cleaning the machines between different production batches. The consequences of these are that counterfeit medicines cause harm to patients, increasing morbidity and mortality, and exposing patients to the risk of experiencing adverse events (or not achieving their treatment goals) (2, 20, 55).

Patients who take counterfeit medicines and then do not improve as they expected from taking an apparently reputable medicine can lose confidence in conventional allopathic drugs and even in the health system. Especially in developing countries, the widespread distribution of counterfeit medicines can lead to people seeking out alternative medicines such as traditional remedies and unlicensed healers as being more trustworthy (12, 27).

Additionally, because of counterfeiting leading to reduced revenue flows to the pharmaceutical industry, increased litigation costs, as patients anticipated that the medicine is genuine, and ever-rising insurance rates, consumers will be asked to pay more for their medicines. Counterfeiting also has consequences for developing countries; their markets can become less profitable, meaning that pharmaceutical companies are less likely to invest in research and development to combat diseases that are endemic, which in turn makes these poorer countries less attractive to foreign investors (19, 35, 55).



## 2.4 Efforts to combat counterfeit medicines

Since the early modern appearance of counterfeit medicines, the WHO, as well as some national medicines regulatory agencies, have been making efforts to combat counterfeit medicines through different approaches and different levels of engagement.

### 2.4.1 International and national agencies

The task of tackling counterfeit medicines has been taken on by many international and national health and medicines agencies. At the international level, the WHO recognized the importance of tackling counterfeit medicines in a systematic way; therefore, in 1999, the WHO published guideline entitled “*Guidelines for the Development of Measures to Combat Counterfeit Medicines*”, where the WHO tried to provide comprehensive guidance (30). Rather than having a strategy specifically designed to combat counterfeiting, it has developed an approach aimed at aiding the strategies of other countries. The WHO therefore became involved in training law enforcement officers and laboratory technicians, in helping to advance technology, and in supporting and developing the regulations of the countries.

The guidelines published by the WHO propose particular courses of action to be followed by countries to remedy their counterfeit medicines problem. These include raising the political priority of combating counterfeit medicines; alerting countries to the dangers of counterfeit medicines; developing a suitable legislative framework to protect the medicines supply chain and improving the screening of medicines at ports of entry; establishing medicine regulatory authorities, with effective enforcement powers; increasing the enforcement of the existing medicine control laws; developing partnerships between governmental agencies and pharmaceutical companies to foster communication and cooperation; and increasing patient education and awareness concerning counterfeit medicines. In 2005, the WHO developed a system (“*Rapid Alert System*” (RAS)) to help countries and the partner organizations in the Western Pacific Region to be notified of any counterfeit medicine case. This system would immediately alert those using it about any such incident and the action that should be taken. Moreover, as part of the efforts in the fight against counterfeit medicines, the WHO

formed and launched the International Medical Products Anti-counterfeiting Taskforce (IMPACT) in 2006. IMPACT is a partnership of international organizations, non-governmental organizations, enforcement agencies, pharmaceutical manufacturing associations and drug and regulatory authorities. The objective of IMPACT was to stop the production and trade in counterfeit medicines, but it also focused on improving coordination and harmonization between its members. However, the drawback for IMPACT was that it did not have legislative authority nor the financial resources to help its members (3, 5, 7, 8, 20, 74).

Also at an international level, in European countries, the MEDICRIME convention has been adopted by the Council of Europe as the first international agreement to criminalize the trading in counterfeit medicines. The Council of the European Union and the European Parliament adopted the Falsified Medicine Directive in 2011 which is scheduled to be implemented fully by 2018. This directive requires all medicines to have a unique serial number applied during their manufacture and that this should be displayed on the medicine packaging in the form of a 2D barcode. Every prescription only medicine (POM), except those exempt resulting from their risk assessment, will be covered while all over the counter medicines (OTCs) will be exempted unless identified as being at high risk of counterfeiting. Prior to supplying the medicine to the patient they will be scanned and the unique number checked against a database (20, 44, 75, 76).

National health and medicine regulatory agencies add to international efforts to combat counterfeit medicines. For example in the USA, the FDA has developed its own stance on combating counterfeit medicines, which shares some of the same points as the WHO method and has six main objectives: to secure both the medicine and its packaging, to secure the passage of medicines throughout the distribution chain, to enhance regulation and enforcement, to increase penalties for the counterfeiting of medicines, increasing vigilance and awareness of such counterfeiting, and developing international collaboration (3, 4, 34, 38, 77, 78).

In Nigeria, the National Agency for Food and Drug Administration and Control (NAFDAC) as one of Africa's leading agencies in combating counterfeit medicines, has conducted several activities to combat counterfeit medicines. As part of its efforts NAFDAC adopted a Mobile Authentication Service (MAS) which helps patients make sure that their medicines are not counterfeit by using their mobile phones, as well as

collaboration with pharmaceutical companies and other national medicine regulatory agencies. In 2010, Health Canada published a policy on Counterfeit Health Products as part of the effort to combat counterfeit medicines in the country. This policy was focussed on educational activities and advice to the public, health professionals and members of the supply chain about counterfeit issues; developing a vigilance system; working with its stakeholders; conducting marketing lab tests; and working with other international regulators (4, 34, 38, 43, 77-81).

In the United Kingdom, the MHRA which is responsible for regulating medicines and medical devices to protect public safety, launched its “*Anti-counterfeiting strategy 2007-2010*”. The strategy was the first document published by a national medicines regulatory agency that aimed to tackle counterfeit medicines in the country across three key areas, communication (with the public and health professionals), collaboration (with stakeholders and agencies at a national and international level) and regulation (by gathering intelligence, investigation and risk assessment of the threat of counterfeit medicines in the supply chain). In 2012, the MHRA published its second strategy which was called “*Falsified Medical Products Strategy 2012-2015*”. The second strategy was a natural successor to the first strategy; and it was also based on three main key points (prevention, incident management and investigation). For the prevention area, the MHRA aimed to prevent counterfeit medicines reaching the public through a series of activities: communication (with public and health professionals), collaboration (with its stakeholders) and participate in the international activity to combat counterfeit medicines. For incident management, the MHRA aimed to be more efficient in handling any incidence of counterfeit medicines and improve the medicines recall process when needed. Regarding the investigation part, the MHRA aimed to be pro-active in investigation through its enforcement group within the agency to detect counterfeits and evaluate and monitor medicines supplied online and work with other law enforcement counterparts at an international level. In addition to these strategies the MHRA published, in collaboration with the Dispensing Doctors Association (DDA) and the Royal Pharmaceutical Society of Great Britain (RPSGB), guidance for pharmacists and dispensing doctors which contained information and advice on counterfeit medicines (23, 25, 39, 44, 82-85).

The common features seen in the published international and national activities to combat counterfeit medicines are in highlighting educative communication with the public, raising public awareness about counterfeit medicines and improving collaboration with counterpart agencies and stakeholders. However, the method used to develop and implement such activities and to evaluate their impact is not reported in the literature. Also, the literature did not report any cooperation between different organizations in the development of those activities which suggests that each organization develops its own activities in isolation from other organizations.

### **2.4.2 Non-profit organizations**

Many non-profit organizations, from national professional bodies, to global alliances and manufacturer representatives, have also played a part in the worldwide efforts to combat counterfeit medicines and many such organizations deal with such issues as all or part of their activities. For instance, in 2002, some of the pharmaceutical companies formulated the Pharmaceutical Security Institute (PSI) which is now has twenty-eight pharmaceutical manufacturers members. PSI activities would help in tackling counterfeit medicines by sharing information and working with the national medicines regulatory agencies. Also, in 1999 health professionals worldwide (pharmacists, GPs, dentists, nurses, and physical therapists) formed a non-profit organization called the World Health Professions Alliance (WHPA). The WHPA has been part of the efforts of combating counterfeit medicines through educating its members. Another non-profit organization, is the Alliance for Safe Online Pharmacies (ASOP), which focuses mainly on counterfeit medicines via online sources, The ASOP is playing a role in combating counterfeit medicines through increasing the awareness of the danger of buying medicines via online websites through education activities for patients and health professionals; raising awareness of the danger of such websites to the policymakers and other internet stakeholders and working in collaboration with medicines regulatory agencies to improve the safety of online pharmacies (24, 86-88).

In the UK, the General Pharmaceutical Council (GPhC), which is responsible for regulating pharmacists, pharmacy technicians and pharmacy premises in Great Britain, as well as the Royal Pharmaceutical Society (RPS), which is the professional

membership body for pharmacists seeking to continue improving pharmacy services in UK are both working with MHRA on the issue of counterfeit medicines through educating their members, including, for example, publishing the guidance for pharmacists and dispensing doctors on counterfeit medicines (65, 84, 89).

All these efforts and activities on the part of many organizations and agencies combine to highlight the seriousness of the danger of counterfeit medicines to the public health, and to demonstrate that they are working individually and in some cases cooperatively to combat counterfeit medicines.

### **2.4.3 Health professionals**

Many medicines regulatory agencies' efforts to combat counterfeit medicines, like the MHRA's strategies as well as the WHO's guideline, flag up the importance of working with healthcare professionals in order to raise their awareness of counterfeit medicines which will help in combat counterfeit medicines (25, 39, 90). However, the methods used for raising such awareness in healthcare professionals have not been described.

The role of health professionals (pharmacists and GPs) is reported in some literature as to be vigilant for any counterfeit medicines, as well as to educate and raise awareness among their patients of the danger of counterfeit medicines. Also, for pharmacists there is mention of the need to secure the supply chain from any penetration by counterfeit medicines and to report any suspicions of this to their national medicines regulatory agency (3, 12, 91, 92). However, in this literature these roles are reported as derived from authors' opinions rather than from empirical research directly involving those health professionals (pharmacists and GPs). Neither has health professionals' awareness of counterfeit medicines been determined within this literature. Therefore, the views of pharmacists and GPs on the issue of counterfeit medicines and their role in combating counterfeit medicines need to be understood by the national health and medicines regulatory agencies.

In summary, even with no unified definition of counterfeit medicines, all definitions commonly used share the same conceptual meaning of purposefully-produced unregulated copies of genuine medicines that are physically very similar to the genuine

medicines and which may or may not have pharmaceutically active ingredients. In addition, figures that try to estimate the scale of counterfeit medicines in the worldwide legitimate pharmaceutical supply chain raise concern as the accuracy of those figures may be limited by, for instance, a lack of formal reporting mechanisms and different methodologies have been used to identify them. However, these figures could serve to flag up to the national medicines regulatory agencies the seriousness of the counterfeit medicines problem.

Identifying the source of counterfeit medicines is no easy task although the literature has indicated that counterfeit medicines may mainly come from countries such as India or China. Counterfeit medicines can, nonetheless, also be produced in any country including those with a highly regulated pharmaceutical market such as the UK or the USA. Many published reports show how counterfeit medicines impose a danger to consumers as they might cause death or at least lead to treatment failure. Also, the danger associated from buying medicines from online sources is very high as it been estimated that at least 50% of medicines bought online would be counterfeit and that is because online sites are an effective method for counterfeiters to distribute their products. The literature also shows that weak pharmaceutical regulatory systems, weak penalties, low risk of being caught, and high economic profits all provide reasons for the increasing trade in counterfeit medicines.

The legitimate pharmaceutical industry is also affected by counterfeit medicines which could be seen in reducing profits, increasing the industry costs, and damage to the reputation of genuine medicines. The impact of counterfeit medicines extends to governments through undermining government agencies' reputations, as they would be seen as not protecting the public from counterfeit medicines and reducing tax income. Patients are also affected by counterfeit medicines through therapeutic failure, increased resistance to some medicines and increasing morbidity and mortality.

Correspondingly, some hope can also be seen for addressing the counterfeit medicines problem worldwide as exemplified by the efforts of international and national health and medicines agencies as well as of other non-profit organizations. At international and national levels, the WHO and many national medicines regulatory agencies like the MHRA began to combat counterfeit medicines with the cooperation of non-profit

organizations through publishing guidelines or strategies aiming to organize activities on tackling counterfeit medicines.

The process of designing, developing and implementing such strategies could not be identified within these publications. This knowledge would be important for other countries trying to introduce their own strategies. Neither did such publications include the expected outcomes from such activities nor methods which could be used to measure these outcomes was not found in the publications.

Whilst the role of health professionals (pharmacists and GPs) in combating counterfeit medicines is frequently included in such strategies, healthcare professional views on their training needs, potential contribution and preferred communication methods are unknown.

## **2.5 Research aim and objectives**

### **2.5.1 Rationale**

While the incomplete and problematic nature of counterfeit medicines statistics has been correctly identified; it is clear that they are a significant danger to public health and the legitimate supply chain and that there is a strong reason to believe that this threat will grow in the future as more supply goes through the online route. Therefore, on a general level an anti-counterfeit medicines strategy represents a valid and important field of study. Furthermore, many of the activities to combat counterfeit medicines have been shown to involve different approaches and different levels of engagement revealing a lack of consistency of approach among jurisdictions as well as a lack of published evidence of some of these methodologies. The WHO evidence clearly demonstrated that counterfeit medicines are a greater danger in countries where the medicines regulatory system is weak; cooperation between the national medicines regulatory agencies would make them more efficient and address any weakness might they have (93).

While there is also evidence of co-operation this can be ad hoc and periodic. A more comprehensive and systematic approach is needed which could be used by any national

medicines regulatory agency to strengthen its efforts in combating counterfeit medicines by putting in place a strategy which appropriately apportions responsibilities and describes roles and practices for its successful implementation and evaluation. The more countries which broadly align themselves in strategic terms the more international co-operation there is likely to be and the more likely these activities are to be effective (5, 93). Moreover, the absence of either empirical study of the experiences and perceptions of health professionals (pharmacists and GPs) in respect to counterfeit medicines, revealed in the process of conducting this review confirms that there is a need for exploratory inquiry in this area to identify these experiences and views including those on their own roles in combating counterfeit medicines and their communication with the national medicines regulatory agency. Finally, the researcher has a personal motive as part of his work duties is to run activities to combat counterfeit medicines at a national level for the Saudi Food and Drug Authority (Saudi-FDA).

These reasons together offer a rationale for conducting a research study as potentially useful for evidencing and informing understanding of what might be key components of approaches to combating counterfeit medicines. These in turn could provide principles for informing the processes for developing a national strategy for combating counterfeit medicines including by any national medicines regulatory agency.

### **2.5.2 Aim and objectives**

This research therefore aims to investigate current practice with respect to combating counterfeit medicines in UK in order to understand key components in developing anti-counterfeit medicines strategies

Therefore, the objectives of this research are:

- To describe and understand the process involved in the development, implementation and evaluation of a national anti-counterfeit medicines strategy.
- To describe and understand the views and roles of pharmacists and GPs in combating counterfeit medicines.



## **2.6 Conclusion**

Counterfeit medicines have been shown here to be a threat to public health all over the world. However, such medicines also can be seen to have consequences for pharmaceutical companies as well as governments. The literature review presented in this chapter shows that some activities have been undertaken to combat counterfeit medicines at an international and national level alongside efforts by non-profit organizations. However, the method of developing, implementing and evaluating those activities as well as the degree of cooperation among different partners involved in medicines supply chain is unknown. Also, the views and the roles of pharmacists and GPs in combating counterfeit medicines have not been identified in the literature. Therefore, research that addresses those issues is needed in order to help any national agency to develop its own strategy to combat counterfeit medicines.



# ***Chapter 3***

## ***Research methodology***

### 3.1 Introduction

This research aims to investigate current practice in the UK with respect to combating counterfeit medicines in order to inform future practice in these processes in any country where such a strategy is being contemplated. The key components for this research are the regulatory agency, the regulatory agencies stakeholders and the healthcare professionals. This is because it is these actors whose views can best inform an investigation into the development, implementation and evaluation of an anti-counterfeit medicines strategy. Therefore methods need to be used which are considered appropriate for meeting the data needs of the research.

When working in a complex multidisciplinary field, a researcher can adopt specifically selected approaches and use various research methods, involving “*plans and the procedures for research that span the steps from broad assumptions to detailed methods of data collection, analysis, and interpretation*” (94). Therefore, in order to select the research approach that fulfils the research question, researchers should understand the available research approaches, their strategies, methods and techniques. In light of that, researchers would be able to identify the research methodology that would suit the research objectives.

This chapter will highlight the research methodology applied in this research; first by identifying the underlying research approach and then the related research strategy, after this is will explain the rationale behind the choice of the mixed-methods approach and the chosen methods of data collection and analysis.

### 3.2 Research Approach and Design

The research approach is derived from the researcher's beliefs, preferences, and past experiences each of which can influence how the researcher may conduct their research and the rationale behind their choices for their research strategy (95). These may be informed by one or more paradigms in use within contemporary relevant research communities. According to Bryman, a paradigm is “*a term deriving from the history of science, where it was used to describe a cluster of beliefs and dictates that for scientists in a particular discipline influence what should be studied, how research should be done, and how results should be interpreted*” (96). The research paradigm will therefore

frame the nature of reality (ontology); the relationship between this reality and the researcher (epistemology); and the various techniques applied when examining this reality (methodology) (97-99). A research paradigm is a set of basic tenets framing the ideas of the researcher about “*What is the nature of reality?*”, “*What is the relationship between the inquirer and the known?*”, and “*How do we know the world, or gain knowledge of it?*” (100).

The research problem requires that data on the views, perceptions and practices of the key actors in the development, implementation and evaluation are collected and analysed. Different methodological approaches have been identified as guiding researchers in different research fields; these include: positivism, constructivism and post-positivism. Positivism based on the assumption that social phenomena are objectively measurable and can be analysed using scientific methods via generation and testing of a hypothesis, mirroring the natural sciences. Whereas, constructivism, which suggests that “*truth is a particular belief system held in a particular context, and it is interested in the values which underpin the findings*”, meaning that phenomena can be analysed and understood by experiencing things and reflecting on those experiences (96, 101, 102). Therefore, constructivism claims that individuals (including researchers) construct (or interpret) reality based on their own subjective perceptions of the social world and that, in contrast to positivism, there is no one single objective reality. Post-positivism is a paradigm that shares features from both constructivism and positivism. Post-positivism assumes that reality exists imperfectly and is open to different perceptions upholding the assumption that the researcher’s background, knowledge, and values combined with the theories they subscribe to can influence both what is observed and how they observe it. Post-positivism emphasises the importance of multiple research methods to gain a better picture of what is happening in reality (96, 97, 101, 103, 104).

The research in this thesis requires the post-positivist approach based as it is on data collected and analysed using both qualitative and quantitative research methods that have been selected in order to gain an understanding of the issues associated with developing, implementing and evaluating an anti-counterfeit medicines strategy. In determining the research strategy there are two approaches, quantitative and qualitative. Qualitative research methods “*usually emphasize words rather than quantification in the collection and analysis of data*” (96). On the other hand, according to Creswell, quantitative research approach is defined as “*an inquiry into social or human problems,*

*based on testing a theory composed of variables, measured with numbers and analyzed with statistical procedures in order to determine whether the predictive generalizations of the theory hold true” (94).*

Qualitative research aims to study the phenomena in-depth using data gathering methods including among others: interviews, documents and participant observations, to gain understanding and explain a particular social phenomenon. Researchers conduct qualitative studies when they need to distinguish people from their environments and to understand their individual actions in these environments, something which is made possible through a process of communication. Qualitative research assists researchers to understand people, societies and cultural issues for which quantification is problematic and subjective data need to be collected and examined (96, 105, 106).

From the perspective of analysis, quantitative research is associated with deductive reasoning, which progresses from the general to the specific and is referred to as a top-down approach; whereas qualitative research approach tends to be associated with inductive reasoning, which goes from the specific to the general and is known as a bottom-up approach. A quantitative research approach is most effective where pre-existing knowledge must be considered in order to be able to generalize the study’s findings; this allows the researcher to employ standardised data collection methods to document any prevalence. A quantitative study emphasises metrics as a basis for the collection of data and its analysis and usually derives and tests a model based on measurement to derive objective knowledge. In contrast, qualitative studies examine meanings in place of numbers during data collection and analysis and is concerned with questions of interpretation not numerical measures (102, 107, 108).

### **3.2.1 Researcher bias**

All researchers have their own set of values and personal beliefs and these need to be recognised as it would not be feasible to entirely set these values and beliefs aside during the research process (96). As part of the post-positivist approach underlying this research it is important for the researcher to clearly state how researcher subjectivity and bias is inevitably present in this research and to understand its consequences. The researcher works as a pharmacist within another country’s medicines regulatory agency (Saudi Food and Drug Authority) with past working experience of the issue of

counterfeit medicines. Therefore, it would not be possible to carry out this work without developing a personal perspective and set of assumptions regarding counterfeit medicines and how to combat them. When considering this data it is therefore important to recognise that the data collection and interpretation processes may have been affected by this perspective and personal assumptions.

### 3.3 Research Strategy

A research strategy is essentially a plan of action and is key to ensuring that the research questions are addressed in an appropriate manner consistent with all of the topics, questions and objectives of the research. The selection of a research strategy will be influenced by the research paradigm drawn on, the research approach adopted, the specific research aims and questions, the time and resources available, and the existing knowledge available to the researcher on the research problem being investigated (109).

#### 3.3.1 Mixed Methods Research

Although normally associated with opposing epistemological beliefs and contrasting research strategies, qualitative and quantitative research approaches are not simply contradictory in terms of a researcher seeking to understand his/her field of study. In fact, it is increasingly recognised that each method presents different opportunities to access different kinds of knowledge which when combined offer a deeper understanding and richer interpretation (110). The nature of the research problem being investigated determines the choice of study approach as the researcher aims to build a wider picture of the phenomenon being studied. The selected approach should also enable the researcher to validate the research findings. For this research, it was concluded that a mixed methods approach offered the best opportunity to achieve the aims. A mixed-method study is described as “*research in which the investigator collects and analyses data, integrates the findings, and draws inferences using both qualitative and quantitative approaches or methods in a single study or program of inquiry*” (111). By using mixed methods, a researcher is better able to build a wider picture of the phenomenon at hand and validate the research findings, while working within the inherent method limitations (96, 112). In light of that, to fulfil the research objectives,

both the qualitative and quantitative approaches have been used which defines this study as mixed-method research.

In order to achieve the research objectives, in-depth study was needed to gain better understanding of the current practice with regard to development, implementing and evaluating anti-counterfeit medicines strategy, which required qualitative studies. Also, to gain the pharmacists and GPs views with respect to their roles in combating counterfeit medicines which required quantitative studies. According to Bryman, mixed method research is “*a term that increasingly employed to describe research that combines the use of both quantitative research and qualitative research*” (96). In using a mixed method approach, the researcher can discover more about the phenomenon being studied by combining the strong points of qualitative and quantitative research while at the same time compensating for the weaknesses in each method. The use of a variety of data collection methods applied to different sources can enhance the validity of the findings and reduce the inherent weaknesses of a one method approach.

### 3.4 Research Design

This research, therefore, combines qualitative and quantitative strategies in its research design. A research design is effectively a framework for the collection and analysis of data (96). Four main mixed-method research designs have been identified: triangulation design, embedded design, explanatory design, and exploratory design (94, 96, 106, 111-113).

**Triangulation design** refers to combining quantitative and qualitative methods to explore the same data set in order that the results can be mutually corroborated or at least compared.

**Embedded design** has one data set playing a supportive secondary role in a study based primarily on the other data type. An embedded design is based on the premise that a single data set is insufficient, that a number of questions need answering, and that each type of question requires a different type of data to answer it.

**Explanatory design** refers to using one set of data to explain the results from the other set of data. It is two stage data collection process, the first stage is quantitative data collection then the second qualitative data collection. This design is used to explain



significant (or non-significant) results from the quantitative data by using qualitative data.

**Exploratory design** is similar to the explanatory design through using quantitative and qualitative methods in two stages; however, in the exploratory design qualitative data are collected firstly then quantitative data. The assumption here is that quantitative investigation is not appropriate until exploratory qualitative methods have put in place a foundation of understanding.

This research shares characteristics with three of the above-described mixed-method research designs. Firstly, in conducting four separate studies, two qualitative and two quantitative, the research is aiming to bring the benefits associated with triangulation to this research. Secondly, in order to gain support for the findings from qualitative studies from quantitative investigations, this research also adopted an embedded mixed-method approach. A qualitative method was used in the first two studies (chapter 4 and chapter 5) to gain better understanding of the phenomena being examined. Then, quantitative methods were used in chapter 6 and chapter 7 to support the understanding of the phenomena. Thirdly, this research is exploratory because significant aspects of the research problem concerning the development, implementation and evaluation of an anti-counterfeit medicines strategy have yet to be defined and this is understood to be the initial research into these aspects of the problem. This research design is also associated with post-positivism because the researcher's motivations for and commitment to research are recognised as central and important to the research. Having said this the researcher avoids allowing prior knowledge and assumptions to lead to a dogmatic attitude to the research problem. Additionally, this research reflects the feature of post-positivism which recognises the value of both qualitative and quantitative methods either separately or combined together in mixed methods approaches.

### **3.5 Research Methods**

In conducting research, researchers may select from a variety of methods available for data collection, such as observations, interviews, documents, field surveys and experimental surveys, which need to be appropriate to their research design.

### **3.5.1 Data collection**

Data collection is the basic process in any research project and is dependent on the study's aim and objectives and is further influenced by the researcher's environment. For a coherent study, the choice of data collection methods is based on its research objectives and underlying approach (96, 97, 102). As this research needed to acquire a deep understanding of the views of the participants regarding the counterfeit medicine issue, semi-structured interviews were appropriate for collecting data on the participant views as these would provide data in which participants could provide their own qualitative insights on their own experience facilitated by a conversation with the researcher. In addition, to provide measurable and descriptive data on the knowledge, understanding and experiences of a sample of both pharmacists and GPs working in England, i.e. quantitative data suggested that a questionnaire survey would be suitable to collect these data. The participant recruitment procedures for the interview-based qualitative studies involving MHRA participants and MHRA stakeholders are explained in chapters 4 and 5 respectively. The sampling methods used, and the implementation and administration of the questionnaires for the quantitative studies of pharmacists and GPs are explained in chapters 6 and 7 respectively.

#### **3.5.1.1 Qualitative data collection methods**

In qualitative research, personal semi-structured interviews are commonly used to collect meaningful and relevant information, enabling the researcher to gather large amounts of rich data relevant to the phenomenon under study. The qualitative data collected from MHRA representatives and MHRA stakeholders would be relevant to addressing the research problem because the participants can be viewed as experts capable of offering important insights into the processes of developing, implementing and evaluating an anti-counterfeit medicines strategy. Mason (2002) explains that the qualitative interview technique is usually recognised as a means providing meaningful and relevant information that would achieve research's objectives (96, 102, 106, 114). Therefore, the personal interview method was adopted as a data collection technique as it met the requirements of the two exploratory studies involving MHRA participants and MHRA stakeholders respectively.

Having decided on face-to-face interviews the researcher must then select the appropriate format and technique for the interviews. This choice essentially involves identifying the most effective degree of structure along a continuum from structured at one end (suited to a research area where much of the information is known) to unstructured at the other (suited to a largely unknown research area) or somewhere between the two (semi-structured). Semi-structured interviews are well suited to this context as the researcher is cognisant of most of the issues in the field but would like to learn more from highly experienced practitioners and gather more in-depth data and a richer interpretation, as well as to learn of issues that he has not hitherto encountered. Face-to-face semi-structured interviews afford the opportunity for the researcher and interviewees to probe complex issues in depth and to clarify answers; developing a rapport will be necessary as some of the issues may be security-sensitive (96, 102, 106). Therefore, the data collection starts with two sets of semi structured personal interviews with participants from MHRA and participants from MHRA stakeholders (see chapter 4 and chapter 5) that help in identifying issues associated with developing a counterfeit medicines strategy to be explored further and supported by the subsequent studies with pharmacists and GPs (chapter 6 and 7). In conducting the interviews and subsequently analysing the data the researcher was mindful that the counterfeit medicines issue might be considered as a sensitive issue for the country, and that the researcher might be seen by participants as an outsider (or an international audience) which may affect the data they communicate with the researcher, in that the participants (particularly those from the MHRA) may be more guarded in their responses than they would be in another environment.

### **3.5.1.2 Quantitative data collection methods**

A survey method is a research strategy in which is used “*at a single point in time in order to collect a body of quantitative or quantifiable data in connection with two or more variables*” (96). The studies involving GPs and pharmacists needed to yield data on a range of issues concerning their practices and preferences apropos of counterfeit medicines and their possible roles in combating them. Such data need to have a reasonable degree of generalisability. The survey method is one of the commonest designs in social research. The survey is generally associated with a quantitative approach and allows gathering of a specific and limited range of quantitative data that

can be representative of the whole population at a low cost (98, 115-117). For quantitative data, a questionnaire survey tends to be a common strategy with which researchers can gain more control over the research process and can obtain representative findings that can be generalised to the whole population at a low cost. Therefore, a questionnaire survey was used in this thesis to support and elaborate upon some of the findings from the qualitative research such as confirming or not whether these health professionals agreed with MHRA representatives and MHRA stakeholders on matters such as the roles health professionals could play in combating counterfeit medicines. A questionnaire survey enables a lot of data to be collected from a relatively large sample of people in a short period of time and so is a highly practical research method. A self-completion questionnaire is convenient for the respondent and does not have the potential for interviewer variability which in this instance is beneficial (94, 96, 102, 106, 118, 119). Hence, the qualitative study was followed by two quantitative studies using a questionnaire survey (chapter 6 and chapter 7) to help understand the roles of health professionals in combating counterfeit medicines.

### **3.5.2 Data Analysis**

Having two methods of data collection and collecting both quantitative and qualitative data meant that two distinct methods of data analysis were also required. Together, the analysis of these data helped to build understanding of the current practice concerning counterfeit medicines in the UK with a view to generating findings and recommendations which may assist a medicine regulatory agency in the future development of anti-counterfeit medicines strategy.

#### **3.5.2.1 Qualitative data analysis methods**

The qualitative data analysis needed to produce findings on the views and perceptions of MHRA representatives and MHRA stakeholder participants on a range of issues related to the development, implementation and evaluation of an anti-counterfeit medicines strategy. Four main criteria were set for the selection of data analysis method. Firstly, it had to be a tested analytical technique for data collected using semi-structured interviews. Secondly, it needed to be highly systematic and provide an auditable process. Thirdly, it needed to be flexible enough to work with either an inductive or

deductive approach. Fourthly, it needed to be within the capabilities of the researcher (98, 116, 120, 121).

For the qualitative data collected using face-to-face interviews the framework analysis approach was used. This analytical technique falls into the broader category of qualitative content analysis or thematic analysis. Framework analysis approach, has become widely used as a means of analysing primary qualitative data, particularly in fields of healthcare research and policy making research. The framework analysis approach has been highlighted as being a reliable and appropriate tool for research which has already been defined as highly focused, specific questions, a defined and limited timeframe, a sample which is pre-designed (e.g. professional participants) and *a priori* issues that require addressing. The framework analysis approach sees the researcher apply an analytical framework comprising codes and categories (also referred to as indexing) which are used to manage and organise the data. A thematic framework is derived from this into which the data are placed according to a process of charting, mapping and interpretation.

### **3.5.2.2 Quantitative data analysis methods**

Quantitative data analysis is required to generate findings on the practices and preferences of healthcare professionals (pharmacists and GPs) on a range of issues related to counterfeit medicines. Quantitative data analysis is more standardised than the qualitative equivalent and as such involves less choice for the researcher with respect to which analytical tests should be applied to the data. Once the completed postal questionnaires were received back from respondents, the responses were entered into two software application for analysis: Microsoft Excel and the Statistical Package for the Social Sciences (SPSS) software. The data were summarised using descriptive statistics, a process which enabled the demographic characteristics of each group of respondents to be summarised and also helped detect outliers and entry errors (102, 122). Following the descriptive statistics further analysis of the data was undertaken, mainly bivariate analysis to establish empirical relationships between two variables, mainly a particular characteristic with a behaviour or view. Fisher's exact test, chi-squared analysis, the Mann-Whitney U test and Kruskal-Wallis test were each used.

### **3.6 Ethical Considerations**

The researcher should consider the ethical implications of their work to insure that their work does not harm participants or the public or infringe their rights. According to Diener and Crandall, researchers should divide their considerations of ethical issues into four areas: harm to participants, informed consent, invasion of privacy and deception (96, 123). In this study the researcher considered the implications of the research for the qualitative and quantitative study separately as in each case the implications were different. The risk of harm through participation in the interview studies was considered to be negligible but not zero. As either the MHRA participates or stakeholders participates in the research may have been perceived as having potential conflicts of interest or consequences which may have been negatively perceived by the participants. This risk was greatly reduced by both clarifying that the performance of the MHRA was not a line of inquiry for the study and by ensuring that the research was undertaken on an anonymous and confidential basis. Furthermore, the researcher anonymised any personally-identifying information, and where necessary to use direct quotations in the reports or publications, they were edited in such a way as to protect the identity of the speaker.

The principle of informed consent was strictly applied in this research. For the interview study a signed informed consent form was obtained before each interview. For the survey questionnaire, completion of the questionnaire which was accompanied by an explanation of the nature and purposes of the study was considered informed consent. Giving informed consent does not mean giving up the right to privacy. Anonymity and confidentiality were the two main ways privacy was maintained (96). Also, all studies in this research were approved by University of East Anglia Faculty of Medicine and Health Ethics Committee (Appendices 1.1, 2.1, 3.1 and 4.1), no NHS ethical approval was required in this research.

### **3.7 Conclusion**

The current study needed to describe and understand the process of the developing, implementing and evaluating an anti-counterfeit medicines strategy as well as describe

and understand the views of pharmacists and GPs on their roles in combating counterfeit medicines. This chapter presented a detailed description of the research methodology used in this research and set out the key methodological choices made in order to arrive at a research design which matched the objectives of the research. After discussing the researcher's epistemological standpoint and the choice of a post-positivist approach, this chapter justified the choice of a mixed qualitative and quantitative design for this research based on the need to collect and combine findings from data from different samples in order to present a complete picture of the processes involved in developing, implementing and evaluating a national anti-counterfeiting medicines strategy and also to understand the views and describe the roles of pharmacists and GPs in combating counterfeit medicines. The main determining factors in the research design were the nature of the findings which needed to be generated. While the data from the MHRA representatives and the MHRA stakeholder participants needed to be rich and more nuanced and did not require generalisability, the data from the health professionals needed to cover a wide range of issues uniformly and with a reasonable degree of generalisability. This study was therefore designed to employ both qualitative and quantitative data collection techniques, specifically face-to-face interviews and a questionnaire survey.

# ***Chapter 4***

## ***The MHRA perspective on developing an anti-counterfeit medicines strategy***



## **4.1 Introduction**

In this study, the qualitative data collected from MHRA representatives is highly relevant to addressing the research problem because the participants can be viewed as experts capable of offering important insights into the processes of developing, implementing and evaluating an anti-counterfeit medicines strategy. Furthermore, their organisation has already developed two such strategies and could form a template for other countries. There are, however, certain gaps in knowledge concerning the development, implementation and evaluation of the MHRA's strategy, and the study described in this chapter is intended to go some way to filling these gaps.

The UK's Medicines and Healthcare Products Regulatory Agency (MHRA) is a government agency that is responsible for regulating all pharmaceutical products, medical devices and blood components for transfusion in the UK to ensure these products are safe and effective for consumers. The participants for this study were therefore staff and managers working at the MHRA whose place in the divisional structure of this organisation will now be described to provide context for the study. The MHRA also protects the public from the risks that are associated with medicines; including illegal and counterfeit medicines. The MHRA evaluate the risk-benefit ratio of products to ensure the benefits of the pharmaceutical products and medical devices justify any risks. To fulfil its responsibilities, the MHRA is divided into nine divisions: inspection, enforcement and standards (IE&S) division; licensing division; policy division; vigilance and risk management of medicines (VRMM) division; communications division; devices division; operations and finance division; human resources division; and information management division.

### **1. Inspection, Enforcement and Standards Division**

This division is responsible for ensuring that the manufacture and distribution of medicines in the UK complies with the required standards. To ensure compliance, it subjects all UK manufacturers, wholesalers and medicine importers to licensing and inspection. The process involves examining clinical trials and toxicology laboratories. The Inspection, Enforcement and Standards (IE&S) division collects information about and examines potentially illegal advertising, manufacture, importation and sale or supply of human medicines. This can also lead to related activities, which sometimes extends to taking legal action. The IE&S division is also responsible for providing

services to the agency for laboratory testing, for distinguishing between medicines and products, assessing the import of unlicensed medicines, and ensuring that suitable actions are taken after any reports.

## 2. Licensing Division

Many responsibilities fall under the scope of the licensing division which focuses on examining and accepting or declining applications for marketing authorization for medical products, new methods of administration or new formulations for current drugs, generic drugs, parallel import applications, and non-safety variations to active licenses for medicinal products. It also has the responsibility to examine various medicinal products, which include high tech biotechnology product applications, chemical medicinal products, homeopathic and herbals. Its licensing responsibilities include those for examining and authorising clinical trials.

## 3. Policy Division

The policy division works with the other divisions to ensure the agency's regulatory and public health mandate aligns with the external environment in which the agency works. The division works across the agency co-ordinating its regulatory approach and responding to developments. It also coordinates the agency's EU and international business and its corporate strategy.

## 4. Vigilance and Risk Management of Medicines Division

The objective of the Vigilance and Risk Management of Medicines (VRMM) division is to protect public health by ensuring the safety, quality and efficacy of marketed medicines. The work of the division involves several inter-related functions including pharmacovigilance and pharmacoepidemiology, research and intelligence, benefit-risk review, access to medicines. This division's responsibilities include ongoing vigilance in monitoring any health risks presented by marketed medicines.

## 5. Communications Division

The communications division helps towards the agency's mission to safeguard public health, by ensuring that the agency communicates in a clear, accurate and timely way with all its stakeholders. The division has an enquiry line to provide information to the patients, public and others who have an interest in the MHRA's work. It also maintains a publicly available internet website including detailed information on medicines and medical devices and operates a 24-hour press office. This division runs conferences and

events to explain MHRA work with its stakeholders. It also carries out market research to assess the needs of the agency's stakeholders, and recommends actions to address those needs.

#### 6. Devices Division

This division is responsible for all medical devices manufactured or marketed in the UK. All reports of illegal incidents involving such devices are made to the devices division. These reports are received from different parties including the UK National Health Service (NHS), private hospitals, care homes, manufacturers and from the public. The division gives healthcare practitioners adequate advice to make better use of devices and ensure safety.

#### 7. Operations and Finance Division

All of the agency's financial activities are controlled by this division. It assists the agency by ensuring customers are having value for money, distributing information, advice and assistance on financial issues. This division cooperates with other divisions of the agency to develop its own budgets. It will also assess and report on monthly budgetary performance and publishes accounts.

#### 8. Human Resources Division

In cooperation with MHRA managers and staff, this division provides professional human resources services such as continuous learning and development culture.

#### 9. Information Management Division

The responsibility for information management lies with this division. It entails the development and conducting of all aspects of the agency's information management strategy, like e-Business and the General Practice Research Database.

Some of these divisions might therefore have more or less direct involvement in the activities conducted by the MHRA to combat counterfeit medicines such as the IE&S division; whereas, some divisions might have a lesser degree of involvement in these activities, for example the policy division. Therefore, the view of participants from such divisions could be very helpful in developing a 'big picture' understanding of the process from the strategy development to the evaluation of an anti-counterfeit medicines strategy. Also, gaining their definitions of the function and duties of the MHRA's divisions could help build a more precise understanding of their view on how such a

strategy would be implemented. It is from the above described organisational structure that two anti-counterfeit medicines strategies have emerged in the manner now described.

In 2007, the MHRA published its first strategy to combat counterfeit medicines in the UK that covered the period 2007-2010. The MHRA titled it “Anti-Counterfeiting Strategy 2007-2010”, and it aimed to reduce the risks to patients and consumers in the UK from the threats posed by counterfeit medicines while increasing the risk to those behind this illegal activity. This strategy was based on three main streams of activity: communication, collaboration and regulation. Under this strategy the communication component was designed to reassure the public by providing it with timely, accurate information, as well as publicising contact numbers to report suspected incidents of counterfeiting. Collaboration was aimed at identifying products at most risk of being counterfeited, enabling resources to be targeted appropriately, ensuring timeliness of countermeasures by facilitating reporting and follow-up, and taking part in international initiatives aimed at combating counterfeit medicines. With the regulation element the MHRA aimed to disrupt the counterfeit medicines market and increase both the risk of prosecution and the severity of penalties for counterfeiting. Following its first anti-counterfeiting strategy, the MHRA published its second strategy called the “Falsified Medical Products Strategy 2012-2015”, which was also aimed at protecting the public in the UK from the threat of counterfeit medicines. Like the first strategy, this one comprised three main components: prevention, incident management and investigation. Through prevention activities, the MHRA’s objective was to reduce how many counterfeit medicines entered the regulated supply chain in the UK. The purpose of incident management activities was to make sure that reported incidents of fake or counterfeit medical products were investigated quickly and efficiently, with the main focus on reducing the risks to public health. Finally, the investigation component aimed to implement the investigation and when necessary deploy all available legislative powers to bring prosecutions against those responsible for the manufacture, distribution and supply of counterfeit medicines and other medical products (25, 39, 44, 82).

The literature review for this study found the UK’s MHRA to be the only national medicines regulatory agency that published an anti-counterfeit medicines strategy aimed at combating counterfeit medicines in a systemic manner. However, the process involved in the design, development and implementation of the strategy could not be

found within these publications. Such knowledge would be very useful for researchers into counterfeit medicines and policymakers in government or government agencies in other national agencies trying to introduce their own national strategy in this area. Furthermore, the reviewed publications omitted describing the desired outcomes from implementing the strategy something which would have been useful in devising suitable evaluation criteria. The setting of outcomes and their evaluation would enable the government, the agency, its stakeholder and the wider public form an opinion as to the effectiveness of the strategy. By clearly describing and explaining reasons for and experiences of the MHRA's process of developing, implementing and evaluating its strategies from an insider viewpoint, one of the objectives of this study, an important research need would be satisfied.

## **4.2 Aims and Objectives**

The aim of this study is to gain a better understanding of the views of MHRA managers and staff on the anti-counterfeiting strategies of the MHRA successively published in 2007 and 2012, by exploring their views on its processes from development to evaluation.

Therefore, the objectives of this study in relation to an anti-counterfeit medicines strategy are:

- to explore the drivers for the development and implementation of an anti-counterfeit medicines strategy.
- to describe an agency's process for development of its strategy.
- to describe the processes through which a medicines regulatory agency implements its strategy.
- to explore the likely form of the engagement with and involvement of stakeholders in the process.
- to describe the strategy outcomes and how these should be evaluated.

## **4.3 Methods**

Face-to-face interviews were conducted with key persons from the MHRA to understand the perspectives from inside this organisation. This study focuses on gaining a more complete and complex understanding of the counterfeit medicines issues by drawing on the experiences of key participants at the MHRA through exploring their views on the issues associated with the anti-counterfeiting strategies of the MHRA and particularly on how such a strategy should be developed, implemented and evaluated including the participant perceptions of the roles of pharmacists and general practitioners (GPs) and other stakeholders. In this study a qualitative approach was selected to facilitate the collection and analysis of rich data, comprising their views and experiences which facilitates the highlighting of key values, and relevant language used, which in turn enables the generation of conclusions and recommendations (96).

A semi-structured interview format was adopted as it offered participants the flexibility to pursue their own threads of thought, something important because of the exploratory nature of the study. The interview questions combined main questions asked of all interviewees with a set of sub-questions pertinent to each interviewee; using a question topic guide (Appendix 1.2). This approach gave the researcher more flexibility over the order for asking the questions and for pursuing topics of importance to each interviewee. The research question guide included the research questions designed to explore the knowledge, experiences and opinions of the participants relating to their strategy for combating counterfeit medicines. The researcher also referred to a set of optional sub-questions that could be used flexibly during the interview to clarify or gather more details on a certain point where the researcher saw the need to gain a deeper or more contextual understanding of that issue.

### **4.3.1 Participant recruitment**

The main aim of this research was to explore the knowledge, experiences and opinions of key personnel from the medicines regulatory agency with respect to a strategy to combat counterfeit medicines. Starks and Trinidad (2007) argue that a purposive sampling method is suitable for recruiting participants who have experienced the

phenomenon under study (124). This research therefore recruited key personnel from the MHRA, who were organisation members in a position to have an overview of the work conducted by their agency, which could address the first objective of this thesis which was to describe and understand the process involved in the development, implementation and evaluation of a national anti-counterfeit medicines strategy. The purposive sampling approach here therefore aimed to recruit participants from the senior echelons and non-senior of staff within the agency, who should then have been well-placed to assist in identifying all the factors and characteristics seen as important for the agency in developing and implementing their anti-counterfeiting strategy.

Mason (2002) states that sampling, data generation and data analysis are processes that should be conducted dynamically and interactively in order to develop a set of dimensions that focus on exploiting the participants' experience (in this context, experience of anti-counterfeiting) (106). The participants were key personnel within the agency who were linked to activities that have been, are being or are planned to be undertaken in combating counterfeit medicines in the UK. The participants were identified by the researcher from the MHRA's organizational structure and selection was based on their job description. However, some names on the proposed participant list were changed by decision-makers from the MHRA at the point of seeking approval of this study. The participants received and signed a consent form. A preliminary questionnaire was used to gather demographic data (qualification, age group, work experience, etc.) in order to ensure that the sample was as diverse as possible. The sample comprised both males and females, having various work experiences.

Eleven key personnel from the MHRA were successfully recruited for the interviews. All participants received the following:

- An invitation letter explaining the nature, aims and implications of the study (Appendix 1.3).
- An information sheet explaining the topic and organisation of the study, and its aims and intended outcomes, as well the implications of the study for the participants who wished to take part (Appendix 1.4).

- An Interview Consent Form to be addressed to the researcher, signed by the participant as confirmation that he/she has agreed to be part of the research (Appendix 1.5).

After a positive response from a potential participant, the researcher arranged the date and time for the interview with him/her in the agency's building.

## **4.2.2 Ethical approval**

This study was approved by University of East Anglia Faculty of Medicine and Health Ethics Committee (Appendix 1.1)

## **4.2.3 Research Questions Topic Guide**

The interviews with the MHRA personnel covered eight broad questions (Appendix 1.2); six of these (Questions 2 to 7) focused on the core topic of the interview, and were designed to reflect the aim of the study. However, the researcher had other sub-questions to be asked during the interview depending on the flow of the interview.

These questions and sub-questions were developed by the researcher to comprehensively cover factors relating to the MHRA's strategy to combat counterfeit medicines. However, the research team recognised that new factors might be added to this research following the interviews, depending on what the researcher learned.

The first question in the interview "Can you please tell me about your role" was the opening question for the interview. The objective of this question was to give the participant the opportunity to talk about his/her responsibilities and experiences in the agency. Also, it informed the researcher of how long he/she had been in their current position to assist the researcher in identifying how the participant is linked to the various counterfeit medicine issues. Also, a personal opinion of the participants regarding the counterfeit medicines issues was asked as a warm-up for the main interview questions.



The second question in the interview was the first question directly addressing the main research topic, aiming to elicit the participant's understanding of how the agency views the counterfeit medicines issue. These MHRA participants were employed at about the time when the first strategy was developed. The researcher attempted, through the sub-questions, to explore any relevant areas not spontaneously offered by the participants and to cover the factors that assisted in developing the views that had evolved inside the agency and assisted in identifying the precise factors that motivated such an agency into combating counterfeit medicines. This also pursued whether there were any changes in these motivation factors between the first and the second anti-counterfeiting strategies.

The third question was aimed at gaining an overview of how the first MHRA anti-counterfeiting strategy was formulated. The sub-questions highlighted the departments that were involved in the formulation process and why these departments were chosen. Moreover, as the MHRA's Anti-Counterfeiting Strategy 2007-2010 was divided into three branches (Collaboration, Regulation and Communication) while the MHRA's Anti-Counterfeiting Strategy 2012-2015 was divided into three different branches (Prevention, Incident management, and Investigation), the sub-questions attempted to clarify why these branches were chosen. Also, the sub-questions allowed the participants to talk more widely about the process of formulating the strategy.

The fourth question focused on the implementation process of the counterfeit medicines strategy. The sub-questions sought to identify the departments that were involved in the implementation process; as well as, it identified what the participant thinks about the involvement of these departments and allowed him/her to talk about the factors that led to this selection. The sub-questions addressed the department managers' general responsibilities in the implementation process.

One branch of the MHRA's Anti-Counterfeiting Strategy 2007-2010 was related to communicating with health professionals. Question 5 focused on the roles designed for pharmacists and GPs in the strategy to combat counterfeit medicines. The sub-question aimed to illuminate the way in which the MHRA communicated this role to them and what the participants thought of this communication. Besides these issues, the roles of other stakeholders were addressed in this part of the interview, including the manner in which those roles were communicated to them.

The sixth question related to the outcomes of the anti-counterfeiting strategy. In this, the researcher wished to identify the expectations of the MHRA toward the strategy. In the sub-question, the researcher emphasised the types of outcome that were expected and described by the participants.

The seventh question was the last question pertaining to the core topic of the interview and explored the evaluation process relating to the outcomes of the strategy. The sub-questions led the participants to comment on the criteria that will be used to evaluate the outcomes and the selection methods for these criteria. Moreover, the sub-questions allowed the participants to talk about the department responsible for the evaluation of and the justification for its selection. A sub-question was asked about the evaluation results of the MHRA's Anti-Counterfeiting Strategy 2007-2010.

Question 8 was the final question and was designed to give the researcher the opportunity to thank the participant for his/her time and to give the participant the opportunity to add more information or comments. Also, if the participant had any questions relating to the interview or the research, he/she was given an opportunity to put them to the researcher. Then, the researcher ended the encounter.

#### **4.3.4 Data analysis**

The data collected in this study were the spoken words of participants from the MHRA. Semi-structured, face-to-face interviews, with their use of open-ended questions, typically generate high volumes of data and as the participants can be considered experts in the field being studied the data collected could be expected to be highly relevant. With this in mind, a data analysis method was required which would enable the researcher to manage the data and also summarise and synthesise it, but do so in a transparent and systematic way. Resources on qualitative data analysis were consulted before the framework analysis approach was chosen (94, 96, 119). The framework analysis approach is now widely used as a means of analysing primary qualitative data, particularly when relevant to policy making (116). The approach has been highlighted as appropriate for research which has specific questions, a defined and limited timeframe, a sample which is pre-designed (e.g. "professional participants") and *a priori* issues identified from the outset as requiring to be addressed (115). However, the

researcher, as in most qualitative approaches to analysis, analysed the data by identifying the themes that emerged from the interviews. The further developed analysis, relating to the range of themes, was used to generate a theory relating to the anti-counterfeiting medicines strategy from the perspective of key personnel from the MHRA. The researcher anonymised any personally-identifying information, and where it was necessary to use direct quotations in the reports or publications, they were edited in such a way as to protect the identity of the speaker.

Nvivo software was used for data analysis; the data transcripts were entered and then the software was used to generate codes from the data transcripts, which were subsequently grouped those codes. Then the researcher generated the themes emerged from the data manually. The researcher developed the themes from the codes that emerged from the software, thereby becoming more engaged with data, which greatly assisted the researcher in the data analysis phase. The codes generated and the themes emerged from that data were reviewed and supported by the supervisory team.

### **4.3.5 Researcher training for interviews and on-going support**

To enable this research, the researcher was enrolled on the research methods courses that provided by Faculty of Medicine and Health Sciences, University of East Anglia. In addition, the researcher attended skills-specific qualitative research methods short courses, organized by NatCen Social Research Centre, focusing on interviewing methods. The researcher was actively supported by the supervisory team to ensure appropriate and accurate interview management and transcription from the outset.

### **4.3.6 Structure of interviews**

It is important to ensure that the interview organisation can encourage an in-depth, freely-expressed discussion of sensitive issues. The researcher therefore conducted the interviews in a private room in the MHRA building at a time when the interview was unlikely to be interrupted. The interviewers had been ask for permission to audio-record the interview (an interview consent form have been signed by all participants).

## **4.4 Results**

This study included eleven key personnel from the MHRA, at different employment levels. A data saturation was reached from the semi-structured interviews lasting for up to 90 minutes were conducted with them by the researcher at the participants' workplace building in London, UK. The study results started by exploring the participants' views about the counterfeit medicines circumstances in the UK before the anti-counterfeit medicines strategy. Then, the drafting and implementing of an anti-counterfeit medicines strategy were highlighted by the participants. Also, the study addressed the role of pharmacists and general practitioners (GPs) as well as other stakeholders in combating counterfeit medicines. Finally, the views of participants on the outcomes from an anti-counterfeit medicines policy and the methods used to evaluate those outcomes were discussed.

### **4.4.1 Understanding the MHRA position before the anti-counterfeit medicines strategy**

To understand the context in which an anti-counterfeit medicine strategy could be developed, the overall environment surrounding the decision-makers at the MHRA needed to be understood. The study therefore started by exploring the participants' views regarding the counterfeit medicines issue, and then moved to find out how the problem of counterfeit medicine in the UK was perceived before the strategy was introduced. The participants then described the factors that they thought had motivated the decision-makers at the MHRA to develop an anti-counterfeit medicines strategy. They highlighted the factors that they perceived as key to the published strategy and discussed whether, in their view, there had been any changes to those factors between the first and the second of MHRA anti-counterfeit medicine strategies. The participants also described the limitations that they thought the agency encountered at the time the anti-counterfeit medicine strategies were being developed.

#### 4.4.1.1 Individuals' views on counterfeit medicines issue

The participants explained their perceptions of the effects of counterfeit medicines on the public and on the health system drawing on their views regarding both its relevance and its prevalence in the UK pharmaceuticals market. They were able to express their views on the responsibility and reaction of the MHRA regarding this problem.

The participants who voiced their perceptions of the effects of counterfeit medicines expressed strong feelings on the issue, all arguing that it represented a risk to public health and that it was innocent consumers who suffered the most from counterfeit medicines, and could potentially die as a result of consuming them. This feeling was consistently expressed at all levels of professional positions at the MHRA. The risk to the public from counterfeit medicines was seen by many participants as arising because such medicines were manufactured and distributed in conditions unregulated by the regulatory agency; also, these products may have contained ingredients that had not been approved by the agency. The perceived risk arising from such lack of control was clearly stated by one of the senior managers within the MHRA:

*“Counterfeit medicines are by definition a risk to public health. They’ve been made in conditions that are uncontrolled, so they can contain impurities. They can be defective because of the uncontrolled conditions of the manufacture, but they will also on occasions contain the wrong active or no active or the wrong amount of active substance..... They’ll have been distributed under uncontrolled conditions” [MM09]*

Also, some participants considered that counterfeit medicines would affect the trust of the public in the health system.

*“It undermines the trust in the system, it undermines trust in pharmacists and doctors; it undermines trust in medicine.” [MD11]*

One participant qualified this by suggesting that the seriousness of the potential problem depended on the type of medicine, and whether or not it was categorized as being for a life-limiting condition or for a non-life limiting condition.

*“It depends on the medicine. I think if the counterfeit medicine is for a life-limiting condition then I think that’s pretty unforgiveable to manufacture*

*and sell that type of medicine. I think if it's for a non-life limiting condition then I would consider it to be similar to a counterfeit DVD or watch or something similar or counterfeit Coca-Cola or something else.” [MC04]*

The appearance of counterfeit medicines in the UK in the past was understood by most of the participants as starting with rare cases in the legitimate supply chain and then growing into a significant issue. It was seen as increasingly serious because now counterfeiting occurs with all kind of medicines.

*“They tended to be lifestyle drugs but we've seen over that time a move into mainstream drugs, including things like anti-schizophrenics and cancer agents.” [MP09]*

All the participants felt that combating counterfeit medicines was a central aspect of their work within the MHRA and took their responsibilities in doing so very seriously. They emphasised the need to work in a well-structured manner and to work together to safeguard the public from counterfeit medicines and prevent their spread as much as they could.

*“It's probably the most important aspect of it we deal with at the MHRA because our objectives are to safeguard public health and I would imagine that's the worst possible scenario where people are trying to counterfeit legitimate medicines.” [EP15]*

Participants emphasised their common belief in the dangers of counterfeit medicines to consumers and since it become a major issue they felt it had become an important task for the MHRA to tackle.

#### **4.4.1.2 MHRA views on the problem of counterfeit medicines in UK before the strategy**

The participants tried to explain how the counterfeiting problem was perceived as increasingly recognised by characterising a previous general attitude denial and a widely-shared feeling that everyone could have confidence in the supply chain because it was adequately overseen by the regulators. The participants described a change for the

worse of the appearance of counterfeit medicines in the UK market and the reaction of the MHRA to that change.

This earlier attitude of denial was shared by the regulators and many within the industry, according to the participants' interpretation of the situation. Most participants commented that no one spoke of the issue of counterfeit medicines in the UK or indeed in the Western world, believing that such harmful practices only happened in Africa and Asia.

*“In the past there was a perception that counterfeit medicines did not exist in the UK or European marketplace. So, within the MHRA, there was denial about counterfeit products.”* [SM04]

A few participants believed that the main focus of the MHRA at that time was on testing the quality of generic drugs against a brand leader, but there was no testing for illegal/counterfeit products. They also identified reluctance among regulators to recognise counterfeit medicines as a problem because they felt that they had a very well regulated system in the UK and that many within the MHRA lacked adequate knowledge of counterfeiting practices.

*“Also, because there was a lack of knowledge and also there was perhaps a feeling of if we ask too many questions we might get answers that we don't want to hear.”* [MI09]

Denial was not only prevalent for regulators; it was also widespread within the pharmaceutical industry. The participants commented that the branded pharmaceutical companies appeared to them as being in fear of their products' reputation from the bad reputation that might affect their brand from the counterfeiting. Therefore, those companies were dealing with any case of counterfeiting in a secretive way and not sharing information about this with the regulatory agency.

*“The industry was in denial as well because they didn't want adverse publicity; they didn't want to risk their reputation. If they did find counterfeits they'd keep it quiet, keep it to themselves, they didn't want anybody to know”* [SM04]

The regulator participants highlighted the feeling of confidence in the UK supply chain they perceived at the agency, saying that this was because of the regulatory system that was then in place; that the supply chain was secure, that MRHA conducted inspections regularly, and that therefore counterfeit medicines would not be found in pharmacies. Also, some participants recalled that in the past the regulatory agency believed if there had been any cases, it would have been reported by companies or through the patient or health professionals directly to the MHRA, so the agency will know about it.

*“If there were wide-scale counterfeits, we would know about it because MHRA have a very well developed adverse drug reporting system (called the Yellow Card System, which has been operating for 45 years), which is an adverse reporting system not just from healthcare professionals but also from the public; they can report directly into it.” [MM09]*

All participants stated that they believed that the MHRA decision-makers thought counterfeit medicines cases were limited to the internet market and possibly to non-licensed markets such as pubs and nightclubs. Therefore the decision-makers had a feeling that such medicines would not be seen in regulated supply chain.

*“MHRA were aware that that the online market existed but we didn’t necessarily perceive it to be a huge problem in getting into genuine wholesalers and genuine pharmacies.” [MC09]*

According to the all participants, a wake-up call for the MHRA came when a number of counterfeit products suddenly appeared in high street pharmacies. In 2005, the MHRA decision-makers realized that the UK pharmaceutical market had changed and they began finding cases of counterfeit medicines in the regulated supply chain; also, these cases were on the increase.

*“Prior to 2005 there was almost nothing ever detected of counterfeit medicines, then, between 2002 and 2007, we had a succession of cases of identified counterfeits in the UK supply chain. So almost nothing and then 14 cases (in the legitimate supply chain) in 4 or 5 years and we could see that this was a new position in the UK.” [MM09]*

The participants said they felt that the MHRA decision-makers then assumed that the problem of counterfeit medicines in the UK market would only grow, so that the



MHRA had to take the issue much more seriously. All participants thought that the MHRA had sufficient resources and an effective team that could start combating the problem before any other country.

*“MHRA have a very well-developed fraud team here and enforcement team and a big inspectorate. And because of that, MHRA became aware in the UK of the possibility that there were counterfeit medicines out there before a lot of other member states did.” [SC15]*

Participants perceived the MHRA as proactive and started to combat counterfeit medicines in the UK even before a strategy had been developed. Participants across all employee levels specifically stated that some initiatives were undertaken by the MHRA to tackle the issue even though they were not structured into a cohesive strategy.

*“Between 2004 and 2007, MHRA had, like, an informal in-house anti-counterfeit strategy, if you like, so we had various areas of work which we were doing as a result of counterfeited cases.” [MI09]*

Overall, from the viewpoints of the participants, in the past there appeared to have been common denial across the regulatory agencies and pharmaceutical industries in western countries. This was explained by the perception of having a good supply system and effective reporting system in these countries; and furthermore for protecting the product image by pharmaceutical companies. Also, there was a belief among the decision-makers within the regulatory agencies that the counterfeit medicines cases were limited to the internet and non-licensed channels. Once the MHRA found counterfeit medicines in the regulated supply chain in the UK, the MHRA started to take this seriously as a threat to public health and then launched activities to combat counterfeiting which began a few years before the strategy had been devised.

#### **4.4.1.3 Motivating factors in creating an anti-counterfeit medicines strategy**

To help consider what motivated decision-makers at the MHRA to develop a strategy to combat counterfeit medicines, the participants were asked to identify reasons for their decisions. Participants considered some of these motivating factors as external ones, whereas other factors were driven from within the MHRA as internal factors. Also, the

participants expressed how they thought these motivating factors affected the strategies developed. Finally, the participants described how they thought such motivating factors may have changed between the first and the second MRHA anti-counterfeit medicines strategies.

The external motivating factors described by the participants as informing decisions to develop the strategy, were the appearance of the counterfeit medicines cases, the agency duty to protection of the public, securing the supply chain, and pressure from stakeholders. Most participants considered the increase in the number of counterfeit cases found by the MHRA (or reported to them) in the UK's legitimate supply chain as the most important motivating factor.

*“Quite a lot of cases in the UK where they have actually reached the legitimate supply chain. So that was a driver really, to look at the resources and see if any more needed to be put into it, as a result of that, the strategies were developed.” [MP09]*

Other external motivating factors mentioned were the responsibility of the MHRA to protect public health and to secure the pharmaceutical supply chain in the UK. Moreover, some participants argued that some pressure from stakeholders on the MHRA in the form of inquiries as to how those stakeholders could protect themselves from counterfeit medicines had required the MHRA to do more to fight counterfeit medicines in the UK, something eventually leading to the production of the first strategy.

*“We faced questions from our Minister; parliamentary questions were being asked as well; and quite rightly, the members of the public, and the press. Also other stakeholders were then asking us the same questions. Wholesalers were also starting to ask, probably more from a point of view of 'how do we protect ourselves'.” [MI09]*

On the other hand, another group of participants thought that the MHRA's decision-makers did not develop an anti-counterfeiting strategy because of being exposed to pressure from the stakeholders but rather that this was driven by internal factors.

*“No, I wouldn’t say there was any pressure from stakeholders – media, industry, wholesalers, the Government – on MHRA to fight counterfeit medicines.” [EP15]*

The internal motivating factors participants mentioned included the personality of the MHRA’s staff at that time and the support they had from senior management and persistent key individuals; they also thought the decision-makers saw the MHRA as holding a leading position worldwide.

*“The personalities of the people who drove the anti-counterfeiting strategy; we had some very good people and they saw what was going on, they saw the risk to public health, not only in the UK but worldwide, and they drove it through. So it was the persistence and the professionalism of a few key people within MHRA that drove it through, plus the backing of the board of directors, the executive directors.” [SM04]*

However, participants did not widely agree that the leading position of the organisation was a key motivating factor. Some participants thought that it was a factor in developing the strategy.

*“There’s certainly a pressure on the UK agency, as well on the US FDA, to try and drive the change forward because of the size of the agency and the respect we have within the regulatory authorities.” [MC04]*

Other participants did not think the leading position of MHRA had been a motivating factor for the decision-makers to develop such strategy.

*“There was no pressure on MHRA as one of the leading regulatory authorities worldwide to start developing a strategy. So, no any sort of signal coming down that ‘we’re the MHRA, we’re the leader, we need to deal with this’.” [MI09]*

All the participants felt that the motivating factors mentioned here were reflected in the strategy, and tried to highlight this by giving examples (as stated by some of the participants) from the strategy that supported their view.

*“It also talks about more international rules and actions that are supposed to strengthen the supply chain and as goods moving around from country to the end user. Then making it more difficult to get illegal medicines into the supply chain is a key thing, which is what ourselves and lots of the other agencies involved are thinking about.” [MC04]*

Some participants thought that there had been no changes in the motivating factors underlying the decision to develop the second strategy since the first strategy.

*“I don’t think there were any changes from that really. As I said, the second strategy document was just really an evolution of the first one.” [MP09]*

Participants perceived that counterfeit medicine cases in the UK supply chain, protection of the public health, securing the supply chain, and some pressure from stakeholders were the external motivating factors for MHRA decision-makers to develop an anti-counterfeit medicines strategy. The possible internal motivating factors mentioned were the personality of the MHRA’s staff, the management support and its world leading position. All participants felt that these motivating factors were reflected in the strategy while some saw no change in those factors between the two strategies.

#### **4.4.1.4 Limitations and boundaries on developing an anti-counterfeit medicines strategy**

To characterise what was said about the context for developing an anti-counterfeiting strategy, participants were seen to distinguish between the internal and the external limitations that decision-makers at the MHRA had to face when planning to develop the strategy. Most participants stated that the decision-makers had to deal with staff and resource limitations, a lack of communication and some resistance within the MHRA.

*“I mean obviously resources are limited and if you’ve identified a particular problem and you need resources to address it” [SC15]*

In terms of external limitations and boundaries, some participants stated that any regulatory agency should consider regional and international legislation and boundaries when developing an anti-counterfeiting strategy. Also, most participants thought a

regulatory agency needed support from other government agencies who may create barriers to effective actions and cooperation from the relevant industry.

*“There are certain areas where we might have wanted to do more but the legislation as it was then drafted from Europe wouldn’t permit us to do.”*

[SC15]

Some internal and external limitations and boundaries were seen to challenge the decision-makers in any regulatory agency when developing an anti-counterfeit medicines strategy. Participants considered such internal limitations were staff and resources, the lack of internal communication and resistance within the agency. They stated the external limitations were about dealing with regional and international legislation and boundaries, having support from other government agencies and from industry.

To summarize, participants described their perceptions of the context that the agency faced in deciding to develop an anti-counterfeit medicines strategy as a sense within the agency of the dangers of counterfeit medicines (to the public and to the health system) and its responsibility to tackle the problem. Also, participants said the denial attitude among the regulatory agency and pharmaceuticals industries and the believing in secure supply chain had been changed once counterfeit medicines had been found in the regulated supply chain. The MHRA started its activities to combat it even before the MHRA’s strategy developed. Thus, the agency started to combat counterfeit medicines activities by defining specific motivating factors (internally and externally) which led the agency to seek to develop an anti-counterfeit medicines strategy. Participants believed that decision-makers within an agency should understand its limitations when developing such a strategy.

#### **4.4.2 Drafting an anti-counterfeit medicines strategy**

The preceding sections have built some understanding of the overall environment surrounding the decision-makers at the MHRA for devising an anti-counterfeit medicines strategy, as interpreted by the participants. This section covers the process of drafting an anti-counterfeit medicines strategy, using the MHRA’s strategy as an

example. These participants described the process of drafting the MHRA's anti-counterfeit medicines strategy offering their thoughts for what they believed could be done to improve the strategy drafting process. Participants also highlighted the role of the MHRA anti-counterfeiting stakeholder groups. Finally, participants illustrated their views on any differences between the content of the first and second MHRA anti-counterfeit medicines strategy.

#### **4.4.2.1 The process of drafting an anti-counterfeit medicines strategy**

The actual process of drafting the first and second MHRA anti-counterfeit medicines strategy was described by only a few participants; however, the remaining participants did indirectly express some ideas about the drafting of these strategies. The department that led in drafting the strategy and the departments involved in the drafting process were illustrated by the participants. Also, participants identified the stakeholders who had a role in the drafting process and highlighted various aspects of the process.

A few of the participants who were not directly involved in the drafting process were able to articulate what they thought took place. All of these agreed that the responsibility of leading and drafting an anti-counterfeit medicines strategy should lie with the enforcement department within Inspection, Enforcement and Standards (IE&S) Division.

*“I think it was written mainly by the enforcement group” [MC09]*

Those participants nonetheless had varying views regarding the departments that were involved in drafting the strategy. Participants identified certain other departments within the IE&S division which were involved, specifically the Inspections Department as they were practitioners and they can reflect the situation in the field and secondly the Defective Medicines Report Centre as it received the reports for defective products. Also, other divisions within the MHRA were included; participants stated the Vigilance Risk Management of Medicines (VRMM) Division as it deals with reports received from the public and health professionals and can help in detecting the signals of any counterfeit medicine in the supply chain. The communication division was also mentioned as being part of the drafting in so far as they were responsible for the

communications delivered from the MHRA to its stakeholders. There was a mixture of opinions among the participants about what part was played by the policy division; some of the participants thought the policy division was part of the drafting process as they were perceived as playing an important role in it.

*“I’m just saying that drafting those sorts of documents is where the policy function skills should be brought to” [SC15]*

Other participants did not see the policy division as playing a part in drafting. However, on their view, the policy division had only viewed the first draft of the strategy and checked whether there were any legal conflicts in it. A final group of the participants did not see the policy division as having any role in the drafting the strategy.

*“Personally can’t see a reason why policy should be involved” [EP15]*

Some participants described stakeholders involved in the strategy drafting process as including representatives of the police, customs and pharmaceuticals industry. Others suggested that there were some other kinds of input as a consultation from similar national regulatory agencies and international pharmaceutical organizations.

*“I’m not quite sure and I would imagine they would have representation on our policy, you know, somewhere or another, I don’t know whether they come here or not but we will certainly seek their advice I would imagine” [MC04]*

The participants not directly involved in the drafting the MHRA’s anti-counterfeit medicines strategy appeared to assume that the drafting process was conducted by an internal committee within the MHRA. This committee was led by the enforcement department and included the departments that they mentioned before as having had a role in the drafting process. As described by the participants, this committee held initial consultations with industry and other stakeholders and asked for their input. This committee also conducted consultations between themselves and other divisions, then compiled the first draft and held the second round of consultations with industry and other stakeholders and took their feedback. Finally, the committee would complete the strategy and sent it to MHRA’s top management for approval.

*“I imagine we would have consulted with industry and the security people within pharma companies” [MC04]*

The actual drafting was described by only few participants, their account sharing some features described by those not directly involved in the drafting process. In drafting the MHRA’s strategies, there was no drafting committee organized by MHRA decision-makers for this task. Instead it was led and carried out mainly by a few people from the enforcement department within the division of Inspection, Enforcement and Standards (IE&S) as mentioned by participants describing the actual process of the drafting. Participants gave reasons for this as being that the anti-counterfeiting strategy deals with a very specific crime and the enforcement team has the ability to deal with it.

*“The drafting was by this Division [IE&S] because of the specialist nature of the content” [MM09]*

*“People in the enforcement group are from a law enforcement background ..... and we know what to look for to spot the indications of people that are counterfeiting” [EP15]*

Participants stated their understanding that the enforcement team had some input in terms of comments from other MHRA’s division and departments (the communication division, the inspectorate, the Defective Medicines Reporting Centre). The MHRA’s legal advisors also provided some legal consultation on the strategies. While the policy division within MHRA did not play a role in the drafting stage as mentioned by a participant; however, this participant believed that MHRA’s strategy was not therefore seen as suffering from this.

*“You might have expected that the drafting of a strategy like that would be done at least in close collaboration with the policy division. On this occasion it wasn't. .... However, this did not affect the document.” [SC15]*

The people who were drafting the strategy within the enforcement team were not seen as having consulted any stakeholders. Instead, the drafters identified the MRHA stakeholders in relation to counterfeit medicines during the drafting process. Those stakeholders were identified as the key pharmaceutical companies, the pharmaceutical organisations, and other UK law enforcement departments. Then, it was reported that



this drafting team tried to understand from their experiences the stakeholders' expectations of the MHRA in combating the counterfeit medicines issue in the UK and the elements in an anti-counterfeit medicine strategy those stakeholders expected to find in the strategy. The drafters also drew on the previous experiences of the enforcement department in drafting the strategy as highlighted by a senior manager.

*“What do they expect from us, what would they look for in a strategy, what do we need to communicate then, but it was very much ourselves drafting that”* [MI09]

Before the drafting process, the enforcement group were seen as already realizing that counterfeit medicines had become an issue in the UK which needed to be addressed. Participants mentioned most activities as included in the strategies had actually been put in place and begun to be used to tackle counterfeiting before the strategy had been developed. The people who were drafting the strategy reviewed and grouped those activities; organizing them in a structured way to build a strategy.

*“a lot of the processes we had already started, we just hadn't formalised them. So it was really a case of us looking at it, right what are we doing, why are we doing it, what is it achieving and let's draw those things into the strategy”* [MI09]

The first draft, as described by the participants, was then shared within the IE&S division, in particular the Inspectorate department and Defective Medicines Reporting Centre, for comments on the first draft. The drafters then sought evaluation feedback on the first draft and any amendments seen as necessary were implemented.

*“After the draft has gone out, ‘this is the approach we're taking to this’, you know. And their comments would come back, we'd make amendments”*  
[MD09]

The next step was for the drafting team to send out the strategy to the MHRA's senior executive team and non-executive board for approval and signing off and then to publish it. This process of the drafting the anti-counterfeiting strategy was seen to be repeated by the drafting team to the MHRA's first and second strategies.

*“The drafting of the first and the second strategies were following the same procedure” [MD09]*

Nonetheless, those participants who explained the actual drafting of the strategies also recommended potential improvements for developing an anti-counterfeiting strategy, in what they referred to as an ideal world. One idea was to set up a drafting committee which involved various key players within the regulatory agency.

*“It would be healthier if you had a small committee that sat from various parts of the agency to develop the drafting of the strategy” [MD09]*

Participants suggested that the members of this committee could be from various departments within the division of Inspection, Enforcement and Standards (IE&S) Division like the enforcement department, the inspection department, the laboratory department and, the Defective Medicines Report Centre. The committee could be joined by other divisions like pharmacovigilance division, policy division, and the communications division. They saw inspectors' input as needed because inspectors were the practitioners in the field and could help in many ways like collecting information and samples. The role of the laboratory would be to help to plan for the testing capabilities which would create an understanding of the best and quickest way of doing the analysis and sharing the results with other members. They saw policy involvement as needed to ensure the strategy was well written and raised no legal conflicts. However, this view of the role of the policy division in the drafting committee was not shared by all participants. Pharmacovigilance division input in the drafting was seen as valuable as reports of drug side effects come to them, and they could detect any signal suspicious counterfeit cases in the supply chain from these reports. Most participants recognised that help from the communications division in wording and writing the strategy could make it easy reading for the public and other stakeholders and in developing a simplified way to communicate it. In contrast, the communications division was seen as not having any role in the drafting stage particularly as the committee could involve lawyers to help at the drafting stage for the legal advices. The licensing division was also seen as helpful at the drafting stage to identify products which might be at high risk of counterfeited as seen by one participant. Participants believed the involvement of those departments and divisions in the drafting activities would increase the sense of ownership of the strategy.

*“I think it would engage multiple disciplines across the agency, because everyone has I suppose one part or several parts that they can bring together to help culminate and drive a strategy or produce a strategy”*  
[MC04]

Most of the participants said the chairing of the committee should be left to the enforcement department. One participant highlighted another view that the drafting committee could be led by the policy division. According to him this gives the enforcement department a more objective view as they are the most significant contributor and would be challenged internally about their thinking and their processes.

Participants identified stakeholders able to play an important role in drafting an ideal anti-counterfeiting strategy as pharmaceuticals manufacturers, wholesalers, distributors, brokers, and the pharmaceuticals importers, police and customs. Patient groups were also seen as having a role in the stakeholder group, as able to assist the committee in understanding the motive factors that encourage people to obtain medicines from outside the regulated supply chain and put themselves at risk in so doing, and if best methods of overcoming this behaviour could be included in the strategy. Participants stressed the drafting committee should have some degree of engagement with stakeholders. They suggested this would necessitate trust, sharing of information, working together, and understanding each other’s agenda and priorities. The drafting committee was seen as needing to undertake consultation and ask for input from stakeholders at the outset of the drafting stage. This initial consultation could be conducted by the chair of the drafting committee through meeting with each stakeholder group and asking them for their ideas. Participants also warned that open forum consultations involving all stakeholders could be risky because of conflicting interests among the stakeholders. After the initial consultation, the drafting committee would formulate the strategy and then request another round of consultation. Participants highlighted that the decision-makers should consider timing, resources, energy and effort needed when conducting a consultation in drafting anti-counterfeiting strategy.

These recommendations from those participants who played a direct part in the drafting of the MHRA’s anti-counterfeiting strategies echoed the views of other participants regarding the development of the MHRA’s first and second strategies. They underlined that the agency should have a committee to draft such a strategy within the agency

and of interacting with the stakeholders to understand their expectations and to learn from their experiences.

#### **4.4.2.2 MHRA's Anti-counterfeiting stakeholders group**

Some participants drew attention to the role of the MHRA's anti-counterfeiting stakeholder groups, which they thought could usefully play a part in the developing an anti-counterfeit medicine strategy. This was a group formulated and chaired by the Inspection, Enforcement and Standards (IE&S) Division; having started its work in 2006 before the first MHRA anti-counterfeit medicines strategy had been published. Its members were drawn from MHRA's stakeholders (branded pharmaceutical manufacturers, generic pharmaceutical manufacturers, wholesalers, importers and parallel traders) and representatives from MHRA (from enforcement, inspection, and laboratory departments); and representatives from UK's law enforcement agencies (from police and from customs). Pharmaceutical organizations were also represented in the group by the Pharmaceutical Security Institute (PSI) and the General Pharmaceutical Council (GPhC). The group was meeting twice a year, chaired by the enforcement department within IE&S Division.

*“an anti-counterfeiting stakeholders group had been formulated by MHRA. ....by 2005 (sic) the first meeting that was chaired by MHRA was started. The stakeholders involve in this group are UK-police, UK-customs, pharmaceutical manufacturers (branded and generic), wholesalers, importers” [MI09]*

According to the participants, the MHRA set up this group in order to build trust between the stakeholders and to exchange information and intelligence regarding the counterfeit issue in the UK and the wider world and furthermore, to target resources where the risk of counterfeit medicine was greatest. One participant saw an essential output from the anti-counterfeiting stakeholders group, as “a watch list of medicines”; a term used in the MHRA's strategy documents, as a key element for combating counterfeit medicines in the UK. The “watch list of medicines” usually comprised twelve or fourteen medicines at high risk of being counterfeited based on the most recent intelligence from the anti-counterfeiting stakeholders' group members. However,

one participant believed that the watch list was not as helpful as expected. He thought that the counterfeiters would shift their activities from the medicines on the list to other medicines.

*“if there’s a watch list of products I think the counterfeiters will turn to the other products not on the list” [MP09]*

Some participants saw the anti-counterfeiting stakeholders group formulated by MHRA can be helpful in the drafting stage of an anti-counterfeit medicines strategy. So during the initial phase of the drafting stage the drafting committee could request suggestions and input from that group. These suggestions can be used for drafting the strategy and then drafting committee could begin a wider consultation phase.

Some participants mentioned the MHRA's anti-counterfeiting stakeholders. This group was set up by the MHRA before its strategy was published with the objective to build trust and share information among stakeholders. Participants said an outcome from this group was used by MHRA in its strategy; and that this group could be more helpful in the drafting committee for an anti-counterfeit medicines strategy.

#### **4.4.2.3 The difference between the first and the second strategies**

Participants seemed to make very similar observations about what differences they recognized between the first and the second of the MHRA's anti-counterfeit medicines strategies. Participants had described the first strategy as the foundation that steered the direction of the agency whereas the second strategy was the development of the first one which was building on the resultant experience.

*“From my perspective it was always the first one that really steers the direction of the agency. The second one is just adding a bit of details” [MD09]*

All participants saw the key components of the two strategies as similar. However, participants considered the difference between the first and the second strategies were only in grouping and presenting of those activities within the strategy.

*“So I think it's, the activities are probably pretty similar, I think it's just the way of grouping them slightly differently” [MC04]*

In the first strategy, the three main elements were strands around communication, collaboration and regulation. At that time of drafting the first strategy, the MHRA was tackling counterfeit medicines which were something new in the UK. The MHRA's aim in terms of communication was to ensure stakeholders including both the public and healthcare professionals have sufficient information about counterfeit medicines, how to avoid them, and how to report any related suspicions to the MHRA. For the collaboration part MHRA focused on close working relationships with its stakeholders and other regulatory bodies to ensure an awareness and recognition of the threat from counterfeit medicines, and encourage collaborative working where appropriate. In the regulation part, the MHRA planned to conduct a threat assessment of the risk from counterfeit medicines and to prepare market surveillance projects. Therefore, it seemed sensible to participants that the strategy should be built around these three elements which would help the decision-makers to build more knowledge on respect of the counterfeiting in UK market.

*“In the first one we didn't know the extent of the problem. We needed to have a much better understanding of the counterfeiting business” [SM04]*

Some participants agreed that the first strategy provided more description of what the MHRA was doing to address the counterfeiting problem, some saw the second strategy as explaining more about why the MHRA was undertaking these activities.

*“the first strategy is more about actually the what we were doing – communicating, collaborating or regulating – whereas the second one is probably more to do with why we're doing it” [MI09]*

Some participants also highlighted some enhancements had been made in the second strategy in respect to the activities of the changes relating to the supply chain and more details had been added to the incident handling, and financial investigation activities due to the international nature and the international implications of the counterfeiting medicines crime which had developed from the experience of the MHRA in applying the first strategy.

*“So a lot of the strategy is similar, we've just fine-tuned it, but incident handling was the big thing we wanted to point out, and also we wanted to point out the financial investigation and we increased our capacity to do financial investigations.” [MI09]*

Participants believed the first anti-counterfeit medicines strategy was a milestone for the MHRA which directed the activities of the agency. The main activities within the first and the second MHRA's strategies were viewed as the same, however, participants stated the grouping of those activities was different.

Summarizing participants' views on drafting an anti-counterfeit medicines strategy, only a few were directly involved in actually drafting the strategies, but the others had some indirect ideas about drafting these strategies. Participants involved in the drafting process offered some recommendations to improve the drafting of an anti-counterfeit medicines strategy which were reflected in ideas offered by the other participants. These suggested that the drafting process should be led by the enforcement department within the agency, and a drafting committee should be composed of members from diverse departments and divisions within the agency. They also thought the agency's stakeholders should play a consultancy role during the drafting of an anti-counterfeit medicines strategy. Participants stated that MHRA stakeholders, representatives from the MHRA, representatives from UK law enforcement agencies and representatives of pharmaceutical organizations were brought together to compose an MHRA anti-counterfeiting stakeholders group. An outcome from this group (“a watch list of medicines”) had been used in the anti-counterfeit medicines strategy; in addition, participants believed this group could play more roles in drafting the strategy. Participants believed the main activities to combat counterfeit medicine within MHRA's first and second strategy were the same, but that there were differences between both strategies in how those activities were grouped.

#### **4.4.3 Implementing an anti-counterfeit medicines strategy**

By 2007, the MHRA had approved, published and was implementing its first anti-counterfeit medicines strategy. This section examines participants' comments on the implementation of the first MHRA's strategy. They specifically identified the

departments responsible for directly managing and implementing it, those playing some role in implementing it, and the implementation process and their opinions on it.

#### **4.4.3.1 The departments leading the implementation**

A few participants said the overall ownership of the anti-counterfeit medicines strategy should lie with the top management of the agency as it is the agency's strategy and their success as an agency for combating the counterfeit medicines in the UK is bound closely to the success of the strategy. In relation to running and implementing the strategy, all participants stressed that the IE&S division particularly its enforcement department, should lead here with its head being mainly responsible for running it.

*“The implementation – the primary responsibility still stays within this Division [IE&S] and with the Enforcement group within this Division [IE&S]” [MM09]*

Participants explained their reasons for seeing it as essential for one person to be responsible for the implementation of the strategy because implementing this kind of strategy involved multiple departments could fail without communication between departments or the overall process could break down. This did not mean that the responsible person would do all the work, but would ensure that the strategy runs smoothly and there are good communications between the departments involved in the implementation.

*“this person is responsible’ and then they don’t necessarily do the work for the implementation but they liaise with the departments and make sure that they’re doing the appropriate work and communicating appropriately with one another” [MC04]*

Also, they saw implementing this strategy as requiring a person who fully understands the counterfeit medicines issue and understands what the agency is trying to achieve. Participants also selected the enforcement department to implement the strategy because many activities within the strategy seen by them are part of the enforcement department's duties and in general part of IE&S division duties.



*“the implementation I think would always come down to our IE&S division because we've got the biggest stake in it” [MI09]*

Furthermore, participants saw the IE&S division as having the biggest role in the strategy because this is the only division within the MHRA actually dealing with the medicines in practice, with the enforcement department which dealt most with incidents of counterfeiting that are reported to the MHRA, supporting participants' view of the enforcement department as the right department to implement this strategy.

#### **4.3.3.2 Departmental roles in implementation**

The anti-counterfeit medicines strategy was seen by participants as cutting across several departments within the agency, therefore besides the enforcement departments responsible for the implementation they thought other departments should have a role.

*“So within the agency I'd say most divisions have a role in making sure that the strategy is implemented” [SM04]*

They saw three other divisions as having relevant roles: the policy division, the communication division and pharmacovigilance division. In addition to those divisions, some other departments would have a more indirect role in the implementation as highlighted by the participants.

The policy division within the agency was seen as linking the MHRA with other government ministries, therefore their main task would be informing other government departments about the new regulations which would be applied by the MHRA to reflect the strategy.

*“the implementation of the strategy required changes to our guidance and to our legal position, then policy would be a key interface for doing that” [MM09]*

Also, participants believed if the anti-counterfeit medicines strategy needed any change in current legislation, the policy division would negotiate on behalf of the MHRA with other government agencies, so the change would support the implementation of the strategy.

*“Interviewer: you mentioned the Policy Division – is the Policy Division a part of the implementation?”*

*Respondent: Yes they are because where the implementation of the strategy required changes to our guidance and to our legal position, then policy would be a key interface for doing that” [MM09]*

Moreover, as the UK is a member of the European Union, changes to medicine regulations in UK must also be consistent with overall European legislation. Therefore, the policy division was seen as playing a significant role to make sure that any change to the MHRA’s medicine regulations as a result of the implementation were not in conflict with the European arena.

*“The other thing is that a number of these medicines have been European authorisations, not strictly UK so of course then that brings in the European element, the European Medicines Agency and those issues as well” [MP09]*

Participants saw the role of the Communication Division as being to support the enforcement department in implementing the strategy by communicating with the MHRAs’ stakeholders, raising public awareness and dealing with media in general.

*“the Communication Division has worked closely with us you know both in terms of for instance the public awareness but also Enforcement activity generates a lot more press interest and media interest than most other areas. So the Communications Division have supported Enforcement in its responding to television and radio and the press and so on” [MM09]*

However, they thought this role ought to be carried out in close contact with the enforcement department as the message may contain some words that are not suitable to the audience as participants highlighted. That is because the communication division does not have technical knowledge about the problem and therapeutic knowledge about potential impacts on the public. Therefore, within MHRA, the enforcement department was working very close with the communication division in the implementation of its role.

*“I mean I have seen cases where communications have been drafted initially by the press office but sometimes they contain content which is unsuitable,*

*you know, they might talk about tablets as being pills or they might dramatize the potential risks. The issue is probably that no-one in the press office is a pharmacist or a law enforcement person, they're communication people" [MP09]*

Participants described how the pharmacovigilance division (VRMM) dealt with reports via a system of 'yellow card' warnings sent from health professionals and the public to the MHRA. They can detect any flags or signals of any suspicion of counterfeit medicines from those defect reports or lack of efficacy reports which they receive and then report these cases to the enforcement department when they consider something unusual. Therefore, the pharmacovigilance division played an important role in the implementation of the strategy as described by the participants.

*"VRMM, they're the ones that may detect the signal of hang on a second we've got a batch that we're getting a lot of reports for lack of efficacy we need to make sure that that's flagged as a defective medicine, not necessarily a counterfeit, and then we would investigate or we would basically refer on to case referrals to look into further" [MC09]*

Participants also mentioned other departments could taking specific roles in the implementation of the strategy: the laboratory department helping through analysing the samples of suspicious items and by developing quicker and efficient techniques for analysis; the inspection department especially Good Distribution Practice (GDP) inspectors would be part of the hands on implementation as members of the MHRA working in the field and visiting pharmaceuticals warehouses view pharmaceutical shipments at first hand to see what is actually being traded, stored and distributed. Participants recognised that because of resource limitations, the inspectors only managed to obtain a snapshot of what was happening but they still felt this was valuable in monitoring counterfeit medicine cases, as those inspectors can evaluate how the warehouses following the MHRA's regulations and also can judge some of those warehouses need more monitoring.

*"It's only a very small snapshot because there's a limited number of them – but you know we can see and they can go and they can see maybe which wholesalers are less willing to follow the rules perfectly well and more*

*willing to bend them and then maybe we could be more suspicious about how those wholesalers may act” [MC04]*

Dealing with counterfeit medicine cases required the MHRA to undertake prosecutions as part of implementation, therefore, the finance department and government lawyers were also seen to play a role in the implementation as seen by participants.

*“Finance obviously have a role because we’re a very expensive division. When we’re doing a prosecution, a big prosecution, then we will have Queen’s counsel which is very very expensive, you know, it’s thousands and thousands of pounds” [SM04]*

Therefore, to sum up, the participants underlined their views about who could play a role in the implementation of an anti-counterfeit medicines strategy, namely the policy division, the communication division, pharmacovigilance division and the inspection and finance department as all important for implementation an anti-counterfeit medicines strategy.

#### **4.4.3.3 Implementation process of an anti-counterfeit medicines strategy**

Participants reviewed their perceptions of the managers' performance in the implementation process of the MHRA’s anti-counterfeit medicines strategy. Generally, all divisions and departments within the MHRA were reported as having to work through an annually-published business plan. That for the IE&S division had objectives fed through from the various departments within the division. The enforcement department's plan set out their intended objectives, some of which would relate to the implementation of the anti-counterfeit medicines strategy which would then cascade into the objectives of individual people within that department whose annual appraisal would review these objectives against their performance measured on meeting the objectives. Ultimately, the working out of the strategy was broken down into and dependent on specific tasks that individuals undertook.

*“Enforcement is a group within the Inspection, Enforcements and Standards Division – and Enforcement would publish a business plan each year which*

*indicates the actual objectives that they intend to complete within that year and a number of those objectives would relate to the implementation of that strategy and then that would cascade down to the objectives of individual people within that group and they would be subject to an annual review of their objectives and their own performance would be measured on the basis of those objectives and so on. So ultimately the outworking of the strategy ends up with jobs that individuals have to undertake” [MM09]*

However, for the implementation of the strategy to be agency-wide it was recognised by some participants that the implementation needed to be ‘joined up’ and communication between the departments with a role in the strategy was seen to be crucial; therefore, the whole agency would need to work together to combat counterfeit medicines; participants stressed failure to do so would mean that things can get lost and forgotten. As the enforcement department is responsible for implementation, the head of department’s success or failure depends not just on his or her own department but on other departments as well.

*“you need to make sure that, as a whole, you're all joined up so that you know the communication is there from the start is to, yes we’re going to run this strategy so we want to implement it so therefore you need to have that communication between each department, rather than ‘OK you work in a silo, you work in a silo, you work in a silo’, you're having that communication across the board” [MC09]*

To make sure the strategy was well implemented participants thought each department with a role in the strategy should have a contact person or project leader for the anti-counterfeit medicines strategy. Those persons should have regular meetings or even email communication for regular feedback and updates on the implementation to ensure continuous communication.

Participants who commented on the strategy implementation judged that the managers involved in the implementation of the first MHRA’s anti-counteracting strategy were working well. They justified this opinion by pointing out that members of the enforcement department had been asked to participate in conferences, workshops and symposiums to reflect the experience of the MHRA in combating counterfeit medicines; also that their European counterparts felt the need to adopt a similar approach to the

MHRA regarding combating counterfeit medicines. They saw also the decrease in the number of counterfeit medicines as an appropriate measure of the good implementation by managers.

*“I think we did well to implement the strategy”* [MI09]

*“I would kind of reference the activities at European level, the very strong belief that we had a very effective anti-counterfeiting approach”* [SC15]

To sum up, participants agreed that the implementation of an anti-counterfeit medicines strategy would be the responsibility of the enforcement department within the Inspection, Enforcement and Standards (IE&S) Division as having the main role and interest in the strategy with the policy, communication and pharmacovigilance divisions. In addition, laboratory department, inspection department and finance department could play a specific role in the implementation of the strategy. Participants highlighted the importance of communication between those divisions and departments to ensure effective implementing of an anti-counterfeit medicines strategy.

#### **4.4.4 Roles of pharmacists and general practitioners (GPs) and other stakeholders in an anti-counterfeit medicines strategy**

This section of the research findings will cover the contribution of the pharmacists and general practitioners (GPs) in combating counterfeit medicines as those who deal directly with patients. Participants described the role of pharmacists and GPs in an anti-counterfeit medicines strategy and roles which might have been played in the strategy by other MHRA stakeholders.

#### 4.4.4.1 Pharmacists and General Practitioners (GPs) and the anti-counterfeit medicines strategy

Participants' views on the pharmacists and the GPs roles in the strategy against counterfeit medicines have been addressed along with what decision-makers within an agency should consider when defining those roles and how those roles should be communicated to the pharmacists and GPs.

Some participants saw the role of the pharmacists and GPs in the strategy as rather limited, especially for the GPs because of their lack of physical contact with medicines. They also saw pharmacists and GPs as not having enough knowledge about the counterfeiting issue.

*“there is a lack of knowledge and understanding because most doctors don't handle the medicines themselves, they just write a prescription, they never see the medicines”* [SM04]

However, other participants said the pharmacists and GPs acted as gatekeepers to patients, so that their roles would in fact be very important in the strategy.

*“They have clearly a duty of care towards their patients or their customers . . . So I think they've got a very fundamental role in the whole work”* [MC15]

As a role pharmacists could play to protect patients from the counterfeit medicines, participants thought pharmacists should be vigilant about medicines' packaging and printing and to actively consider that those medicines about which they receive a complaint from patients might be counterfeited, after discounting other reasons.

*“we want them to think is I've looked at all possible other solutions, really can't work this out, maybe we should just consider if it's a counterfeit”* [MI09]

Another important role for the pharmacists mentioned by all participants was to be a source of reporting of any incident to the MHRA either as a lack of efficacy as a medicine or as a counterfeit case. The pharmacists could report to the MHRA through

the tools promoted by the MHRA which are the Yellow Card scheme, the MHRA's Counterfeit Hotline and the Defective Medicines Report Centre.

*“Pharmacists are involved in the sense that they are the final point often between the supply chain and the patient and Pharmacists need to be aware – to report any suspicions that they have” [SC15]*

They also thought it important for pharmacists to ensure that they sourced their medicines from a secured supply chain.

*“It's about ensuring that where they're sourcing their medicines from is reliable and trusted and probably authorised and a licensed source” [MD09]*

A final role identified for the pharmacists was to perform an awareness and advisory function for their patients, about buying from online sources or advising and reassuring the patient in the case of a particular medicine being recalled.

*“So I think they've got a very fundamental role in the whole work about you know buying medicines on-line and the dangers associated with counterfeit medicines” [MC15]*

Participants identified GPs as having a similar role to pharmacists again in terms of being vigilant for any suspicion of counterfeit cases reported to them by patients, also as a good source of reporting to the MHRA through the Yellow Card scheme, the MHRA's Counterfeit Hotline and the Defective Medicines Report Centre. GPs had a role as an awareness and advisory source for patients.

*“Doctors - we would see them as well as a potential reporting source” [MD09]*

Participants also raised points to be considered by decision-makers when defining the roles of pharmacists and GPs in combating counterfeit medicines. As participants generally saw the pharmacists and GPs as largely unaware and they needed better communication from the MHRA.

*“they've got to tell them more than once because those people I saw had never heard anything, they didn't have a clue what was going on” [EP15]*



Also, as pharmacists and GPs were considered by participants as very busy people they needed quick access to the information and more engagement from the MHRA.

*“For me it’s about quick access to the information that they need and in a format that they are most receptive to” [MC15]*

The requirement for patient-pharmacist and patient-GP confidentiality needed to be appreciated by the MHRA decision-makers including when pharmacists and GPs reported a case to the MHRA.

*“But if they were to give information regarding counterfeiting or any suspicions of counterfeiting, they need to be assured that it’s completely confidential. So they have to be given that sterile corridor to be able to talk to someone without any comeback on them at all” [EP15]*

Also, they believed that pharmacists and GPs needed to be confident that any case reported to the MHRA will be treated very seriously.

*“we have I think developed a more 24-hour approach to reporting incidents or sort of mechanisms that actually encourage people to report and encourage them to believe that we will take seriously what they have reported” [SC15]*

Finally, participants drew attention to the small but possible incidence of corruption among these two groups which they thought the MHRA needed to consider when deciding what information to share.

*“I’ve dealt with corrupt pharmacists- not many, obviously-, you know, who have dealt with counterfeit so you’ve got to be very careful what information you share” [EP15]*

Participants recommended a few methods of communicating their roles in the strategy to pharmacists and GPs. Participants said the media tools can and have already been utilised for this.

*“we use a number of what we call media tools to get information out to Healthcare Publications – so for example we might put out what we call it a press release to the Media to highlight to them a particular issue and we*

*send that from our own office via e-mail and that goes directly to the e-mail address of the journalist so that they get the information through that route”*  
[MC15]

Participants identified those media tools which could be used to communicate the roles of pharmacists and GPs to them as press releases to the general media or, being selective, to each professional publication like pharmaceutical journals.

*“we can be quite selective and say ‘right, there’s a real issue here for GPs to do x, y and z and therefore we may just contact the Trade Publications for the GP Media and get them in for a briefing or we may send information out to directly to them on e-mail”* [MC15]

They also thought MHRA’s website could be used by sending emails to the subscribers for MHRA news updates and using the local radio and newspapers, particularly those published in other languages.

*“I think local radio, local newspapers and because now of course you’ve got Polish newspapers, Spanish newspapers, all kinds of things”* [EP15]

However, the level of resource available to the agency was an important factor in using the media tools. Participants stressed that media tools were not guaranteed to provide the pharmacists and GPs with the messages that the MHRA would like to send to them as this was highly dependent on them reading these emails and also depended on the media to deliver the messages.

*“there’s no guarantee that they’ll cover the story or write a story about it or broadcast a story about it. So because clearly it depends on the news agenda of the day, it depends whether their editor likes it or not”* [MC15]

An additional potential method, participants suggested to be used to communicate with the pharmacists and GPs was working with their professional bodies (like the Royal Pharmaceutical Society) as they were responsible for regulating them and could be more efficient in delivering the messages. Participants saw working with the professional and regulatory pharmaceutical body as more effective than working with the equivalent GP body.

*“we don’t have responsibility for regulating either of those groups of people so we would work through the bodies that do regulate and to try get the message out, you know, that’s been more effective with the Royal Pharmaceutical Society than it has with GPs” [MD09]*

The final method mentioned by participants to engage with pharmacists and GPs was through the training tools as the issue of counterfeit medicines could be brought to pharmacists’ and GPs’ attention in e.g. undergraduate courses.

*“I mean I think as an undergraduate so you’re putting it on the radar of pharmacists at an early stage” [MD09]*

Participants thought the MHRA could contribute in delivering the message about the counterfeit medicines issue to pharmacists and GPs through other kind of training tools like workshops, conferences, seminars and forums organized by their professional bodies. They also saw the MHRA as able to work with professional bodies to make the counterfeit medicines issue part of their Continuous Professional Development (CPD) Programmes; as they have to participate in continuing professional development and they have to undergo an assessment by their professional body.

*“We could maybe do some kind of continuing professional development module for Pharmacists or Doctors because they all have to do CPD – some kind of regular development on the latest ways and key messages in anti-counterfeiting or something like that” [MC04]*

Participants had some concerns about the efforts being made by the MHRA to deliver the message on the roles of the pharmacists and GPs. They believed the pharmacists and GPs were not getting sufficient information from the MHRA and thought more effort can be made in this area.

*“they didn’t seem to get a lot of information really and I’m not quite sure how much information we give them. Which I don’t think is good enough really” [EP15]*

Up to this point participants were seen to describe the roles of the pharmacists and GPs in combating counterfeit medicines as about being vigilant for any suspicion of counterfeit cases, being a good source of reporting to the medicines regulatory agency

and having an awareness and advisory function to the patients as well as needing to source their medicines from the secured supply chain. Also, elements seen as needing to be considered for their roles were needing to counter their general unawareness of the counterfeit medicines issue by better communication from the medicines regulatory agency and quick access to the information, given their very busy routines. However, the medicines regulatory agency needs to show that it respects the confidentiality of the reporter, show the seriousness in dealing with this issue and the amount of information shared with the pharmacists and GPs regarding counterfeit medicines issue were also among those elements. To communicate their roles in the strategy to pharmacists and GPs, participants recommended using media tools, working with their professional bodies and training like undergraduate courses and CPD.

#### **4.4.4.2 MHRA's stakeholders and the anti-counterfeit medicines strategy**

Participants gave illustrations of their views regarding MHRA stakeholders in respect to the anti-counterfeit medicines strategy and their roles in combating counterfeit medicines in general and methods they thought could be used to communicate these roles to them.

Participants defined the MHRA stakeholders within the pharmaceuticals industry as manufacturers, wholesalers, distributors, brokers, parallel importers, importers and exporters together with the law enforcement agencies like police, customs and border agencies. Other organizations like the Pharmaceutical Security Institute, Interpol, the World Health Organisation, and the General Pharmaceutical Council were also identified as stakeholders. Furthermore, the broader UK government, MHRA's international counterparts, patient groups and transportation companies were added to the list of MHRA stakeholders. All these stakeholders were seen as being able to play various roles in the anti-counterfeit medicines strategy.

The roles that could be played by the stakeholders were highlighted by the participants as securing the supply chain, protecting public health, sharing information, reporting to the MHRA, being vigilant and working in collaboration with the MHRA. Participants thought manufacturers and traders working in the pharmaceuticals industries should

work together and with the MHRA to secure the medicines supply chain from the manufacturers to the patients.

*“our view is that all the stakeholders should do their bits to secure the supply chain ... everyone has to do their little bit to secure their part of the supply chain”* [MI09]

Participants also identified the MHRA as working with industry, police, customs, border agencies, and broader government in general in protecting public health.

*“The Police and clearly you know they have a role in protecting Public Health as well and we would work closely with them”* [MC15]

Sharing information between stakeholders was stressed by participants as being important. Some participants saw that MHRA as having a good record of cooperation and sharing information with industry, wholesalers, police, and custom, also organizations like the Pharmaceutical Security Institute, Interpol, the World Health Organisation, and the General Pharmaceutical Council.

*“the information you get and the more stakeholders and relevant stakeholders that you’re engaged with, the more little pieces of information you pick up that help you adjust to the way that these guys are operating”* [MD09]

Stakeholders were also seen as having a role to be vigilant for any suspicion of counterfeit cases so as to help secure the supply chain and protect public health. They saw all stakeholders with a role in the supply chain of the medicines, such as wholesalers or distributors, as needing to be mindful of the vigilance aspect of their work and to have training programmes for their workers on that aspect.

*“I suppose that the stakeholder side of things is more, kind of, the vigilance aspect of we know it. so I suppose it’s really around the vigilance side of things of, you know, wholesalers being vigilant of who they’re receiving product from”* [MC09]

Participants also identified reporting any suspicions or cases of counterfeiting to the MHRA as one of the stakeholders’ key roles. Stakeholders in the pharmaceuticals

industry like wholesalers and parallel importers might come across a case of suspicion of counterfeit medicines which they should report to the MHRA. They also believed that police and customs should report any case of counterfeit medicines beside the other medicine related crimes, to the MHRA. Also, as the medicines are transported through private companies, these companies would have a duty to report any suspicions to the MHRA.

*“there’s Transport Agency and stuff like that because, obviously, these products have to be couriered and transported around, so if there’s concerns with a transportation company, that they’re doing something that they shouldn’t be doing, then again they may be able to give us information”*  
[MC09]

A final role shared among all MHRA stakeholders, according to the participants, was to work collaboratively to help the MHRA to combat counterfeit medicines.

*“We work with other regulators because we don’t have jurisdiction in countries outside the UK but they do, so we’ll work closely with other regulators and we’ll work with groups like Interpol – which are international Police activities and we’ll work with people like the World Health Organisation who also has an international role. So dealing with pharmaceutical crime has to be an international, cross agency activity”*  
[MM09]

Participants thought that the MHRA could make use of the media to communicate the stakeholders’ roles and also that a manager from the MHRA could participate in stakeholder gatherings such as forums, or MRHA team members could make presentations to the stakeholders; so the message can reach to those stakeholders.

*“at an international level there would be the permanent forum on international pharmaceutical crime. We’d send a manager there to do that”*  
[MD09]

Participants defined stakeholders for the MHRA’s anti counterfeit medicines strategy as including the pharmaceuticals industry to other enforcement agencies and at the international level. They saw stakeholders’ roles as being to secure the supply chain, protect public health, sharing information, to be vigilant, reporting to the MHRA any

suspicious and working in a collaborative manner. Also, by using the media and engaging with the stakeholders, the MHRA could effectively communicate those roles to the stakeholders.

#### **4.4.5 Outcomes of an anti-counterfeit medicines strategy**

The MHRA had published its first anti-counterfeit medicines strategy in 2007 and the second strategy was published in 2012. These participants highlighted the outcomes that decision-makers in the medicines regulatory agency had or should have expected from an anti-counterfeit medicines strategy and how outcomes should be formulated in the strategy.

##### **4.4.5.1 Outcomes to be expected from an anti-counterfeit medicines strategy**

The participants described the outcomes that the decision-makers within an agency should be seeking from an anti-counterfeit medicines strategy. They stressed the importance of setting the objectives from the outset, as this would direct the efforts and resources to the said objectives and also publicly indicate that the agency is working hard to tackle the counterfeit issue.

*“it gives you, you know, you’ve then thought about in advance what you’re going to measure against and then it gives you something to focus your measurement against at the end” [MI09]*

The first outcome from the strategy highlighted by some participants was changing people’s behaviour and perceptions as an outcome from an anti-counterfeit medicines strategy.

*“..... to really try and help influence behaviour and you know change people’s perceptions if that’s what we want to do” [MC15]*

Participants appeared to understand that an agency needs to undertake many activities within the strategy to raise public awareness of the dangers of counterfeit medicines on

the consumer's health, including buying from un-regulated online sources. These kinds of awareness-raising activities should also be targeted at the agency's stakeholders and could be extended to an international level. The activities have the dual purpose of changing people's behaviour and perceptions and gaining more visibility in the eyes of the public and industry showing that the medicines regulatory agency is combating counterfeit medicines.

*"We want to see evidence of a growing awareness in the public of the risk of Internet purchases of product" [MM09]*

Another strategy outcome wanted from the strategy which was shared by all the participants was to make the pharmaceuticals supply chain more secure. They perceived the agency as trying to strengthen the supply chain and make it very hard for counterfeiters to put their counterfeit products into the supply chain.

*"...strengthening the supply chain or making the supply chain secure is a key" [MC15]*

Also, they saw the agency as looking to their anti-counterfeit medicines strategy to improve collaboration and information sharing among all those stakeholders involved with the medicines business. All participants saw working together nationally and internationally as important for helping in the fight against the counterfeiting of medicines.

*"I think that's really what we're trying to achieve is that we need to work together with industry, with the public to identify any falsification but also prevent the falsification in the first place" [MC09]*

All participants reported that protecting public health through decreasing the risk of counterfeit medicines to the patients would be another desirable outcome from the strategy.

*"if we don't safeguard public health then any strategy you put up is out of the window" [EP15]*

Another outcome from the strategy seen as important was reducing the number of counterfeit medicine cases in the supply chain



*“I think the outcome would be that we minimise the number of counterfeit medicines that get in the legal supply chain” [MC04]*

However, the reduction in the number of counterfeited products in the supply chain should, according to the participants, be treated with caution as it might not be seen by itself as an indication of the success of the strategy. Therefore, the declining incidence of counterfeits should be taken as a percentage of the overall number of cases the agency look at. A few participants even disagreed with the idea that the number of counterfeit cases could be seen straightforwardly as an outcome of the strategy, since many other factors could be involved; for example, the criminals have not targeted the country or the agency could not see the counterfeit products in its supply chain.

*“the number of cases you get are dependent upon the intelligence you receive, whether your country is being targeted or not by the counterfeiters and there are many other factors. So you can’t say we will decrease the number of counterfeit medicines in the UK by X per cent” [SM04]*

Participants said the agency has been unable to devise suitable key performance indicators for the number of counterfeiting cases in the supply chain.

*“All we know of the ones that we’ve found are not the total that are out there” [SM04]*

Participants also saw as a good outcome the agency seeking to changing the legislation and the regulations by the government to make them stronger in relation to counterfeit medicine crime, not only at the national level but also internationally through the government (in this case within the European Union).

*“The fact that we’ve got a European directive that now actually expands European legislation, or extends it, means – and that we have played a leading role in making sure that that legislation is as we wanted it to be” [SC15]*

Convicting people for counterfeit medicine crimes and sending them to prison with strong sentences was another hoped-for outcome from an anti-counterfeit medicines strategy.

*“some outcome measures and we looked at the number of convictions we’d had during the time of that strategy, so the people we’d prosecuted for counterfeit medicines cases” [MI09]*

Some participants’ final desired outcome was an increase in the number of the incidents freely and openly reported to the agency by its stakeholders.

*“if they report it to us freely and openly then that would be an outcome” [SM04]*

In response to the possibility that the decreasing number of counterfeit medicines cases reported in the supply chain (as an outcome from the strategy) could be seen by outsiders as the agency not working hard enough to combat the counterfeit medicines, all participants believed that this claim could not be accepted as the strategy has helped the agency more to actually make people think twice about putting counterfeiting medicines in the supply chain. This assumption was justified by participants because they saw the strategy increase the activities of market surveillance through more testing medicines, increasing risk for counterfeiters through more stakeholders’ engagement, increasing awareness throughout the supply chain players and the public. Also, it is because more people within the agency are become dedicated to this issue.

*“you’ve got not only us, not only the public, not only Healthcare professionals you’ve also got industry who are looking very carefully . . . . So it’s not true that in any way we’re less vigilant” [MM09]*

However, a view was mentioned by some participants that an agency might face a decrease in the number of cases reported. They said this could be a result from the efforts made by the agency causing the counterfeiters to become more careful in their activities and hence being detected less often.

*“I think that’s one of the key things to evaluate is to say ‘well are we getting as much falsification’, not necessarily, I suppose, it’s a double-edged sword with that, because have we driven it more underground so we’re not getting reports and we’re not seeing it, or is it that we’ve actually reduced it” [MC09]*

Participants posited what types of outcomes the agency's decision-makers should expect from an anti-counterfeit medicines strategy, namely: changing people's behaviour and perceptions to counterfeit medicines; more securing of the supply chain; increased collaboration and sharing of information among stakeholders; increased public health protection from counterfeit medicines; decreasing the number of counterfeit medicines cases that reach the supply chain; more tightening of the legislation and regulations; more convictions of people involved in this crime; and growth in the incidences reported to the agency.

#### **4.4.5.2 Formulating the outcomes expected from an anti-counterfeit medicines strategy**

Participants appeared to implicitly query the means of formulating outcomes during the drafting stage of the MHRA's anti-counterfeit medicines strategies in expressing their view of outcomes to be expected from an anti-counterfeit medicines strategy. Participants stated that the outcomes from the MHRA's anti-counterfeit medicines strategies were not included within the strategy. The MHRA's hoped-for outcomes were written in a general way within the strategy as being to increase the risk to those involved in counterfeiting and protecting the public by decreasing the incidence of counterfeit medicines.

*“all we'd said was that the success of the strategy is a reduction in the risk to the patients of suffering adverse reactions to the counterfeit medicine and medical devices; and an increase in the risk to those engaged in manufacturing, distributing and supplying. So, you know, that was kept fairly open” [MD09]*

This generalised approach to the setting of outcomes from MHRA's strategy was justified by participants because the overall picture of the counterfeiting issue in the UK was not clear for the drafting team during the drafting of the first strategy. Having said this, participants believed this has not changed in the second strategy.

*“we didn't write in any target for that because we had no way of knowing – what you don't know is whether the environment actually is getting worse as*

*you are seeking to correct the situation. So in fact the job gets harder rather than easier. These sorts of things we didn't know at the time we wrote the strategy so the outcomes that are reflected from the strategy are not quantitative, they're not specified exactly"* [MM09]

Some participants suggested the specific outcomes from the strategy had been left by the drafting team for each department to set its own outcomes based on the strategy's overall objectives. Other participants said that at the end of the implementation of the first MHRA strategy, the department that led the implementation would have evaluated outcomes that were observed and achieved from the strategy.

*"we didn't really sort of think what the expected outcomes might be, but at the end of it when we said 'right let's have a look at the outcomes, let's have a look at how many people were convicted, how many cases we've had where we've had to recall or counterfeit medicines in a legitimate supply chain and how much money we've seized from criminals', the key one really was number of incidences on the legitimate supply chain"* [MI09]

Other participants particularly wanted the outcomes to be written clearly during the drafting stage and that these outcomes should be measurable.

*"I would hope that they would be – when writing the strategy they are clear about what it is they're trying to achieve and how they're going to achieve it and how they will know whether they're successful or not"* [MC15]

Participants stressed that outcomes expected from the strategy should be formulated during the drafting stage, which was not the case with either of the MHRA's anti-counterfeit medicines strategies.

#### **4.4.5.3 Operation Pangaea**

Many participants made mention of Operation Pangaea during the study in relation to success outcomes from the MHRA's anti-counterfeit medicines strategy. According to them, Operation Pangaea was first carried out in London in 2009 when the MHRA seized illegal medicines and shut down websites illegally trading in counterfeits. Over

the years Operation Pangaea attracted more countries to participate in it; subsequently, Operation Pangaea ballooned into a vast international cooperative activity with coordination passing from the MHRA to Interpol. The Interpol since then took the responsibility of these operations which became an annual event. Participants said that the MHRA continues to play an active part in the activity as secretary. They also believed that Operation Pangaea was an excellent example of how national initiatives can become international ones

Operation Pangaea was seen by some of those participants as a great success for the MHRA's anti-counterfeit medicines strategy not just in enforcement terms but also as part of the communication activities, especially in terms of raising public awareness about the danger of websites that were selling medicines.

*“again was part of the implementation about communication strategy, getting the message out, and that Pangaea proved to be a real winner as far as that's concerned” [MD09]*

Other participants mentioned Operation Pangaea it was seen as a success in terms of co-operation activates within the strategy.

*“now have this Operation Pangaea which, you know, hundreds of agencies are involved in which is an international action” [MC04]*

Participants identified Operation Pangaea as an example of success in the MHRA's anti-counterfeit medicines strategies though with different opinions as to which type of outcome it represented.

Participants thus, focussed on the outcomes that the decision-makers within the agency should expect from their anti-counterfeit medicines strategy such as changing people's behaviour, securing the supply chain, decreasing the number of counterfeiting cases, changing legislation and regulations among others. Also, participants emphasised that these outcomes should be clearly written during the drafting stage of the strategy. Operation Pangaea was mentioned by the participants as an example of the success of MHRA's anti-counterfeit medicines strategy from communication activities and co-operation activates within the strategy.

## 4.4.6 Evaluating the outcomes of an anti-counterfeit medicines strategy

This study also obtained the views of the participants on how the decision-makers within the medicines regulatory agency should evaluate the strategy's outcomes, the criteria and methods that should be used, who would be responsible for evaluation and what they thought of the evaluation of the MHRA's anti-counterfeit medicines strategy.

### 4.4.6.1 Criteria and methods for evaluating the outcomes

Participants saw conducting such an evaluation as very important for the decision-makers within a regulatory agency. However, they recognised the difficulty of conducting an overall evaluation for such a strategy. Participants highlighted their idea of appropriate criteria for evaluating the strategy; furthermore, they mentioned the methods for evaluating the outcomes from the strategy which can be used by the agency.

*“I want to be able to identify from the strategy what the objectives of the strategy were and then have the elements that they were putting in place to achieve those objectives and then you would clearly be able to take a judgement based on some research as to whether or not those have been satisfied” [SC15]*

However, participants also identified difficulties that face a regulatory agency in conducting such an evaluation and described them from different angles. One difficulty that could face the agency is the lack of sufficient data for the counterfeiting cases being recorded at national level. To overcome this, participants suggested that the decision-makers within the agency could carry out an evaluation on the basis of either regional or even international level data.

*“you have to come up with innovative ways of doing it and sometimes a country on its own doesn't have sufficient statistics to create any meaningful conclusions from that. That's why you have to do it on either a regional or a global level to get a better picture” [MD09]*

Participants also said most regulatory agencies had extensive workloads and limited resources; this makes it difficult to conduct a thorough evaluation. However, participants said when the strategy had clear objectives that will make the evaluation easier for the agency.

*“That’s all resource intensive and having worked at a busy agency that is full on, it’s hard to devote time to that discipline. But if you were starting with a clean slate I think that would be the way to go” [MD09]*

They also saw some kinds of outcomes from the strategy as difficult to evaluate due to their nature, and they gave some example of those outcomes including measuring public perception and public awareness. Also, as one participant observed, measuring communication effectiveness with stakeholders could be highly problematic as it is not easy to measure the efficacy of communication.

*“We want to see evidence of a growing awareness in the public of the risk of Internet purchases of product. That’s more difficult to measure” [MM09]*

Given the perceived difficulties mentioned by participants, only some participants felt able to identify criteria that they felt could be used to evaluate the strategy. These included the number of counterfeit medicine incidences that reach the supply chain, the number of inspections carried out by agency inspectors, the number of reports to the agency regarding suspicion of counterfeit medicines, the number of media articles and interviews regarding the counterfeiting issue, the number of recall of medicines because of counterfeiting and the number of successful prosecutions. Such criteria could be readily quantified for use in the evaluation. Also, participants observed that any change in the law as a result of the strategy could be used as measurement criteria and that the agency should try to evaluate its public and stakeholder awareness activities.

*“We want to see evidence of a growing awareness in the public of the risk of Internet purchases of product” [MM09]*

A few participants had ideas for the methods they thought should be used by the agency to measure the criteria that could be used to evaluate the strategy; most frequently they referred to statistical analysis.

*“Yeah, that would be just purely looking at the statistics, you know, it would be looking at the – we’d look at the statistics” [MD09]*

Another method identified by those few participants was a survey of the agency’s stakeholders asking for their feedback on the strategy or of the public or health professionals asking them for feedback, or a survey study of the public to measure the success of its awareness activities.

*“Respondent: some sort of probably stakeholder survey.*

*Interviewer: In what sense?*

*Respondent: As to whether they consider that the strategy is working well or that there are other areas that could be, you know, all of that I think would be useful” [MD09]*

They also suggested the agency could ask other national agencies for feedback on its strategy or could apply a benchmarking exercise with them.

*“we could ask for feedback from again other agencies and other countries and other agencies like ourselves to ask about what do we do, how do we do it, is it helpful the things” [MC04]*

To summarise, some participants provided ideas concerning how decision-makers should evaluate an anti-counterfeiting strategy at the MHRA. They highlighted some of the difficulties in achieving evaluation such as the paucity of nationally recorded data on counterfeiting cases and resource limitations. For the evaluation, quantified criteria could be applied including the number of counterfeit medicine incidents that reached the supply chain, the number of inspections carried out by agency inspectors and the number of reports to the agency regarding suspicion of counterfeit medicines. Only few participants thought the evaluation could be mainly achieved by using statistical data and by conducting surveys of the public and stakeholders.



#### 4.4.6.2 Responsibility for evaluating the strategy outcomes

Participants gave diverse views about who should be responsible for conducting an evaluation of the outcomes from an anti-counterfeiting strategy. Some participants suggested this task should be carried out by the department that led the strategy implementation, as this department has a very close relationship with the strategy.

*“whoever is responsible for that strategy is responsible for evaluating it and how it is evaluated or ensuring that if other” [MC15]*

Another view held by participants was that each department should evaluate itself, and then all departments would send its evaluation to a committee or a specific department that gathers all the evaluations together. They did not appear to think there would be any sort of bias if the department evaluated itself. However, they thought the risk associated with this suggestion is that the departments could become more subjective which could indeed be a source of bias.

*“I think the departments themselves should evaluate the, I suppose their own metrics” [MC09]*

Also, participants said the evaluation could be completed by those responsible for drafting the strategy.

*“I would imagine that those how have drafted the counterfeiting strategy then they will be responsible for then pulling together the evaluation for it, yeah” [MC15]*

Participants suggested giving the responsibility of the evaluation to an internal auditor or a different department within the agency that does not have any link with the strategy because an internal evaluator would know the structure of the agency and how things interconnect within the agency.

*“In terms of effectiveness inside, you’d need a separate, you’d need somebody separate to those that have either developed the strategy or are running it on a daily basis to look at it with a fresh pair of eyes to determine whether there is anything else that could be done or could be done better” [MD09]*

However, participants saw disadvantages with all these ideas, as that any evaluation process conducted entirely internally would be open to suggestions of bias and an incentive to produce a positive result.

*“there is a risk that somebody will say ‘well they’re only reviewing their own strategy, of course it’s come out well” [SC15]*

Participants’ final suggestion for evaluation was that it could be completed by an external evaluator such as an external auditor or another government agency. Participants therefore stressed that the strategy should be properly drafted with clear objectives to enable any such external evaluator to analyse whether or not the agency achieved them.

*“I think it’s reasonably healthy to have an external auditor come in to audit your effectiveness in this area. I think that would give the director general or whoever, the chief executive, some level of confidence that there’d been that external review and it’s a fairly healthy” [MD09]*

In summary, participants’ views on evaluation of the outcomes from the anti-counterfeiting strategy suggested a number of options: it could be carried out by the department that led the strategy, each department could do it for itself, or it could be done by those who drafted the strategy, or it could be conducted by an individual or department with no link with the strategy, or, finally, an external evaluator.

#### **4.4.6.3 The evaluation of the MHRA’s anti-counterfeit medicines strategy**

Participants reviewed their knowledge of the evaluation result from the MHRA’s anti-counterfeit medicines strategy and their feelings regarding the outcomes of this strategy. They also discussed what type of evaluation had been conducted.

Most participants had no information as to whether any evaluation had been conducted for the first MHRA anti-counterfeit medicines strategy, pointing out that they had not taken part in any kind of evaluation or simply lacked knowledge in that area.

*“Interviewer: And are you aware of any results for the first evaluation?”*

*Respondent: No. I really wasn't involved"* [MP09]

Nevertheless, participants shared the view that the MHRA was successful in its anti-counterfeit medicines strategy, based on their knowledge of successful investigations that had been carried out into cases of counterfeiting and the sentences given to perpetrators, they also referred to the drop in the number of counterfeit medicine cases since the strategy was launched.

*"I don't think we have slackened off in our efforts so you could say the strategy was successful"* [SC15]

Only a few participants had ideas about the kind of evaluation that had been carried out for the first MHRA anti-counterfeit medicines strategy. According to those who commented on that evaluation, there was no overall evaluation conducted for MHRA's anti-counterfeit medicines strategy. Participants stressed, the evaluation was restricted to specific aspects of the outcomes, like the number of counterfeiting cases, the number of prosecutions and the sentences resulting from those prosecutions. This kind of evaluation did not cover other, possibly relevant, aspects of the outcomes such as public awareness.

*"there's some evaluation, but it's not covering every aspect I don't think"*  
[MM09]

Most participants did not have any direct information about the evaluation of the first MHRA anti-counterfeit medicines strategy, although there was a widely-shared perception that it had been successful. Others did suggest an evaluation had taken place but that this had not been comprehensive.

## **4.5 Discussion**

The use of semi-structured interviews for data collection purposes was satisfactory in enabling the views from MHRA participants. The participants were able to pursue their own threads of thought without being restricted by the interviewer meaning a good degree of richness of depth was achieved as exemplified in the extracts reproduced above. There may have been an element of presenting the organisational line in some

responses from some participants, but on the whole it is considered that the data and findings are reflective of the views of the participants. This study aimed to capture the views and perceptions of MHRA participants on the anti-counterfeiting strategies published by the MHRA in 2007 and 2012 which would help in understanding its process from development to *post hoc* evaluation. This required participants to reflect back, particularly in the case of the now completed first strategy. This is more problematic than asking for views on current matters probably at the front of their minds, but nevertheless the data gained are considered useful. The framework approach to data analysis was also appropriate in identifying the main themes emerging from the data.

Findings showed participants sharing the view that the agency recognised the dangerous consequences arising from counterfeit medicines, which contrasted with an attitude of denial that was shared among the regulatory agency and pharmaceuticals industries about counterfeit medicines in the UK. Furthermore, appearance of counterfeit medicine cases in the supply chain, protection of public health, securing supply chain, and pressure from stakeholders were believed by the participants to be motivating factors for the agency to develop an anti-counterfeit medicines strategy. Participants highlighted that the agency's limited staff and resources, the lack of internal communication and resistance within the agency were internal limitations; whereas, regional and international legislation, having support from other government agencies and from industry were seen as external limitations that the agency should consider when planning to develop its anti-counterfeit medicines strategies in the future.

In relation to the process of designing an anti-counterfeit medicines strategy, findings showed that participants believed this would be best done by a drafting committee across several agency's departments/divisions probably led by the enforcement department and enriched by the agency stakeholder's consultation role. Findings also showed the steps during the drafting stage that could be applied in order to develop such strategy. The drafting committee would start with initial thoughts for a strategy which was then shared with stakeholders to obtain their input. Then, the drafting committee will use the input from the stakeholders to write the first draft for the strategy which then would also be shared with the stakeholders. Finally, the committee would complete the strategy and send it to senior managers for approval before publishing it.

Findings also showed participants thought that such a strategy would be more effective if the implementation process become a responsibility of the enforcement department in cooperation with other departments/divisions. Participants particularly emphasised the importance of communication between the agency's divisions and departments to ensure effective implementation of an anti-counterfeit medicines strategy.

Participants' were found to identify pharmacists' and GPs' potential roles in supporting an agency in combating counterfeit medicines as being vigilant, reporting any suspicion to the agency, maintaining awareness, advising patients about the issues and buying medicines from secure suppliers. Participants were found to suggest that stakeholders could support the strategy by securing the supply chain, protecting public health, sharing information, being vigilant, reporting to the MHRA any suspicions and working collaboratively with the agency.

The study found that the outcomes of such a strategy were likely to change people's behaviour, secure the supply chain, decrease the number of counterfeiting cases, change legislation and regulations. Participants also identified a lack of nationally recorded data on counterfeiting cases which, combined with resource limitations, might make it difficult for the agency to evaluate the strategy. They also suggested that to overcome these difficulties in evaluation, the agency might use quantitative measures for the evaluation process such as the number of counterfeit medicine incidents that reached the supply chain and the number of reports to the agency regarding suspicion of counterfeit medicines.

A limitation of this study is that it was developed in the context of a very limited range of published literature, specifically making reference to anti-counterfeit medicines strategies. In fact only two articles were found that commented specifically on the MHRA's anti-counterfeiting strategy, and both were written by the same author, Chaplin (52, 82). Another limitation related to recruiting participants, who were selected with some influence exerted by decision-makers at the MHRA. The initial participant list was developed by the researcher, based on the departments and divisions within the MHRA, which indicated their roles within the published MHRA strategies. During the stage of seeking approval to conduct this study from the MHRA decision-makers, some names on the proposed participant list were changed by those decision-makers; this was justified by them as they argued that the new names would be more

suitable for this study. This may have led to some bias in the study, as those new participants might have been included to affect the image of the MHRA presented during the interviews. To minimize the possibility of this bias, the researcher tried to explain to the participants at the beginning of each interview that the study was not aimed at evaluating the MHRA's work; also, the researcher tried not to ask questions that could be directly linked to the MHRA's performance. A further limitation to this study is related to the researcher, as he is from other country (Saudi Arabia) and works as a pharmacist with that country's national medicines regulatory agency (Saudi Food and Drug Authority). Participants might perceived this as a form of international audit and may have felt defensive toward the MHRA as a response to the research situation and may not have given as full a picture of their views about the strategy as they could have given. Also, the background knowledge and experience of the researcher may have introduced some level of bias to the data analysis undertaken by the researcher because as a pharmacist working within a national regulatory agency in another country the researcher cannot have worked without developing a personal perspective and set of assumptions regarding counterfeit medicines and how to combat them.

While it could be seen as one type of limitation that not all participants were wholly engaged with all the processes of the MHRA's anti-counterfeiting strategies covered in this study, because one focus of this study was to detail and distinguish the different roles that people played in developing and advancing the strategy and because all study participants did some work in the area of combating counterfeit medicines as a part of their duties within the MHRA, it can be argued that such variation actually represents a study strength. Also, another strength of this study is that it is the first study that has addressed the views of participants from a medicines regulatory agency on issues associated with an anti-counterfeit medicines strategy.

This study generated several findings which were grouped to six main themes that accomplished the following study objectives: i) understanding the medicines regulatory agency position before the anti-counterfeit medicines strategy; ii) highlighting the process of drafting an anti-counterfeit medicines strategy, taking MHRA's anti-counterfeit medicines strategy as a model; iii) the participants' comments on the implementation of the anti-counterfeit medicines strategy; iv) identifying the potential role of GPs, pharmacists and other stakeholders in combating counterfeit medicines; v) outcomes that could be derived from an anti-counterfeit medicines strategy; and vi)

identifying potential evaluation criteria and methods for an anti-counterfeit medicines strategy.

**i) Understanding the medicines regulatory agency position before an anti-counterfeit medicines strategy**

The study participants were in agreement that counterfeit medicines are very risky to public health and may even cause death, as Chika et al. (12) have reported (e.g. 62 deaths in the USA due to a counterfeited Heparin). They also agreed and were most greatly concerned because little was known about the extent of the manufacturing and distribution of counterfeited medicines. It would be worth to consider expressions of agreement here may have been influenced by the participant's knowledge that the interviewer (researcher) had background experience of the counterfeit medicines issue. Participants agreed that the counterfeit medicines could have a significant impact on the reputation of government agencies, as argued by Nsimba SED (28), and it could affect the public's trust in the health system. Therefore, this study showed that agency participants saw it as a vital duty for their agency to effectively combat counterfeit medicines. Those elements were considered by the agency participants as the driving factors for a medicines regulatory agency to develop an anti-counterfeit medicines strategy.

Findings show that MHRA's percipients believed the pharmaceutical companies were in denial about counterfeit medicines, a possibility also highlighted by Bate et al. in 2011 (18), and other medicines regulatory agency staff. This suggests that decision-makers should understand that the counterfeiting of medicines may not be restricted to developing countries but can happen anywhere. Furthermore, holding the view that there are well-regulated systems in place could lead to over-confidence in the medicines supply chain and a complacency which would make the supply chain vulnerable. Also, participants notified that the agency should understand that the pharmaceutical industry might not share information that they hold on counterfeit medicines fearing their products may gain a bad reputation (12, 18). Also, it should be noted that expert study participants emphasised the need for a medicines regulatory agency to be proactive in combating counterfeit medicines even before any strategy was put in place.

The most important consideration identified in this study was the discovery of counterfeit medicine cases in the legitimate supply chain. In terms of motivating factors,

this suggests that a medicines regulatory agency might consider the need to decrease the number of counterfeit cases, the need to protect the public health, and the need to secure the supply chain as external motivating factors to develop such a strategy. These motivating factors are all evident in the stated aims and objectives of the MHRA's anti-counterfeiting strategies (25). Also, another external motivating factor study participants identified was stakeholder pressure on an agency to develop such a strategy. However, it was considered in this study as the least important motivating factor and was not accorded the same weight as the other external factors; also there appeared to be no link between the seniority of the MHRA participant and their perceptions of this factor. In examining internal motivating factors for developing an anti-counterfeit medicines strategy, participants suggested that the personality and attitude of the agency's staff, along with the availability of management support, would be relevant here. Also, another less emphasised internal factor might be the worldwide leadership position of the agency as seen in this study. It appears from this study that whilst the reputation of the agency as a worldwide leader in medicines regulation and external pressure to create a strategy were recognised as drivers their importance was perceived as less than the desire to protect public health, secure the supply chain and reduce the number of counterfeit cases.

Participants perceived the need for the agency to identify its external and internal motivating factors alongside the external and internal limitations experienced by the MHRA; so the final findings in this theme concerned the limitations and boundaries of the medicines regulatory agency in developing its anti-counterfeit medicines strategy. Bryson (125) argues that a public organization seeking to develop an effective strategy should analyse both its external and internal environments. A medicines regulatory agency cannot work in isolation from its operating environment, and therefore regional and international legislation were considered as external limitations for the agency when planning to develop an anti-counterfeit medicines strategy as such legislation also shapes this environment. The implication of this was interpreted in this study as participants believing that the agency was being held back from certain areas of anti-counterfeiting activity by limitations beyond their control such as those arising from legislation drafted to cover the European Union. Participants also identified a lack of support from other government agencies and relevant companies as a further external limitation. Not only external limitations were considered in this study, limitations within the agency itself, which may be staff and resource limitations, lack of internal



communication, and resistance to change within the agency. Understanding and evaluating those external and internal limitations is part of the process of identifying the agencies strengths, weakness, opportunities and threats (referred to as a SWOT analysis) which is a valuable tool in the development of any strategy (125). This assumption was supported by the study findings which showed that the participants perceived the need for the agency to identify its external and internal motivating factors alongside the limitations, which might be consider as delimitations for an agency in order to develop such a strategy.

## **ii) How an agency could draft an anti-counterfeit medicines strategy**

This study highlighted features of the drafting process seen as relevant for understanding the process of developing an anti-counterfeiting strategy. Whilst only some of the participants in this study were directly involved in drafting the MHRA's anti-counterfeiting strategies, all contributed to MHRA efforts to combat counterfeiting. This gave the researcher the opportunity to elicit a broader and potentially more objective set of views about drafting than if the study had recruited only those directly involved in strategy development. Findings showed that the views of those who were directly involved in the development process were closely aligned with those of the participants who were not directly involved in the strategy development.

The findings also suggested that an internal drafting committee perhaps called "the strategic management team" should be responsible for drafting an anti-counterfeiting strategy (126). Participants saw the responsibility of leading this internal drafting committee could be given to the enforcement department. This opinion would carry logical weight as producing and distributing counterfeit medicines is a criminal activity and the enforcement department may have greater motivation and experience for dealing with such activities. Participants may have held this view because they were influenced by the two already-published MHRA anti-counterfeiting strategies that had been drafted by the enforcement department. However, few participants offered the alternative opinion that the policy division/department could lead here. Some participants argued that the policy department may be more appropriate as they may have a better understanding of external stakeholder perspectives and could offer a more holistic approach; also, if the policy division took on this role might give more freedom to the enforcement department to contribute more objectively. A third option which was

not raised by the participants in this study but may, on reflection be worth considering is that a senior manager from the agency rather than a department might take the lead here as this may encourage more even participation with all departments/divisions involved in this committee feeling they have the same weight and are not dominated by a single department/division.

The participants also proposed departments and divisions that might be represented on the internal drafting committee for an anti-counterfeiting strategy. These included the departments dealing with inspections, defective medicines reports, the laboratory, pharmacovigilance, communications, policy, government lawyers and licensing. Participants gave reasons for involving these departments which included: the inspections department as reflecting the situation in the medicines supply chain field; the laboratory department as being responsible for product testing; the department responsible for dealing with defective product reports (in case of the MHRA, the Defective Medicines Report Centre); and the department/division that deals with pharmacovigilance duties within the agency as being likely to play an important part in detecting the signals of any counterfeits in the supply chain. The strategy would need to be communicated to the agency's stakeholders, and therefore the division/department of communications would also be part of the drafting process. The policy division/department was seen as helping ensure that any strategy would align with other government policies; government lawyers providing legal advice ; licensing as helping identify the products at likely high risk of being counterfeited. Involving this range of departments/divisions could also enhance the agency's feeling of ownership over the strategy within the agency, which participants expressed as important. This finding raises a question for those medicine regulatory agencies in other countries who may not have so many departments/divisions and who would need to evaluate their own structure and then create its internal drafting committee.

Involving agency stakeholders in the drafting process was also seen as valuable by study participants. Those stakeholders would be pharmaceutical manufacturers (branded and generic), wholesalers, distributors and brokers. Also, police, customs and patient groups (if existing). The involvement of these stakeholders was seen in this study to increase the level of trust as well as the sharing of information between the agency and those other stakeholders; also, it would help build understanding of each other's agenda

and priorities, meaning they are likely to then work together more fruitfully to tackle any counterfeiting issues.

Participants expressed a view that once an internal drafting committee had been established and its membership identified, the committee should start with a consultation phase with the agency's stakeholders, to identify the needs and expectations of these stakeholders. The participants proposed the chair of the committee should lead consultations; while recognising the timing, resources, energy and effort required for those consultations. The internal committee should prepare a first draft having also considered stakeholders' input, with a second consultation round with stakeholders as essential; to seek comments and feedback on the first draft. The drafting committee would need to finalize the strategy, having made any amendments as necessary to accommodate stakeholders' comments. After finalizing the strategy, the internal drafting committee would send it to the agency's higher management for approval, before the agency finally published its strategy. Participants saw these steps as constituting a systematic organized method for drafting an anti-counterfeiting strategy.

Study participants underlined the importance of formulating an anti-counterfeiting stakeholder group; as seen with the MHRA. This group was seen as having an input into developing anti-counterfeiting strategy and that involving them would continue to help to build trust between the agency and its stakeholders, which could encourage more information-sharing over a range of counterfeiting issues. Participants were found to support the proposal for the agency to set up such a group to be set to include agency members alongside stakeholders with a role in combating counterfeit medicines. Such stakeholder members would continue to be drawn from the pharmaceutical industry (branded and generic manufacturers, wholesalers, importers and parallel traders), representatives from government law enforcement bodies (police and customs), and representatives from pharmaceutical organizations such as the Royal Pharmaceutical Society. The study findings showed that an agency was seen as being able to use this group's outputs in drafting its anti-counterfeiting strategy, as seen when the MHRA was reported as including in its strategies "a watch list of medicines" drawn from the anti-counterfeiting stakeholder group.

### iii) How an agency could implement an anti-counterfeit medicines strategy

The study found that study participants' findings saw leading and running an anti-counterfeit medicines strategy as a task for one person from the enforcement department/division within the agency. They saw this as ensuring the smooth running of the strategy throughout the whole agency, as such a strategy would involve multiple departments/divisions within the agency. This is supported by the assertion of Theodore et al. that "*If plans are not implemented in a very purposeful way, then the strategies will not take hold, no matter how compelling or inspiring the planning process*" (126). Participants supported allocating this task to the enforcement department/division as it had more duties to perform in relation to the strategy than any other department/division, so that the strategy would be incorporated into its duties in the natural course of events and also would not be forgotten. It should be recognized that the implementation of the MHRA's anti-counterfeiting strategy had previously and currently been allocated to the enforcement department which may have therefore encouraged the participants to see it as the 'natural order of things'.

The researcher raised some potential limitations with the participants which they did not feel had materialised. Participants did not recognise any lack of cooperation from other department/division managers (with the leading enforcement department) arising because they may perceive matters related to the strategy as the duty of the enforcement department/division manager. Also, they did not perceive a potential issue with department/division managers not accepting tasks that come from a person at a similar management level which would affect the implementation of the strategy. It may be that the participants were comfortable with having the enforcement division take the lead as this was the course taken for the first two strategies adopted by the MHRA. One alternative would be to have one of the senior managers of the agency assigned as the leader to give added weight to the importance of successful implementation and solve any inter-departmental issues.

The study's findings identified the departments/divisions that would have a role to play in the implementation an anti-counterfeiting strategy alongside the enforcement department/division. These are: the policy, communications, pharmacovigilance, laboratory, Good Distribution Practice (GDP), inspection and finance departments/divisions and possibly government solicitors. The implementation of such

a strategy may need to change in line with government legislation and regulations, and the policy department/division would have a role in this part of the implementation. In addition, the policy department/division would be the link between the agency and other government agencies, and it would ensure that the implementation of the strategy remains consistent with regional and international legislation. The communication department/division would assist in the implementation by raising awareness in both the public and the agency's stakeholders; it would also deal with the media in general. The participants emphasized that this role should be done in coordination with the enforcement department/division. As the pharmacovigilance department/division deals with defect reports or lack of efficacy reports from health professionals and the public, it could play a role in the implementation by detecting flags or signals relating to any suspicion of counterfeit medicines, and then reporting these cases to the enforcement department; the laboratory department/division would then be able to move more quickly and efficiently in testing and analysing suspicious items. The GDP inspectors would also assist in the implementation as they are working in the field, and would be in a position to report the real-world circumstances to the agency. The finance department and government solicitors would help in the implementation through dealing with any prosecutions of counterfeiters.

It was also found that the expert participants from the MHRA perceived the need for the best possible communication and cooperation between those departments/divisions involved in the implementation of the strategy and was vital for the strategy's ultimate success. In addition, the allocation of tasks in the implementation should be part of the annually revised business plan for each department/division. One means of promoting good communication and cooperation highlighted by the participants was the identification of a contact person or project leader.

#### **iv) Identifying the potential role of GPs, pharmacists and other stakeholders in combating counterfeit medicines**

Participants were found to identify four roles that pharmacists and GPs could play in combating counterfeit medicines and which were also identified in some of the literature (3, 12, 91, 92, 127). First, was for pharmacists and GPs to be vigilant for any suspicion of counterfeit cases, particularly relating to packaging and printing. Second, was that these two groups would be a good source of reports to the medicine regulatory

agency for any suspicions, which Besançon called reactive risk communication (128). Third, was because pharmacists and GPs are in contact with patients, they were seen as having a role of raising awareness and giving them advice on the danger of counterfeit medicines, in particular on buying from online sources. The final role that pharmacists and GPs (mainly dispensing doctors) could play was seen as being to source their medicines from a secured supply chain. It should be noted that the roles identified by participants in this study were not set out in the MHRA anti-counterfeit medicines strategies but were likely to have related to participants' personal experiences. Having said this, the work done by the MHRA in association with the Royal Pharmaceutical Society (RPS) and the Dispensing Doctors Association who cooperated to publish "Counterfeit Medicines Advice for Healthcare Professionals: Guidance for Pharmacists and Dispensing Doctors" is an example of the agency working together with health professionals (84). This guidance aimed to educate pharmacists and dispensing doctors to be vigilant, to report to the agency and to source their medicines from a secured supply chain. However, it cannot be evidenced from the literature whether pharmacists or dispensing doctors had received or were aware of this guidance, whether they accepted these roles or whether they were applying guidance recommendations to their practice. Neither were the roles of general practitioners (GPs) reported as being addressed by any of the MHRA activities; or whether GPs were aware of or accepted the guidance.

Another study finding highlighted three methods of communication between the medicines regulatory agency and pharmacists and GPs about counterfeit medicines. First was using media tools, such as press releases or websites, or more specific targeted media tools, such as bulletins in professional publications (e.g. pharmaceutical journals). However, this study did not clarify the criteria for choosing between these different media tools nor anything about pharmacists and GPs use of these media tools nor did existing literature. A second route of communication raised was via the professional organizations of pharmacists and GPs, as they are responsible for regulating their members' practice which could represent a more efficient and targeted means for delivering messages to these healthcare professionals. This study neither identified how the agency could work with the professional organizations; nor the degree of such cooperation. However, the guidance jointly published by the MHRA and the RPS could be an example of such cooperation; but, the success of this method of communication has not been evaluated by the MHRA or the RPS. The third method

highlighted in this study was the suggestion of using training tools in communicating roles to pharmacists and GPs; these tools could be post-qualification workshops, conferences and seminars, as part of their continuous development programme (CDP) or introduced into undergraduate courses. However, this study did not evaluate these methods or which of the tools would be more welcomed by pharmacists and GPs.

Study participants did identify agency stakeholders who might play a role in combating counterfeit medicines as being from the pharmaceuticals industry (importer, wholesaler, generic and branded manufacturers), those from the government's law enforcement agencies (customs and police), and other organizations like the Royal Pharmaceutical Society. They were identified as having roles in working with the agency to secure the supply chain; information-sharing and collaboration. Also, they thought stakeholders should be vigilant for any suspicious cases and should report them immediately to the agency. Participants highlighted that the MHRA engaged with its stakeholders via the MHRA's anti-counterfeiting stakeholder groups. However, the success of this engagement was not evaluated, and neither has any literature evaluated the views of the stakeholders on the value of the likelihood that they might take on these roles.

#### **v) Outcomes that could be derived from an anti-counterfeit medicines strategy**

Study participants foresaw several outcomes from an anti-counterfeiting strategy. However, participants stressed that setting strategy outcomes was not an easy task and that a regulatory agency should attempt to establish them from the outset, during the drafting stage. Setting measurable targets was described as very difficult making it unsurprising that these were not included in the strategy. While participants did not identify any specific outcomes as being stated within the MHRA's published strategies, they were able to identify these outcomes from their own personal experiences.

The outcomes that have emerged from study participants' experiences were : changing people's behaviour and perceptions relating to counterfeit medicines through raising public and stakeholder awareness; making the pharmaceutical supply chain more secure to protect it from penetration by criminals; and improving collaboration and information-sharing among stakeholders (nationally and internationally) considered essential in these days (129). However, these outcomes were identified in a general way without participants specifying how the strategy could incorporate them within the strategy or fulfil them.

However, a potentially problematic outcome reported by the participants would be if the number of counterfeit medicine cases in the supply chain reduced; some saw this as a positive outcome, whereas others saw such a reduction as misleading because confounding factors could have been at play, such as counterfeiters not targeting the country or the agency failing to identify cases in the supply chain. Therefore, demonstrably decreasing the number of counterfeit medicine cases could be a good outcome but one that should be treated cautiously.

Two more outcomes highlighted by study participants were to strengthen legislation and regulations in relation to counterfeit-medicine crimes and punishing counterfeiters with stiffer sentences. But, this study did not identify how the strategy might achieve these outcomes as amending legislation and sentencing policy is not within the remit of a medicines regulatory agency.

#### **vi) Identifying potential evaluation criteria and methods for an anti-counterfeit medicines strategy**

The previous theme concerned what outcomes could be expected from an anti-counterfeit medicines strategy. The final theme addresses the methods of evaluation of these outcomes. In line with Chaplin (2008), study findings suggested that evaluating such a strategy might not be easy as seen from participants view, but that the evaluation would nevertheless be an important task (82). This difficulty was seen to arise from the lack of data on counterfeiting; however, to minimise this difficulty the agency could conduct their evaluation based on either regional or even international data. Another difficulty seen for executing an effective evaluation is that a medicines regulatory agency usually have both extensive workloads and limited resources; nevertheless, study participants highlighted the need for the strategy to set clear objectives from the outset which would simplify the evaluation process meaning less resources may be required. Another difficulty might be that some expected outcomes of the strategy (such as public awareness) would be difficult to measure. Therefore, the agency should identify and anticipate any such difficulties and put in place measures to overcome them.

The study findings have helped indicate potential criteria that could be used to evaluate such a strategy. According to these findings, the agency could use the quantified outcomes included in the strategy, to conduct such evaluation; which might be



incidences of counterfeit medicines reaching the supply chain, the number of reports of suspected counterfeiting cases, the number of recalls due to counterfeiting cases, the amount of communication activities (such as media articles and interviews), the number of inspections, and the number of successful prosecutions. However, it is important to note that participants were not aware of any evaluation conducted on MHRA's anti-counterfeit medicines strategy and those criteria suggested by them were based on their personal views and had not been tested before.

A further two potential evaluation criteria emerged from this study. These were changes in legislation or regulations resulting from the strategy and benchmarking exercises undertaken by the agency with other national agencies. However, the effect of any legislative changes would be unknown until sometime after they have been introduced. The benchmarking criteria might also be misleading as the topic of counterfeit medicines could be considered sensitive and other agencies might give out false results.

This study does not offer a clear single answer about who should be responsible for carrying out the evaluation, as participants did not agree on this issue, perhaps because the participants were not part of any evaluation process. However, their responses suggested a few options which could be used in assigning responsibility for conducting an evaluation of its anti-counterfeiting strategy. In total, five options emerged from the study findings with potential to help the agency with this task. First was for the department that led the implementation to also do the evaluation, as this department would have a close relationship with the strategy. A second option would be for each department to evaluate itself, and then for all the evaluations would be gathered together by a certain committee. The third option was for the drafting committee to carry out the evaluation of the strategy they authored. These options might have advantages as the evaluation would be conducted by someone who was familiar with the strategy which could make it easier and quicker to complete. However, self-evaluation which this effectively would be, is always going to be open to accusations of bias, something which should be considered. The fourth was for an internal auditor or a different department (with no link with the strategy) could do the evaluation. This option might impose less bias as an internal auditor does not have any link to the strategy, but still coming from within the agency means that some residual concern over bias will still be there. The final option was for decision-makers to hire an external evaluator (such as an auditor) or another government agency carry out the evaluation. This option would

eliminate any bias in the evaluation as the external auditor would not have any conflict of interest and would increase the evaluation's validity; but would require cooperation from the different agency's departments/divisions. However, as none of these options have been tested or evaluated before so their relative merits remain unknown.

## **4.6 Conclusion**

The findings from this empirical chapter provide an insight into the process of developing, implementing and evaluating an anti-counterfeit medicines strategy from a medicine regulatory agency perspective. This study identified as useful or potentially-useful, elements that help improve wider understanding of the issues associated with an anti-counterfeit medicines strategy from design to implementation and evaluation. These might also be informative for decision-makers within other medicine regulatory agencies to consider in developing counterfeit medicines strategy. Study findings have emphasised the need for decision-makers to recognise that counterfeit medicines represent a threat to public health, and reasons why their proliferation could have a significant impact on the agency's reputation, in turn potentially affecting the public's trust in their health system. Therefore, combating counterfeit medicines is increasingly likely to be a central aspect of any agency's duties. This suggests that decision-makers may need to guard against denying the presence of counterfeit medicines, or in having over-confidence in the supply chain. Findings also indicated that decision-makers should understand that sometimes the pharmaceutical industry may not share information they may have about such problems, as they may fear for the reputation of their products.

Thus, the decision-makers were seen as needing to be proactive in combating counterfeit medicines; to analyse the external and internal environments of the agency when planning to develop a strategy so as to identify and assess the relevant external and internal motivating factors for developing such a strategy as well as any potential limitations. The motivating factors to develop such a strategy were seen in the study as the occurrence of counterfeit medicine cases in the supply chain, protection of public health and securing the supply chain as well as the personality and attitudes of the agency's staff, along with the availability of management support. Likewise, any

potential limitations such as the quality and availability of agency staff and resources, quality of internal communication, resistance within the agency, barriers provided by regional and international legislation, lack of support from other government agencies and from industry should be identified and assessed in seeking to develop an anti-counterfeiting strategy.

Decision-makers might refer to this study when planning and drafting such a strategy to identify key components of the process. These were: establishing an internal drafting committee from the agency's departments/divisions with an existing role in combating counterfeiting activities; identifying the agency's stakeholders for all counterfeiting issues. During the first stage, the drafting committee could conduct a consultation process with those stakeholders; then, the committee would draw up a first draft, which would be reviewed by the stakeholders for any comments or feedback. Following this, the committee would finalize the strategy and would ask for management approval before publishing it.

In the implementation phase, many departments/divisions were seen as needed to implement such a strategy; but, the assigning of one department to a leading role in implementation was viewed by the participants as highly requisite. For both the drafting and implementation of the strategy, the importance of locating the centre of responsibility appropriately is clear and careful consideration should be given to whether it is placed in one department/division or centralised to ensure equal partnership and ownership. Furthermore, the importance of communication between those divisions and departments to ensure effective implementation was also recognised.

The roles of agency's stakeholders could assume to support the strategy implementation were seen as securing the supply chain, protecting public health, sharing information, being vigilant, reporting to the agency any suspicions and working in a collaborative manner with the agency. Moreover, this study identified the roles that participants felt should be assigned to pharmacists and GPs to support an agency in combating counterfeit medicines. These were to be vigilant, to report any suspicion to the agency, to have an awareness raising and advisory function to the patients and to buy medicines from secure suppliers. Recognising the roles of agency's stakeholders as well as pharmacists and GPs could assist the decision-makers in incorporation within an anti-counterfeit medicines strategy during the developing and implementing stages, through

understanding the roles that can reasonably be expected from each group and how the agency should communicate these roles to them. Whilst this study reported the views held by representatives from the MHRA the views of agency stakeholders, including GPs and pharmacists, on their roles and these suggestions are, up to this point, unknown. There is a strong indication in the data that stakeholder engagement was restricted at the early stages, during the development of the strategy, and there could be a case for engagement of stakeholders earlier and more extensively, something which is considered in the next chapter.

Finally, the study recognized the need to set the desired strategy outcomes from the outset. Changing people's behaviour, securing the supply chain, decreasing the number of counterfeiting cases, and changing legislation and regulations were each identified as outcomes that would be expected from an anti-counterfeit medicines strategy. In order to evaluate those outcomes the agency might use quantitative criteria for the evaluation process like the number of counterfeit medicine incidents that reached the supply chain and the number of reports to the agency regarding suspicion of counterfeit medicines. However, the lack of nationally recorded data on counterfeiting cases and resource limitations might be inhibiting factors for the successful conduct of strategy evaluation.



# *Chapter 5*

## *MHRA stakeholders' perspectives on developing an anti-counterfeit medicines strategy*

## **5.1 Introduction**

A medicines regulatory agency does not operate in isolation from its environment. Any anti-counterfeit medicines strategy developed by a medicines regulatory agency will impact on stakeholders. This study elicits the views of representatives of MHRA stakeholder groups on a counterfeit medicines strategy. The qualitative data collected from MHRA stakeholder participants is relevant to addressing the research problem as the participants can be viewed as experts capable of offering important insights into the threats from counterfeit medicines to both patients and to the medicines supply chain. There are certain gaps in knowledge concerning the development, implementation and evaluation of anti-counterfeit medicine strategies, and as in the study reported in chapter 4, the study described in this chapter is also intended to go some way to filling these gaps.

A medicines regulatory agency will deal with many stakeholders who have an interest in its work in one way or another. Those stakeholders relevant to counterfeit medicines issues were identified by participants in the agency study (see Chapter 4). These stakeholders include the pharmaceuticals manufacturing companies (branded and generic) with strong interests in protecting their products reputation and its economic revenue, and which may be represented by a trade association in some countries as seen in the UK. Also, medicines wholesalers, distributors, and parallel traders who deal with medicines on a daily basis and which might also be represented by a trade association in some countries as seen in the UK. Additionally, government law enforcement agencies (including police and customs) which have the authority to apprehend the counterfeiters and non-profit organisations (NGOs) which deal with health professionals, for example the General Pharmaceutical Council (GPhC) and the Royal Pharmaceutical Society (RPS).

Some stakeholder groups have initiated their own activities to combat counterfeit medicines. For example, pharmaceutical companies formed the Pharmaceutical Security Institute (PSI) with the aim of tackling counterfeit medicines by sharing information and cooperating with the national medicines regulatory agencies. There are also examples of close cooperation between the MHRA and major pharmaceutical

corporations such as the work carried out by Pfizer and the MHRA to educate the public of the danger of counterfeit medicines (24, 130).

Findings from the previous study (Chapter 4) highlighted a number of activities that stakeholders might undertake in developing an anti-counterfeiting medicines strategy. Also, the MHRA participants identified specific roles that agency stakeholders might play in combating counterfeit medicines which would help in implementing such a strategy. The views of the MHRA stakeholders on their role in the strategy were not indicated in previous studies and therefore needed to be examined, not simply because they have yet to be evidenced in this context but more importantly any complete conceptualisation of the process of developing, implementing and evaluating the strategy needs to include the stakeholders dimension and it is this dimension which the current study aims to add.

As agency stakeholders usually work more closely with pharmacists and GPs, this gives value here to stakeholders' perspectives on the roles of these healthcare professionals in combating counterfeit medicines. As MHRA participants had views expressed only limited views on setting outcomes for an anti-counterfeiting medicines strategy and how to evaluate such a strategy, eliciting the views of stakeholders on these two issues could also be useful in having outsider views which might assist in gaining more understanding. Therefore, eliciting the views of the stakeholders on the processes of developing, implementing and evaluating an anti-counterfeiting medicines strategy and the view of the stakeholders on the degree of stakeholders' involvement in such strategy would improve overall understanding of the issues associated with the development of an anti-counterfeit medicines strategy and would help in supporting and enriching the findings of the study involving MHRA participants.

## **5.2 Aims and Objectives**

The aim of this study is to gain an understanding of the views of the stakeholders of the MHRA in relation to an anti-counterfeiting strategy, by exploring their views on its processes from development to evaluation.



Therefore, the objectives of this study in relation to an anti-counterfeit medicines strategy are:

- to identify stakeholders' perceived reasons for a medicines regulatory agency to develop such a strategy;
- to identify how stakeholders see their role in its development and implementation;
- to identify stakeholders' perceptions of the potential roles of pharmacists and GPs in supporting the strategy;
- to describe the stakeholders views on the strategy's outcomes and how these should be evaluated.

## **5.3 Methods**

This study aimed to gain a more complete and complex understanding of the counterfeit medicines issues by exploring from MHRA stakeholder participants' views on an anti-counterfeiting strategy. In this study qualitative methods were selected to facilitate the collection and analysis of rich data, comprising their appropriately-informed views and experiences, which facilitates the highlighting of key values and relevant language, which in turn enables the generation of conclusions and recommendations (96). Furthermore, these views should represent individual participant's opinions though it is understood that may be formed in the context of the particular stakeholder groups they are from.

Semi-structured interviews offered the flexibility to participants to pursue their own threads of thought, something required to achieve the aims of the study and something important because of the exploratory nature of the research. The interview questions combined the main questions to be covered in all interviews and a subset of questions pertinent to each interviewee and were included in an interview guide. This approach gave the researcher more flexibility, both over the order in which the questions were asked and to pursue topics of importance to each interviewee. The interview guide therefore included questions aimed at exploring the knowledge, experiences and

opinions of the participants related to a strategy for combating counterfeit medicines. The researcher also held an optional set of prompt questions to clarify or gather more details on a certain point as situation-appropriate to gain a deeper or more contextual understanding of that issue.

### **5.3.1 Participant recruitment**

The main aim of this research was to explore the knowledge, experiences and opinions of key participants from different MHRA stakeholder groups, who were familiar with the workings of the MHRA in respect of the counterfeit medicines issue, regarding a strategy to combat these counterfeit medicines. Starks and Trinidad (2007) argue that the purposive sampling method is appropriate for recruiting participants who have experienced the phenomenon under study (124). Therefore, this research applied a purposive sampling approach in recruiting participants from key MHRA stakeholder groups from within the pharmaceuticals industry, who were anticipated to be able to assist in identifying all the factors and characteristics seen as important for developing and implementing an anti-counterfeiting strategy.

Mason (2002) states that sampling, data generation and data analysis are processes that should be conducted dynamically and interactively in order to develop a set of dimensions that focus on exploiting the participants' experience (in this context, experience of anti-counterfeiting activity) (106). The participants were key members of MHRA stakeholder groups from within the pharmaceuticals industry who were linked in different ways to activities that have been, or are planned to be undertaken in combating counterfeit medicines in the UK. The participants were identified by the researcher with some assistance from a gatekeeper through identifying names and their working position of some participants and based on their participation in the MHRA's anti-counterfeiting stakeholder groups. The participants received and voluntarily signed an informed consent form. A preliminary questionnaire was used to gather demographic data (qualification, age group, work experience, etc.) in order to ensure that the sample was as diverse as possible. The sample was planned to comprise both male and female participants, with diverse work experiences; however, only male participants could be recruited.

A limit of 12 participants was set as a maximum for this study who have been selected to represent different stakeholder groups. To recruit the participants, the researcher requested the assistance of a 'research access gatekeeper', who was a member of the wider project supervisory team and had actively supported the project from its inception. All participants received the following:

- An invitation letter explaining the nature, aims and implications of the study (Appendix 2.2).
- An information sheet explaining the topic and organisation of the study, and its aims and intended outcomes, as well the implications of the study for the participants who wished to take part (Appendix 2.4).
- An Interview Consent Form to be addressed to the researcher, signed by the participant as confirmation that he/she has agreed to be part of the research (Appendix 2.5).

The researcher provided participants with further information on the study (where needed) and arranged the date and time for the interview in a suitable room at their place of work. A pre-paid envelope was provided to help maximise the response rate. If no response was received, no further letters were sent to that prospective participant.

The outcomes from the previous study (Chapter 4), enabled the researcher to identify potential participants. In addition, two MHRA participants suggested some individuals from the stakeholder groups who could, in their opinion based on their participation in the MHRA's anti-counterfeiting group, make a relevant contribution to the study as they would have good experience of the MHRA's strategies. The researcher then finalized a list of 12 potential participants who were represented from different stakeholder groups. Those candidates were contacted through email by a gatekeeper to introduce the researcher and the study to them; then the researcher followed up and contacted them by email. Only two of those 12 potential participants replied to the email; one of them agreeing and the other declining to take part in the study. The remaining 10 potential participants neither replied to the emails sent by the gatekeeper nor to those sent by the researcher. At that point, the researcher sought support for the recruitment from the MHRA's senior manager, who agreed to send emails to those 10 potential participants and explained to them that the MHRA had taken part in this research and encouraged

them to do likewise. However, even with the assistance of the MHRA's senior manager, none of these 10 potential participants responded to the emails.

To overcome this obstacle, the researcher had to compromise and tried to identify participants who could still be considered as able to represent MHRA stakeholders regarding the counterfeiting medicines issue, even if they had not had direct links with the MHRA's anti-counterfeiting medicines strategies. However, one criterion for selecting these new potential participants in that they must have some knowledge and hold some role within their organizations which related to counterfeiting medicines. The research team assisted the researcher by using their connections to find new potential participants from MHRA stakeholder groups. Finally, the researcher managed to recruit five more participants bringing the total to six. Those participants are representatives from the UK pharmaceuticals manufacturing industry, the UK pharmaceutical wholesalers/distributors group and other pharmaceutical organizations in the UK.

### **5.3.2 Ethical approval**

This study was approved by University of East Anglia Faculty of Medicine and Health Ethics Committee (Appendix 2.1).

### **5.3.3 Research Questions Topic Guide**

The interviews with MHRA stakeholders comprised nine questions, eight of which focussed on the core topic of the interview (Questions 2 – 8), and were designed to collect data which could reflect the aim of the study. The researcher also had other sub-questions prepared that might be asked during the interview depending on the flow of the interview.

The research team developed these questions and sub-questions (Appendix 2.2) to cover all the factors relating to a regulatory agency's strategy to combat counterfeit medicines.

The question "Can you please tell me about yourself?" was the opening item for the interview. The objective of this question was to give the participant the opportunity to

talk about his/her background and work experience. Also, it informed the researcher of how long he/she had been in their current position; this was to assist in identifying how the participant was linked to the various counterfeit medicine issues.

The second question in the interview was the first one pertaining to the main research topic; it acted as a warm up question. The researcher's aim from this question was to define how stakeholders can work with a medicines regulatory agency in preventing the counterfeiting of medicines from the participant's perspective and also to gain a better understanding of whether the participants think an anti-counterfeiting strategy is needed.

The third question focussed on the participant's views regarding the role of the stakeholders in developing an anti-counterfeiting strategy. The sub-questions were to highlight what they believe is needed to improve this role; also, participants could give their opinion regarding the development process of such a strategy.

The fourth question focussed on the roles of the stakeholder in an anti-counterfeiting strategy from the participant's viewpoint. The sub-questions covered the methods used to communicate those roles and what could be done to improve these methods. Additionally, barriers preventing stakeholders fulfilling these roles were highlighted.

The fifth question addressed the roles of pharmacists and GPs in an anti-counterfeiting strategy from the participant's perspective. The sub-questions covered the methods used to communicate those roles and the participants' view of those roles in MHRA strategies.

The sixth question emphasised the implementation process of the counterfeit medicines strategy. The sub-questions attempted to identify what the participant thought the role of stakeholders should be in the implementation. The sub-questions addressed views on the implementation of the MHRA's strategy.

The seventh question related to the outcomes of the anti-counterfeiting strategy. It sought to identify the expectations of the strategy from the participants' perspective. In the sub-questions, the researcher emphasised the formulation of the outcomes that were expected and described by the participants and additionally what the participants believed the MHRA expected from its strategy.

The eighth question was the last question of the main research topic and explored the evaluation process of the outcomes of the strategy. The sub-questions led the participants to comment on the criteria that would be used to evaluate the outcomes and the selection methods for these criteria and what stakeholders can do to help in the evaluation process. In addition, the participants gave their opinion regarding the MHRA's evaluation of its own strategy.

Question nine was the last question of the interview and gave the researcher the opportunity to thank the participant for his/her time as well as to give the participant the opportunity to add more information or comments. Also, if the participant had any questions related to the interview or the research, he/she was free to put them to the researcher at this point. Then, the researcher ended the meeting.

### 5.3.4 Data analysis

The data collected in this study were the spoken words of participants from MHRA stakeholders, specifically pharmaceutical companies. As with the previous study (chapter 4), semi-structured, face-to-face interviews, with their use of open-ended questions, typically generate high volumes of these data and as the participants can be considered experts in the field being studied the data collected could be expected to be highly relevant. With this in mind, a data analysis method was required which would enable the researcher to manage the data and also summarise and synthesise it, but do so in a transparent and systematic way. Resources on qualitative data analysis were consulted before the framework analysis approach was chosen (94, 96, 119).

The framework analysis approach is now widely used as a means of analysing primary qualitative data, particularly when relevant to policy making (116). The approach has been highlighted as appropriate for research which has specific questions, a defined and limited timeframe, a sample which is pre-designed (e.g. "professional participants") and *a priori* issues identified from the outset as requiring to be addressed (115). However, the researcher, as in most qualitative approaches to analysis, analysed the data by identifying the themes that emerged from the interviews. The further developed analysis, relating to the range of themes, was used to generate a theory relating to the

anti-counterfeiting medicines strategy from the perspective of MHRA stakeholders. The researcher anonymised any personally-identifying information, and where it was necessary to use direct quotations in the reports or publications, they were edited in such a way as to protect the identity of the speaker.

Nvivo software was used for data analysis; the data transcripts were entered and then the software was used to generate codes from the data transcripts, which were subsequently grouped those codes. Then the researcher generated the themes emerged from the data manually. The researcher developed the themes from the codes that emerged from the software, thereby becoming more engaged with data, which greatly assisted the researcher in the data analysis phase. The codes generated and the themes emerged from that data were reviewed and supported by the supervisory team.

### **5.3.5 Structure of interviews**

It is important to ensure that the interview organisation can encourage an in-depth, freely-expressed discussion of sensitive issues. The researcher therefore conducted the interviews in a private room in the participants' work place building at a time when the interview was unlikely to be interrupted. The interviewers had been ask for permission to audio-record the interview (an interview consent form have been signed by all participants).

## **5.4 Results**

Overall, the researcher approached sixteen potential participants who covered the different MHRA stakeholder groups and included members from the UK pharmaceuticals manufacturers (branded and generic), UK pharmaceutical traders (wholesalers, distributors and parallel traders), UK law enforcement agencies (police, border agency and UK customs) and other pharmaceuticals bodies (Royal Pharmaceutical Society, General Pharmaceutical Council and Pharmaceutical Security Institute). However, only six participants replied and agreed to take part in the study (table 5.1). A data saturation was reached from the semi-structured interviews lasting

for up to 90 minutes were conducted at the participants' workplace in different UK cities.

**Table 5. 1 Role of participants within stakeholder groups**

Participant's code	Role within the stakeholder groups
SK01	Pharmaceutical Regulatory Organization
SK02	Wholesaler
SK03	Wholesaler
SK04	Manufacturers Association
SK05	Manufacturers Association
SK06	Wholesaler

The presentation of the findings starts by exploring the participants' views about counterfeit medicines in the UK and the need for an anti-counterfeit medicines strategy. Then, the need for involving stakeholders in the development of an anti-counterfeit medicines strategy and their roles in the drafting and implementation of such a strategy are addressed. Also, the study highlights the role of pharmacists and GPs in combating counterfeit medicines and the way those roles can be communicated. Lastly, the views of participants on the expected outcomes from an anti-counterfeit medicines strategy and the methods used to evaluate those outcomes are discussed.

### **5.4.1 Personal opinions about combating counterfeit medicines**

To understand the MHRA stakeholders' perceptions and interpretations in respect of counterfeit medicines, the study started by seeking their views about counterfeit medicines in the UK and more specifically the issue of the online sale of such medicines. Here, the participants highlighted their assessment of the need for an anti-counterfeit medicines strategy for any regulatory medicines agency in their fight against counterfeit medicines. The participants also revealed their judgment regarding the



MHRA's anti-counterfeit medicines strategy as an example of the effort to combat the issue in the UK.

#### 5.4.1.1 Participants' views in respect to counterfeit medicines

When expressing their views on the danger of counterfeit medicines, participants differentiated between those obtained through a legitimate supply chain and those purchased through online websites. The participants explained the changes in the legitimate supply chain in recent years and referred to the dangers associated with generic medicines. Regarding the online websites, they described some of the challenges that would face governments with those sites.

All participants believed that counterfeit medicines are imposing a high risk on consumers in the UK as well as globally. Their view was formed from the number of cases that had been found in the UK's legitimate supply chain. Some participants perceived the issue of counterfeit medicines in the UK as being more serious than the government realises as it is not that easy to identify the scale of it in the legitimate supply chain.

*“In the legitimate supply chain coming through community pharmacy, you know, spot checks wouldn't necessarily pick up on what the problem is. So I think on the one side it's an underestimated problem” [SK03]*

However, those participants still view the danger of counterfeit medicines in the UK as being less than in some other countries.

*“It's obviously a bigger threat in places like Africa and Asia where there are a lot more cases” [SK05]*

Furthermore, most participants argued that the incidence of counterfeit medicines in the UK in recent years was less than it was 5 years ago. This was concluded because no cases have been found in the UK legitimate supply chain in the last 5 years. But, this does not mean that the effort to combat the issue of counterfeit medicines in the UK has decreased.

*“The evidence has been that there haven’t been any substantial recent cases of genuine or legitimate counterfeits” [SK01]*

In respect of the danger from counterfeit medicines for generic medicines, the views of the participants were diverse. Some participants did not differentiate between the counterfeiting risks associated with generic medicines and branded medicines even though the price of generic medicines is relatively low in the UK.

*“I’ve never, ever accepted the argument that for example that generics are not a risk because they’re too low in price” [SK03]*

Those participants said that even if the price was low for generic medicines the counterfeiters can still make money from them because sales volumes are high. So, the profit margin for generic medicines was slim but with high volumes sold it is still attractive for the counterfeiters. Another reason for the participants interpretation is the degree of the awareness linked to generic medicines is low compared to branded medicines.

*“I think you know people are less, there’s less awareness about the potential of counterfeiting generics, than there is of, you know, the lifestyle drugs” [SK01]*

Some participants do not disregard the risk of counterfeiting of generic medicines but said the counterfeiting of generic medicines is very rare. Their interpretation was based on the fact that the price of generic medicines in the UK is very affordable and may in fact be one of the lowest priced countries in the world. In addition, the UK market is a freer market so generic medicines are priced freely by drug companies. Another reason mentioned by participants is that generic medicines in the UK are supplied by many different companies and usually the consumers do not recognize the generic names, therefore it is less attractive to counterfeit this kind of medicine. Hence overall the risk from counterfeiting for generic medicines was perceived as low but was not excluded altogether.

*“In this country [counterfeited generic medicines] hasn’t really been a threat and isn’t really on our radar” [SK04]*

Some participants have offered explanations for the threat of counterfeit medicines being high within the legitimate supply chain in the UK. The first one addressed was that the lack of supply of some medicines in the UK attracted the counterfeiter to fill the gap.

*“I think you know, you're probably aware about short supply issues. That can sometimes I think lead to counterfeiting issues in its own right, because of the demand”* [SK01]

The other reason offered was the high price for some branded medicines in the UK which make it attractive for counterfeiters. The final reason mentioned was the relatively light penalties provided for in the relevant legislation for trading in counterfeit medicines compared to trade involving illicit drugs, something which also makes it attractive for counterfeiters.

*“penalties for counterfeiting medicines are far, far less than penalties for selling, you know, illicit drugs, you know, selling cocaine or heroin”* [SK03]

All participants mentioned the threat of counterfeit medicines linked with supply through online websites. They perceived that the major threat for consumers comes from online websites rather than the legitimate supply chain.

*“I think for me the real, the real challenge from counterfeit medicines is one that is largely a problem of the growth of the internet and online provision”* [SK03]

Participants justified their views by stating that it is very difficult for governments to control what was being sold through the internet. The counterfeiters can actually distribute their product very easily via the internet and can do so while running low risks of being caught.

*“The risks of having a whole batch seized and tracking people and using individuals basically in that country, the risks are lower if you use the internet”* [SK01]

Also, the participants believed the number of consumers using online websites is increasing which increases the threat. The final justification for concern offered by the

participants was the lack of data revealing the number of websites that sold counterfeit medicines.

Participants mentioned a few challenges that the government faced in relation to the sale of counterfeit medicines through online websites. One challenge would be the difficulty for any government that wishes to regulate online sales of medicines as the location of these websites is either unknown or is in another jurisdiction. This leads to another challenge which is the need for cooperation and communication between countries to overcome this threat.

*“But that demands a lot of international cooperation to do that. So I think that for me, that’s where the biggest problem lies, but that’s also the biggest challenge”* [SK03]

Furthermore, according to the participants, a challenge facing the government is understanding the motivation for consumers to use the internet to buy their medicines which may go beyond mere cost and this understanding could help the government according to some participants.

*“So understanding the motivation hopefully will help inform how you need to tackle the problem”* [SK04]

To recap, participants described their views in respect to the counterfeit medicines as being a threat to consumers in the UK through the legitimate supply chain but argued that the risk is much greater from medicines via the online websites. They addressed the risk of generic medicines being counterfeited in the UK. Finally, participants highlighted the challenges for government that were associated with the threat of counterfeit medicines via online sellers.

#### **5.4.1.2 Participants' views in respect of an anti-counterfeit medicines strategy**

Having illustrated their views with reference to the counterfeit medicines issue, participants emphasized the need for an anti-counterfeit medicines strategy and the

reasons for their viewpoints. Also, they described their views regarding the MHRA's anti-counterfeit medicines strategy.

All participants agreed on the need for an anti-counterfeit medicines strategy for any medicine regulatory agency combating the threat. Some of the participants saw it as a must for the agency to have such strategy.

*“I think it should, I think every country should take it seriously. I think it would be very unwise not to take it seriously, because it is a real threat I think”* [SK05]

Participants gave a number of reasons for their views on the need for a strategy. Such a strategy would help the government to protect public health from the threat arising from counterfeit medicines. Also, without such a strategy a country's legitimate supply chain would be targeted by counterfeiters. Some participants believed that by having a strategy, awareness of the issue of counterfeit medicines will be higher among the regulatory agency and its stakeholders. This will help the agency to be ready should any case appear in the supply chain and to deal with it in an effective way. Furthermore, participants said the issue of counterfeit medicines is a complicated one, and without such a strategy the supply chain would be at risk and the counterfeiters would find a weak point to put their product into the market.

*“It's got to be done right, because if you have a small chink in the system, without a strategy then the problem is the counterfeiters will find a loophole. If you, if you fail to plan, then you plan to fail. That's why they should have a strategy”* [SK02]

One participant highlighted their belief that when a medicines regulatory agency does not have an anti-counterfeit medicines strategy to match other countries they put themselves at risk as their system will be seen as vulnerable and will be targeted by the counterfeiters. This view applied even if the agency did not believe they had a counterfeiting issue in its system as it would stop the counterfeiters from considering targeting the country's market. The last reason mentioned concerned the reputation of the agency in the public mind, as without such a strategy the agency would be seen as not doing enough to protect public safety.

*“you’ve got to do everything you can to protect them. And therefore if a regulator which is actually in the public interest is not acting to save patient’s lives, then they are not doing their jobs. So I think every regulator must, not should, have a strategy” [SK02]*

Two points were highlighted by a few participants regarding the importance of an anti-counterfeit medicines strategy. Firstly, the agency should understand the actual size of the pharmaceuticals market that it regulates and the effect counterfeiting has on this market.

*“It is a tricky balance. And quite often and this again is a challenge for regulators” [SK03]*

Also, the agency should be careful to be balanced in the strategy so they can address the potential problem but not to the degree where it might have a negative impact on the continuous supply of medicines to patients.

Considering the effort made by the MHRA on the issue of counterfeit medicines in the UK and the outcomes seen from its anti-counterfeit medicines strategy, all participants thought that the MHRA had performed well on the issue and pointed to how the strategy helped the MHRA to pursue its aims. To support their view, participants highlighted the successes that had come out of the MHRA strategy. They said that the agency had been successful in removing the threat from the UK supply chain.

*“The actual strategy that MHRA have used has actually been successful in perhaps removing the threat from the UK supply chain” [SK01]*

Also, highlighted was the fact that the MHRA had put a lot of their resources into defeating counterfeiting and had worked very closely with the other enforcement agencies. Besides this, the MHRA understood the dynamics of the market and therefore listened to people more and had become more attentive to what its stakeholders say. This, according to participants, made the MHRA the leader in the effort to combat counterfeit medicines.

*“MHRA have obviously done a great job in the UK and we are probably at the forefront of this kind of activity through them” [SK05]*

One participant stated that even with the success of the MHRA's anti-counterfeit medicines activities, it should re-evaluate its strategy as traditionally the strategy was more about the legitimate supply chain, whereas the danger from online websites is increasing.

To sum up the participants' beliefs regarding the counterfeit medicines issue, they saw it as threat to public health, however, they believed the risk from online websites was greater than the legitimate supply chain for many reasons including the difficulty in controlling the internet and the low penalties associated with counterfeit medicines compared with trading in illicit drugs. The perceptions of the counterfeiting danger associated with generic medicines in the UK were split between those participants who felt the risk was no less than for branded medicines while others felt the risks of generics being counterfeited in the UK was very low. Perceived risk may be linked to the precise role of the individual and the organisations for which they worked. For example, a participant only involved with a supplier of branded medicines may be more likely to see their own medicine category as being at high risk from counterfeiting. Also, all participants highlighted the need for an anti-counterfeit medicines strategy for any regulatory agency. Furthermore, they believed that the MHRA's anti-counterfeit medicine strategy was successful and a demonstration of the importance of having such a strategy.

#### **5.4.2 The views of the participants on developing and implementing an anti-counterfeit medicines strategy**

This part will focus on the views of the participants on how the agency's stakeholders were involved in developing an anti-counterfeit medicines strategy and which stakeholders they thought should be part of this process. They described what the stakeholders could do at the drafting stage to help the agency. Finally, it considers how participants described the roles stakeholders could play in the implementation of an anti-counterfeit medicines strategy.

### **5.4.2.1 Should the stakeholders be involved in the development of an anti-counterfeit medicines strategy?**

All the participants who could comment on the involvement of stakeholders in the development of strategy agreed that these stakeholders should have a role from the beginning of the drafting of the agency's strategy.

*“So it's important to have stakeholders involved very early on so they can support it, and to spot any weaknesses in it, from very early on before it's moved too far down the line” [SK02]*

A few of them also added that the leading role in the drafting must be played by the agency as it is the agency's strategy. The degree of stakeholder involvement in the developing of such a strategy was not entirely clear for these participants as a medicines regulatory agency has a diversity of stakeholders.

*“In an ideal world yes; I don't know how much they would input in to that because I think they're background will be different” [SK01]*

Whereas, other participants believed the substance of stakeholders' involvement would be in providing information to the agency during the drafting stage as these stakeholders are at the ground level and they see more things first hand than the agency and this would help the agency to become better informed.

*“So actually providing all that information so the MHRA can take a better, well informed opinion and can focus it” [SK04]*

Participants illustrated many reasons for their belief in the importance of stakeholders' involvement. Most of them stated that such a strategy would not be successful in any country without the involvement of its stakeholders.

*“If you don't then it's not going to be successful; simple as that” [SK01]*

Also, participants thought the agency and its stakeholders were equally interested in making the anti-counterfeit medicines strategy work; therefore, the stakeholders should be involved at the drafting stage.



*“It probably wouldn't be the best way to go forward yeah to go ahead and try and draft a strategy without some kind of involvement of stakeholders, because at the end of the day everyone's got to make it work” [SK05]*

Another reason given, to involve stakeholders was to get them to 'buy in' to it and this will encourage them to support its implementation.

*“It's essential that you get some buy in and some involvement from them in drafting up, because if it's not workable, it's not practical, it becomes too much of a burden. It's going to fail” [SK03]*

Participants argued that the strategy cannot be drafted or the issue of counterfeit medicines successfully combated without the involvement of the full range of stakeholders as no single one holds the complete picture of the problem on their own.

*“So yeah without the industry, don't think the MHRA can make that kind of announcement on their strategy, without forming dialogue with everybody else” [SK06]*

Finally, participants commented that the stakeholders deal with medicines in their daily work, and part of their effort is to try to prevent penetration of the legitimate market by counterfeiters and being alert to what is going on out in the real world. They are ideally placed to spot any weaknesses. As a result, engaging with the stakeholders' experiences will be very helpful in drafting the strategy.

*“I think they need to involve the stakeholders who are on the ground actually dealing with these things and the sorts of issues on a day to day basis” [SK01]*

All the reasons emphasised by the participants lead them to believe in the importance of involving stakeholders in the drafting stage of an anti-counterfeit medicines strategy by the agency.

### **5.4.2.2 The stakeholder groups who should be involved in the drafting stage of an anti-counterfeit medicines strategy**

Participants tried to identify those stakeholders who should help the agency in developing its anti-counterfeit medicines strategy. They said the pharmaceutical industry was one of them, which included generic manufacturing and research-based manufacturing as they have a responsibility for their products and brands. This can be achieved through trade associations such as the British Generics Association. Also, the wholesalers were considered key players as they have responsibility to monitor where they are buying products from. Participants said wholesalers can be represented either through its trade association or individually. The distributors and parallel importers and exporters should also be among those stakeholders helping the agency.

*“I think there may be merit in looking to involve people that are actively involved in the parallel trade of medicines to Europe” [SK01]*

Furthermore, the law enforcement agencies need to be included which would mean the regulator of pharmacies, the police, border control and customs. In addition a few participants mentioned that pharmacists within hospitals and the community should be represented as stakeholders.

*“You’ve got the hospital pharmacists. Community pharmacists. Got the industry, pharmaceutical industry” [SK02]*

Finally, one participant said it would be helpful for the agency to listen to patient groups in the drafting stage to capture their perspective.

*“I think there is obviously a need for I think broader communication to patients” [SK03]*

Participants pinpointed the agency's stakeholders that could be part of the drafting stage of an anti-counterfeit medicines strategy from the pharmaceutical industry and law enforcement.

### 5.4.2.3 The role of stakeholders during the drafting stage of an anti-counterfeit medicines strategy

Participants stated that the actual drafting of an anti-counterfeit medicines strategy should be initiated by the medicines regulatory agency as it is ultimately responsible for it. Assertion of the need for a drafting committee comprising the agency and its stakeholders to draft such a strategy was, however, not a constant among the participants. Some participants did not see that the strategy could be drafted through such drafting committee as the agency owned the strategy. On the other hand, other participants insisted that this kind of strategy needed a committee to develop it as the stakeholders play an important part of the development. A third group of participants could not come out with any view on this matter.

*“Whether they should be actively sitting around as a committee, drafting the actual policy or not I’m not always sure” [SK01]*

The process of drafting the strategy with a contribution from the agency’s stakeholders was described by the participants. They believed the agency should start the drafting by conducting an internal analysis to evaluate the problem and to identify the strengths and weaknesses. This would be a start point and not necessarily that detailed. The next stage would be consultation with stakeholders and an open discussion about improving the strategy.

*“We’re developing our own opinions, but this is very much a template to get your views and then call them in to that meeting and that’s then your first stage” [SK04]*

Then the agency would go back with all the feedback and comments from the stakeholders and develop a second draft of the strategy. However, the agency would not be bound by the feedback.

*“So yes I mean we have consulted, but you know, but as part of the consultation process, you know, they are free to believe what they want to believe” [SK03]*

When the second draft is ready, the agency would conduct a second round of consultations and would also open the process for public comment to allow those interested to further widen its relevance.

*“I would then open it up to probably to public consultation. Because there may be people beyond the people that you’ve initially thought of that would be helpful” [SK04]*

Lastly, the agency would finalize its anti-counterfeit medicines strategy based on the public comments and the second round of stakeholders' consultation and publish the strategy. Participants stressed that without consultation and feedback the strategy cannot move forward.

#### **5.4.2.4 The roles of stakeholders in implementing an anti-counterfeit medicines strategy**

In respect to the roles that a medicines regulatory agency's stakeholders could play in the implementation of an anti-counterfeit medicines strategy, all participants assumed the agency cannot apply the strategy on its own and that it could not be implemented without the involvement of stakeholders.

*“I think you can't really impose a strategy without the involvement and willing and active involvement of stakeholders” [SK05]*

To support their assumption, they said that anything the agency said or did because of the strategy was going to affect stakeholders. Also, the agency would be policing the strategy but the stakeholders would operate most of it and would ultimately dictate its success or failure. Another reason is that the involvement of the stakeholders would add more power to the strategy as a number of agencies or associations would be working behind it.

*“But if they're all behind one particular target, then you've got the power of 3 or 4 agencies all looking at one particular aspect” [SK01]*

The availability of the resources to implement such a strategy is an issue as no agency would have enough resources to complete the work in isolation. One participant commented that any anti-counterfeit medicines strategy simply would not work properly if the stakeholders cannot make it work, so their involvement is essential.

In relation to what stakeholders can do for the implementation of an anti-counterfeit medicines strategy the participants defined some roles that stakeholders could play. Stakeholders would be involved through collaboration and cooperation with the medicines regulatory agency and with each other for combating counterfeit medicines.

*“I think there is that responsibility to help educate regulators on the market dynamics, because you know, the markets in buying and selling of medicines which is legitimate, you know, can be quite complex and complicated”*  
[SK03]

Another role identified by participants involves the stakeholders having open communication with the agency and exchanging information with it. The stakeholders would also gather their own intelligence in respect to counterfeit medicines issues and help the agency in its investigation.

*“Providing intelligence to the regulators when in your everyday business you may pick up on, you know, cases where someone is trying to sell you something”* [SK03]

The stakeholders were perceived as needing to support the agency by providing the technical expertise that they have. An additional role for stakeholders was to work hard to secure the supply chain by checking the credentials of the people they bought from.

*“secure the supply chain and to get stakeholders to be, act responsibly within that supply chain and to try and secure their routes of supply, their supply chain, upstream supply chain to make sure that that's secure, that you're only buying from accredited secures”* [SK05]

Furthermore, according to the participants, the stakeholders would be vigilant for any suspicion in the supply chain that might sound the alert for counterfeiting. The stakeholders would have a role in reporting any of the suspicions or actual cases of

counterfeiting to the agency. Finally, the stakeholders would play a role in education and awareness for their own members and the general public about the counterfeiting of medicines.

To summarise, participants said the medicines regulatory agency's stakeholders have a role in the development of an anti-counterfeiting strategy and should be involved in the drafting from the beginning because this will not only improve the quality of the strategy but also its ultimate implementation. Also, the stakeholders who should play a part in the drafting stage were defined by the participants as members of the pharmaceuticals trades (manufacturers, wholesalers, distributors and parallel traders), the law enforcement agencies and maybe patient groups. Stakeholders would help the agency in drafting such a strategy through consultations and feedback. For the implementation of the anti-counterfeiting strategy, the stakeholders would have an essential role in collaboration and cooperation with the agency, securing the supply chain and educating and raising awareness among their own members and the general public.

### **5.4.3 Role of Pharmacists and General Practitioners (GPs) in combating counterfeiting medicines**

Participants highlighted their views in regard to the roles that pharmacists and GPs could have in combating counterfeit medicines. Also, they commented on ways of communicating those roles to pharmacists and GPs.

#### **5.4.3.1 Stakeholders' views on the role of the pharmacists**

Participants believed that pharmacists have a major role to play in the effort to combat counterfeit medicines as they are the last link between the supply chain and the patients. Those pharmacists are considered to be on the frontline as they see and handle the medicines on a daily basis.

*“They are the last stop gap between the patients getting the right medicine and the patient getting the wrong medicine” [SK02]*

The participants distinguished some roles that pharmacists could play to combat counterfeit medicines. The main and most important role pharmacists can play as identified by all participants is to work hard to secure their supply chain by purchasing their products only from reliable and licensed sources.

*“Pharmacists need to be sure that they’re purchasing medicines from companies that are licensed to do so. So that is the most important thing that they can do” [SK04]*

In addition, the participants perceived the need for pharmacists to be vigilant about any alteration to the medicines' packaging even if they have received it from trusted suppliers. Also, pharmacists should identify comments and feedback from patients which might indicate counterfeiting.

*“You know the minute a security seal has been tampered with or the pack looks damaged, or it doesn’t look, or it looks out of the ordinary, yeah they can question it, yeah just to be vigilant” [SK06]*

Another role that pharmacists can play to help in the combating of counterfeiting medicines as described by the participants would be exercising their duty to report any suspicious cases to the medicines regulatory agency. Besides this they should report the feedback from patients too.

*“it very clear to people that if you have concerns about the quality of medicines they have to be reported, it’s a professional obligation that you report them on to the marketing organisation or the licensing authority organisation which is MHRA” [SK01]*

Also, participants said the pharmacists would have a role in raising awareness among and educating patients on the danger of counterfeit medicines as they deal with patients on a day-to-day basis and they are trusted by the patients.

*“They need to make the patient aware, if they’re not aware, because not a lot is actually reported in the media from time to time, but you know*

*because the pharmacist is face fronted, you know, the patient coming in trusts what the pharmacist tells them” [SK06]*

The final role, pharmacists can educate the patients on the best method that patients can use if they would like to buy medicines from online sources such as, for example, only using websites that are accredited by the GPhC.

### **5.4.3.2 Stakeholders' views on the role of General Practitioners (GPs)**

Considering the roles that GPs play in combating counterfeit medicines, some participants thought there would be no role that GPs can play as the GPs do not physically deal with medicines. However, they considered the dispensing doctors' role would be the same as the pharmacists'. Whereas, other participants said GPs would have some role but it would be less important than the pharmacists' role. A few roles were defined by the participants for GPs. Participants said GPs could be a source of education and awareness for the patients on the danger of the counterfeiting medicines and how the patients could protect themselves.

*“I suppose using the reputation of GPs with the public in those areas where you can educate the public is probably a good thing” [SK04]*

Additionally, the GPs should be vigilant to the feedback and complaints from patients concerning their medicines. Finally, GPs should report any suspicion they may have in respect to the counterfeiting issue to the medicines regulatory agency.

*“The professional duties are in GPs, but certainly if they become aware that there's a counterfeit I would suspect that they have an obligation to report that” [SK01]*

For the dispensing doctors, the participants added one more role they can play which is to secure their supply chain in the same way as the pharmacists.



### 5.4.3.3 Communicating the roles of pharmacists and GPs

With the respect to the roles that have been identified for the pharmacists and GPs in combating counterfeit medicines, participants also mentioned the methods that could be used to communicate those roles. Some participants believed that pharmacists and GPs need more information and support from the medicines regulatory agency and their professional bodies in regard to counterfeit medicine issues. A few participants also highlighted the need for training the pharmacists and GPs and educating them when at university level.

*“I think it’s a variety of sources to educating pharmacists at university”*  
[SK01]

In addition, participants claimed the best source of communication for the pharmacists and GPs would be their professional bodies because the messages that come from those bodies would be more tailored and specific to either the pharmacists or GPs and not as general as if the information came from the medicines regulatory agency.

*“I think the information has to come from the, either the professional body. So the General Pharmaceutical Council or you know or the General Medical Council or from the Royal College of General Practice for example or from, you know, the associations representing pharmacy”* [SK03]

Finally, the communication tools that might be used with the pharmacists and GPs as seen by the participants would be professional journals and articles and also the internet, emails and social media. These communication tools should be used on a regular basis so the pharmacists and GPs were reminded of the topic of counterfeit medicines.

In summary, participants believed that pharmacists could play five important roles in combating counterfeiting medicines. Pharmacists should secure their supply chain, be vigilant to packaging, attentive to the feedback from patients, report any suspicions and be a source of awareness and education for the patients. GPs have less important roles than pharmacists: GPs could be a source of education and awareness for the patients, be vigilant and report any suspicion to the medicines regulatory agency. Also, participants believe the best communication to pharmacists and GPs in respect to counterfeiting would come from their professional bodies.

## 5.4.4 The expectations from the anti-counterfeit medicines strategy

This section highlights the participants' views on the outcomes that a medicines regulatory agency might expect from an anti-counterfeit medicines strategy. Also, the participants discuss their opinions on the evaluation concept for the outcomes from such strategy.

### 5.4.4.1 Stakeholders view on the outcomes from an anti-counterfeit medicines strategy

As a general statement, participants believed that medicines regulatory agencies should be realistic in their expectations from its anti-counterfeit medicines strategy. Also, from the beginning the regulatory agency needs to be quite clear about what it is trying to achieve from the strategy. However, all participants agreed that defining exact outcomes would be difficult as, at the outset, the agency does not have the full picture of the problem of the counterfeiting of medicines in the country when they are drafting the strategy.

*“that can be quite difficult when you're not exactly sure what the scope of what you're trying to, well the scope of the problem, what it is at the beginning” [SK01]*

Participants tried to identify what the results could be from a successful anti-counterfeiting strategy. The most important outcome would be protecting the public as this is the duty of any government. Another possible outcome seen by participants is securing the supply chain, so that counterfeit medicines would not reach the patients.

*“The second good strategy is that you're closing the loopholes where they can introduce counterfeit medicines in to the system” [SK02]*

One outcome would be a reduction in the number of counterfeit medicine cases in the supply chain. Participants believed that if counterfeit medicines continue to reach the patients then public confidence in the supply chain will be lost.

*“Patients get what it says on the box, you know, and they can take it with confidence that what they’re getting is what it says on the box, you know, so the bottom line is to make sure that it’s, that patients are safe” [SK05]*

Another outcome would be changing people’s behaviour in respect to counterfeit medicines and that could be achieved through better education and raising awareness.

*“I think there is a bit that says better education, better awareness, hopefully - To the patient, to the consumer, to the patient, would certainly make them think, you know, even though I want to, the risk is too high and therefore I won’t buy it” [SK03]*

Also, changing behaviour would lead to another outcome which is an increase in the number of reports to the medicines regulatory agency from the public as well as from pharmacists. Besides this, an increase in the number of product seizures and the number of prosecutions and tighter penalties would also be an expected outcome from the strategy as seen by the participants.

*“I think objectives really should be about, you know, tighter penalties for those that you can identify and deal with” [SK03]*

Likewise, an increase in the number of unregulated websites, which could be sources of counterfeit medicines, closed by the agency would be a positive outcome. The final outcome would be an improvement in international cooperation in combating counterfeit medicines because the problem of counterfeiting is worldwide and a single country cannot deal with it by itself.

#### **5.4.4.2 Stakeholders’ views on the methods could be used to evaluate the strategy’s outcomes**

All participants agreed that any kind of evaluation for an anti-counterfeiting strategy would be the responsibility of the agency as it is the owner of this strategy. However, there was doubt among some participants as to whether the medicines regulatory agency could effectively conduct this kind of evaluation.

*“When you try to stop something happening, it’s very difficult to prove that you’ve stopped it happening, that it hasn’t happened” [SK05]*

Other participants' opinions were also that to evaluate such a strategy would be very difficult for the agency. They believed the agency might only be able to partly evaluate the strategy, specifically for those parts over which it had direct control (manufacture and wholesale) and even here the evaluation would only be basic.

The tools that could be used to conduct an evaluation for such a strategy would be the kind of metrics that the agency designs for that purpose.

*“I think you need to be sensible in the way that you will design the kind of metrics. The kind of measurements that will inform the evaluation” [SK03]*

Participants suggested the agency use the number of counterfeit medicine cases that have been reported or detected. The economic value of counterfeit medicines seized and the cost of patients' hospitalisation due to counterfeit medicines.

*“I mean hospitalisations I suppose I don’t know how many, I don’t think MHRA have really done much research in to how much money or what the costs are of, on patient health and caring for people that have taken counterfeit medicines” [SK01]*

In addition, the number of reports by patients, pharmacists and GPs that relate to counterfeit medicines can be measured. The agency can also use the number of prosecutions and sentences for people trading in counterfeit medicines. Finally, to measure the change in public behaviour as a result of the strategy, the agency could conduct a public survey regarding their views on the counterfeiting of medicines.

*“I think doing polling of the public after maybe 3 years or 5 years, you know what is your attitude towards purchasing medicines” [SK04]*

In respect of the role of stakeholders in the evaluation of the strategy, participants thought stakeholders would have a limited role. They said the stakeholders could help the agency by providing it with the data they have regarding the counterfeit medicines issue. Also, the stakeholders can feedback to the agency on what they have seen on the ground. Finally, the stakeholders help the agency by providing expertise when needed.

One participant suggested that evaluation could be carried out by an independent body, the reason being to avoid possible bias that could arise should the agency evaluate its own work.

*“Because then you’re not biased, you’re not skewed in your results and therefore there’s more authenticity, more recognition, more integrity if it’s an outside group like an academic institution or university or something”*

[SK02]

This section presented the views of the participants on the potential outcomes from an anti-counterfeit medicines strategy. They believed that it would not be an easy task for a medicines regulatory agency to define specific outcomes from such a strategy. However, they managed to mention some outcomes that could be expected from the strategy such as protecting the public, securing the supply chain and changing people’s behaviour in respect to the counterfeiting medicines issue. The evaluation of those outcomes would be a difficult task for the agency as seen by the participants. They said the agency could use metrics including the number of counterfeit medicine cases and the number of reports by patients, pharmacists and GPs to conduct the evaluation.

## **5.5 Discussion**

The aim of this study was to gain further understanding of the issues associated with developing an anti-counterfeit medicines strategy through eliciting the stakeholders’ views about the process from development to evaluation. Having a multi-dimensional or triangulated understanding is important if a complete conceptualisation of how to develop an effective anti-counterfeit medicines strategy is to be reached. This study therefore first elicited the views of the participants on the need for an anti-counterfeit medicines strategy. The study found that stakeholder participants clearly perceived counterfeit medicines as a significant risk to public health and that the main source of this risk was online supply. They also identified the difficulty of controlling the internet and the low penalties associated with counterfeit medicines compared with trading in illicit drugs which they saw as being associated with online websites. In other words, they saw the ease of reaching the market and low risk for counterfeiters in terms of

chance of detection and penalties as particularly attractive to criminals and drawing them to online routes. The threat to generic medicines from counterfeiting was found to be perceived by some but not all participants as less acute than the threat to branded medicines. Stakeholders were also found to believe that an anti-counterfeit medicines strategy is a requirement for any national medicines regulatory agency to successfully combat counterfeit medicines.

This study also highlighted how the stakeholders view their own role in the process of developing and implementing an anti-counterfeit medicines strategy, stressing that they should be involved in the drafting of such a strategy from the beginning as this would improve the quality of the strategy and facilitate the implementation process. They saw their roles during strategy development as being consultative and providing feedback. Participants believed the stakeholders' roles in implementing the strategy would be essential and which would be able to draw on their collaboration and cooperation with the agency, securing the supply chain and educating and raising awareness among their own members and the general public.

Stakeholders also expressed views on the roles of pharmacists and GPs in supporting the strategy, identifying five roles for pharmacists. These roles were: securing their supply chain, being vigilant to packaging, being attentive to the feedback from patients, reporting any suspicions to the medicines regulatory agency and being a source of awareness and education for the patients. They saw roles of GPs as less important than those of pharmacists in relation to this issue. Nevertheless, they suggested that GPs could be a source of education and awareness for the patients, be vigilant and report any suspicion to the agency. Participants also believed that communicating those roles to pharmacists and GPs would be better achieved via their professional bodies.

Finally this study elicited the views of the stakeholders on the anticipated outcomes of an anti-counterfeit medicines strategy and how these desired outcomes could be evaluated. The study found that participants perceived that both identifying the outcomes and evaluating them *post hoc* would be a problematic task. Nevertheless, protecting the public, securing the supply chain and changing people's behaviour in respect to counterfeit medicines could be set as desired outcomes of the strategy. While seen as problematic participants observed that quantitative metrics such as the number

of counterfeit medicine cases and the number of reports by patients, pharmacists and GPs may form part of the evaluation.

A major limitation of this study occurred during the recruitment stage. The aim of this study was to get the views of main MHRA stakeholders, who had direct involvement with the MHRA's activities in combating counterfeit medicines in the UK. However, only one participant was recruited who was fully involved with these MHRA activities. The rest of participants were not directly involved with the MHRA's activities; however, their work tasks were related to counterfeit medicines. However, this study was designed to gain a better picture on the issue associated with an anti-counterfeit medicines strategy from development to evaluation rather than an examination of the MHRA's activities under the two already published strategies; therefore this minimises the effect of this limitation on the overall study's findings. Another limitation is related to the number of participants involved on this study. Only six people agreed to take part in this study which might give weakness to the study as those participants did not represent all stakeholder groups. A further limitation may be the background knowledge and experience of the researcher which may have introduced some level of bias to the data analysis undertaken by the researcher because as a pharmacist working within a national regulatory agency in another country the researcher cannot have worked without developing a personal perspective and set of assumptions regarding counterfeit medicines and how to combat them. Another limitation of this study is that it was developed in the context of a very limited range of published literature specifically making reference to anti-counterfeiting medicines strategies; which could be used to assist the researcher in identifying appropriate methodologies and in providing some context in which to discuss the findings.

While not all participants were wholly engaged with the MHRA's anti-counterfeiting medicines activities, which could be seen as a limitation to this study, this could also be considered as a strength as the participants will not have been influenced by or biased toward those activities. Overall, the stakeholder participants demonstrated in their responses that they held appropriately-informed views with respect to the counterfeit medicines strategy which met the criteria set out in the methods section. Also, another strength for this study is it would be the first study that addressed the view of the

stakeholders on the issues associated with developing an anti-counterfeit medicines strategy.

This study generated findings which could be conceptually grouped into four main themes relevant to the study objectives as follows: i) understanding the medicines regulatory agency's stakeholders' opinion about combating counterfeiting medicines; ii) understanding stakeholder perceptions of the roles of the medicines regulatory agency's stakeholders in the strategy's development and implementation processes; iii) understanding stakeholder perceptions of the roles of pharmacists and GPs in combating counterfeiting medicines; and iv) the outcomes expected from an anti-counterfeiting medicines strategy and its evaluation methods. The discussion of the findings which follows is organised into these four themes.

**i) Understanding the medicines regulatory agency's stakeholders' opinions about combating counterfeiting medicines:**

It was found that stakeholder participants shared a common perception of the risks for consumers from counterfeit medicines which participants viewed as not being restricted to the UK but as a global risk; this view is supported by published reports (2, 12, 28, 55). Furthermore, the risks associated with counterfeit medicines were perceived by the participants to be lower in the UK than other countries, which could be justified from participants' belief in the effective efforts conducted by the MHRA in combating counterfeit medicines in the UK. It is worth considering that there may have been a reluctance among participants to make observations which could be interpreted as critical of the MHRA, especially to a researcher from another country. Participants also recognized that the efforts in combating counterfeit medicines in the UK had not subsided as a result of the MHRA's data which showed that the number of cases found in the legitimate supply chain has been reducing. Participants identified three driving factors behind the emergence of counterfeit medicines in the country: lack of availability of some legitimate medicines which encourages patients to look for those medicines online; secondly, the light penalties for engaging in the supply of counterfeit medicines that makes it attractive for criminals; and thirdly, the high price of some branded medicines in the country.



The study found that some participants perceived the risk from counterfeiting of generic medicines to be lower in the UK than the risk to branded medicines, while others saw no difference. The logic of the former was, that with generic medicines sold more cheaply and at lower margins than their branded equivalents, counterfeiting them was less lucrative for the counterfeiters who would be more attracted to the profits to be made by supplying counterfeit branded drugs. In addition, the names of generic medicines are not recognized by patients. In contrast, other participants perceived the threat of counterfeiting as being the same for generic and branded medicines as the counterfeiters might gain profit from selling higher volumes of generics than branded medicines thus making up for the thinner margins. This difference in participants' views might result from the specific backgrounds of the participants and the interests of their respective organisations. Having said this, the evidence from MHRA recall data, which shows that all recalls made were for branded medicines, indicates support for views of participants who rated the risk to generics as lower; also, it might reflect the focus of the vigilance activities i.e. more time was spent on branded products than on generics (131).

It was also found that participants were more concerned with the threat of counterfeit medicines purchased online rather than through the legitimate supply chain. The reasons for the higher threat, according to participants, were the fact that: counterfeiters found it lot easier to distribute counterfeit medicines via the internet; regulatory control and interceding in the supply of counterfeit medicines is much more problematic when they come through the online channel as the location of the websites that sell counterfeit medicines is either unknown or in another country; the number of consumers using websites to buy medicines is increasing; and there are no data available revealing the number of websites that sold counterfeit medicines. In support of this view, it has been reported that 10% of men obtain medicines without prescription via the internet (132). According to the current study, when tackling counterfeit medicines being supplied online a regulatory agency would face a number of challenges. These include the need for cooperation and communication between countries to overcome this threat from online sources as the location of these websites is either unknown or is in another jurisdiction and building an understanding of the motivations behind consumers' decisions to use the internet to buy their medicines.

The study found that the stakeholder participants were unanimous in recognising the need for any medicines regulatory agency to have a strategy in place. The strategy would help the agency to organise and prioritise its activities, to protect public health and the pharmaceutical products supply chain; and would increase awareness of the issues and what was being done to address them among all stakeholders. A more nuanced concern from the participants was that the MHRA should calibrate its responses to the counterfeit medicines problem in such a way which does not run the risk of having a negative impact on the supply chain of pharmaceutical products. The participants, representing the interests of their respective organisations, appeared to have a concern that should the MHRA be too vigorous in its attempts to raise awareness of the counterfeiting issue the public may lose confidence in the supply chain in the UK and ultimately buy less medicines from the pharmaceutical companies. It was also found that the stakeholders valued the efforts made by the MHRA in combating the counterfeit medicines in the UK. Participants acknowledged that the MHRA's strategies had made the supply chain safer for patients, and that had been achieved by working closely with other enforcement agencies in the UK and that the agency had been making a valuable contribution to the stakeholders of the pharmaceuticals market. The statements by participants expressing support for the efforts already made by the MHRA were positive but highly general in nature. Again, the researcher considered the possibility that these stakeholders were reluctant to comment on specific issues which may appear to qualify their support for the agency. One possible exception was the emphasis placed on paying greater attention to the threat posed by the online supply channel with its inference that this may have not been given sufficient priority in the past.

**ii) Understanding stakeholder perceptions of the roles of the medicines regulatory agency's stakeholders in the strategy's development and implementation processes**

It was found that participants saw the involvement of an agency's stakeholders in the process of drafting an anti-counterfeit medicines as important. Justification for this comes from the belief that stakeholders are more directly linked to the field activities and could potentially provide more valuable information than the agency might obtain through its own endeavours. Also, it was argued by the participants that the involvement of stakeholders would increase the sense of ownership and would provide a more

complete picture of the counterfeiting issue within the country through the sharing of stakeholder experiences. Therefore, the earlier engagement of stakeholders in the process was believed by participants to increase the likelihood of success for the strategy.

Moreover, the study identified different stakeholder groups which may become part of the strategy's drafting process which are representatives of pharmaceuticals industries (branded and generic) which may be their respective trade associations; wholesalers, distributors and parallel traders who could also be represented by their trade associations or individually; the country's law enforcement agencies (police, customs and regulators of the pharmacies); and finally the pharmacists (community and hospital) as well as patients. However, the degree of the involvement each group might have in the drafting process was not addressed by the participants. This might be because participants did not have direct involvement or past experience with drafting an anti-counterfeit medicines strategy.

In terms of the specifics of responsibility for and input into the drafting process the participants were clear that the responsibility lay with the medicines regulatory agency. The role of stakeholders in the drafting process as interpreted by participants would commence with a consultation on an initial concise document that had been written by the agency. The advantage of this, as seen by participants, would be that it would help the agency in identifying its own strengths and weaknesses effectively conducting a SWOT analysis for the agency (125). This role could be performed through a committee involving both the agency and its stakeholders which will allow the stakeholders to share their feedback and advice to improve the document. The next role that stakeholders could perform in the drafting process as suggested by participants, would be following completion of the first draft of the strategy. Participants interpreted this as a second round of consultation for further improvements between the agency and its stakeholders. The possibility of also involving the general public at this stage was also raised by participants. Ultimately, however, it was recognised that the agency would finalise the document itself as those primarily responsible for it.

The theme of stakeholder roles also covered the implementation process of an anti-counterfeit medicines strategy and it was found that participants viewed the involvement of stakeholders in this process as a prerequisite. In all, seven specific roles

were identified: communication and sharing of information between the stakeholders and the agency regarding counterfeiting medicine matters; securing the pharmaceuticals supply chain; staying vigilant and alert to any suspicious actions regarding medicine counterfeiting; reporting any suspicious activities to the agency; conducting their own intelligence activities; supporting the agency with skills and expertise; and finally assisting the agency in educating and growing awareness among the members of the various stakeholder groups and also among the general public.

There is a clear recognition among the participants in this study that the medicines regulatory agency has limitations on its resources and abilities and cannot carry out all aspects of the implementation by itself. Furthermore, even if it could go it alone, this would be neither desirable nor fully effective. Combined with this there is an understanding that major pharmaceutical companies are highly resourced in both financial and knowledge/expertise terms. They also have substantial commercial interests, including reputational interests, to protect, giving them substantial motivation to participate in the implementation of the strategy and contribute to its success. On a cautionary note a medicines regulatory agency would need to recognise that private sector pharmaceutical companies also have responsibilities to shareholders whose interests may not always align with the agency's or indeed the general public's interests.

### **iii) Understanding stakeholder perceptions of the roles of pharmacists and GPs in combating counterfeiting medicines**

Findings showed that the role of pharmacists arise from their patient-facing position in the supply chain being the last link before the medicine reaches the patients and the fact that they deal physically with medicines every day as highlighted by participants. On the other hand, the GPs' roles differ because they do not physically deal with the medicines. Stakeholders recognised that both pharmacists and GPs are the people most likely to identify problems which have affected patients and need to be aware of the possibility of counterfeit medicines being a cause of a patient's problem.

Findings identified five roles that pharmacists might do to help in the fight against counterfeit medicines; which are: securing their supply chain by only purchasing from reliable sources, remaining vigilant to any sign of counterfeiting medicines in their stock, receiving feedback from patients, reporting any suspicious cases to the medicine

regulatory agency and educating and raising awareness among the patients regarding counterfeit medicines especially those which are sold online. Moreover, three roles that GPs might play in combating counterfeit medicines have been revealed in this study. Those roles are GPs being a channel through which to educate the patients and to raise awareness regarding the dangers of the counterfeit medicines, staying vigilant to the comments and feedback from patients that might indicate a possible counterfeit medicine case, and reporting to the medicine regulatory agency any suspicions that they might have. The proposed roles for pharmacists and GPs have also been discussed in some publications and, as with those publications, this study could not address the perceptions of pharmacists and GPs in these roles (3, 12, 91, 92, 127, 128).

Furthermore, findings showed that stakeholder participants believed that pharmacists and GPs might need more information and support from the medicines regulatory agency in respect to counterfeit medicines as well as from their professional bodies. Professional journals, email and social media were seen as appropriate communication tools for pharmacists and GPs. The participants highlighted the need for more training for pharmacists and GPs in regards to the counterfeit medicines issue which could be fulfilled at the pre-registration or post-registration level. This study did not explore how pharmacists and GPs perceive these stakeholder observations.

#### **iv) The outcomes expected from an anti-counterfeiting medicines strategy and evaluation methods**

Stakeholders stressed that the agency should be realistic and have a clear vision from the beginning about the objectives that could be achieved from an anti-counterfeiting medicines strategy, as participants considered the setting and evaluation of outcomes would be problematic. The stakeholders believed the ultimate objective from such strategy is to protect the public from the risks associated with counterfeit medicines. In light of this, the findings identified six outcomes that could be expected from the strategy as seen by stakeholders. Those outcomes are: securing the pharmaceuticals supply chain; reduce the number of counterfeit medicines penetrating the legitimate supply chain; educating and raising awareness to change people's behaviour regarding pharmaceutical counterfeiting issues; improve cooperation in combating counterfeiting medicines. Additionally, increasing the number of reports from public and health professionals of any suspicion of counterfeiting. Finally, increasing the number of

actions taken by the agency against, and closures of, unregulated websites which may be involved in the supply of counterfeit medicines

This study also addressed the question of the view of stakeholder participants' on how the outcomes of an anti-counterfeit medicines strategy should be evaluated. Participants did not see such an evaluation as an easy task for a medicines regulatory agency as the agency might not know the full picture the counterfeit of medicines in the country during the drafting stage. They thought that the agency could opt to develop certain metrics to help in the evaluation process to include: the number of counterfeiting cases recorded, the number of the reports from the public and health professionals, and the number of prosecutions and sentences handed down in counterfeiting cases. Participants also identified some novel approaches as measuring the effectiveness of a counterfeit medicines strategy. These included measuring the economic value of the counterfeit medicines seized, the hospitalization costs of patients suffering due to counterfeit medicines and the degree of change in public behaviour as a result of an anti-counterfeiting medicines strategy. On the other hand, the participants did not address the viability of using such criteria to conduct a strategy evaluation, which would require the agency's time and resources. Clearly, any benefits derived from setting up and conducting an evaluation process need to be weighed against resources required to so do, as these resources may be diverted away from the 'front-line'. There also may be a tendency at an agency in a country which is believed to have a secure supply chain that such evaluation was unnecessary. A third possibility is the general organisational trait of reluctance or resistance to new methods of performance measurement, although in the UK such measurement of public agencies is now almost universal.

Participants saw the role of a medicines regulatory agency stakeholders in the evaluation process was limited. This perception may have arisen because they were not part or aware of any evaluation conducted by the MHRA on its strategies, which might have limited their comments on the evaluation process as a whole. However, these participants did recognise that stakeholders could help in providing the agency with the data and expertise that it might need to conduct the evaluation. Finally, the participants made a suggestion regarding the use of an independent body to conduct this monitoring and evaluation as this would counteract any potential bias arising from the agency essentially writing its own report card. This external and independent monitoring and

evaluation option may be a viable alternative provided it did not involve additional costs or perceptions of extra bureaucracy as this may not be supported by the government.

## **5.7 Conclusion**

This study aimed to explore stakeholders' views on an anti-counterfeiting strategy which would widen understanding of the issues associated with the processes from development to evaluation of such a strategy by adding an additional dimension to the previous study with MHRA representatives. Stakeholders held the view that counterfeit medicines posed a risk to consumers in all countries. Also, the perceptions of stakeholders associated with the counterfeiting of branded and generic medicines was found to vary among the participants and are likely to vary in the wider stakeholder population which is something that the agency should take into account. The study showed an anti-counterfeiting strategy was considered necessary for a medicines regulatory agency to effectively combat counterfeit medicines. However, there was a note of caution from the stakeholder participants that the agency should proceed with its strategy in a measured way so that it did not produce undesirable consequences for the supply chain, such as lowering consumer confidence. The study revealed that participants perceived the role of stakeholders at the drafting stage to be one of consultation and giving feedback. Stakeholders were seen as essential to the implementation which would not be effective without such input. This participation in the implementation would be in the form of collaboration and cooperation with the agency, securing the supply chain and educating and raising awareness. Regarding the roles of pharmacists and GPs, the stakeholder participants suggested certain roles which, from their standpoint, may be suitable for these healthcare professionals. The study also explored the issues surrounding anticipated outcomes and evaluation of these outcomes. The anticipated outcomes included securing the pharmaceuticals supply chain; reducing the number of counterfeit medicines penetrating the legitimate supply chain; educating and raising awareness; and improved cooperation. However, this study reported that the role stakeholders could play in the evaluation process would be limited and stakeholders could only help the agency in providing the data and expertise. Also, this study revealed that in the opinion of agency stakeholders the agency might need to

develop a range of performance metrics to evaluate the progress of the strategy. Also, a recommendation was made by participants aimed at eliminating any bias in the evaluation of the strategy by appointing an independent body to conduct the evaluation process. To continue building a multi-dimensional conceptualisation of the processes of developing, implementing and evaluating an anti-counterfeit medicines strategy, the views and practices of pharmacists and GPs regarding counterfeit medicines and their perceptions of their roles in combating them will be explored in the next two chapters.





# ***Chapter 6***

## ***Community pharmacists' views of their role in combating counterfeit medicines***

## **6.1 Introduction**

The MHRA plays the leading role in developing and implementing an anti-counterfeit medicines strategy as do its stakeholders; however, their contact with the end users of such medicines, the general public, is limited. It is health professionals such as pharmacists and GPs who have most of this direct contact. Pharmacists are responsible for dispensing medicines to patients in the UK and so form part of the supply chain, physically handling the medicines and directly communicating with the end user. Therefore, in order to build a multi-dimensional, triangulated conceptualisation of the processes of developing, implementing and evaluating an anti-counterfeit medicines strategy and so address the research problem, then views, perceptions and practices of pharmacists need to be understood. The quantitative data collected from pharmacists is intended to provide a broadly representative picture of the views preferences and practices of the pharmacist population concerning a range of counterfeit medicines issues.

Pharmacists are frequently the final link in the medicines supply chain before medicines reach the patients and therefore are the last barrier protecting patients from counterfeit medicines. The roles that pharmacists can play in combating counterfeit medicines have been identified in the literature as sourcing their medicines from secure supply chains, being vigilant for any suspicion of counterfeited medicines, reporting any of those suspicions to the national medicines regulatory agency and raising patients' awareness regarding counterfeit medicines (3, 12, 91, 92). These roles were also identified by the participants from both the MHRA study (chapter 4) and the stakeholders study (chapter 5). However, the views of pharmacists themselves on their roles to combat counterfeit medicines have not been examined in the literature, nor by the MHRA.

In addition, the MHRA, the WHO and many other national and international medicines agencies highlighted the need for the agencies to have dialogue with pharmacists (as one of the health professionals groups) to improve their awareness and educate them on counterfeit medicines. Also, findings from participants in the MHRA study (chapter 4) and the stakeholder study (chapter 5) addressed how the respective participants viewed the communication methods with pharmacists. But, neither the literature nor the two earlier studies (chapters 4 and 5) examined the awareness of pharmacists about

counterfeit medicines nor the views of pharmacists about the communication methods that could be used by the agencies. However, the MHRA with cooperation with the RPS and DDA had tried to have communication about counterfeit medicines with pharmacists by publishing a guidance leaflet “Counterfeit Medicines Advice for Healthcare Professionals” (appendix 5). This guidance was aimed to improve pharmacists’ awareness of counterfeit medicines by educating them about the definition of counterfeit medicines and highlighting the counterfeit medicines situation in the UK. Also, the guidance identified the actions to be taken should a suspected case of counterfeiting arise; and it offered a few suggestions for pharmacists which would help them in sourcing their medicines from a secure supply chain (10, 25, 39, 90). Then again, the awareness of pharmacists about this guidance, whether or not they adopted the recommendations, and whether this guidance has influenced the pharmacists practice to a secure supply chain remained unknown. Therefore, this highlighted a need to identify the pharmacists’ awareness and experience of counterfeit medicines as well as examining their views of their roles in combating them. Addressing the research problem requires constructing a complete conceptualisation of the process of developing, implementing and evaluating the strategy which requires the data collected in this study to add the pharmacist dimension.

## **6.2 Aims and Objectives**

This study aimed to understand the views and describe the roles of community pharmacists in combating counterfeit medicines.

Therefore, the objectives of the study were:

- to describe the knowledge and experience of pharmacists working in England about counterfeit medicines and what they saw as educational opportunities available to them to enhance this.
- to identify the current practices of England’s community pharmacists in securing the medicine supply chain.

- to describe how England's community pharmacists view their roles in combating the counterfeiting of medicines.
- to identify what methods community pharmacists working in England preferred for a medicines regulatory agency to communicate with them.
- to examine how educational opportunities and past experience of England's community pharmacists affected their views and practice relating to counterfeit medicines.

## **6.3 Methods**

In this study the aim was to gain an understanding of pharmacists' views on a range of issues related to counterfeit medicines. As this constituted a large and geographically spread population, and as the sample needed to offer a reasonable degree of generalizability for the results, certain research methods were ruled out, including the face-to-face interviews used in the previous two studies (chapters 4 and 5). It was decided that a survey questionnaire would be a more appropriate method of data collection and as the full addresses of the workplaces of pharmacists were readily identifiable it was further decided to administer this by post.

This study is one of two aimed at providing support to the findings of the previous two studies involving MHRA participants and MHRA stakeholder participants. Including a quantitative research design offered the means of triangulating within this group of studies by addressing its objective of describing the knowledge and experience of England's community pharmacists on the counterfeit medicines issue. The quantitative research method is most appropriate where pre-existing knowledge must be taken into consideration; this allows the researcher to employ standardised data collection methods to document any prevalence of knowledge being examined. In this study the researcher needed quantifiable answers to questions aimed at establishing the distribution of types of views and practices across members of a group, the extent to which these views and practices were shared and what variables may influence the holding of a particular view or the adoption of a particular practice. All these requirements indicate that a

quantitative study was appropriate. Hence, a retrospective descriptive survey was used to describe the sample and to examine any associations between variables (102).

The quantitative methods used in this study were selected because they were most appropriate for the second objective of the study which was to describe and understand the views and roles of pharmacists and GPs in combating counterfeit medicines. These methods were also appropriate for accessing the population and were consistent with the desire for generalisability. The benefits of triangulation as “an opportunity to enrich research findings and deepen insight” were a consequence of the choices as the qualitative approach of the first two studies could now be complemented and strengthened with quantitative input (133).

### **6.3.1 Ethical approval**

This study has been approved by University of East Anglia Faculty of Medicine and Health Ethics Committee (Appendix 3.1), no NHS ethical approval required as this study only included community pharmacists.

### **6.3.2 Questionnaire Development**

#### **6.3.2.1 Questionnaire design**

This study is designed based on the findings from two qualitative studies carried out by the researcher in respect of developing a national strategy for a medicines regulatory agency to combat counterfeit medicines (chapter 4 and chapter 5). Those studies captured the views of members of the MHRA (Chapter 4) and of key stakeholders (Chapter 5). The participants from those studies defined some of the roles that could be carried out by pharmacists to assist in combating counterfeit medicines. Also, those participants described the methods that could be used by the MHRA to communicate with pharmacists. As well as using the outcomes from those previous studies, this study is also based on the guidance leaflet for pharmacists and dispensing doctors titled

“Counterfeit Medicines Advice for Healthcare Professionals”, which was published by the MHRA, the RPS and the DDA (10).

Accordingly, the researcher designed a questionnaire to be sent to community pharmacists working in England (Appendix 3.2). The questionnaire aimed to cover the aims and objectives of this study. Section 1 of the questionnaire covered any past experiences community pharmacists might have had of counterfeit medicines. Section 2 aimed to cover any education or training opportunities experiences of counterfeit medicines that community pharmacists might have had, and any recommendations they may have for such education or training opportunities in the future. Section 3 of the questionnaire covered the dispensing and purchasing practices of the community pharmacists. Section 4 sought community pharmacists' views on their role in combating counterfeit medicines, and what would be the best method to communicate information on counterfeit medicines to them. Section 5 of the community pharmacists' questionnaire covered personal information of the participants which would help the researcher to show that the study participants were representative of the general community pharmacist population.

### **6.3.2.2 Questionnaire validity**

Validity in a survey study can be measured through assessing how far the questions collect accurate data and whether or not they are relevant to the study objective (117). To achieve face validity, the questionnaire was evaluated and answered by academics and practice pharmacists working at the UEA's Pharmacy School prior to launching the survey. Moreover, the face validity has been further examined during the piloting stage. Content validity was established in this research through the careful selection and refinement of items during questionnaire development, based on the qualitative data derived from the previous studies as well as on the evaluation and judgement of peers at the UEA's Pharmacy School.

### **6.3.2.3 Improving the response rate**

To increase the response rate for these questionnaires, the researcher applied the findings of the review study conducted by Edwards et al. (2009) (134). The questionnaire was designed to be short and should not take more than 10 minutes to complete. The UEA logo was added to the front page to indicate that these questionnaires are sponsored by the university. The researcher reassured recipients in the invitation letter and on the first page of the questionnaires that confidentiality would be maintained and that questionnaires were anonymous. All pharmacies premises included in the study were contacted by phone to obtain the name of potential participants and thereby enable the invitation letter to be personalised. All invitation letters were personalized and all the potential participants received a pen with the UEA logo as an unconditional incentive. A postcard has been included with the questionnaire which completed and sent back by participants. The postcard allowed the researcher to identify the participants who required follow-up. A stamped addressed return envelope was provided with each questionnaire to increase the response rate. A follow-up letter, which contained a second copy of the questionnaire, was sent to potential participants who had yet to return the postcard.

### **6.3.3 Participants and sample size calculation**

#### **6.3.3.1 Sampling unit**

The target population for this study was England's community pharmacists; it has been reported that the number of community pharmacists working in England is 11,495 (135). The researcher used English pharmacy premises as the sampling unit which were randomly selected. A database was provided to the researcher by the General Pharmaceutical Council (GPhC). Using the pharmacy premises as a unit of sampling is believed to be an acceptable methodology for sampling pharmacists (117).



### **6.3.3.2 Sample size estimation**

A final sample size of 400 respondents provides 95% CI of + or – 3% around a response to question of 10%; and + or – 5% around a response to question of 50%. Assuming that 60% the sample return the questionnaire the researcher needed to post the questionnaire to approximately 650 pharmacists (136).

### **6.3.3.3 Method of sampling**

The random sampling method is desirable as it allows the application of probability statistics and generalisation to the population from which the sample is drawn (96). Moreover, the random sampling method is fundamental to achieving external validity for the study (102). The researcher used the random sampling (using a random number generator provided within Excel) to identify 1 in 20 pharmacy premises which were included in this study. These pharmacy premises were contacted by phone and the community pharmacists who were working at the time of calling were asked to participate in this research. The total number of community pharmacists included in this study was 660.

## **6.3.4 Implementation and follow-up**

### **6.3.4.1 Questionnaire implementation**

For the pharmacists' survey, once the pharmacy premises had been selected, the names of the pharmacists who agreed to participate were identified. This assisted the researcher to personalise the invitation letter and the envelope sent to each pharmacist. Each envelope sent to a pharmacist included a personalised invitation letter (Appendix 3.3), a questionnaire (Appendix 3.2), a prepaid envelope to return the questionnaire, a pharmacist's postcard (Appendix 3.4), a prepaid envelope to return the postcard and an incentive pen.

### **6.3.4.2 Follow-up process**

Those pharmacists in the sample who had not completed and returned a postcard received a follow-up reminder letter (Appendix 3.5) three weeks after the first letter. A copy of the questionnaire was included with the reminder letter. No more action was taken after this point.

### **6.3.5 Data analysis**

All data were analysed using Microsoft Excel and the Statistical Package for the Social Sciences (SPSS) software. The data were summarised using descriptive statistics; also, Fisher's exact test, chi-squared analysis, the Mann-Whitney U test and Kruskal-Wallis test were used to compare pharmacist groups based on their responses on the questionnaires. The chi-squared test is considered invalid if 20% or more of the cells have an expected count of less than 5.

## **6.4 Results**

### **6.4.1 Response rates**

The initial response rate for the pilot stage (65 questionnaires) after one follow up was 64.6% (42 out of 65 questionnaires). No modification was applied to the invitation letter or the questionnaires as the pilot stage showed a good response rate. The response rate after the pilot stage reduced to 33.2% (194 out of 585 questionnaires); 490 pharmacists (83.8%) received a follow-up reminder letter.

The overall response rate to the pharmacists' questionnaire was 36.3% (236 out of 650 questionnaires). In addition, the overall missing data from the pharmacists' answers to the questionnaire was 0.87%.

## 6.4.2 Demographic data

Table 6.1 summarises the demographics of respondents and provides a comparison between independent and multiple pharmacies. It can be seen that a greater proportion of respondents from independent pharmacies were male.

**Table 6.1 Pharmacists' gender and working place**

		No. (%)	Working at	
			Independent community pharmacy	Multi-chain community pharmacy
Gender	Male	138 (58.5%)	63 (68.5%)	74 (51.4%)
	Female	97 (41.1%)	28 (30.4%)	69 (47.9%)
	Missing	1 (0.4%)	1 (1.1%)	1 (0.7%)
Total		236	92	144

In relation to the pharmacists' length of service; 22.9% (54 pharmacists) of the study sample had a length of service of 5 years or less, 9.7% (23 pharmacists) of the pharmacists 6 to 10 years, 7.2% (17 pharmacists) 11 to 15 years, 5.5% (13 pharmacists) 16 to 20 years and 11% (26 pharmacists) between 21 and 25 years. Finally, the majority (43.2% - 102 pharmacists) of this study sample had a length of service of more than 25 years. Only one pharmacist (0.4%) did not answer the length of service question.

For the purpose of data analysis, the pharmacists' lengths of service were re-grouped to three main categories; 0 – 10 years, 11 – 25 years, and over 25 years. In comparing the study's sample with pharmacists general population (only pharmacists' age data available) (137); table 6.2 shows that whilst the age range of the general population of pharmacists is normally distributed, the study sample is bi-modal with greater proportions in the younger and older groups.

**Table 6. 2 Pharmacists' length of service (n=235)**

Pharmacists sampled		Pharmacists' general population <sup>1</sup>	
Length of service	Percentage of the study sample	Age	Percentage of General population
0 – 10 years	32.6%	less than 30 years	21.6%
11 – 25 years	23.7%	30 – 49 years	54.3%
over 25 years	43.2%	50 years or more	24.2%

<sup>1</sup> Phelps A, Nass L, Blake M. GPhC Registrant Survey 2013: General Pharmaceutical Council; March 2014. [http://www.pharmacyregulation.org/sites/default/files/gphc\\_registrant\\_survey\\_2013\\_main\\_report\\_by\\_natcen.pdf](http://www.pharmacyregulation.org/sites/default/files/gphc_registrant_survey_2013_main_report_by_natcen.pdf)

With respect to pharmacists' membership of professional bodies, 127 of the pharmacists in the study sample were members of the Royal Pharmaceutical Society (RPS), 99 of the pharmacists were members of the National Pharmacy Association (NPA), and 87 of the pharmacists were members of the Pharmacists Defence Association (PDA). Four pharmacists (1.7%) did not state a professional body.

## 6.4.3 Descriptive analysis

### 6.4.3.1 Pharmacists' experiences of the counterfeiting issue

In relation to any past experiences the pharmacists had had (Figure 6.1), only 52 (22%) pharmacists in the study sample had had an experience of a medicine being recalled due to suspicion of counterfeiting. In addition, 23 of those pharmacists reported having had only one experience of this kind of recall, 20 pharmacists reported experiencing medicines being recalled between two and five times, and one pharmacist had experienced it eight times. The other two pharmacists did not declare the frequency.

As to whether pharmacists had had any past experiences of counterfeit medicines through their supply chain, 22 (9.3%) pharmacists reported they had had this experience. Also, thirteen of the pharmacists had had this experience once or twice, and three pharmacists had had it three times or more.

For the question of whether the pharmacist had been offered a product from his wholesaler or distributor that he or she suspect might be counterfeit, only 6 (2.5%) pharmacists reported they had had such an experience. Three pharmacists believed they had had it once, and one pharmacist reported he had had it more than 10 times.

Thirty (12.7%) pharmacists in this study had experience of a patient reporting or showing a medicine that might be counterfeit. While 23 of the pharmacists had had this experience between one and four times, and two pharmacists had had such experiences five times or more.

In respect of any experience of adverse effects due to counterfeit medicines that a patient might have used, 11 (4.7%) pharmacists have had such an experience. Also, five pharmacists had one such experience, one pharmacist reported three such experiences, and one pharmacist had had this kind of experience a few times.

**Figure 6.1 Pharmacist's experiences of counterfeit medicine issue**

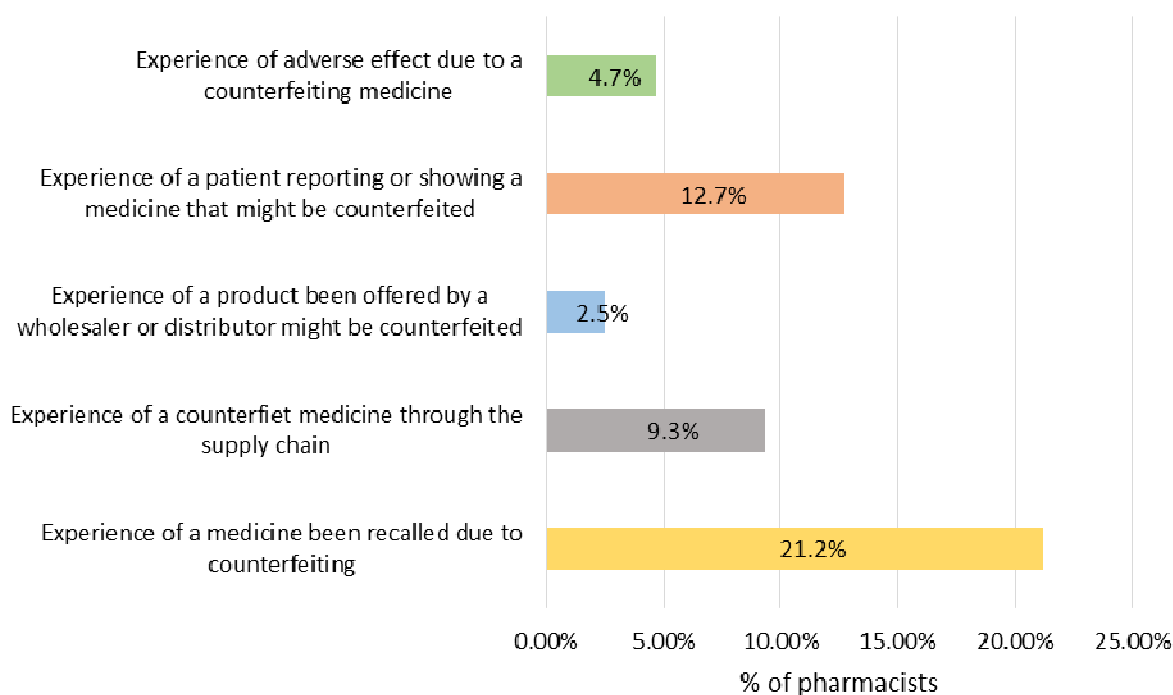


Table 6.3 shows the actions undertaken by pharmacists as a result of their past experience with counterfeit medicines. Five pharmacists selected "Other"; from those one said the medicines have been destroyed, one said the medicine has been returned to the patient, and three pharmacists did not provide any information.

**Table 6.3 Pharmacists' selection for their action as a result of counterfeiting experience (n=236)**

	Rank of action taken by the pharmacists	No. (%)
1	Gave the patient advice	20 (36%)
2	Isolated the item from their stock	13 (24%)
3	Did not do anything	9 (16%)
4	Other	5 (9%)
5	Used the Yellow Card Scheme to report the incident	4 (7%)
6	Communicated to someone within their organization	4 (7%)

On the action that the pharmacists would take in the future if they suspected that a medicine could be counterfeit, the actions selected by this study sample are ranked in order of frequency stated in table 6.4. Seven of the respondents selected "Other"; from those: two said will give an advice to the patient, one will report it to the police, one will contact the patient, one will give it back to the patient, and two were missing.

**Table 6.4 Pharmacist stated future action when counterfeiting suspected**

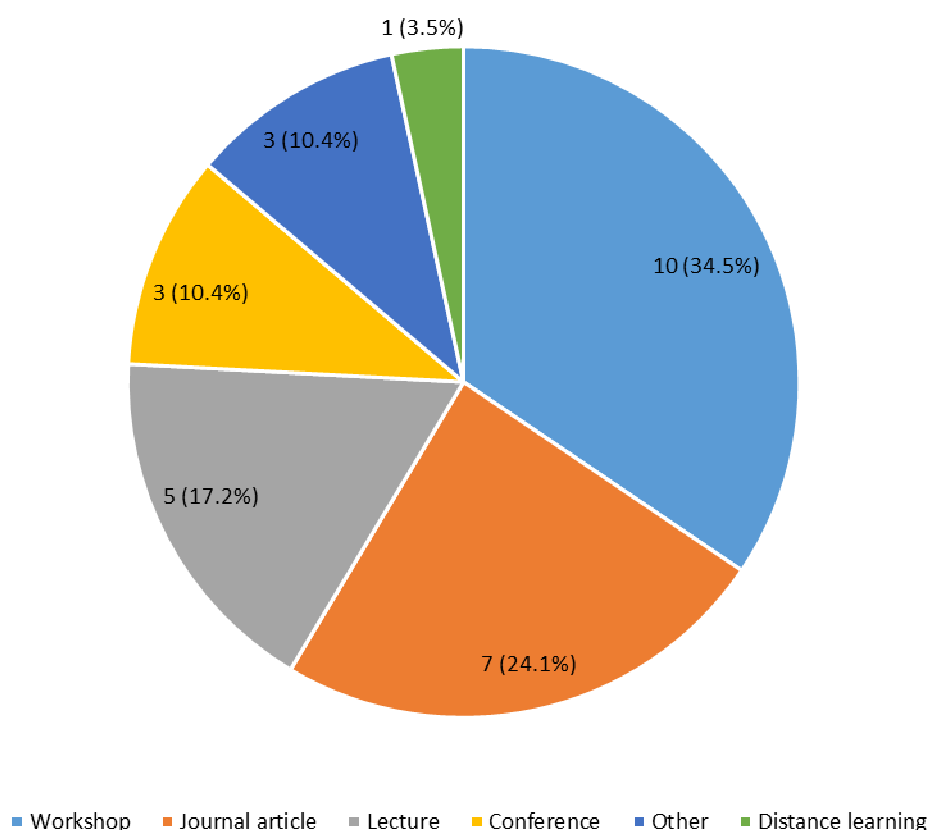
	Rank of action will be taken by the pharmacists	No. (%)
1	Report to the supplier of the medicine	202 (85.6%)
2	Isolate the item from the stock	185 (78.4%)
3	Report to MHRA	149 (63.1%)
4	Communicate to someone within their organization	134 (56.8%)
5	Report to the manufacturer of the medicine	112 (47.5%)
6	Report to the pharmacist's professional body	43 (18.2%)
7	Other	7 (3%)

### 6.4.3.2 Pharmacists' education in respect to counterfeit medicines issues

Only 10.6% (25 pharmacists) of this study sample had previously received formal education or training programme regarding counterfeit medicines. From those, 15 pharmacists had received the past education or training programme within their undergraduate degree, 3 pharmacists received it within the pre-registration year and 7 pharmacists post-registration.

Furthermore, figure 6.2 shows types of educational or training opportunity that the pharmacists had had in the past regarding counterfeit medicines. The most common types were workshops and journal articles.

**Figure 6. 2 The type of pharmacists' past education or training programme (n=25)**



With respect to the education and training programme that should be given to pharmacists regarding the counterfeit medicines issue that been selected by the pharmacists, 30.1% (80 pharmacists) recommended the education and training programme take place within an undergraduate degree at pharmacy school, 35.6% (84 pharmacists) of the study population said it should be within the pharmacists pre-registration year, and 33.9% (80 pharmacists) preferred it to be delivered at the post-registration stage.

Moreover, 105 pharmacists preferred their education and training on counterfeit medicines issues (table 6.5), to be delivered through workshops, 84 pharmacists preferred distance learning, and 47 pharmacists preferred journal articles. However, few pharmacists selected more than one preferred method.

**Table 6. 5 Pharmacists' preferred delivery method for education or training programme**

	Rank of preferred education and training delivery method	No. (%)
1	Workshop	105 (44.5%)
2	Distance learning	84 (35.6%)
3	Journal articles	47 (19.9%)
4	Conference	18 (7.6%)
5	Other	2 (0.8%)

### **6.4.3.3 Pharmacists' dispensing and purchasing practice**

Figure 6.3 summarizes dispensing practices performed by the community pharmacists. It can be seen that the most common approach reported by pharmacists was to checking the package seal and checking for an altered expiry date; while, checking all printing on flaps and surfaces of the box were reported to be undertaken by a very small proportion.



Figure 6. 3 Pharmacists' dispensing practices (n=236)

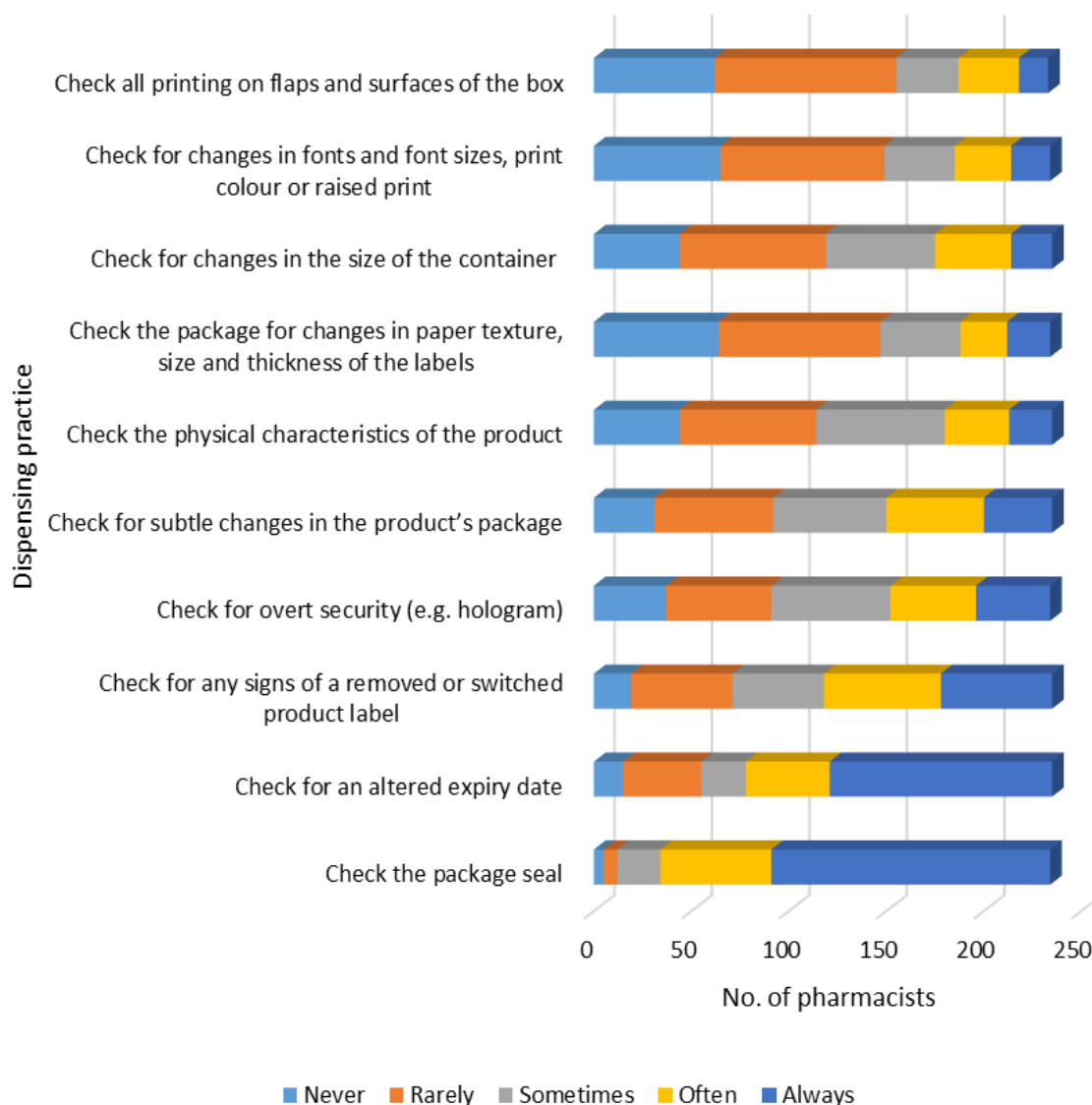


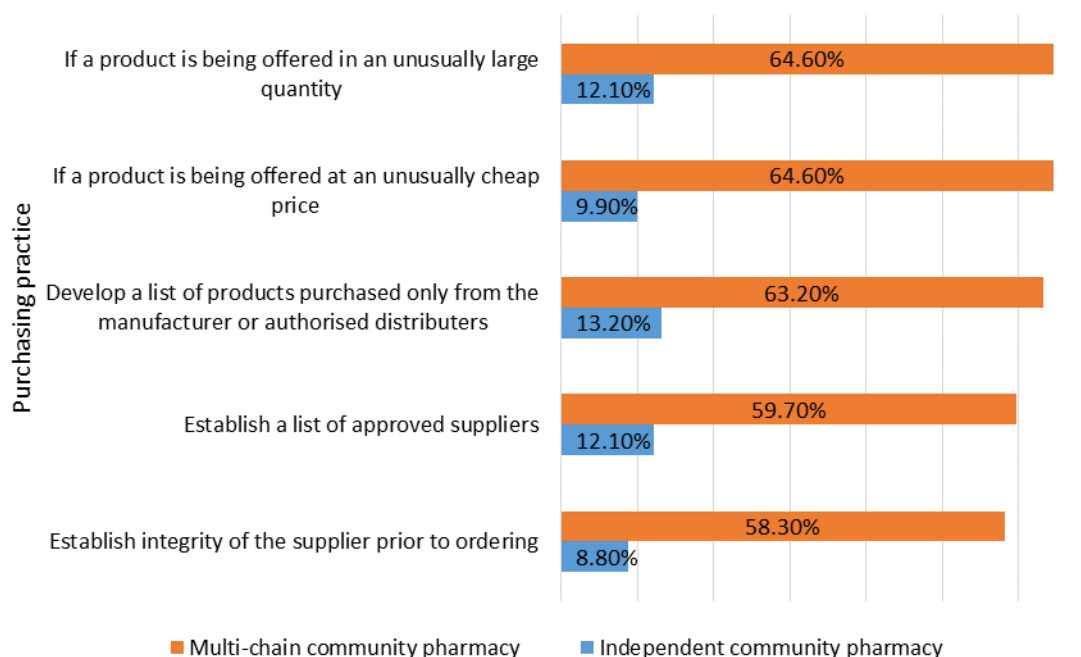
Table 6.6 summarizes purchasing practices performed by the pharmacists and relevant to the counterfeiting issue. This table shows that the majority of pharmacists who perform purchasing practice were trying to secure their supply chain. Also, pharmacists reported their practices in the event that they were offered a product at an unusually low price or in an unusually high quantity, which show that they will be very cautious when they receive such offers.

**Table 6. 6 Pharmacist reported purchasing practices**

Purchasing practice	Performed by someone else	Performed by pharmacists					
		Total	Never	Rarely	Some-times	Often	Always
Establish integrity of the supplier prior to ordering	93 (39.6%)	142	12 (8.5%)	9 (6.3%)	6 (4.2%)	13 (9.2%)	102 (71.8%)
Establish a list of approved suppliers	98 (41.7%)	137	11 (8%)	7 (5.1%)	4 (2.9%)	14 (10.2%)	101 (73.7%)
Develop a list of products purchased only from the manufacturer or authorised distributors	104 (44.3%)	131	24 (18.6%)	9 (7%)	11 (5.8%)	16 (12.4%)	71 (55%)
Purchasing practice	Not applicable	Performed by pharmacists					
		Total	Accept the offer	Treat with caution	Reject the offer		
If a product is being offered at an unusually cheap price	105 (44.7%)	129	10 (7.8%)	95 (73.6%)	24 (18.6%)		
If a product is being offered in an unusually large quantity	107 (44.5%)	128	7 (5.5%)	83 (64.8%)	38 (29.7%)		

With regard to the place of work for pharmacists who reported not carrying out a particular purchasing practice is shown in figure 6.4. It can be seen that pharmacists employed in multi-chain pharmacies were not involved in the purchasing practice.

**Figure 6. 4 Place of work of those pharmacists who reported not performing a particular purchasing practice**



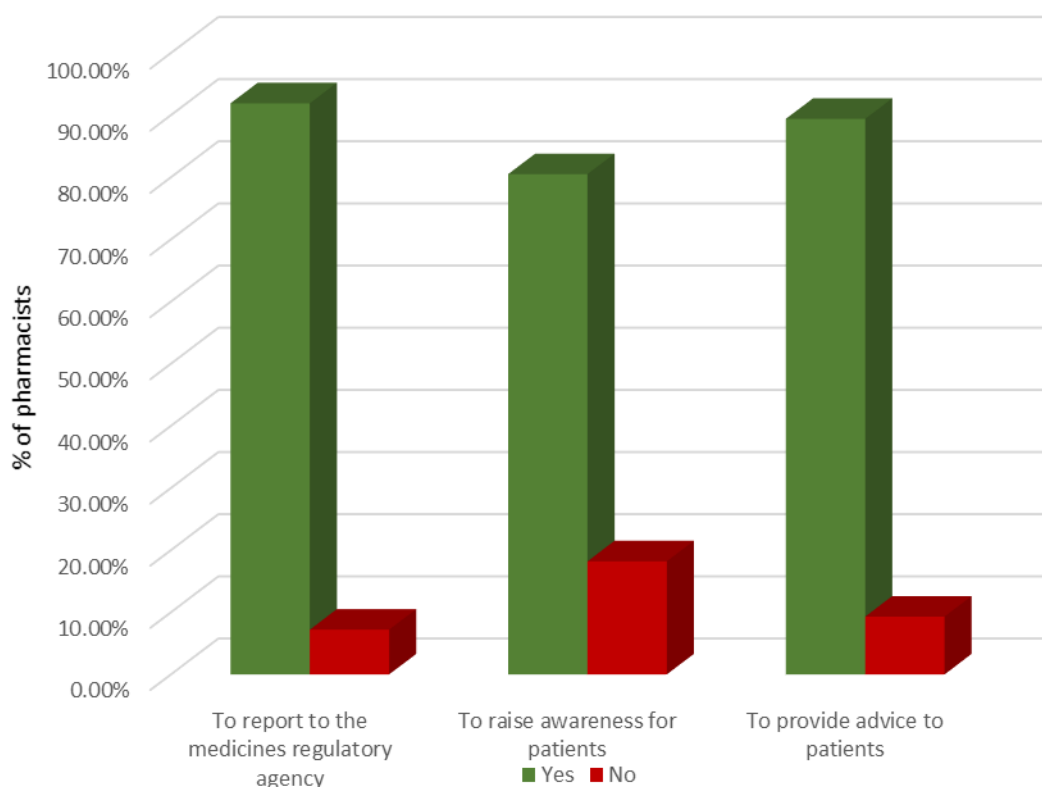
#### 6.4.3.4 Pharmacists' views on their roles in combating counterfeit medicines

The roles pharmacists believed could be carried out by them in combating counterfeit medicines are shown in figure 6.5. 217 pharmacists saw it as their duty to report any suspicion of counterfeit medicines to the medicines regulatory agency. Whereas, the other 17 pharmacists did not believe this is the role of the pharmacist; five of them said it would be the responsibility of someone from their organization and three pharmacists said it was a supplier responsibility.

For the responsibility of raising patient awareness about counterfeit medicines, 190 pharmacists said it would be part of the pharmacist's role to raise patients' awareness of counterfeit medicines. On the other hand, 43 pharmacists did not agree that it was a pharmacist's responsibility; and among them 22 pharmacists (9.3%) saw it as would be the government's responsibility to raise patient awareness.

With regard to providing the patient with advice about the counterfeit medicines issue, 211 of the pharmacists in the study said it would be part of their role in combating counterfeit medicines. But, the other part of the study sample, 22 pharmacists did not see it as their duty to provide the patient with advice about counterfeit medicines; and 6 of them (2.5%) saw it as the government's responsibility.

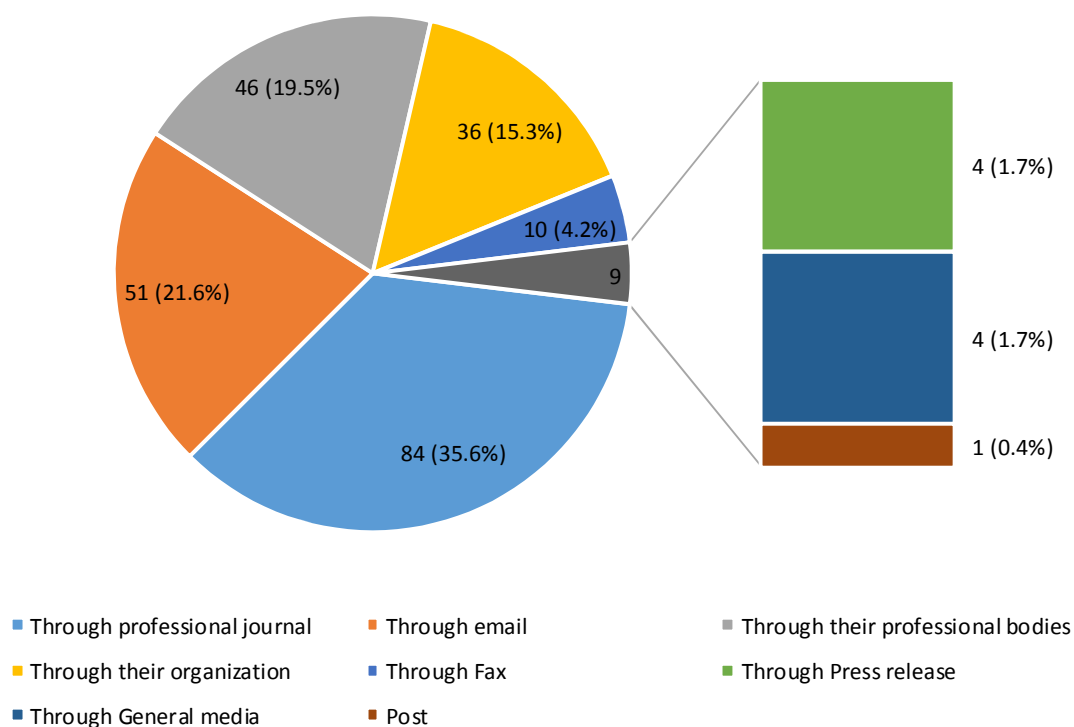
**Figure 6. 5 Pharmacists' view on their roles in combating counterfeit medicines (n=236)**



#### 6.4.3.5 The communication methods preferred by pharmacists

For the methods of communication that the pharmacists in this study preferred to receive information regarding counterfeit medicines issue (figure 6.6); it can be seen that pharmacists preferred such information through a professional journal or email.

Figure 6. 6 Pharmacists' selection of their preferred methods of communication (n=236)



## 6.4.4 Comparative analysis

### 6.4.4.1 Past pharmacist experiences

This section compares the pharmacists' opinion between those who had past experience about counterfeit medicines and the pharmacists who did not have such experiences. The researcher formulated the hypothesis that any past expertise regarding counterfeit medicines would reflect on the answers given by the pharmacists. To examine the hypothesis five comparisons (future actions, preferences for education, pharmacist role, preferred method of communication and dispensing/purchasing practices) have been conducted to compare data between the 74 pharmacists who said they had had an experience with counterfeit medicines and the 162 pharmacists who had not had any such experience.

i) Comparisons of opinion on the future actions

Table 6.7 shows the comparison between the pharmacists who had had an experience and those who had not in their selection of the actions that they would take in case of an incidence of counterfeit medicines. The results show no significant difference between the two pharmacist groups.

**Table 6.7 Past experiences and pharmacists' stated future actions**

Pharmacists' selection for their future action	Pharmacists with past counterfeit medicine experience No. (%)		P*
	No experience	Experience	
<b>Total</b>	<b>162 (68.6%)</b>	<b>74 (31.4%)</b>	
Report to the medicine's supplier	143 (88.3%)	60 (81.1%)	0.158
Report to the medicine's manufacturer	82 (50.6%)	30 (40.5%)	0.162
Report to MHRA	108 (66.7%)	41 (55.4%)	0.110
Isolate the item from the stock	127 (78.4%)	57 (77%)	0.866
Report to someone within their organization	92 (56.8%)	40 (54.1%)	0.778
Report to the pharmacists' professional body	25 (15.4%)	19 (25.7%)	0.072
Other	4 (2.5%)	6 (8.1%)	0.075

\* Fisher's exact test

ii) Comparisons of opinion on the future education preferences

Table 6.8 shows the responses of the two pharmacist groups regarding where any education or training programmes about counterfeit medicines should be delivered. Moreover, table 6.9 highlights which kind of education or training programmes each pharmacist group recommended. There was no significant difference between the pharmacists with past counterfeiting experiences and the pharmacists without such an experience.

**Table 6. 8 Past experiences and the recommendations for future education timing**

Pharmacists' selection for future education timing	Pharmacists with past counterfeit medicine experience <i>No. (%)</i>		P*
	No experience	Experience	
<b>Total</b>	<b>161 (68.2%)</b>	<b>74 (31.4%)</b>	0.478
Within undergraduate degree	42 (26.1%)	25 (33.8%)	
Within the pre-registration year	59 (36.6%)	24 (32.4%)	
in the post- registration	60 (37.3%)	25 (33.8%)	

\* Chi-squared analysis

**Table 6. 9 Past experience and the recommendations for future education preferences**

Pharmacists' selection for future education delivery method	Pharmacists with past counterfeit medicine experience <i>No. (%)</i>		P*
	No experience	Experience	
<b>Total</b>	<b>161 (68.2%)</b>	<b>74 (31.4%)</b>	0.888
Workshop	71 (44.1%)	34 (45.9%)	
Conference	10 (6.2%)	8 (10.8%)	
Distance learning	56 (34.8%)	28 (37.8%)	
Journal articles	36 (22.4%)	11 (14.9%)	
Other	2 (1.2%)	0	

\* Fisher's exact test

### iii) Comparisons of opinion on the pharmacist roles

This comparison (table 6.10) will address the view of the study sample on the pharmacists' roles in combating counterfeit medicines between the pharmacists with past experience and pharmacists without past experience. There is no significant difference found between the two pharmacists groups.

**Table 6. 10 Past experience on pharmacist's role**

Role of pharmacist in combating counterfeit medicines	Pharmacists with past counterfeit medicine experience <i>No. (%)</i>		P*
	No experience	Experience	
<b>Total</b>	<b>160 (67.8%)</b>	<b>74 (31.4%)</b>	
Reporting to the medicines regulatory agency	151 (94.4%)	66 (89.2%)	0.179
Raising patient awareness about counterfeit medicines	133 (93.6%)	57 (77%)	0.276
Advice patient about counterfeit medicines	146 (91.8%)	65 (87.8%)	0.343

\* Fisher's exact test

**iv) Comparison of opinions on the preferred methods of communication**

Table 6.11 shows that there are no real differences in the preferred methods of communication regarding counterfeiting information between pharmacists with and without experience of it.

**Table 6. 11 Past experience on the preferred communication methods**

Pharmacists' preferred communication method	Pharmacists with past counterfeit medicine experience <i>No. (%)</i>		P*
	No experience	Experience	
<b>Total</b>	<b>162 (68.6%)</b>	<b>74 (31.4%)</b>	
Professional journal	62 (38.3%)	22 (29.7%)	Test invalid
Professional bodies	30 (18.5%)	16 (21.6%)	
Via their organization	24 (14.8%)	12 (16.2%)	
Fax	5 (3.1%)	5 (6.8%)	
Email	33 (20.4%)	18 (24.3%)	
Press release	4 (2.5%)	0	
General media	3 (1.9%)	1 (1.4%)	
Other	1 (0.6%)	0	

\* Chi-squared analysis



v) Comparisons between dispensing and purchasing practices

Tables 6.12 and 6.13 compare the pharmacists' past experiences of counterfeit medicines with reported pharmacists' dispensing and purchasing practices that would help to protect patient from counterfeit medicines. No significant differences were seen between those who had previous experiences of counterfeit medicines and those without experience.

**Table 6. 12 Past experiences and reported dispensing practices**

Dispensing practice	Pharmacists with past counterfeit medicine experience				P*
	No experience		Experience		
	No.	Median (IQ) <sup>+</sup>	No.	Median (IQ) <sup>+</sup>	
Check the package seal	162	5 (4, 5)	72	5 (4, 5)	0.308
Check for an altered expiry date	162	5 (3, 5)	73	4 (2.5, 5)	0.585
Check the physical characteristics of the product	161	3 (2, 5)	74	3 (2, 3)	0.974
Check for any signs of a removed or switched product label	161	4 (2, 3.5)	74	3 (2, 4)	0.359
Check for subtle changes in the product's package	161	3 (2, 4)	74	3 (2, 4)	0.382
Check the package for changes in paper texture, size and thickness of the labels	160	2 (1, 3)	74	2 (2, 3)	0.526
Check for changes in fonts and font sizes, print colour or raised print	160	2 (1, 3)	74	2 (2, 3)	0.593
Check all printing on flaps and surfaces of the box	160	2 (1, 3)	73	2 (2, 3.5)	0.356
Check for overt security (e.g. hologram)	161	3 (2, 4)	73	3 (2, 4)	0.152
Check for changes in the size of the container	161	3 (2, 4)	74	1 (2, 4)	0.995

\* Mann-Whitney U test

+ (1=Never; 5=Always)

**Table 6. 13 Past experiences and reported purchasing practices**

Purchasing practice	Pharmacists with past counterfeit medicine experience				P*
	No experience		Experience		
	No.	Median (IQ)	No.	Median (IQ)	
Establish integrity of the supplier prior to ordering <sup>+</sup>	102	5 (4, 5)	40	5 (4.25, 5)	0.639
Establish a list of approved suppliers <sup>+</sup>	97	5 (4, 5)	40	5 (4, 5)	0.968
Develop a list of products purchased only from the manufacturer or authorised distributors <sup>+</sup>	93	5 (3, 5)	38	4 (2, 5)	0.331
If a product is being offered at an unusually cheap price <sup>#</sup>	95	2 (2, 2)	36	2 (2, 2)	0.529
If a product is being offered in an unusually large quantity <sup>#</sup>	96	2 (2, 3)	34	2 (2, 2)	0.71

\* Mann-Whitney U test + (1=Never; 5=Always)

# (1=Accept the offer; 2= Treat with caution, 3=Reject the offer)

#### 6.4.4.2 Past education or training programmes

Past educational or training opportunities which pharmacists had had regarding counterfeit medicines is examined by comparing the answers of the pharmacists who had had a chance to have this with those who had received no previous education or training on the topic. The researcher formulated the hypothesis that any educational or training opportunity about counterfeit medicines would reflect on the answers given by the pharmacists. To test the hypothesis five comparisons (future actions, preferences for education, pharmacist role, preferred method of communication and dispensing/purchasing practices) were conducted to compare data between the 25 pharmacists who said they had had an educational or training opportunity and the 211 pharmacists who had not had any such experience.

i) Comparisons of opinion on the future actions

Table 6.14 provides a comparison between those pharmacists who have had past educational experience of counterfeit medicines and those who haven't on their reported actions in cases of an incidence of suspected counterfeiting. The only significant difference was found with reporting to the MHRA, as those with past educational experience are more likely to report to the MHRA.

**Table 6. 14 Past educational experiences and pharmacists' stated future actions**

Pharmacists' selection for their future action	Pharmacists past educational or training experience No. (%)		P*
	No experience	Experience	
<b>Total</b>	<b>211 (89.4%)</b>	<b>25 (10.6%)</b>	
Report to the medicine's supplier	182 (86.3%)	21 (84%)	0.761
Report to the medicine's manufacture	105 (49.8%)	7 (28%)	0.055
Report to MHRA	128 (60.7%)	21 (84%)	0.027
Isolate the item from the stock	167 (79.1%)	17 (68%)	0.208
Report to someone within their organization	120 (56.9%)	12 (48%)	0.404
Report to the pharmacists' professional body	36 (17.1%)	8 (32%)	0.099
Other	8 (3.8%)	2 (8%)	0.287

\* Fisher's exact test

ii) Comparisons of opinion on the future education preferences

Tables 6.15 and 6.16 shows the responses of the two pharmacist groups regarding the timing and delivery of any education or training programmes for pharmacists regarding counterfeit medicines. No significant differences were found between the pharmacist with past experience and the pharmacists without past experience in their selection for the timing of educational or training programs regarding counterfeit medicines. For the educational or training program type it was found that those who had had previous experience of counterfeit medicine were more likely to prefer training to be provided at conferences.

**Table 6. 15 Past educational experiences and the recommendations for future education timing**

Pharmacist's selection for future education timing	Pharmacists with past educational or training experience No. (%)		P*
	No experience	Experience	
<b>Total</b>	<b>211 (89.4%)</b>	<b>25 (10.6%)</b>	
Within undergraduate degree	58 (27.6%)	9 (36%)	0.586
Within the pre-registration year	74 (35.2%)	9 (36%)	
in the post- registration	78 (37.1%)	7 (28%)	

\* Chi-squared analysis

**Table 6. 16 Past educational experience and the recommendations for future education preferences**

Pharmacists' selection for future education delivery method	Pharmacists with past educational or training experience No. (%)		P*
	No experience	Experience	
<b>Total</b>	<b>211 (89.4%)</b>	<b>25 (10.6%)</b>	
Workshop	92 (43.8%)	13 (52%)	0.525
Conference	12 (5.7%)	6 (24%)	0.006
Distance learning	79 (36.7%)	5 (20%)	0.121
Journal articles	44 (21%)	3 (12%)	0.428
Other	1 (0.5%)	1 (4%)	0.202

\* Fisher's exact test

### iii) Comparisons of opinion on the pharmacist roles

This comparison (table 6.17) will address the view of the study sample on the pharmacists' roles in combating the counterfeiting of medicines between the pharmacists with past educational or training experience and pharmacists without such experience. There is no significant difference found between the two pharmacists groups.

**Table 6. 17 Past educational experience on pharmacist' role**

Role of pharmacist in combating counterfeit medicines	Pharmacists with past educational or training experience No. (%)		P*
	No experience	Experience	
<b>Total</b>	<b>211 (89.4%)</b>	<b>25 (10.6%)</b>	
Reporting to the medicines regulatory agency	193 (92.3%)	24 (96%)	1.000
Raising patient awareness about counterfeit medicines	167 (80.3%)	23 (92%)	0.183
Advice patient about counterfeit medicines	187 (89.9%)	24 (96%)	0.482

\* Fisher's exact test

iv) Comparisons of opinion on the preferred methods of communication

The comparison that will examine pharmacists' past educational or training experience of counterfeit medicines and preferred methods of communication (table 6.18), showed that both groups of the pharmacists preferred similar methods of communication.

**Table 6. 18 Past educational experience on the preferred communication methods**

Pharmacists' preferred communication method	Pharmacists' with past educational or training experience No. (%)		P*
	No experience	Experience	
<b>Total</b>	<b>211 (89.4%)</b>	<b>25 (10.6%)</b>	
Professional journal	76 (36%)	8 (32%)	Test invalid
Professional bodies	40 (19%)	6 (24%)	
Via their organization	31 (14.7%)	5 (20%)	
Fax	9 (4.3%)	1 (4%)	
Email	46 (21.8%)	5 (20%)	
Press release	4 (1.9%)	0	
General media	4 (1.9%)	0	
Other	1 (0.5%)	0	

\* Chi-squared analysis

v) Comparisons of the dispensing and purchasing practices

This comparisons (Table 6.19) examines the pharmacists' past educational or training experience covering counterfeit medicines on the pharmacist's dispensing practices that would help to protect patient from counterfeit medicines. Also, table 6.20 compares the pharmacists' purchasing practices with respect to the pharmacists' past educational or training experience. The p-values in the both tables show no significant difference between the pharmacists with past educational or training experience and the pharmacists without such experience.

**Table 6. 19 Past educational experience and dispensing practices**

Dispensing practice	Pharmacists' past educational or training experience				P*
	No experience		Experience		
	No.	Median (IQ) <sup>+</sup>	No.	Median (IQ) <sup>+</sup>	
Check the package seal	209	5 (4, 5)	25	5 (4, 5)	0.516
Check for an altered expiry date	210	4.5 (3, 5)	25	4 (2, 5)	0.137
Check the physical characteristics of the product	210	3 (2, 3.25)	25	3 (2, 3)	0.883
Check for any signs of a removed or switched product label	210	3 (2, 4.25)	25	4 (2.5, 4)	0.442
Check for subtle changes in the product's package	210	3 (2, 4)	25	3 (2, 4)	0.971
Check the package for changes in paper texture, size and thickness of the labels	209	2 (1, 3)	25	2 (2, 3)	0.486
Check for changes in fonts and font sizes, print colour or raised print	209	2 (1, 3)	25	2 (2, 3)	0.701
Check all printing on flaps and surfaces of the box	208	2 (1, 3)	25	2 (2, 3)	0.557
Check for overt security (e.g. hologram)	209	3 (2, 4)	25	3 (2, 4)	0.281
Check for changes in the size of the container	210	2.5 (2, 4)	25	2 (2, 3)	0.591

\* Mann-Whitney U test + (1=Never; 5=Always)

**Table 6. 20 Past educational experience and purchasing practices**

Purchasing practice	Pharmacists' past educational or training experience				P*
	No experience		Experience		
	No.	Median (IQ)	No.	Median (IQ)	
Establish integrity of the supplier prior to ordering <sup>+</sup>	130	5 (4, 5)	12	5 (4.25, 5)	0.591
Establish a list of approved suppliers <sup>+</sup>	127	5 (4, 5)	10	5 (4.75, 5)	0.657
Develop a list of products purchased only from the manufacturer or authorised distributors <sup>+</sup>	121	5 (2, 5)	10	5 (4, 5)	0.206
If a product is being offered at an unusually cheap price <sup>#</sup>	118	2 (2, 2)	13	2 (2, 2)	0.883
If a product is being offered in an unusually large quantity <sup>#</sup>	117	2 (2, 3)	13	2 (2, 2)	0.391

\* Mann-Whitney U test + (1=Never; 5=Always)

# (1=Accept the offer; 2= Treat with caution, 3=Reject the offer)

#### 6.4.4.3 Length of service of the pharmacists

The study also compares the opinions of the pharmacists based on their length of service, which is categorised into three groups. As the attention to the counterfeit medicines issue increased in recent years (the first MHRA's anti-counterfeiting medicines strategy was published in 2005) (1) the researcher formulated the hypothesis that the pharmacists' length of service would reflect on the answers given by the pharmacists. To test the hypothesis five comparisons (future actions, preferences for education, pharmacist role, preferred method of communication and dispensing/purchasing practices) have been conducted to compare data between pharmacists with less than 10 years' length of service (77 pharmacists), pharmacists with 11 to 25 years length of service (56 pharmacists) and pharmacists with over 25 years length of service (102 pharmacists).

i) Comparisons of opinion on the future actions

Table 6.21 shows the answers of the study sample about the action that would be taken if they had to deal with counterfeit medicines cases in the future. Some tests in the table were invalid, and others found no significant difference between the pharmacist groups. The only significant difference was found with reporting to the MHRA; it appeared that young pharmacists (have length of service 10 years or less) are more likely to report to the MHRA than other pharmacists.

**Table 6. 21 Length of service and pharmacists' stated future actions**

Pharmacist's selection for their future action	Length of Service in years No. (%)			p*
	0-10	11-25	Over 25	
<b>Total</b>	<b>77 (32.6%)</b>	<b>56 (23.7%)</b>	<b>102 (43.2%)</b>	
Report to the medicine's supplier	66 (85.7%)	47 (83.9%)	90 (88.2%)	0.736
Report to the medicine's manufacturer	41 (53.2%)	24 (42.9%)	47 (46.1%)	0.453
Report to MHRA	56 (72.7%)	29 (51.8%)	63 (61.8%)	0.045
Isolate the item from the stock	62 (80.5%)	44 (78.6%)	77 (75.5%)	0.717
Report to someone within their organization	49 (63.6%)	27 (48.2%)	56 (54.9%)	0.197
Report to the pharmacists' professional body	13 (16.9%)	10 (17.9%)	21 (20.6%)	0.806
Report to the other	4 (5.2%)	2 (3.6%)	4 (3.6%)	Test invalid

\* Chi-squared analysis

ii) Comparisons of opinion on the future education preferences

Tables 6.22 and 6.23 show the responses of three pharmacist groups regarding the timing of any education or training programmes covering counterfeit medicines, and which kind of education or training programmes each pharmacist group recommended. The results in both tables show no significant difference between the pharmacist groups.



**Table 6. 22 Length of service and the recommendations for future education timing**

Pharmacists' selection of future education timing	Length of service in years No. (%)			p*
	0-10	11-25	Over 25	
<b>Total</b>	<b>77 (32.6%)</b>	<b>56 (23.7%)</b>	<b>101 (42.8%)</b>	
Within undergraduate degree	23 (29.9%)	16 (28.6%)	28 (27.7%)	0.224
Within the pre-registration year	34 (44.2%)	17 (30.4%)	32 (31.7%)	
in the post- registration	20 (26.0%)	23 (41.1%)	41 (40.6%)	

\* Chi-squared analysis

**Table 6. 23 Length of service and the recommendations for future education preferences**

Pharmacists' selection for future education delivery method	Length of service in years No. (%)			p*
	0-10	11-25	Over 25	
<b>Total</b>	<b>77 (32.6%)</b>	<b>56 (23.7%)</b>	<b>101 (42.8%)</b>	
Workshop	40 (51.9%)	23 (41.1%)	42 (41.6%)	0.312
Conference	9 (11.7%)	2 (3.6%)	7 (6.9%)	0.207
Distance learning	23 (29.9%)	23 (41.1%)	37 (36.6%)	0.390
Journal articles	13 (16.9%)	11 (19.6%)	23 (22.8%)	0.621
Other	1 (1.3%)	0	1 (1%)	Test invalid

\* Chi-squared analysis

### iii) Comparisons of opinion on the pharmacist's roles

The view of pharmacists roles in combating counterfeit medicines based on the pharmacists' length of service has been summarized in table 6.24. There is no significant difference found between the pharmacists' groups.

**Table 6. 24 Length of service and the pharmacist's roles**

Role of pharmacists in combating counterfeit medicines	Length of service in years No. (%)			p*
	0-10	11-25	Over 25	
<b>Total</b>	<b>77 (32.6%)</b>	<b>56 (23.7%)</b>	<b>101 (42.8%)</b>	p*
Reporting to the medicines regulatory agency	69 (90.8%)	52 (92.9%)	95 (94.1%)	0.709
Raising patient awareness about counterfeit medicines	60 (78.9%)	48 (85.7%)	81 (81%)	0.606
Advice patient about counterfeit medicines	70 (92.1%)	51 (91.1%)	89 (89%)	0.774

\* Chi-squared analysis

iv) Comparisons of opinion on the preferred methods of communication

The methods of communication about counterfeiting information preferred by the three pharmacist groups based on their length of service are shown in table 6.25. No real differences can be seen other than those with over 25 years of experience preferring communication via professional journals.

**Table 6. 25 Length of service and preferred communication methods**

Pharmacists' preferred communication method	Length of service in years No. (%)			p*
	0-10	11-25	Over 25	
<b>Total</b>	<b>77 (32.6%)</b>	<b>56 (23.7%)</b>	<b>102 (43.2%)</b>	p*
Professional journal	28 (36.4%)	18 (32.1%)	38 (37.3%)	Test invalid
Professional bodies	17 (22.1%)	11 (19.6%)	18 (17.6%)	
Via their organization	11 (14.3%)	11 (19.6%)	13 (12.7%)	
Fax	3 (3.9%)	2 (3.6%)	5 (4.9%)	
Email	15 (19.5%)	13 (23.2%)	23 (22.5%)	
Press release	1 (1.3%)	0	3 (2.9%)	
General media	2 (2.6%)	1 (1.8%)	1 (1%)	
Other	0	0	1 (1%)	

\* Chi-squared analysis

v) Comparisons of the dispensing and purchasing practices

These comparisons (table 6.26) examine pharmacists' length of service and the pharmacists' dispensing practices that would help to protect patient from counterfeit medicines. Also, table 6.27 compares the pharmacists' purchasing practices with the pharmacists' length of service. Table 6.26 shows no significant difference in the pharmacists' dispensing practices by their length of service.

**Table 6. 26 Length of service and the dispensing practices**

Dispensing practice	Pharmacists' length of service						p*
	0 – 10 years		11 – 25		Over 25 years		
	No.	Median (IQ) <sup>+</sup>	No.	Median (IQ) <sup>+</sup>	No.	Median (IQ) <sup>+</sup>	
Check the package seal	76	5 (4, 5)	55	5 (4, 5)	102	5 (4, 5)	0.546
Check for an altered expiry date	77	4 (3, 5)	55	4 (2, 5)	102	4.5 (3, 5)	0.858
Check the physical characteristics of the product	77	2 (2, 3)	56	3 (2, 4)	101	3 (2, 4)	0.229
Check for any signs of a removed or switched product label	77	3 (2, 4)	56	3 (2, 5)	101	4 (2, 5)	0.518
Check for subtle changes in the product's package	77	3 (2, 4)	56	3 (2, 4)	101	3 (2, 4)	0.237
Check the package for changes in paper texture, size and thickness of the labels	76	2 (1, 3)	56	2 (1, 3)	101	2 (2, 3)	0.134
Check for changes in fonts and font sizes, print colour or raised print	76	2 (1, 3)	56	2 (1, 3)	101	2 (2, 3.5)	0.099
Check all printing on flaps and surfaces of the box	76	2 (1, 3)	55	2 (1, 3)	101	2 (2, 3)	0.360
Check for overt security (e.g. hologram)	77	2 (2, 4)	55	3 (2, 5)	101	3 (2, 4)	0.169
Check for changes in the size of the container	77	2 (2, 4)	56	3 (2, 4)	101	2 (2, 3)	0.583

+ Kruskal-Wallis Test

+ (1=Never; 5=Always)

Table 6.27, which relates length of service to purchasing practice, shows two significant differences in the pharmacists' purchasing practices in establishing integrity of the supplier prior to ordering and establishing a list of approved suppliers, which shows that older pharmacists are more likely to follow those good purchasing practices than other two pharmacists group.

**Table 6. 27 Length of service and the purchasing practices**

Purchasing practice	Pharmacists' length of service						p*
	0 – 10 years		11 – 25		Over 25 years		
	No.	Median (IQ)	No.	Median (IQ)	No.	Median (IQ)	
Establish integrity of the supplier prior to ordering <sup>+</sup>	38	4.5 (2, 5)	34	5 (4, 5)	70	5 (5, 5)	0.001
Establish a list of approved suppliers <sup>+</sup>	34	5 (2, 5)	34	5 (4, 5)	69	5 (5, 5)	0.035
Develop a list of products purchased only from the manufacturer or authorised distributors <sup>+</sup>	33	4 (1, 5)	33	5 (2, 5)	65	5 (3, 5)	0.402
If a product is being offered at an unusually cheap price <sup>#</sup>	40	2 (2, 2)	28	2 (2, 2)	63	2 (2, 2)	0.544
If a product is being offered in an unusually large quantity <sup>#</sup>	41	2 (2, 2)	28	2 (2, 3)	61	2 (2, 3)	0.232

+ Kruskal-Wallis Test + (1=Never; 5=Always)

# (1=Accept the offer; 2= Treat with caution, 3=Reject the offer)

Table 6.28 shows young pharmacists (have 10 years or less) length of service are less likely to establish integrity of the supplier prior to ordering than other pharmacists and they are less likely to establish a list of approved suppliers than those who have over 25 years length of service.

**Table 6. 28 Length of service and the purchasing practices (*Further comparisons*)**

Purchasing practice	Pharmacists' length of service				p*
	0 – 10 years		11 – 25		
	No.	Median (IQ) <sup>+</sup>	No.	Median (IQ) <sup>+</sup>	
Establish integrity of the supplier prior to ordering	38	4.5 (2, 5)	34	5 (4, 5)	0.030
Establish a list of approved suppliers	34	5 (2, 5)	34	5 (4, 5)	0.124
Purchasing practice	0 – 10 years		Over 25 years		p*
	No.	Median (IQ) <sup>+</sup>	No.	Median (IQ) <sup>+</sup>	
Establish integrity of the supplier prior to ordering	38	4.5 (2, 5)	70	5 (5, 5)	0.000
Establish a list of approved suppliers	34	5 (2, 5)	69	5 (5, 5)	0.011
Purchasing practice	11 – 25		Over 25 years		p*
	No.	Median (IQ) <sup>+</sup>	No.	Median (IQ) <sup>+</sup>	
Establish integrity of the supplier prior to ordering	34	5 (4, 5)	70	5 (5, 5)	0.316
Establish a list of approved suppliers	34	5 (4, 5)	69	5 (5, 5)	0.425

\* Mann-Whitney U test

+ (1=Never; 5=Always)

#### 6.4.4.4 Professional body membership

This section of the comparisons covers the opinions between pharmacists' membership with different professional bodies on the responses given; the differences in views of those within and not within professional bodies have been examined. Therefore, the researcher formulated the hypothesis that there will be differences in the opinions between the pharmacists regarding the counterfeit medicines issue according to their membership of the professional bodies (127 pharmacists are members of the RPS, 88 pharmacists are members of the PDA and 99 pharmacists are members the NPA). To

test this hypothesis the following comparisons (future actions, preferences for education, pharmacist role, preferred method of communication and dispensing/purchasing practices) have been analysed.

i) Comparisons of opinion on the future actions

Table 6.29 shows the comparison between pharmacists in their responses on the future actions they would take in case of an incidence of counterfeit medicine based on their membership of a given professional body. No significant difference between the pharmacist groups is found in the table, except with those who are members of the NPA will more likely to report to their professional body.

**Table 6. 29 Professional body membership and pharmacists' stated future actions**

Pharmacist's selection of their future action	Membership of RPS No. (%)			Membership of NPA No. (%)			Membership of PDA No. (%)		
	No	Yes		No	Yes		No	Yes	
<b>Total</b>	<b>105</b> (44.5%)	<b>127</b> (53.8%)	p*	<b>133</b> (56.4%)	<b>99</b> (41.9%)	p*	<b>144</b> (41.9%)	<b>88</b> (37.3%)	p*
Report to the medicine's supplier	93 (88.6%)	107 (84.3%)	0.445	116 (87.2%)	84 (84.4%)	0.701	126 (87.5%)	74 (84.1%)	0.557
Report to the medicine's manufacturer	49 (46.7%)	60 (47.2%)	1	57 (42.9%)	52 (52.5)	0.183	62 (43.1%)	47 (53.4%)	0.137
Report to MHRA	62 (59%)	86 (67.7%)	0.217	83 (62.4%)	65 (65.7%)	0.679	95 (66%)	53 (60.2%)	0.401
Isolate the item from the stock	84 (80%)	96 (75.6%)	0.435	109 (82%)	71 (71.7%)	0.080	113 (78.5%)	67 (76.1%)	0.746
Report to someone within their organization	62 (59%)	68 (53.5%)	0.427	78 (58.6%)	52 (52.5%)	0.422	75 (52.1%)	55 (62.5%)	0.135
Report to pharmacist's professional body	20 (19%)	23(18.1 %)	0.867	15 (11.3%)	28 (28.3%)	0.001	30 (20.8%)	13 (14.8%)	0.298
Report to the pharmacist	6 (5.7%)	4 (3.1%)	0.354	8 (6%)	2 (2%)	0.195	6 (4.2%)	4 (4.5%)	1.000

\* Fisher's exact test

ii) Comparisons of opinion on the future education preferences

The comparisons between the responses of the pharmacists who were members of the RPS, the NPA and the PDA regarding the timing and kind of education or training programmes about counterfeit medicines are presented in table 6.30 and table 6.31. No

significant difference between the pharmacist groups is found in table 6.30. In table 6.31, two results showed a significant difference in journal articles as future education preferences; pharmacists who are members of the NPA prefer this method of education whereas pharmacists who are members of the PDA prefer this method of education less.

**Table 6. 30 Professional body membership and the recommendations for future education timing**

Pharmacist's selection for the timing of future education	Membership of RPS No. (%)			Membership of NPA No. (%)			Membership of PDA No. (%)		
	No	Yes		No	Yes		No	Yes	
<b>Total</b>	<b>104</b> (44.1%)	<b>127</b> (53.8%)	p*	<b>133</b> (47.9%)	<b>98</b> (41.5%)	p*	<b>143</b> (60.6%)	<b>88</b> (37.3%)	p*
Within undergraduate degree	35 (33.7%)	31 (24.4%)	0.295	37 (27.8%)	29 (29.6%)	0.953	38 (26.6%)	28 (31.8%)	0.669
Within the pre-registration year	35 (33.7%)	47 (37%)		48 (36.1%)	34 (34.7%)		53 (37.1%)	29 (33%)	
in the post- registration	34 (32.7%)	49 (38.6%)		48 (36.1%)	35 (35.7%)		52 (36.4%)	31 (35.2%)	

\* Chi-squared analysis

**Table 6. 31 Professional body membership and the recommendations for future education preferences**

Pharmacist's selection of future education delivery method	Membership of RPS No. (%)			Membership of NPA No. (%)			Membership of PDA No. (%)		
	No	Yes		No	Yes		No	Yes	
<b>Total</b>	<b>104</b> (44.1%)	<b>127</b> (53.8%)	p*	<b>133</b> (56.4%)	<b>98</b> (41.5%)	p*	<b>143</b> (60.6%)	<b>88</b> (37.3%)	p*
Workshop	51 (49%)	52 (40.9%)	0.233	58 (43.6%)	45 (45.9%)	0.789	57 (39.9%)	46 (52.3%)	0.077
Conference	11 (10.6%)	7 (5.5%)	0.217	14 (10.5%)	4 (4.1%)	0.085	13 (9.1%)	5 (5.7%)	0.452
Distance learning	35 (33.7%)	47 (37%)	0.679	53 (39.8%)	29 (29.6%)	0.126	48 (33.6%)	34 (38.6%)	0.480
Journal articles	16 (15.4%)	31 (24.4%)	0.102	20 (15%)	27 (27.6%)	0.022	36 (25.2%)	11 (12.5%)	0.028
Other	0	2 (1.6%)	0.503	0	2 (2%)	0.179	1 (0.7%)	1 (1.1%)	1.000

\* Fisher's exact test

iii) Comparisons of opinion on the pharmacist's roles

The pharmacists' membership with the professional body and their views regarding the roles of pharmacist in combating counterfeit medicines has been compared in table 6.32. The results show significant differences only with pharmacists who are members of the NPA who have a greater belief that reporting to the medicines regulatory agency is part of pharmacist's role in combating counterfeit medicines.

**Table 6. 32 Professional body membership and the pharmacist's roles**

Pharmacist's selection for their future education delivery method	Membership of RPS <i>No. (%)</i>			Membership of NPA <i>No. (%)</i>			Membership of PDA <i>No. (%)</i>		
	No	Yes		No	Yes		No	Yes	
<b>Total</b>	<b>104</b> <b>(44.1%)</b>	<b>126</b> <b>(53.4%)</b>	p*	<b>132</b> <b>(55.9%)</b>	<b>98</b> <b>(41.5%)</b>	p*	<b>142</b> <b>(60.2%)</b>	<b>88</b> <b>(37.3%)</b>	p*
Reporting to the medicines regulatory agency	95 (91.3%)	118 (93.7%)	0.615	118 (89.4%)	95 (96.9%)	0.04	131 (92.3%)	82 (93.2%)	1.000
Raising patient awareness about counterfeit medicines	84 (80.8%)	103 (82.4%)	0.864	111 (84.7%)	76 (77.6%)	0.172	113 (80.1%)	74 (84.1%)	0.488
Advice patient about counterfeit medicines	92 (88.5%)	115 (92%)	0.378	118 (90.1%)	89 (90.8%)	1.000	127 (90.1%)	80 (90.9%)	1.000

\* Fisher's exact test

iv) Comparisons of opinion on the preferred methods of communication

Table 6.33 shows the comparison examining the pharmacists' memberships of a given professional body and their preferred methods of communication regarding counterfeit information.



**Table 6. 33 Professional body membership and the preferred communication methods**

Pharmacists preferred communication method	Membership of RPS No. (%)			Membership of NPA No. (%)			Membership of PDA No. (%)		
	No	Yes		No	Yes		No	Yes	
<b>Total</b>	<b>127</b> (53.8%)	<b>127</b> (53.8%)	<b>p*</b>	<b>133</b> (56.4%)	<b>99</b> (41.9%)	<b>p*</b>	<b>144</b> (61%)	<b>88</b> (37.3%)	<b>p*</b>
Professional journal	27 (25.7%)	55 (43.3%)	Test invalid	46 (34.6%)	36 (36.4%)	Test invalid	51 (35.4%)	31 (35.2%)	Test invalid
Professional bodies	30 (28.6%)	15 (11.8%)		31 (23.3%)	14 (14.1%)		26 (18.1%)	19 (21.6%)	
Via their organization	17 (16.2%)	19 (15%)		23 (17.3%)	13 (13.1%)		23 (16%)	13 (14.8%)	
Fax	5 (4.8%)	5 (3.9%)		7 (5.3%)	3 (3.0%)		7 (4.9%)	3 (3.4%)	
Email	22 (21%)	28 (22%)		21 (15.8%)	29 (29.3%)		34 (23.6%)	16 (18.2%)	
Press release	1 (1%)	3 (2.4%)		2 (1.5%)	2 (2%)		2 (1.4%)	2 (2.2%)	
General media	2 (1.9%)	2 (1.6%)		3 (2.3%)	1 (1%)		0	4 (4.5%)	
Other	1 (1%)	0		0	1 (1%)		1 (0.7%)	0	

\* Chi-squared analysis

v) Comparisons of the dispensing and purchasing practices

Table 6.34 compares the pharmacists' membership of a given professional body with their dispensing practices that would help to protect patients from counterfeit medicines. The results show significant differences in checking the physical characteristics of the product as the pharmacists who are members of the RPS are more likely to perform this practice compared with those who are not members of the RPS; whereas, those who are members of the PDA are less likely to perform that practice compared with those who are not members of the PDA.

Furthermore, table 6.35 compares the pharmacists' purchasing practices with the pharmacists' memberships of different professional bodies. Results show that pharmacists who are members of the PDA are less likely to establish the integrity of the supplier prior to ordering compared to those who are not members of the PDA. Also, pharmacists not members of the PDA will be more likely to reject a product if it being offered at an unusually cheap price or large quantity compared to the pharmacists members of the PDA.

**Table 6. 34 Professional body membership and the dispensing practices**

Dispensing practice	Membership of RPS No. (%)					Membership of NPA No. (%)					Membership of PDA No. (%)				
	No		Yes		p*	No		Yes		p*	No		Yes		p*
	No.	Median (IQ) <sup>+</sup>	No.	Median (IQ) <sup>+</sup>		No.	Median (IQ) <sup>+</sup>	No.	Median (IQ) <sup>+</sup>		No.	Median (IQ) <sup>+</sup>	No.	Median (IQ) <sup>+</sup>	
Check the package seal	105	5 (4, 5)	125	5 (4, 5)	0.923	132	5 (4, 5)	98	5 (4, 5)	0.974	142	5 (4, 5)	88	5 (4, 5)	0.223
Check for an altered expiry date	105	5 (3, 5)	126	4 (2, 5)	0.097	132	4 (2.25, 5)	99	4 (3, 5)	0.594	143	4 (3, 5)	88	4 (3, 5)	0.714
Check the physical characteristics of the product	105	2 (1.5, 3)	126	3 (2, 4)	0.021	132	3 (2, 3)	99	3 (2, 3)	0.648	143	3 (2, 4)	88	2 (2, 3)	0.034
Check for any signs of a removed or switched product label	105	4 (2, 5)	126	4 (2, 4)	0.998	132	3.5 (2, 4.75)	99	4 (2, 4)	0.839	143	4 (2, 5)	88	3 (2, 4)	0.115
Check for subtle changes in the product's package	105	3 (2, 4)	126	3 (2, 4)	0.894	132	3 (2, 4)	99	3 (2, 3)	0.357	143	3 (2, 4)	88	3 (2, 4)	0.813
Check the package for changes in paper texture, size and thickness of the labels	104	2 (1, 3)	126	2 (2, 3)	0.237	131	2 (1, 3)	99	2 (2, 3)	0.118	143	2 (2, 3)	87	2 (1, 3)	0.186
Check for changes in fonts and font sizes, print colour or raised print	104	2 (1, 3)	126	2 (1, 3)	0.519	131	2 (1, 3)	99	2 (1, 3)	0.232	143	2 (1, 3)	87	2 (1, 3)	0.492
Check all printing on flaps and surfaces of the box	104	2 (1, 3)	125	2 (1.5, 3)	0.780	130	2 (1, 3)	99	2 (2, 3)	0.185	142	2 (1.75, 3)	87	2 (1, 3)	0.531
Check for overt security (e.g. hologram)	105	3 (2, 4)	125	3 (2, 4)	0.450	131	3 (2, 4)	99	3 (2, 4)	0.347	142	4 (2, 4)	88	3 (2, 4)	0.252
Check for changes in the size of the container	105	2 (2, 4)	125	3 (2, 4)	0.475	132	2 (2, 3)	99	3 (2, 4)	0.466	143	2 (2, 3)	88	2 (2, 4)	0.930

\* Mann-Whitney U test + (1=Never; 5=Always)

**Table 6. 35 Professional body membership and the purchasing practices**

Purchasing practice	Membership of RPS <i>No. (%)</i>					Membership of NPA <i>No. (%)</i>					Membership of PDA <i>No. (%)</i>				
	No		Yes		p*	No		Yes		p*	No		Yes		p*
	No.	Median (IQ)	No.	Median (IQ)		No.	Median (IQ)	No.	Median (IQ)		No.	Median (IQ)	No.	Median (IQ)	
Establish integrity of the supplier prior to ordering <sup>+</sup>	58	5 (4, 5)	82	5 (4, 5)	0.686	73	5 (4, 5)	67	5 (5, 5)	0.299	91	5 (5, 5)	49	5 (3, 5)	0.059
Establish a list of approved suppliers <sup>+</sup>	57	5 (4, 5)	78	5 (4, 5)	0.970	70	5 (4, 5)	65	5 (5, 5)	0.216	87	5 (5, 5)	48	5 (4, 5)	0.144
Develop a list of products purchased only from the manufacturer or authorised distributors <sup>+</sup>	51	5 (2, 5)	78	5 (3, 5)	0.960	66	5 (2.75, 5)	63	5 (2, 5)	0.760	83	5 (2, 5)	46	5 (2.75, 5)	0.929
If a product is being offered at an unusually cheap price <sup>#</sup>	56	2 (2, 2)	73	2 (2, 2)	0.640	64	2 (2, 2)	65	2 (2, 2)	0.612	83	2 (2, 3)	46	2 (2, 2)	0.029
If a product is being offered in an unusually large quantity <sup>#</sup>	59	2 (2, 2)	69	2 (2, 3)	0.640	66	2 (2, 3)	62	2 (2, 3)	0.910	80	2 (2, 3)	48	2 (2, 2)	0.009

\* Mann-Whitney U test

+ (1=Never; 5=Always)

# (1=Accept the offer; 2= Treat with caution, 3=Reject the offer)

### 6.4.4.5 Pharmacists' workplace

This section compares the opinions of pharmacists based on their workplace about counterfeit medicines. The researcher formulated the hypothesis that pharmacists' workplaces may affect the answers given by the pharmacists. To test the hypothesis five comparisons (future actions, preferences for education, pharmacist role, preferred method of communication and dispensing/purchasing practices) have been conducted to compare data between 91 pharmacists who worked at an independent pharmacy and 143 pharmacists who worked at a multi-chain pharmacy.

#### i) Comparisons of opinions on future actions

Table 6.36 compares the two pharmacists groups' selection of actions that they would do in case they found counterfeit medicines. This identified three significant differences between the two groups. Pharmacists working in independent pharmacies were more likely to report to the MHRA and to their professional body than those working at a multi-chain pharmacy, while pharmacists working at a multi-chain pharmacy were more likely to report this to someone within their organization.

**Table 6. 36 The workplace and pharmacists' stated future actions**

Pharmacists' selection for their future action	Pharmacists' workplace No. (%)		P*
	Independent pharmacy	Multi-chain pharmacy	
<b>Total</b>	<b>91 (38.6%)</b>	<b>144 (61%)</b>	
Report to the medicine's supplier	81 (89%)	121 (84%)	0.338
Report to the medicine's manufacturer	44 (48.4%)	68 (47.2%)	0.894
Report to MHRA	66 (72.5%)	83 (57.6%)	0.026
Isolate the item from the stock	73 (80.2%)	110 (76.4%)	0.523
Report to someone within their organization	30 (33%)	101 (70.1%)	0.000
Report to the pharmacist's professional body	24 (26.4%)	20 (13.9%)	0.025
Report to the pharmacist	3 (3.3%)	7 (4.9%)	0.745

\* Fisher's exact test

ii) Comparisons of opinion on the future education preferences

Table 6.37 shows the responses of the two pharmacist groups regarding the timing of any education or training programmes about counterfeit medicines. Moreover, table 6.38 highlights which kind of education or training programmes they preferred. There were no significant difference between the two pharmacist groups in their selection for the timing of educational or training programmes regarding counterfeit medicines.

**Table 6. 37 The workplace and the recommendations for future education timing**

Pharmacist's selection for the timing of future education	Pharmacists' workplace No. (%)		P*
	Independent pharmacy	Multi-chain pharmacy	
<b>Total</b>	<b>90 (38.1%)</b>	<b>144 (61%)</b>	
Within undergraduate degree	24 (26.7%)	43 (29.9%)	0.869
Within the pre-registration year	33 (36.7%)	50 (34.7%)	
in the post- registration	33 (36.7%)	51 (35.4%)	

\* Chi-squared analysis

**Table 6. 38 The workplace and the recommendations for future education preferences**

Pharmacist's selection for future education delivery method	Pharmacists' workplace No. (%)		P*
	Independent pharmacy	Multi-chain pharmacy	
<b>Total</b>	<b>90 (38.1%)</b>	<b>144 (61%)</b>	
Workshop	41 (45.6%)	63 (43.8%)	0.789
Conference	4 (4.4%)	14 (9.7%)	0.207
Distance learning	35 (38.9%)	49 (34%)	0.485
Journal articles	17 (18.9%)	30 (20.8%)	0.426
Other	2 (2.2%)	0	0.147

\* Fisher's exact test

iii) Comparisons of opinion on the pharmacist roles

This comparison (table 6.39) addresses the views of the study sample on the pharmacists' roles in combating counterfeit medicines based on their place of work. There is no significant difference between the two pharmacist groups.

**Table 6. 39 The workplace and the pharmacist' role**

Role of pharmacist in combating counterfeit medicines	Pharmacists' workplace No. (%)		P*
	Independent pharmacy	Multi-chain pharmacy	
<b>Total</b>	<b>90 (38.1%)</b>	<b>143 (60.6%)</b>	
Reporting to the medicines regulatory agency	86 (95.6%)	130 (90.9%)	0.208
Raising patient awareness about counterfeit medicines	76 (85.4%)	113 (79%)	0.297
Advice patient about counterfeit medicines	82 (92.1%)	128 (89.5%)	0.646

\* Fisher's exact test

iv) Comparisons of opinion on the preferred methods of communication

The comparison that examines the pharmacists' place of work and their preferred methods of communication regarding counterfeiting information between the two pharmacist groups is given in table 6.40. Results show that the first selection for both groups of pharmacists is a professional journal. On the other hand, the second selection for pharmacists working in independent pharmacy is Email; whereas, for pharmacists working in multi-chain pharmacy it would be via their organization.

**Table 6. 40 The workplace on their preferred communication methods**

Pharmacists preferred communication method	Pharmacists' workplace No. (%)		P*
	Independent pharmacy	Multi-chain pharmacy	
<b>Total</b>	<b>91 (38.6%)</b>	<b>144 (61%)</b>	Test invalid
Professional journal	35 (38.5 %)	48 (33.3%)	
Professional bodies	16 (17.6%)	30 (20.8%)	
Via their organization	1 (1.1%)	35 (24.3%)	
Fax	4 (4.4%)	6 (4.2%)	
Email	29 (31.9%)	22 (15.3%)	
Press release	2 (2.2%)	2 (1.4%)	
General media	3 (3.3%)	1 (0.7%)	
Other	1 (1.1%)	0	

\* Chi-squared analysis

v) Comparisons of dispensing and purchasing practices

These comparisons (table 6.41) compare pharmacists' place of work on the pharmacists' dispensing practices that would help to protect patients from counterfeit medicines. Also, table 6.42 compares the pharmacists' purchasing practices by the pharmacists' workplace. Results show that pharmacists working in independent pharmacies are more likely to check the package for changes in paper texture, size and thickness of the labels. Also, pharmacists working in independent pharmacies are more likely to establish integrity of the supplier prior to ordering and to establish a list of approved suppliers.

**Table 6. 41 The workplace and the dispensing practices**

Dispensing practice	Pharmacists' workplace				P*
	Independent pharmacy		Multi-chain pharmacy		
	No.	Median (IQ) <sup>+</sup>	No.	Median (IQ) <sup>+</sup>	
Check the package seal	90	5 (4, 5)	143	5 (4, 5)	0.315
Check for an altered expiry date	91	5 (3, 5)	143	4 (2, 5)	0.161
Check the physical characteristics of the product	90	3 (2, 4)	144	2 (2, 3)	0.187
Check for any signs of a removed or switched product label	91	4 (2, 5)	143	3 (2, 4)	0.201
Check for subtle changes in the product's package	91	3 (2, 4)	143	3 (2, 4)	0.201
Check the package for changes in paper texture, size and thickness of the labels	91	2 (2, 3)	142	2 (1, 3)	0.021
Check for changes in fonts and font sizes, print colour or raised print	91	2 (2, 3)	142	2 (1, 3)	0.067
Check all printing on flaps and surfaces of the box	91	2 (2, 3)	141	2 (1, 3)	0.061
Check for overt security (e.g. hologram)	91	3 (2, 4)	142	3 (2, 4)	0.138
Check for changes in the size of the container	91	3 (2, 3)	143	2 (2, 4)	0.632

\* Mann-Whitney U test + (1=Never; 5=Always)



**Table 6. 42 The workplace and purchasing practices**

Purchasing practice	Pharmacists' workplace				P*
	Independent pharmacy		Multi-chain pharmacy		
	No.	Median (IQ)	No.	Median (IQ)	
Establish integrity of the supplier prior to ordering <sup>+</sup>	83	5 (5, 5)	59	5 (3, 5)	0.002
Establish a list of approved suppliers <sup>+</sup>	80	5 (5, 5)	57	5 (2, 5)	<0.001
Develop a list of products purchased only from the manufacturer or authorised distributors <sup>+</sup>	79	5 (3, 5)	52	4 (1.25, 5)	0.107
If a product is being offered at an unusually cheap price <sup>#</sup>	82	2 (2, 2)	49	2 (2, 2)	0.942
If a product is being offered in an unusually large quantity <sup>#</sup>	80	2 (2, 3)	50	2 (2, 2)	0.352

\* Mann-Whitney U test + (1=Never; 5=Always)

# (1=Accept the offer; 2= Treat with caution, 3=Reject the offer)

## 6.5 Discussion

This study was designed to obtain a better understanding of pharmacists' knowledge and experiences of counterfeit medicines. It also aimed to explore pharmacists' perceptions of their possible roles in combating counterfeit medicines. The study found that less than a quarter of the pharmacists had had a past experience of counterfeit medicines and that they preferred to report any future incidents to their suppliers rather than the MHRA. Only one in ten pharmacists had received past education or training regarding counterfeit medicines. They also said that they would prefer workshops and distance learning as the delivery method for these education or training programmes. It was also found that many of the dispensing practices that were recommended by the MHRA and the RPS to secure the supply chain and to protect patients from counterfeit medicines were not being performed or were rarely being performed by pharmacists. Fewer than half of pharmacists were following the purchasing practices that were

recommended by the MHRA and the RPS to secure their supply chain from counterfeit medicines. Not all pharmacists agreed that reporting to the medicines regulatory agency was a role for the pharmacist in combating counterfeit medicines, nor did they all agree that it was their role to raise patients' awareness or to provide advice to patients. Although very few pharmacists had previously received any formal training or education regarding counterfeit medicines, they were receptive to future training in a wide variety of formats.

In comparing the responses between the pharmacists in respect to any past experience of counterfeit medicines, education experience, length of service, membership of a professional body, and working place; there was no significant differences in the responses between the pharmacists. As the number of pharmacists who participated in this study and who had had past experience of counterfeit medicines or had past education experiences was small, the few significant differences that were found might perhaps be considered as false positives. However, those few significant differences indicated between younger pharmacists and older ones as well as between pharmacists working in independent and multi-chain pharmacies with regard to reporting any counterfeit medicines incident to the medicines regulatory agency might provide some indications of the pharmacists' attitudes and responses to counterfeit medicines.

This study, to the best knowledge of the researcher, was the first to be designed and implemented in the UK to understand the practices, experience and opinions of community pharmacists regarding counterfeit medicines. The questionnaire was completed well with limited missing data suggesting that it was relatively easy to use. It may have been useful to follow up with a limited sub-sample of respondents to determine their views on the content, their understanding of questions and on what we could have done to further enhance our response rate. Also, the sampling process was random giving all of England's community pharmacist population the same probability of being part of the study; this could be seen from the demographic data collected on the participants. According to a report published in 2013 by the General Pharmaceutical Council (GPhC) (138), 39.6% of overall registered pharmacists were male and 60.4% were female; whereas, in this study 58.7% of the participants were male and 41.3% were female. This difference could be partially explained by the fact that female pharmacists are more likely to work in hospital pharmacies than male pharmacists and

are also more likely to be working part-time and therefore would have been less likely to see the questionnaire. Regarding pharmacists' workplaces, according to the report by the Health & Social Care Information Centre (HSCIC) published in 2014 (135); 39% of community pharmacists in England are working in independent pharmacies and 61% are working in multi-chain pharmacies which very closely reflects the numbers seen within the study sample.

The results need to be considered while noting the survey response rate, which was only 36.3%, as this limits the generalizability of the findings of the study to suggest whether the opinions of respondents reflect those of non-respondents. This response rate might be because pharmacists perceived that the questionnaire was assessing their practice. Also, as the questionnaire was sent at the end of the month which considered a busy time for the pharmacists which could affect the response rate. Another, unexpected, finding of the study was the low percentage of community pharmacists who had had past experiences of counterfeit medicines; as well as there being only a small number of pharmacists taking part in the study had received prior education and training regarding counterfeit medicines. These limitations affected the data analysis when comparing the answers of the pharmacists to find out the impact of those past experiences or education. Also, this study was conducted with a very limited range of published literature to support its design.

This study suggests, with less than a quarter of community pharmacists in England reporting having experienced counterfeit medicines, that either it is not a major problem or that it is not being detected. The most regularly reported relevant experience was of medicines being recalled by the MHRA due to a counterfeit medicine incident. The last such recall was issued by the MHRA in 2009 (131) and this could explain why such a low number of pharmacists (22%) reported that they had had a past experience with such recalls. These results could also reflect that those kinds of recalls may be dealt with by wholesalers and senior pharmacy managers who may have done so without sharing the information with their community pharmacists.

This study also shows that one out of ten of the pharmacists had received a counterfeit medicine from their supply chain; a few pharmacists even said that they had been offered medicines from their supply chain that had made them suspicious that they might be counterfeited. These results highlighted the importance of pharmacists

applying the guidance published by the MHRA with the RPS (84). Interestingly, more than one out of ten pharmacists reported patients showing them medicines they believed were counterfeit. This indicates that patients are obtaining medicines from the black market and suggests that, with such a high prevalence of occurrence, pharmacists could be used to report such instances to the MHRA. This, however, would only be effective if the pharmacists collected data in a standardised manner which was acceptable to patients. Consequently, they may have a role in supporting the identification of websites which are supplying counterfeit medicines. It is also interesting that pharmacists are approached by patients for such advice as they are seeking advice on a potentially unsafe action which they have undertaken. Pharmacists are increasingly being recognised as having a public health role due to the anonymity they afford patients (who do not have to register with them) and therefore identifying potential counterfeit medicines may be another potential public health role.

The fact that most pharmacists stated that if they came across a counterfeit medicine issue they would report it to their supplier is perhaps to be expected. By reporting this to the supplier, the supplier can then retrace the supply chain and contact the manufacturer to identify the likelihood of the medicine being counterfeit. The pharmacist, however, needs to recognise that the supplier would be responsible for any harm resulting from poor purchasing practices and therefore it may not be in their interest to identify or highlight counterfeit medicines. Consequently, pharmacists should be encouraged to report to the MHRA who are independent and can quickly identify repeated reports. It is perhaps pleasing that almost two-thirds of pharmacists stated that they would report incidents of counterfeit medicines to the MHRA. On the other hand, with such questionnaires it is not possible to determine whether respondent answers accurately reflect true practice. Therefore, it could be that providing the MHRA as an option may have encouraged participants to select this option, although without prompting the respondent may not have spontaneously considered this or even been aware of it. It is of some concern that although pharmacists may report their concerns to their supplier they would not all immediately isolate the stock to prevent it from reaching the patient. A medicine for which the pharmacist has any concerns should be immediately isolated to ensure that it is not supplied until its authenticity has been verified or not.

With highly regulated pharmacist training in the UK and EU it is perhaps surprising that the subject of counterfeit medicines does not seem to be routinely included. Whilst this may reflect respondent inability to recall training which occurred along time ago it is not whether they recall the training which is important it is whether previous knowledge informs their current practice; the results suggest that this is not the case. This study shows how large numbers of pharmacists were not aware of best practice when dealing with any suspected case of counterfeit medicines. As the pharmacists' first selection in a case of counterfeit medicines is reporting to the supplier, the decision-makers at the medicines regulatory agency could use these findings to understand the current knowledge of pharmacists and to increase the education and training activities for pharmacists about the prompt reporting of any suspicious counterfeit medicine incident to the agency; also, to working closely with medicine suppliers in improving the pharmacists' knowledge of best practice when dealing with counterfeit medicines.

As the majority of pharmacists in this study had not had any training with respect to counterfeit medicines in the past, their recommendation on the best timing for delivering such education to pharmacists could be purely speculative as seen in their lack of agreement on the issue. However, pharmacists deal with medicines physically in their daily work life a fact which could be the reason for almost half of the pharmacists preferring workshops as a training method for counterfeit medicines. Community pharmacists have to obtain cover for the whole day if they attend workshops at this time and may not want to give up their own time; this could explain the selection of distance learning by one-third of the pharmacists. In spite of this, the guidance for pharmacists published by the MHRA and RPS with respect to counterfeit medicines which could be considered as a distance learning tool was not identified by the respondents and did not seem to have affected the reported practice of pharmacists. These results could help the decision-makers at the medicines regulatory agency to work more with pharmacy schools to design workshop training about counterfeit medicines that would be delivered to them within undergraduate degree courses and within pharmacists' pre-registration year as the pharmacists will have more time for education and training during these two periods. Furthermore it is perhaps appropriate to ensure that practitioners are trained in counterfeit medicines before registration and autonomous patient facing practice.

Most of the dispensing practices examined in this study, which are aimed at protecting patients from counterfeit medicines, were never or rarely performed by the pharmacists. Due to the pharmacists' workloads, they might be delegating these tasks to pharmacy technicians or pharmacists might assume the pharmacy's management checked all medicines before being stocked on the shelves. However, according to this study, nearly half of pharmacists did not even perform a check of the medicine's name and expiry date something which should be part of the pharmacists' routine before dispensing the medicines to patients and which might indicate a weakness in the system. Two things are worth considering at this point; firstly pharmacists may not have time to do all of the tasks recommended for them concerning counterfeit medicines and may not prioritise them as they believe the provenance of their suppliers; secondly medicines are increasingly supplied through robots and therefore this checking would be undertaken in the future by a technician when filling the machine. In addition, this study showed that between 40% and 45% of the pharmacists did not have any responsibility for purchasing the medicines; which could be understood as more than half of the pharmacists in this study worked at a multi-pharmacy chain and the purchasing process would be conducted centrally by a dedicated buying department. However, the results show that not all pharmacists involved in the purchasing process (who could be those working at an independent pharmacy) were applying MHRA and RPS recommendations to secure the supply chain from counterfeit medicines. These results might be helpful for the decision-makers within a medicines regulatory agency, as well as for the pharmacists' regulatory agency, in considering the content of any training. Also it can help achieve a better understanding of the real dispensing and purchasing practices of community pharmacists which will help identify the weaknesses in the medicines supply chain.

It was found that not all pharmacists agreed with the roles that had been identified for them in combating counterfeit medicines in the MHRA study and the stakeholders study (chapter 4 and chapter 5) and in some literatures. However, findings showed that some pharmacists saw reporting to the medicines regulatory agency as the responsibility of the pharmacy management or the medicines supplier to whom this study has shown pharmacists are most likely to report any case of the counterfeit medicines. It may be that pharmacists need to be educated with regard to the importance of reporting to the medicines regulatory agency as the medicines' supplier might have a conflict of interest and they may not report it onwards to the medicines regulatory agency. Also, in this

study not all pharmacists agreed that raising patient awareness and education was part of their role. Pharmacists might see themselves as not having enough time to carry out such roles as they are operating under the pressure of a high workload (139, 140). Nevertheless, pharmacists should realise that patients have a high regard for them and view them as medicine experts from whom advice can be sought as part of the pharmacist's non-dispensing responsibilities (141, 142). These results suggest that the roles proposed for the pharmacists may not have been communicated sufficiently to the pharmacists and that more effort would be needed to re-design the methods of communications used in line with the preferred methods identified in this study.

### **6.5.1 Comparing pharmacists' responses**

This study compared the pharmacists' answers about counterfeit medicines based on their past experience, past education, length of service, membership of professional bodies and workplace. In general no significant difference was found for those comparisons. This finding might be due to the small number of pharmacists who had had past experiences or might be a consequence of a low response rate. The fact that very few differences between experience and education and reported practices were seen could be due to the small number of pharmacists in this study with such past experience and therefore the limited power of the tests, or it may just be that those experiences were so limited that they did not change pharmacists' views or practices.

Certain comparisons revealed some interesting results; but, due to the large number of tests performed there is a possibility of false positives. However, for the purposes of discussion these are considered to be true differences whilst it is accepted that this could be proved otherwise with a larger sample. Pharmacists without any past experiences of counterfeiting incidents were found to say they were more likely to report to the MHRA; whereas the pharmacists with such past experiences stated that they would be more likely to report to their professional bodies. Also, the pharmacists without any past experiences of counterfeit medicines agreed more on the roles of the pharmacists in combating counterfeit medicines. These were unexpected results as pharmacists with past experiences should be more aware of good practice when dealing with counterfeit medicines including reporting to the MHRA which is not shown in these results. It also

worth considering the possibility that pharmacists with previous experience might have found reporting to the MHRA to be difficult and therefore choose an alternative route.

This study also shows that pharmacists who had had a past educational or training experience related to counterfeit medicines were more likely to choose to report to the MHRA than those who had not had a past educational or training experience; additionally, the first selection for pharmacists who had had a past educational or training experience was to report to the MHRA as well as to their supplier should a suspected case of counterfeiting arise. In addition, pharmacists with past education or training experience are more agreed on the roles of pharmacists in combating counterfeit medicines. This result might suggest that education or training would make a difference to pharmacists' actions when they come across a counterfeit medicines case.

Also by comparing pharmacists' length of service, it was found that less experienced pharmacists would be more likely to report any counterfeit medicines incident to the medicines regulatory agency, which might suggest that those pharmacists might be being trained on counterfeit medicines during their degree or pre-registration year. Also, the results showed less experienced pharmacists preferred the education and training programmes on counterfeit medicines to be integrated into the pharmacist's pre-registration year as workshops, which may support that explanation.

When comparing pharmacists' responses based on their workplace (independent pharmacy or multi-chain pharmacy), the study showed that pharmacists working in an independent pharmacy would be more likely to report to the MHRA and to their professional body than those working in a multi-chain pharmacy; which may be because pharmacists working in independent pharmacy would be more involved in management roles whereas in multi-chain pharmacy the pharmacists might believe this would be the pharmacy management's duties. Pharmacists working at an independent pharmacy are slightly more likely to be following the recommendations published by the MHRA for good practice to combat counterfeit medicines; which could be expected as pharmacists in independent pharmacy are more involved in the purchasing process than those in multi-chain pharmacy. The same pharmacists had more conviction in their roles in combating medicine counterfeiting. The study also showed pharmacists working at a multi-chain pharmacy were more likely to report to their organization, which might be



because many independent pharmacies are not part of an organisation therefore the option of reporting to their organization is not applicable for them. Another point to be considered, pharmacists working in multi-chain pharmacy might believe that as they are part of a larger organization that all work related issues should be handled through the organization including the reporting of counterfeit medicines cases. This is supported by the view the second preferred method of communication regarding counterfeit medicines for the pharmacists working at a multi-chain pharmacy would be via their organization. This third study added to the previous two (chapters 4 and 5) and has made an important contribution to constructing a complete conceptualisation of the process of developing, implementing and evaluating the strategy. The health professional studies in this chapter and the following chapter involved highly significant actors in the issue of combating counterfeit medicines which have contributed to the overall research aim.

## **6.6 Conclusion**

This study investigated current community pharmacists' knowledge and experiences of counterfeit medicines as well as identifying pharmacists' views on their own roles in combating this problem. It also highlighted the distribution of types of views and practices according to a set of variables including past experiences of counterfeit medicines, past education or training programmes, length of service, membership of professional bodies and the nature of their workplace. The study was able to establish the extent to which certain views and practices were shared and what variables may influence the holding of a particular view or the adoption of a particular practice. It showed that fewer than one in four community pharmacists in England had had a past experience of counterfeit medicines during their professional life; also, the first action for pharmacists should they have to deal with any counterfeit medicine incident in the future would be to report it to the medicine's supplier. This study showed that only a low percentage of pharmacists had attended an education or training programme about counterfeit medicines in the past. Pharmacists were also found not to apply the dispensing and purchasing practices recommended by the medicines regulatory agency to combat counterfeit medicines. Not all pharmacists agreed that reporting any

suspicion of counterfeiting medicines to the medicines regulatory agency is part of their role in combating counterfeit medicines; also, less agreement was seen between pharmacists on their role to raise patients' awareness and to provide advice to patients about counterfeit medicines. Finally, this study could not distinguish any differences in opinion between the community pharmacists' responses regarding their views on counterfeit medicines based on their past experience or past education of counterfeit medicines, length of service or workplace.

The study could not identify any impact from pharmacists' past experience of counterfeiting incidents or past education, pharmacists' length of service or workplace or membership of professional bodies. Nevertheless this study suggested that a medicine regulatory agency might need to work closely with schools of pharmacy, the pharmacists' professional bodies and multi-chain pharmacy organizations which would improve the education and communication activities with the pharmacists which in turn would help in combating counterfeit medicines. This study might be useful for the decision-makers within a medicines regulatory agency in understanding the knowledge and views of pharmacists on their roles in combating counterfeit medicines together with their dispensing and purchasing practices, something which would help in their efforts to engage pharmacists in the planning and implementation of its counterfeit medicines strategy.



# ***Chapter 7***

## ***General Practitioners' views on their role in combating counterfeit medicines***

## **7.1 Introduction**

The MHRA plays the leading role in developing and implementing an anti-counterfeit medicines strategy as do its stakeholders; however, their contact with the end users of such medicines, the general public, is limited. It is health professionals such as pharmacists and GPs who have most of this direct contact. Pharmacists were the subject of the previous study and in this chapter attention turns to GPs currently working in England. Most GPs do not dispense medicines in England, which is the role of pharmacists. They are, however, responsible for prescribing medicines and for treating patients who may have health problems arising from the use of counterfeit medicines. As such GPs represent an important group for this research if we are to build a multi-dimensional, triangulated conceptualisation of the processes of developing, implementing and evaluating an anti-counterfeit medicines strategy and so address the research problem. The views, perceptions and practices of GPs need to be understood. As with pharmacists, the quantitative data collected from GPs is intended to provide a broadly representative picture of the views, preferences and practices of the GP population concerning a range of counterfeit medicines issues.

Discussion of the extent and nature of GPs role in combating counterfeit medicines has been largely a matter of conjecture to this point. *GP* magazine had published results of a polling survey and subsequently reported by the MHRA in which 423 GPs had taken part. One finding was that 25% of GPs reported having treated patients for adverse reactions to medicines they had purchased online, where counterfeit medicines are known to be particularly prevalent (85, 143). While this suggests that GPs frequently encounter cases of counterfeit medicines, the full published results of the study could not be located for examination in this study, for its methodology and robustness of findings to be evaluated.

GPs do not normally deal directly and physically with medicines in the UK (except for dispensing doctors who are usually in rural areas where patients live remotely from a pharmacy). However, GPs are likely to regularly encounter patients who experience side effects from medicines prescribed for them and GPs are required to report these side effects to the MHRA via the “Yellow Card Scheme”. In this scheme, GPs also have an option to report a counterfeit medicines case if they suspect the side effect is from a

counterfeit medicine (144). Participants from the MHRA study (chapter 4) and the stakeholder study (chapter 5) identified roles that GPs could play in combating counterfeit medicines. These roles were: reporting to the MHRA through the Yellow Card scheme, being vigilant for any suspicion of counterfeit cases, and giving advice to and raising awareness of the dangers of counterfeit medicines among their patients. However, the views of GPs on these proposed roles have not been systematically investigated outside this study nor elucidated in MHRA publications.

Additionally, the need for communication with and education of health professionals (including GPs) with respect to counterfeit medicines had both been mentioned within the MHRA and WHO publications on the counterfeit medicines issue. Communication methods that could be used with GPs were identified in the MHRA study (reported in Chapter 4) and the stakeholders study (Chapter 5). The preferences of GPs themselves concerning these communication methods have not yet been examined. If such communication is to be effective then the views of those receiving the communication are highly relevant. Furthermore, our understanding of GPs' views can be deepened by exploring, through comparative analysis, whether these views are consistently held or whether they change according to variables such as past experiences of counterfeit medicines, length of service and membership of a professional body. Taken together these gaps in knowledge and understanding of GP views on matters related to counterfeit medicines are significant and represent an opportunity to add new and valuable information to the field of study and particularly to the process of developing and implementing an anti-counterfeit medicines strategy. To address the research problem it is necessary to construct a complete and multi-dimensional conceptualisation of the process of developing, implementing and evaluating an anti-counterfeit medicines strategy and to achieve this within this study requires the addition of the GPs' dimension. It is an important dimension as GPs prescribe medicines, treat patients who may have health problems arising from the use of counterfeit medicines and could have a prime role in educating and advising patients on matters related to counterfeit medicines.

## **7.2 Aims and Objectives**

This study aims to understand the views and describe the roles of general practitioners (GPs) in combating counterfeit medicines.

Therefore, the objectives of this research in relation to counterfeit medicines are:

- to describe the knowledge and experience of GPs practising in England and the educational opportunities available to them to enhance this.
- to describe how GPs practising in England view their roles in combating counterfeit medicines.
- to identify GPs' views on what methods they may prefer for a medicines regulatory agency to communicate with GPs practising in England.
- to relate the educational opportunities and past experience of GPs practising in England to the views and practices they describe.

## **7.3 Methods**

In this study the aim was to gain an understanding of GPs' views on a range of issues related to counterfeit medicines. As with pharmacists, this constituted a large and geographically spread population and as the sample needed to offer a reasonable degree of generalizability for the results, certain research methods were ruled out, including the face-to-face interviews used in the two studies involving MHRA participants and MHRA stakeholder participants (chapters 4 and 5). Therefore, a survey questionnaire would be a more appropriate method of data collection and as the full addresses of the workplaces of GPs were readily identifiable it was further decided to administer this by post.

This study is the second of two aimed at providing support to the findings of the previous two studies involving MHRA participants and MHRA stakeholder participants. Including a quantitative research design offered the means of triangulating

within this group of studies by addressing its objective of describing the knowledge and experience of England's GPs of the counterfeit medicines issue. The quantitative research method is most appropriate where pre-existing knowledge must be taken into consideration; this allows the researcher to employ standardised data collection methods to document any prevalence of knowledge being examined (102). As with the pharmacist study, this study needed quantifiable answers to questions aimed at establishing the distribution of types of views and practices across members of a group, the extent to which these views and practices were shared and what variables may influence the holding a particular view or the adoption of a particular practice. All these requirements indicate that a quantitative study was appropriate. Hence, a retrospective descriptive survey was used to describe the sample and to examine any associations between variables. In order to ensure a reasonable degree of comparability with the pharmacist study, this GP study adopted very similar questionnaire survey methods to those described in Chapter 6, however, with some differences in the questionnaire items.

Furthermore, the quantitative methods used in this study were selected as it would be most appropriate for the second objective of the study which was to describe and understand the views and roles of pharmacists and GPs in combating counterfeit medicines. These methods were also appropriate for accessing the population and were consistent with the desire for generalisability. The benefits of triangulation as “an opportunity to enrich research findings and deepen insight” were a consequence of the choices as the qualitative approach of the first two studies could now be complemented and strengthened with quantitative input from two groups of health professionals with important roles to play in any anti-counterfeit medicines strategy (133).

### **7.3.1 Ethical approval**

This study was approved by the University of East Anglia, Faculty of Medicine and Health Ethics Committee (Appendix 4.1) with NHS ethical approval not required as this study included only GPs.



## **7.3.2 Questionnaire development**

### **7.3.2.1 Questionnaire design**

This study is designed based on two qualitative studies of the views of MHRA staff and stakeholders respectively, carried out by the researcher and relating to the process of developing a national strategy for a medicines regulatory agency to combat counterfeit medicines (chapter 4 and chapter 5). Those studies captured the views of members of the MHRA and of key stakeholders about the issues associated with developing an anti-counterfeit medicines strategy. The participants from those earlier studies defined some roles that could be carried out by GPs to assist in combating counterfeit medicines. Also, those participants described the methods that could be used by the medicines regulatory agency to communicate with GPs. This study is also based on the guidance leaflet for pharmacists and dispensing doctors called “Counterfeit Medicines Advice for Healthcare Professionals”, which was published by the MHRA, the RPS and the DDA; which assisted the researcher confirm some of the ongoing issues, shape parts of the questionnaire and anticipate the themes likely to emerge from the data (10).

The researcher then designed a questionnaire which was sent to GPs practising in England including dispensing doctors (Appendix 4.2). The questionnaire aimed to provide data which could specifically address the aims and objectives of this study. Section 1 of the questionnaire covered any past experiences GPs might have had about counterfeit medicines. Section 2 covered any education or training opportunities and experiences of counterfeit medicines that GPs might have had, and any recommendations they may have for such education or training opportunities. Section 3 sought GPs' views on about their role in combating counterfeit medicines, and what the best method would be to communicate information on counterfeit medicines to them. Section 4 covered the personal information of the participants, to help the researcher to show whether the study participants were representative of the general GPs' population.

### **7.3.2.2 Questionnaire validity**

Validity in a survey study can be measured through assessing how far the questions collect accurate data and whether or not they are relevant to the study objective (117). To achieve face validity, the questionnaire was evaluated by academics and practice pharmacists as well as two GPs working at the UEA's Pharmacy School and UEA's School of Medicine prior to launching the survey. Its face validity has been further examined during the piloting stage. Content validity was established in this research through the careful selection and refinement of items during questionnaire development, based on the qualitative data derived from the previous studies as well as on the evaluation and judgement of peers at the UEA's Pharmacy School UEA's School of Medicine.

### **7.3.2.3 Improving the response rate**

To increase the response rate for these questionnaires, the researcher applied the findings of the review study conducted by Edwards et al. (2009) (134). The questionnaire was therefore designed to be short and usually not to take more than ten minutes to complete. The UEA logo was added to the front page to clearly indicate that these questionnaires are sponsored by the university. The researcher reassured recipients in the invitation letter and on the first page of the questionnaires that confidentiality would be maintained and that questionnaires were anonymous. All invitation letters were personalized and all the potential participants received a pen with the UEA logo as an unconditional incentive. A stamped addressed return envelope was provided with each questionnaire to increase the response rate. A follow-up letter, which contained a second copy of the questionnaire, was sent to potential participants who had yet to return the postcard.

### **7.3.3 Participants and sample size calculation**

#### **7.3.3.1 Sampling unit**

The target population for this study was GPs practising in England; it has been reported that the total number of doctors licensed to work as GPs in England is 47,438 (138). The researcher used the GPs as the sampling unit. Currently, in England there are 211 NHS clinical commissioning groups (CCGs) that provide medical services for patients (145); each of these CCGs consists of many surgery clinics.

#### **7.3.3.2 Sample size estimation**

A final sample size of 400 respondents provides 95% CI of + or – 3% around a response to question of 10%; and + or – 5% around a response to question of 50%. Assuming that 60% of the sample return the questionnaire the researcher needed to post the questionnaire to approximately 630 GPs (136).

#### **7.3.3.3 Method of sampling**

A random sampling method is desirable as it allows the application of probability statistics and generalisation to the population from which the sample is drawn (96). This method is fundamental to achieving external validity for the study (102). The researcher used the random sampling to identify the GPs from clinical commissioning groups (CCGs). All 211 CCGs within England that provide medical services to patients have been included in the sampling (145). From those CCGs; three surgery clinics have been randomly selected; and among those surgery clinics selected, one GP from each CCG was randomly selected to be part of this study (using a random number generator provided within Excel). The total number of GPs included in this study was 633.

## **7.3.4 Implementation and follow-up**

### **7.3.4.1 Questionnaire implementation**

Once the surgery clinics were selected and the GPs from those surgery clinics identified, the researcher used the surgery clinic's website to identify the names of the GPs working there. This assisted the researcher to personalise the invitation letter and the envelope sent to each GP. Each envelope sent to a GP included a personalised invitation letter (Appendix 4.3), a questionnaire (Appendix 4.2), a prepaid envelope to return the questionnaire, a postcard (Appendix 4.4), a prepaid envelope to return the postcard and an incentive pen.

### **7.3.4.2 Follow-up process**

Three weeks after despatching the packs, those who had yet to return their postcard were sent a follow-up reminder letter (Appendix 4.5). A second copy of the questionnaire was included with the reminder letter. No more follow up action was taken after this point.

## **7.3.5 Data analysis**

All data were analysed using Microsoft Excel and the Statistical Package for the Social Sciences (SPSS) software. The data were summarised using descriptive statistics; Fisher's exact test and chi-squared analysis were used to compare between GP groups based on their responses on the questionnaire. The chi-squared test is considered invalid if 20% or more of the cells have expected values of less than 5.

## 7.4 Results

### 7.4.1 Response rates

The initial response rate for the pilot stage (65 questionnaires) after one follow up was 20% (13 out of 65 questionnaires). To improve the response rate, the questionnaire was modified by decreasing the total number of questions, increasing the font size, and adding the WHO definition for counterfeit medicines. In addition, the invitation letter was rewritten and the WHO definition for a counterfeit medicines added to it. The invitation letter and the follow-up letter were signed by a professor from Norwich Medical School and the researcher to encourage the GPs to take part in the study (Appendix 4.3 and Appendix 4.5).

The response rate after the modification slightly improved to 22.5% (128 out of 568 questionnaires); 533 GPs (93.7%) were sent a follow-up reminder letter. The overall response rate to the GPs' questionnaire was 22.3% (141 out of 633 questionnaires). In addition, the overall missing data from the GPs' answers to the questionnaire was 0.99%.

### 7.4.2 Demographic data

Eighty-one of the respondents were male, among those 66 were working as GPs and 15 were working as dispensing doctors. Fifty-nine of the responded were female, among those 47 were working as GPs and 11 were working as dispensing doctors (table 7.1).

**Table 7. 1 GPs' gender and workplace**

		Number of GPs (%)	working as	
			GP (%)	Dispensing doctor (%)
Gender	Male	81 (57.4%)	66 (57.9 %)	15 (55.6%)
	Female	59 (41.8%)	47 (41.2%)	11 (40.7%)
	Missing	1 (0.7%)	1 (0.9%)	1 (3.7%)
	Total	141	114	27

In respect of the GPs' length of service; 2.1% (3 GPs) of the study sample had a length of service of 5 years or less, 4.3% (6 GPs) between 6 to 10 years, 12.1% (17 GPs) between 11 to 15 years, 9.9% (14 GPs) between 16 to 20 years and 12.1% (17 GPs) between 21 and 25 years. Finally, the majority (58.9% - 83 GPs) of this study sample had a length of service of more than 25 years. One GP only (0.7%) did not answer the length of service question

For the purpose of data analysis the GPs' lengths of service were re-grouped to three main categories; 0 – 10 years, 11 – 25 years, and over 25 years. In comparing the study's sample with GPs general population (only GPs' age data available) (138); table 7.2 shows that whilst the age range of the general population of GPs is normally distributed, the study sample is skewed with greater proportions to the older groups.

**Table 7. 2 GPs' length of service (n=140)**

GPs sampled		GPs' general population <sup>1</sup>	
Length of service	Percentage of the study sample	Age	Percentage of General population
0 – 10 years	6.4%	less than 30 years	15%
11 – 25 years	34%	30 – 49 years	58%
over 25 years	58.9%	50 years or more	27%

<sup>1</sup> Council GM. The state of medical education and practice in the UK report: 2014: General Medical Council; <http://www.gmc-uk.org/publications/25452.asp>.

With respect to GPs' membership of professional bodies, 97 of the GPs in the study sample were members of the British Medical Association (BMA), and 69 of the GPs were members of the Royal College of General Practitioners (RCGP). One GP only (0.7%) did not state a professional body.

## 7.4.3 Descriptive analysis

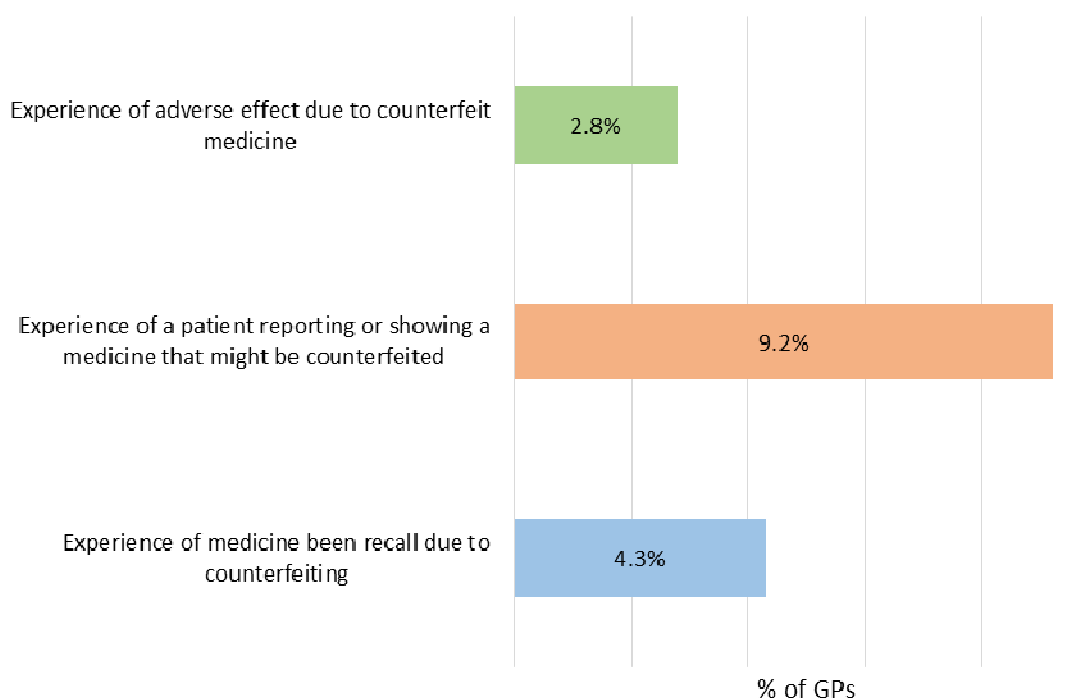
### 7.4.3.1 GPs' experiences in respect of counterfeit medicines

In relating to any past experiences the GPs might have had (figure 7.1); only six (4.3%) GPs of the study's sample have had experience of a medicine being recalled due to counterfeiting. In addition, two of those GPs had had only one experience with this kind of recall, one GP had two such experiences, and one GP had six. The other two GPs did not report a frequency.

13 (9.2%) GPs in this study had experience of a patient reporting or showing a medicine that might be counterfeit. Moreover, 3 GPs had had this experience once, one GP twice, two GPs had it three times, and one GP five times. The remaining GPs did not state the frequency.

In respect of any experience of adverse effects due to counterfeit medicines that patients had used, only four (2.8%) GPs had had such an experience. Also, one GP did not answer how many times he had seen that kind of adverse effect whereas three GPs said they had had such an experience once.

**Figure 7. 1 GPs' experiences of counterfeit medicine issues**



For the action that the GPs who had had an experience of counterfeit medicines, table 7.3 show the actions undertaken by GPs as a result of the past experience with the counterfeit medicines.

**Table 7. 3 GPs' selection for their action as a result of a counterfeiting experience**

	Rank of action taken by the GPs	No. GPs (%)
1	Gave the patient advice	6 (30%)
2	Treated the patient for the adverse effect	4 (20%)
3	Did not do anything	4 (20%)
4	Used the Yellow Card Scheme to report the incident	2 (10%)
5	Informed someone within their organization	2 (10%)
6	Isolated the item from their stock	1 (5%)
7	Other	1 (5%)

With respect to the actions that the GPs would take in the future if they suspected that a medicine could be counterfeit, these are ranked in table 7.4 in order of frequency.

**Table 7. 4 GPs' selection for their future action when suspecting counterfeiting**

	Rank of GP future action intentions	No. GPs (%)
1	Report to the MHRA	81 (57.4%)
2	Report to someone within their organization	72 (51.1%)
3	Report to the supplier of the medicine	57 (40.4%)
4	Isolate the item from the stock	55 (39%)
5	Report to the manufacturer of the medicine	44 (31.2%)
6	Report to the GP's professional body	14 (9.9%)
7	Report to the pharmacist	12 (8.5%)
8	Other	2 (1.4%)



### 7.4.3.2 GPs' education in respect of the counterfeit medicines issue

None of the GPs in this study sample had previously received formal education or a training programme regarding counterfeit medicines. On the education and training programmes that GPs believe should be given; 29.8% (42 GPs) recommended the education and training programme should be within a medicine school undergraduate degree; 31.2% (44 GPs) in the study sample said it should fall within the GPs' foundation year; and 37.6% (53 GPs) indicated it should be in the GPs' post-foundation year.

Moreover, regarding the delivery method for the education and training that covers the counterfeit medicines issue (table 7.5), 57 GPs preferred it to be delivered through distance learning; 51 GPs preferred workshops; and 21 GPs said through journal articles. In their answer few GPs selected more than one preferred method.

**Table 7. 5 GPs' preferred delivery method for education or training programme**

	Rank of preferred education and training delivery method	No. GPs (%)
1	Distance learning	57 (40.4%)
2	Workshop	51 (36.2%)
3	Journal article	21 (14.9%)
4	Conference	16 (11.3%)
5	Other	8 (5.7%)

### 7.4.3.3 GPs' views on their roles in combating counterfeit medicines

The roles GPs believed they could carry out in combating counterfeit medicines are shown in figure 7.2. One hundred and twenty-two GPs saw it as their duty to report any suspicion of counterfeiting medicines to the medicines regulatory agency. However, the other 19 GPs said it would be the pharmacist's responsibility to do this.

For the responsibility of raising patient awareness about counterfeit medicines, only 77 GPs said it would be part of their role to raise patients' awareness of counterfeit

medicines. On the other hand, 64 GPs did not agree that it would be their responsibility; and among them 21 GPs saw it as the government's responsibility and 19 GPs believed it would be the pharmacist's responsibility.

With regard to providing the patient with advice about the counterfeit medicines issue: 72 GPs of the study sample said it would be part of their role in combating counterfeit medicines; however, 69 GPs saw it as not their duty to provide the patient with advice about counterfeit medicines; and 21 of them said it was the pharmacist's responsibility and 14 of them believed it to be the government's responsibility.

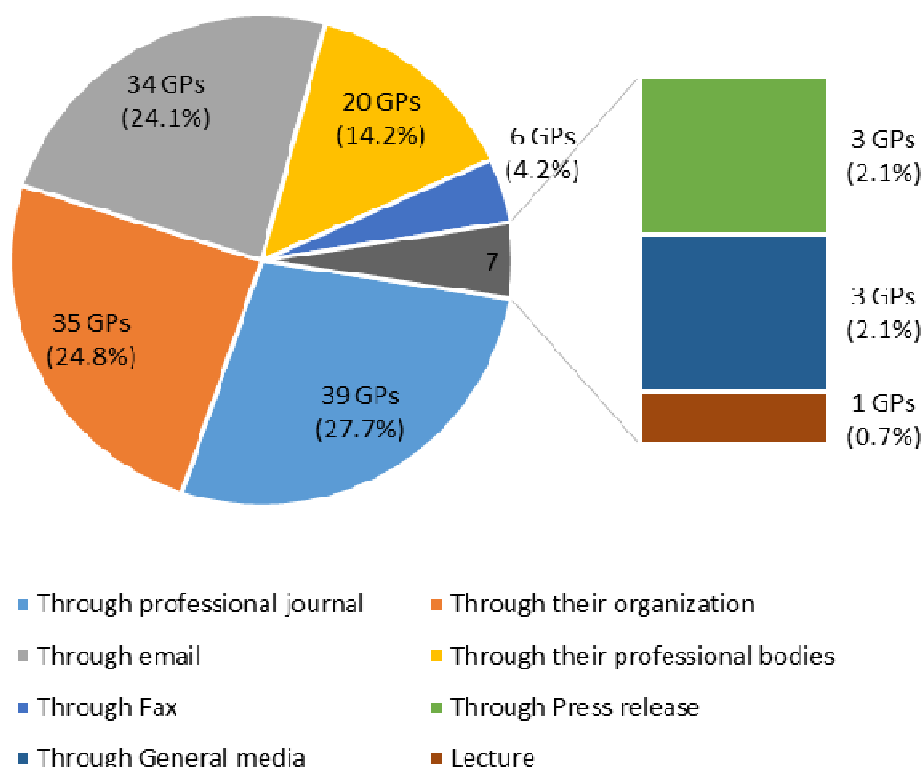
**Figure 7. 2 GPs' views on their roles in combating counterfeiting medicines**



#### 7.4.3.4 The communication methods preferred by GPs

For the methods of communication through which the GPs preferred to receive information about counterfeit medicines issues (figure 7.3); results show that they preferred the professional journal or through their organization.

Figure 7. 3 GPs' selection of the preferred methods of communication



## 7.4.4 Comparative analysis

### 7.4.4.1 Past GP experiences

This section compares the opinions of the GPs who had had past experience of counterfeit medicines and those who had not had such experiences. The researcher formulated the hypothesis that any past expertise on counterfeit medicines would reflect on the answers given by the GPs. To examine the hypothesis, four comparisons (future actions, preferences for education, GPs role, and preferred method of communication) were conducted to compare data between the 17 GPs who said they had had an experience with counterfeit medicines and the 124 GPs who had not had any experience.

i) Comparisons of opinion on the future actions

Table 7.6 shows the comparison between the GPs who have experience and those who did not in their selection of the actions that would be taken by them in case of an incidence of counterfeit medicines. The results show no significant difference between the two GP groups.

**Table 7. 6 Past experiences and GPs' stated future actions**

GP's selection for their future action	GPs with past counterfeit medicine experience No. (%)		P*
	No experience	Experience	
<b>Total</b>	<b>124 (87.9%)</b>	<b>17 (12.1%)</b>	
Report to the medicine's supplier	54 (43.5%)	3 (17.6%)	0.063
Report to the medicine's manufacturer	41 (33.1%)	3 (17.6%)	0.269
Report to the MHRA	74 (59.7%)	7 (41.2%)	0.192
Isolate the item from the stock	50 (40.3%)	5 (29.4%)	0.439
Report to someone within their organization	64 (51.6%)	8 (47.1%)	0.799
Report to the GP's professional body	14 (11.3%)	0	0.219
Report to the pharmacist	12 (9.7%)	2 (11.8%)	0.677

\* Fisher's exact test

ii) Comparisons of opinion on the future education preferences

Table 7.7 shows the responses of the two GP groups regarding when any education or training programmes about the counterfeiting of medicines should be delivered. Moreover, Table 7.8 highlights which kind of education or training programmes each GPs group recommended. There was no significant difference between the GPs with past experience and the GPs without such an experience.

**Table 7. 7 Past experiences and recommendations for future education timing**

GPs' selection for the timing of future education	GPs with past counterfeit medicine experience <i>No. (%)</i>		P*
	No experience	Experience	
<b>Total</b>	<b>123 (88.5%)</b>	<b>16 (11.5%)</b>	
Within undergraduate degree	37 (30.1%)	3 (18.8%)	0.136
Within the GPs' foundation year	41 (33.3%)	3 (18.8%)	
Post-foundation year	45 (36.6%)	10 (62.5%)	

\* Chi-squared analysis

**Table 7. 8 Past experience and recommendations for future education preferences**

GPs' selection for the delivery method of future education	GPs with past counterfeit medicine experience <i>No. (%)</i>		P*
	No experience	Experience	
<b>Total</b>	<b>123 (88.5%)</b>	<b>16 (11.5%)</b>	
Workshop	43 (35%)	8 (50%)	0.276
Conference	15 (12.2%)	1 (6.3%)	0.694
Distance learning	48 (39%)	6 (37.5%)	1.000
Journal article	19 (15.4%)	2 (12.5%)	1.000
Other	8 (6.5%)	0	0.596

\* Fisher's exact test

### iii) Comparisons of opinion on the role of the GP

This comparison (table 7.9) addresses the view of the study sample on the GPs' roles in combating counterfeit medicines between the GPs with past experience and GPs without. There is no significant difference found between the two GPs group.

**Table 7. 9 Past experience and opinion on GP role**

Role of GP in combating counterfeit medicines	GPs with past counterfeit medicine experience No. (%)		P*
	No experience	Experience	
<b>Total</b>	<b>124 (87.9%)</b>	<b>17 (12.1%)</b>	
Reporting to the medicines regulatory agency	110 (88.7%)	12 (70.6%)	0.056
Raising patient awareness about counterfeit medicines	68 (54.8%)	9 (52.9%)	1.000
Advise patient about counterfeit medicines	64 (51.6%)	8 (47.1%)	0.799

\* Fisher's exact test

**iv) Comparisons of opinion on the preferred methods of communication**

The final comparison (table 7.10) shows that there are no real differences in the preferred methods of communication regarding counterfeiting information between GPs with and without experience of it.

**Table 7. 10 Past experience and preferred communication methods**

GPs' preferred communication method	GPs with past counterfeit medicine experience No. (%)		P*
	No experience	Experience	
<b>Total</b>	<b>124 (87.9%)</b>	<b>17 (12.1%)</b>	
Professional journal	33 (26.6%)	6 (35.3%)	Test invalid
Professional bodies	19 (15.3%)	1 (5.9%)	
Via their organization	32 (25.8%)	3 (17.6%)	
Fax	3 (2.4%)	3 (17.6%)	
Email	30 (24.2%)	4 (23.5%)	
Press release	3 (2.4%)	0 (0.0%)	
General media	3 (2.4%)	0 (0.0%)	
Other	1 (0.8%)	0 (0.0%)	

\* Chi-squared analysis

### 7.4.4.2 Length of service of the GPs

The study also compares the opinions between the GPs based on their length of service which had been categorised into three groups. As the attention to the counterfeit medicines issue had increased in recent years (the first MHRA anti-counterfeiting medicines strategy was published in 2007) (25), the researcher formulated the hypothesis that any past expertise regarding counterfeit medicines would reflect on the answers given by the GPs. To test the hypothesis, four comparisons (future actions, preferences for education, GPs role, and preferred method of communication) were conducted to compare data between GPs with less than 10 years' service (9 GPs), GPs with 11 to 25 years' service (48 GPs) and GPs' with over 25 years' service (83 GPs).

#### i) Comparisons of opinion on the future actions and length of service

Table 7.11 shows the answers of the study sample about the action that would be taken if they had to deal with a counterfeit medicines case in the future. Some tests on the table were invalid, and others found no significant difference between the GP groups. The only significant difference was found with reporting to the medicine's supplier; it appeared that GPs with length of service between 11 and 25 years are more likely to report to the medicine's supplier than other GPs.

**Table 7. 11 Length of service and GPs' stated future actions**

GP's selection for their future action	Length of service in years No. (%)			p*
	0-10	11-25	Over 25	
<b>Total</b>	<b>9 (6.4%)</b>	<b>48 (34%)</b>	<b>83 (58.9%)</b>	
Report to the medicine's supplier	1 (11.1%)	27 (56.3%)	28 (33.7%)	0.008
Report to the medicine's manufacturer	2 (22.2%)	15 (31.3%)	27 (32.5%)	0.818
Report to the MHRA	7 (77.8%)	27 (56.3%)	47 (56.6%)	0.457
Isolate the item from the stock	5 (55.6%)	20 (41.4%)	29 (34.9%)	0.416
Report to someone within their organization	5 (55.6%)	29 (60.4%)	38 (45.8%)	Test invalid
Report to the GP's professional body	1 (11.1%)	5 (10.45%)	8 (9.6%)	
Report to other	0	3 (6.3%)	11 (13.3%)	

\* Chi-squared analysis

ii) Comparison of opinion on the future education preferences and length of service

Table 7.12 and table 7.13 show the responses of the three GP groups regarding when any education or training programmes about counterfeit medicines should be delivered, and which kind of education or training programmes each GP group recommended. The results in table 7.12 and table 7.13 show no significant difference between the GP groups. Whereas, one result in table 7.13 suggested that the distance learning for education are preferred by GPs who have 11-25 years length of service.

**Table 7. 12 Length of service and the recommendations for future education timing**

GPs' selection for future education timing	Length of Service in years No. (%)			p*
	0-10	11-25	Over 25	
<b>Total</b>	<b>9 (6.4%)</b>	<b>48 (34%)</b>	<b>83 (58.9%)</b>	
Within undergraduate degree	4 (44.4%)	17 (35.4%)	25 (30.9%)	0.665
Within the GPs' foundation year	4 (44.4%)	21 (43.8%)	25 (30.9%)	0.294
Post-foundation year	2 (22.2%)	16 (33.3%)	37 (45.7%)	0.205

\* Fisher's exact test

**Table 7. 13 Length of service and the recommendations for future education preferences**

GPs' selection of the delivery method for future education	Length of service in years No. (%)			p*
	0-10	11-25	Over 25	
<b>Total</b>	<b>9 (6.4%)</b>	<b>48 (34%)</b>	<b>83 (58.9%)</b>	
Workshop	4 (44.4%)	15 (31.3%)	32 (39.5%)	0.573
Conference	1 (11.1%)	3 (6.3%)	12 (14.8%)	0.340
Distance learning	3 (33.3%)	26 (54.2%)	25 (30.9%)	0.030
Journal article	1 (11.1%)	8 (16.7%)	12 (14.8%)	0.902
Other	0 (0.0%)	4 (8.3%)	3 (3.7%)	Test invalid

\* Chi-squared analysis



iii) Comparisons of opinion on the GP roles and length of service

The view of GPs' roles in combating counterfeit medicines based on the GPs' length of service has been summarized in table 7.14. Two tests were invalid and the third shows no significant difference between the GP groups.

**Table 7. 14 Length of service and the GP's role**

Role of GP in combating counterfeit medicines	Length of service in years <i>No. (%)</i>			p*
	0-10	11-25	Over 25	
<b>Total</b>	<b>9 (6.4%)</b>	<b>48 (34%)</b>	<b>83 (58.9%)</b>	
Reporting to the medicines regulatory agency	9 (100%)	44 (91.7%)	69 (83.1%)	0.183
Raising patient awareness about counterfeit medicines	5 (55.6%)	26 (54.2%)	46 (55.4%)	Test invalid
Advice patient about counterfeit medicines	8 (88.9%)	21 (43.8%)	43 (51.8%)	Test invalid

\* Chi-squared analysis

iv) Comparisons of opinion on the preferred methods of communication and length of service

The preferred methods of communication about information on counterfeit medicines recommended by the three GP groups based on their length of service is shown in table 7.15; no real differences can be seen.

**Table 7. 15 Length of service and preferred communication methods**

GPs' preferred communication method	Length of Service in years No. (%)			p*
	0-10	11-25	Over 25	
<b>Total</b>	<b>9 (6.4%)</b>	<b>48 (34%)</b>	<b>83 (58.9%)</b>	
Professional journal	1 (11.1%)	13 (27.1%)	25 (30.1%)	Test invalid
Professional bodies	2 (22.2%)	6 (12.5%)	12 (14.5%)	
Via their organization	4 (44.4%)	11 (22.9%)	19 (22.9%)	
Fax	0	2 (4.2%)	4 (4.8%)	
Email	2 (22.2%)	14 (29.2%)	18 (21.7%)	
Press release	0	1 (2.1%)	2 (2.4%)	
General media	0	1 (2.1%)	2 (2.4%)	
Other	0	0	1 (1.2%)	

\* Chi-squared analysis

#### 7.4.4.3 Professional body membership

The final section of the comparisons covers the GPs' membership of professional bodies and their responses; the differences in the views of those within and not within professional bodies have been examine. Therefore, the researcher formulated the hypothesis that there will be differences in the opinion between the GPs about the counterfeit medicines issue according to their membership of the professional bodies (69 GPs are members of the RCGP and 97 are members of the BMA). To examine this hypothesis four comparisons (future actions, preferences for education, GPs role, and preferred method of communication) have been analysed.

i) Comparisons of opinion on the future actions and professional membership

Table 7.16 shows the comparison between GPs in their responses to their selection for the actions they would take in case of a counterfeit medicines case based on their membership of a professional body. No significant difference between the GP groups was found in the table.

**Table 7. 16 Professional body membership and GP's stated future actions**

GP's selection for their future action	Membership of RCGP			Membership of BMA		
	No. (%)		p*	No. (%)		p*
	No	Yes		No	Yes	
<b>Total</b>	<b>71 (50.4%)</b>	<b>69 (48.9%)</b>		<b>43 (30.5%)</b>	<b>97 (68.8%)</b>	
Report to the medicine's supplier	30 (42.3%)	26 (37.7%)	0.608	19 (44.2%)	37 (38.1%)	0.576
Report to the medicine's manufacturer	21 (29.6%)	23 (33.3%)	0.717	11 (25.6%)	33 (34%)	0.430
Report to the MHRA	39 (54.9%)	42 (60.9%)	0.498	28 (65.1%)	53 (54.6%)	0.271
Isolate the item from the stock	22 (31%)	32 (46.4%)	0.082	17 (39.5%)	37 (38.1%)	1.000
Report to someone within their organization	34 (47.9%)	38 (55.1%)	0.404	21 (48.8%)	51 (52.6%)	0.717
Report to the GP's professional body	7 (9.9%)	7 (10.1%)	1.000	5 (11.6%)	9 (9.3%)	0.762
Report to the pharmacist	7 (9.9%)	7 (10.1%)	1.000	4 (9.3%)	10 (10.3%)	1.000

\* Fisher's exact test

ii) Comparisons of opinion on the future education preferences and professional body membership

The comparisons between the responses of GPs who were members of the RCGP and the GPs who were members of the BMA regarding when any education or training programmes about counterfeit medicines should be delivered to the GPs and which kind of education or training programmes are shown in table 7.17 and table 7.18. One significant difference found in table 7.17 that show GPs who are members of the BMA were more likely to recommend training within the undergraduate degree. Table 7.18 shows two significant differences between the GP membership groups; which suggested that the distance learning method is preferred by those with RCGP membership whereas journal articles are preferred by GPs without RCGP membership.

**Table 7. 17 Professional body membership and the recommendations for future education timing**

GP's selection for their future education timing	Membership of RCGP <i>No. (%)</i>			Membership of BMA <i>No. (%)</i>		
	No	Yes	p*	No	Yes	p*
<b>Total</b>	<b>71 (50.4%)</b>	<b>69 (48.9%)</b>			<b>43 (30.5%)</b>	
Within undergraduate degree	21 (29.6%)	25 (37.3%)	0.370	7 (16.3%)	39 (41.1%)	0.006
Within the GPs' foundation year	24 (33.8%)	26 (38.8%)	0.597	19 (44.2%)	31 (32.6%)	0.251
Post-foundation year	33 (46.5%)	22 (32.8%)	0.119	19 (44.2%)	36 (37.9%)	0.574

\* Fisher's exact test

**Table 7. 18 Professional body membership and the recommendations for future education preferences**

GP's selection for their future education type	Membership of RCGP <i>No. (%)</i>			Membership of BMA <i>No. (%)</i>		
	No	Yes	p*	No	Yes	p*
<b>Total</b>	<b>71 (50.4%)</b>	<b>67 (47.5%)</b>			<b>43 (30.5%)</b>	
Workshop	26 (36.6%)	25 (37.7%)	1.000	19 (44.2%)	32 (33.7%)	0.258
Conference	11 (15.5%)	5 (7.5%)	0.186	7 (16.3%)	9 (9.5%)	0.261
Distance learning	20 (28.2%)	34 (50.7%)	0.009	13 (30.2%)	41 (43.2%)	0.188
Journal article	16 (22.5%)	5 (7.5%)	0.017	7 (16.3%)	14 (14.7%)	0.803
Other	2 (2.8%)	5 (7.5%)	0.265	4 (9.3%)	3 (3.2%)	0.204

\* Fisher's exact test

### iii) Comparisons of opinions on the GP's roles

GP membership with the professional bodies and their views on the roles of GPs in combating counterfeit medicines has been examined in table 7.19. The results show no significant difference between the GP groups.

**Table 7. 19 Professional body membership and the reported role of GP**

Role of GPs in combating counterfeit medicines	Membership of RCGP			Membership of BMA		
	No. (%)		p*	No. (%)		p*
	No	Yes		No	Yes	
<b>Total</b>	<b>71 (50.4%)</b>	<b>69 (48.9%)</b>		<b>43 (30.5%)</b>	<b>97 (68.8%)</b>	
Reporting to the medicines regulatory agency	58 (81.7%)	64 (92.8%)	0.076	38 (88.4%)	84 (86.6%)	1.000
Raising patient awareness about counterfeit medicines	44 (62%)	33 (47.8%)	0.126	26 (60.5%)	51 (52.6%)	0.462
Advice patient about counterfeit medicines	38 (53.5%)	34 (49.3%)	0.735	25 (58.1%)	47 (48.5%)	0.360

\* Fisher's exact test

**iv) Comparisons of opinion on the preferred methods of communication**

Table 7.20 shows the comparison examining the GPs' membership of professional bodies and their preferred methods of communication about counterfeiting information.

**Table 7. 20 Professional body membership and the preferred communication methods**

GP's preferred communication method	Membership of RCGP			Membership of BMA		
	No. (%)		p*	No. (%)		p*
	No	Yes		No	Yes	
<b>Total</b>	<b>71 (50.4%)</b>	<b>69 (48.9%)</b>		<b>43 (30.5%)</b>	<b>97 (68.8%)</b>	
Professional journal	20 (28.2%)	19 (27.5%)	Test invalid	11 (25.6%)	28 (28.9%)	Test invalid
Professional bodies	7 (9.9%)	13 (18.8%)		5 (11.6%)	15 (15.5%)	
Via their organization	18 (25.4%)	16 (23.2%)		13 (30.2%)	21 (21.6%)	
Fax	4 (5.6%)	2 (2.9%)		1 (2.3%)	5 (5.2%)	
Email	16 (22.5%)	18 (26.1%)		10 (23.3%)	24 (24.7%)	
Press release	2 (2.8%)	1 (1.4%)		1 (2.3%)	2 (2.1%)	
General media	3 (4.2%)	0		2 (4.7%)	1 (1%)	
Other	1 (1.4%)	0		0	1 (1%)	

\* Chi-squared analysis

## **7.5 Discussion**

This study aimed to gain a better understanding of the GPs' knowledge and experiences of counterfeit medicines. It also aimed to explore the views of GPs regarding their possible roles in combating counterfeit medicines. The study found that only a small percentage of GPs had reported a past experience of a counterfeit medicine case and that just under half of GPs would report any future incidents involving counterfeit medicines to the MHRA. Findings also showed that none of the GPs had received any kind of education or training programme regarding counterfeit medicines and that the GPs preferred distance learning and workshops to deliver such education or training programmes. This study also found that most of the GPs agreed that reporting to the medicines regulatory agency was a legitimate role for them in combating counterfeit medicines; however, around half did not agree on the other roles proposed for them by the participants from the MHRA and the stakeholders studies. Although, none of the GPs had had any education or training experiences regarding counterfeit medicines, they were receptive to future training in a wide variety of formats. Also, this study compared the responses between the GPs with respect to any past experience of counterfeit medicines, length of service, and membership of a professional body which revealed no significant difference in the responses among the GPs. As the number of GPs who took part in this study and who had had past experience of counterfeit medicines was small, the few significant differences that were found in the comparisons could be considered as false positives. However, a few comparisons indicated a number of significant differences that could provide some understanding of the GPs' attitudes and behaviour with respect to counterfeit medicines.

This study, to the best knowledge of the researcher, was the first to be designed and implemented in the UK to understand the practices, experience and opinions of GPs regarding counterfeit medicines. The study methods also gave GPs the opportunity to voice their own views on their preferred education and training programmes and on the role of GPs in combating counterfeit medicines. Another strength is that there was very little missing data which suggests a high degree of engagement among the participants and the ease of use of the survey. Also, the sampling process used random sampling techniques which gave all members of the GP population the same chance of being part

of the study; this was demonstrated in the demographic characteristics of the study sample which broadly reflected what is known about the wider GP population.

In this study, the gender representation among the GPs who participated was broadly in line with the overall GP population; according to the UK General Medical Council (GMC), from all licensed GPs 56% were male and 44% were female; whereas, in this study 57.4% of the participants were male and 41.1% were female (138). Regarding the place of work of GPs, in the general population the percentage of dispensing doctors working in England is 13% and GPs 87% (146); whereas, in this study 18.7% of the participants were dispensing doctors and 81.3% were GPs. However, the GPs length of service were skewed to the older GPs which might be those GPs were more aware of past counterfeit cases issued by MHRA.

When considering the results it is important to consider the survey response rate, which was only 22.3%, as this one of the limitations of this study and it made the findings more difficult to generalize which might impose a bias on this study's findings. Another limitation affecting this research was the participation of a low number of GPs with past experiences regarding counterfeit medicines as well as the fact that most of the GPs who participated in the study had not received any prior education and training regarding the counterfeiting of medicines. These limitations affected the data analysis when comparing the answers of the GPs with respect to past experiences or education. Also, this study was conducted with a very limited range of published literature to support its design.

This study showed that only a small percentage of GPs in England had had past experience(s) of counterfeit medicines, as only a few of the GPs stated that they had had experiences with a medicine being recalled by the MHRA due to suspected counterfeiting. This could be due to the GPs not being a target audience of the MHRA regarding recall alerts, which is understandable as the participants in the MHRA study mentioned that GPs do not physically deal with the medicines. Moreover, the MHRA's last recall due to suspected counterfeiting was issued in 2009 (131); which might account for the low number of GPs reporting such an experience.

Also, this study showed that one in ten GPs had received reports from patients regarding a medicine that might be counterfeit, and only a few GPs had experience of dealing with



patients who might have been affected by counterfeit medicines. This percentage is much lower than the figure published by the MHRA (2012) which stated that 25% of GPs had dealt with patients suffering from adverse effects from counterfeit medicines (85). However, it should be recognised the response rate was low and among those who participated in the survey few of them had had past experience with counterfeit medicines. In this study, more than half of the GPs reported that if they came across a counterfeit medicine issue in future their action would be to report it to the MHRA, the second most commonly reported future action was to report it to someone within their organization. The action to report suspected counterfeit medicines to the MHRA, which was reported by GPs, would fall within the existing GP practice of reporting any adverse patient incidents including drug reactions to the medicine regulatory agency via the UK's yellow card scheme.

The results showed that none of the GPs participating in this study had taken part in any kind of education or training programme related to medicine counterfeiting. This is an unexpected result as the MHRA stated in its strategy documents that one of the activities would be to communicate with the health professionals. This raises a concern that GPs might not be fully aware of the counterfeit medicines issue and may not consider counterfeit medicines as a cause of unexpected side effects or treatment failure. However, because of the small number of GPs involved in this study, the researcher could not conclude that this scenario reflected the overall situation for the general GP population in England.

As none of the GPs in this study had had any past training or education experience on counterfeit medicines, their views on the best timing for delivering such education to GPs could be rather speculative which could be seen by their disagreement on the issue. However, GPs saw distance learning as the preferred method of delivery for such education and training programmes, which could be explained by the fact that GPs in England do not normally physically deal with medicines they prescribe, also such training may not be perceived as a priority and hence travel to a workshop may not be viewed as the best use of their time, explaining why they selected distance learning. Furthermore, GPs in this study preferred professional journals first and their organisation (i.e. Clinical Commissioning Groups (CCGs)) second as a methods of communication.

In relation to the roles that GPs could perform in combating counterfeit medicines. This study showed that the majority of GPs considered reporting to the agency as their role. This result is in line with the GPs selection of reporting any future counterfeit medicines case to the MHRA as first choice meaning that GPs would deal with an incidence of suspected counterfeit medicines in the same way as they handle a case of medicine side effects, thus avoiding the need for separate, potentially time-consuming, procedures. However, as none of GPs had had any past training experience and only a few of them had had a past experience of counterfeit medicines, it would be hard to anticipate how and when the GPs would consider using the reporting system to report a counterfeit medicine. Conversely, barely over half of the GPs considered raising awareness among the patients was their role; and slightly less than half believed that providing advice to patients was their role. This could be because GPs see themselves more involved with educating patients on health matters whereas the pharmacists would be more involved with topics specifically related to the prescribed medicines. Also, these findings might give rise to a concern related to the flow of information to the GPs and suggests that GPs need to be trained with respect to their roles in combating counterfeit medicines.

### **7.5.1 Comparisons of GPs responses**

This study compared the GPs' answers based on their past experience, length of service, and membership of professional bodies. The comparisons could not identify significant differences between GPs response which could be a result of the limited number of the GPs who had had past experience with respect to counterfeit medicines or could be due to the low response rate from the GPs, which therefore limited the power of the tests. Also, GP responses could have been influenced by the fact that none of the GPs who participated in the study had attended education or training activities.

A few comparisons showed significant differences; but, due to the large number of tests performed there is a possibility of false positives. However, it considered to be true differences for the purposes of the discussion (whilst accepting that they may not actually exist) they still could show some indications of GPs' views toward the counterfeit medicines issue. The GPs who had had past experiences of counterfeit medicines were seen to be less likely to report an incident to the MHRA which was also

seen with the pharmacists (chapter 6); also, they were less agreeable to the roles proposed for the GPs in combating counterfeit medicines identified in the studies with MHRA participants and stakeholder participants (chapter 3 and chapter 4). These were unexpected results as having had these past experiences should have reminded the GPs of the importance of reporting to the medicines regulatory agency. Perhaps those GPs had found the process of reporting to the agency inefficient or time consuming and as a result preferred to advise the patient or refer the patient to the pharmacists for reporting rather than to report it themselves to the medicines regulatory agency, which might be worth the agency exploring.

These few significant differences indicated that newer GPs were more likely to report any counterfeit incident to the MHRA and showed more conviction in their roles in combating counterfeit medicines than other groups of GPs. This might suggest that newer GPs were adhering more closely to the good practice of reporting to the agency via the Yellow Card Scheme.

Also, the younger GPs were more likely to be in favour of integrating any education and training programmes regarding counterfeit medicines within the undergraduate degree or within the foundation year and to be delivered to them as workshops. These GPs had more recently completed their formal training so may place a greater value on such programmes than those whose formal training is a more distant memory. Also, the longer serving GPs might not favour such education and training programmes within undergraduate courses as it would not be relevant to them at this point of time. Finally, results showed that younger GPs were more likely to favour receiving information via their professional organisations than those with greater lengths of service suggesting that newer GPs may have a greater reliance on these organisations to evaluate and filter information than more experienced GPs.

Regarding professional body membership, GPs who were members of the RCGP were more likely to report any counterfeiting incident to the MHRA and to their organization than GPs who were members of the BMA. This could suggest that the RCGP is more active in informing members on the counterfeit medicines issue and the role of the MHRA than the BMA, something which may be of interest to decision makers at the MHRA when accessing communication strategy. This study has made a valuable contribution to constructing a complete conceptualisation of the process of developing,

implementing and evaluating the strategy. The health professional studies in this chapter involved highly significant actors in the issue of combating counterfeit medicines which contribute to the overall research aim.

## **7.6 Conclusion**

This study provides findings which contribute to understanding of GPs' current knowledge and experiences of counterfeit medicines as well as identifying the views of GPs on their roles in combating this problem. It also highlighted the distribution of types of views and practices according to a set of variables including past experiences of counterfeit medicines, length of service and membership of professional bodies. The study was able to establish the extent to which certain views and practices were shared and what variables may influence the holding a particular view or the adoption of a particular practice.

It was revealed that only a small percentage of GPs had had any past experience of counterfeit medicines during their professional life. According to this study, in case of any counterfeit medicine incident in the future GPs' first action would be to report it to the medicines regulatory agency and then to their organization. In addition, this study showed that none of the GPs had attended an education or training programme about counterfeit medicines in the past. The majority of the GPs agreed that reporting any suspicion of counterfeit medicines to the medicines regulatory agency is part of their role in combating counterfeit medicines. However, about half of the GPs did not see it as part of their role to raise patients' awareness and to provide advice to patients about counterfeit medicines. Finally, this study could not distinguish any differences in opinion between the GPs' responses regarding their views on counterfeit medicines based on their past experience, length of service or workplace. These results indicate that it may be helpful to develop education and training activities for the GPs which would encourage the prompt reporting of any suspicious counterfeit medicine incident to the medicine regulatory agency. This study also highlighted the need for close co-operation between the medicines regulatory agency and GP organizations (i.e. CCGs) as well as with their professional bodies to facilitate developing a better plan for the

education programmes intended to inform GPs of best practice and may be a way to improve communication with GPs with respect to counterfeit medicines; in both cases this is aimed at enabling GPs to fulfil their roles in the overall effort to combat counterfeit medicines. Finally, the results of comparing different GP sub-groups in this study may be valuable to and strengthening for the medicines regulatory agency decision-makers and evaluators in evaluating relevant activities in targeting GPs and planning future such activities.



# ***Chapter 8***

## ***General Discussion and Conclusion***

## **8.1 Introduction**

The problem of counterfeit medicines spans the globe and affects all kind of medicines. The literature has detailed how it imposes a great threat to public health and encouraging national and international efforts to tackle it. Health and medicines regulatory agencies may now be recognising the need to have a systemic and collaborative approach in order to effectively combat this threat. One way of achieving this has been to develop a national strategy for combating counterfeit medicines. Therefore, this research aimed to examine the views of participants from the MHRA and stakeholders on current practice with respect to combating counterfeit medicines in the UK in order to understand the key components in developing anti-counterfeit medicines strategies. To do this, the researcher conducted two studies to describe and understand the processes involved in developing, implementing and evaluating a national anti-counterfeit medicines strategy through capturing the perceptions of participants from the MHRA and MHRA stakeholders of an anti-counterfeit medicines strategy. To support those studies, a further two studies were conducted to describe and understand the views and roles of pharmacists and GPs in combating counterfeit medicines. In order to fulfil the research aim and objectives, a mixed method approach that combined qualitative and quantitative methods to collect and analyse the data were operationalised.

The data collected in this research comprised the views, perceptions, preferences and self-reported practices of four groups involved in the anti-counterfeit medicines strategy development process in some way, and/or with a role to play in implementing such a strategy and in combating counterfeit medicines. This research cannot measure the success of the existing MHRA strategy or know for sure what effect a given preference, recommendation or interpretation would have in making any future strategy more or less effective. There are, however, a wide range of questions concerning the development, implementation and evaluation of an anti-counterfeit medicines strategy which can be considered in the light of the findings of this research, which this chapter aim to address.



## **8.2 Research Findings**

This research showed agreement between the MHRA and stakeholder participants about the dangerous consequences to the public arising from counterfeit medicines and suggesting that the main source of this risk was online supply. Therefore, they saw an anti-counterfeit medicines strategy as a requirement for any national medicines regulatory agency for successfully combat counterfeit medicines. Participants saw in order to develop an anti-counterfeit medicines strategy, a national medicines regulatory agency should fully understand its operating environment. Therefore, participants expressed the view that the agency needs to understand and evaluate its external and internal motivating factors as well as its limitations and boundaries for developing such a strategy. Participants believed that the appearance of counterfeit medicines in the supply chain, protection of public health, securing the supply chain, and pressure from stakeholders were each identified as external motivating factors. On the other hand, they saw the internal motivating factors as personality and attitude of the agency's staff, along with the availability of management support. Also, this research found that participants identified the agency's limited staff and resources, the lack of internal communication and resistance within the agency as internal limitations; whereas, regional and international legislation, support from other government agencies and from industry were considered as external limitations for the agency when planning to develop an anti-counterfeit medicines strategy.

This research also highlighted the design process for an anti-counterfeit medicines strategy as seen by the MHRA and stakeholder participants. Participants focused on the need for a national medicines regulatory agency to formulate an internal drafting committee from its departments/divisions which might be led by one of the agency's department/divisions (such as the enforcement department). Moreover, this research revealed appreciation from both participant groups for the role of the agency stakeholders in the design process as being consultative and as providing feedback to the agency throughout the process. With regard to the implementation phase for such a strategy, this research showed that for the implementation to be effective, the agency should appoint a department/division to be responsible for this implementation in cooperation with other departments/divisions. In the case of the MHRA, their participants saw the enforcement department as being the best for this task. However, a senior manager from the agency might be another option to be considered. Results

highlighted the need to involve the agency's stakeholders in the implementation stage. The roles of stakeholders identified by participants from this research as: collaboration, cooperation and sharing information with the agency, securing the supply chain, educating and raising awareness among their own members and the general public, being vigilant and reporting any suspicions to the medicine regulatory agency.

This research also showed that both MHRA participants and stakeholder participants perceived that identifying an anti-counterfeit medicines strategy's outcomes and evaluating them *post hoc* would be a problematic task for the agency due to the lack of nationally recorded data on counterfeiting cases combined with resource limitations. Nevertheless, those participants suggested several outcomes that could be identified as outcomes from such a strategy: securing the supply chain, decreasing the number of counterfeiting cases, changing people's behaviour, protecting the public, and changing legislation and regulations. However, the findings showed that both MHRA and stakeholder participants thought in order for the agency to overcome the challenges for evaluating such a strategy, the agency needed to develop quantitative metrics for the evaluation process such as the number of counterfeit medicine incidents that reached the supply chain, the number of reports to the agency regarding suspicion of counterfeit medicines and the number of incoming reports from patients, pharmacists and GPs.

Furthermore, this research identified which roles MHRA and stakeholder participants believed were appropriate for pharmacists and GPs to play in combating counterfeit medicines. Both participants groups indicated that pharmacists could play a significant part in combating counterfeit medicines. They identified five roles for pharmacists: securing their supply chain, being vigilant, being attentive to the feedback from patients, reporting any suspicions to the medicines regulatory agency and being a source of awareness and education for patients. Whereas, three roles were identified for GPs: being a source of education and awareness for patients, being vigilant and reporting any suspicions to the agency. However, when the views of pharmacists and GPs on these proposed roles were examined in this research not all pharmacists and GPs agreed with them. In fact, only the role of reporting suspicions to a medicines regulatory agency was agreed by a majority of both pharmacists and GPs. Nearly half of the GPs did not agree that they should have roles in raising patients' awareness or providing advice to patients. This research also found that many recommended dispensing practices were not being performed or were rarely being performed; and that fewer than half of the

pharmacists were following the recommended purchasing practices which were aimed at securing the supply chain.

Another finding from this research was that only a small minority of pharmacists and GPs reported having had any past experience of dealing with one or more counterfeit medicines cases. Findings showed that pharmacists would prefer to report any future incidents of counterfeit medicines to their suppliers rather than the medicine regulatory agency; and, just more than half of the GPs indicated an intention to report any future incidents involving counterfeit medicines to the medicine regulatory agency. With respect to any past education or training regarding counterfeit medicines, it was found that only 10% of pharmacists had received such training. Furthermore, none of the GPs in this research had received any kind of education or training programme regarding counterfeit medicines. Both pharmacists and GPs were seen to prefer workshop and distance learning as the delivery method for any future education or training programmes regarding counterfeit medicines. Finally, the pharmacists and GPs participating in this study expressed a preference for receiving information in counterfeit medicines via professional journals, by email and through their organizations.

### **8.2.1 Comparing MHRA and stakeholders' views with respect to an anti-counterfeit medicines strategy**

This research revealed shared interpretations between MHRA and stakeholder participant groups about the serious risks counterfeit medicines pose to public health. However, the risk associated with counterfeit medicines supplied via online sources were perceived more strongly by stakeholder participants than by the MHRA participants, as only the stakeholder participants urged that more efforts need to be directed toward the supply route. This view from stakeholders might arise because they operate more directly in the field of supplying medicines and are more closely involved in the medicines supply chain than the agency. Also, some stakeholder participants were found to argue that the risk to branded medicines from counterfeiting was greater than that for generic medicines, a view also supported by one of the MHRA participants. This view could be considered controversial as many cases of counterfeiting of generic

medicines have been reported around the world and the majority view of participants was that branded and generic medicines should be treated equally in terms of anti-counterfeiting measures. Stakeholders, particularly those from pharmaceutical manufacturers, are likely to see the risk from counterfeit branded medicines as being greater in commercial terms as brands may be devalued and higher value sales lost. Whereas, the risks to public health from counterfeiting remain the same whether the counterfeit is reproducing a branded medicine or a generic one.

The MHRA and stakeholder participants were found to agree that any medicines regulatory agency should have an anti-counterfeit medicines strategy. However, only MHRA participants were able to identify the factors motivating an agency to develop such a strategy as well as the agency's limitations and boundaries. This might be because the strategy was developed and owned by the MHRA, meaning the MHRA participants would be more familiar with it than stakeholder participants. Furthermore, to develop the strategy, the MHRA and stakeholder participants suggested that the agency needed to have a drafting committee. The MHRA participants may have supported the concept of a drafting committee because it reflects current practice while the stakeholders viewed it as a means for them to become more directly involved at an earlier stage. MHRA participants thought the drafting committee should be internal; whereas, the stakeholders participants saw themselves as part of that drafting committee as they saw themselves adding value to the drafting process. However, in this research, both sets of participants identified the roles of the stakeholders at the drafting stage as consultative and providing feedback to the agency which would fit in with the MHRA participants preference for an internal drafting committee as this committee could involve and consult with stakeholders as required without them actually becoming part of the committee. The process of developing an anti-counterfeit medicines was identified only by the MHRA participants perhaps because they had either had past experience in the drafting of such a strategy or their work within the MHRA was related to the strategy. Therefore, MHRA participants in this research had the opportunity to express their personal but informed views on the drafting process of an anti-counterfeit medicines strategy. Similarly, only the MHRA participants commented on the implementation process for the strategy including which department should lead the implementation, which roles should be allocated to which department and how the actual implementation process should unfold. However, both MHRA and stakeholder participants agreed on which roles were important for stakeholders to play in

implementation. Findings showed that both participant groups thought that the stakeholders could support the strategy by collaboration, cooperation and sharing information with the agency; securing the supply chain, being vigilant; reporting any suspicious activities to the agency. Also, stakeholder participants suggested further roles that the agency's stakeholders could play in the implementation process, based on their likely capabilities to be effective in conducting those roles, which were: stakeholders could conduct their own intelligence activities, they could support the agency with skills and expertise, and assist the agency in educating and raising awareness activities among their members and the general public. These capabilities would vary from one stakeholder group to another. Major pharmaceutical manufacturers are highly resourced organisations employing leading scientists in state of the art laboratories and so are in a strong position to lend testing and technical support.

Also, this research showed closely related views between MHRA and stakeholder participants on the roles that pharmacists and GPs could play in combating counterfeit medicines. Both groups suggested that pharmacists would have more relevant roles than GPs. This may be because pharmacists are perceived by both groups as the final link in the supply chain before the medicine reaches the patients and also because they physically deal with medicines on a daily basis. These two groups defined the roles of pharmacists as: securing their supply chain, being vigilant, reporting any suspicion of counterfeiting to the agency, and being a source of awareness and education for patients. The GP roles were defined by MHRA and stakeholder participants as: being a source of education and awareness for the patients, being vigilant, and reporting any suspicion to the agency. Correspondingly, MHRA and stakeholder participants were seen to agree on the need to use effective methods to communicate these role to pharmacists and GPs, and they suggested that this might best be achieved through their respective professional bodies as professional bodies would be the best able to communicate these roles.

Neither the MHRA nor stakeholder participant groups were able to present a definitive and comprehensive view of the outcomes that the medicines regulatory agency could expect from an anti-counterfeit medicines strategy or the methods which should be used to evaluate those outcomes. This may be because the MHRA's strategies did not clearly identify any outcomes for its strategies meaning the MHRA's participants could not refer to officially stated desired outcomes in their responses and could only offer their

own views about what these could or should be an outcome. For stakeholder participants there was also no official reference point and so their views were likely to be formed by the interests of their own particular stakeholder group. Also, none of the MHRA or stakeholder participants were aware of any evaluation of any such strategy including the MHRA's strategies. With so much emphasis on the performance and 'value for money' of public agencies in the UK this finding is of particular interest.

The participants recognised that the task of setting outcomes for such a strategy and evaluating those outcomes would not be an easy task for the agency. They also stressed the need for the agency to try to identify the desired outcomes right from the outset of drafting the strategy which would be helpful for directing the strategy and would be the starting point for the evaluation process. Nevertheless, certain outcomes to be expected from such strategy were identified by the MHRA or stakeholder participants in this research as: changing people's behaviour, securing the supply chain and decreasing the number of counterfeiting cases. Also, they saw other outcomes as including changes to legislation and regulations presumably because, as a government agency, the MHRA would be expected to take the lead in recommending changes to legislation and regulations that relate to counterfeit medicines. Both MHRA and stakeholder participant groups also suggested that the agency might use specific quantitative metrics criteria for the evaluation process, such as the number of counterfeit medicine incidents reported in the supply chain, the number of reports to the agency regarding suspicions of counterfeit medicines, the number of counterfeit medicine cases and the number of reports made by patients, pharmacists and GPs.

Both study groups perceived strategy evaluation as problematic due to the lack of nationally recorded data on counterfeiting cases combined with resource limitations. Other reasons which had not been highlighted by the participants and might help the understanding of the problematic nature of the evaluation of such a strategy are worth considering. It come from the dilemma that comes with all crime statistics whereby more effective detection and enforcement will lead to increasing levels of recorded crime, which then might appear to reflect an increasing problem. Consequently, it will lead to greater resources being applied to the issue, leading to more recorded crime. Perversely, however, a reduction in the number of recorded cases can just as much reflect poor detection and enforcement as it can be seen as a successful strategy and a rise in recorded cases could reflect either an increase in the supply of counterfeit

medicines or improved detection, or indeed both. Furthermore, the participants' suggestion that changing legislation and/or regulations was a viable desired outcome and/or a valid evaluation method is also problematic because while such a change could indeed be a result of the agency's proactivity, a lack of change could also reflect the effectiveness of the existing regulatory and legislative framework. Likewise, changing legislation/ regulation in itself may not help or at least may take years to properly evaluate.

### **8.2.2 Comparing GPs' and pharmacists' views on counterfeit medicines issues**

In great contrast to the reported, though largely estimated, scale of the global counterfeit medicines trade, the pharmacists reported a low level of past experiences and the GPs an exceptionally low level. This finding raises important questions concerning the nature of the relationship between GPs, patients and the medications they physically obtain from pharmacists. The research findings on past experiences of counterfeit medicine incidents showed that GPs had had less experience with counterfeit medicines than pharmacists. This was perhaps because the GPs would be less aware of the counterfeit medicines issue than pharmacists or could be because patients usually go to the pharmacist rather than their GP if they have a query regarding a medicine's authenticity or efficacy. While pharmacists had rather more previous experiences than GPs, the number reporting such experiences was still relatively low which raises a concern for the degree of awareness among the pharmacists and GPs that will be essential in combating counterfeit medicines. As counterfeit medicines widely reported is increasingly going through the online supply chain; then it should be considered that patients may not wish to reveal the source of their medicines for fear of being criticised by either their GP or pharmacist for making such irresponsible purchases.

This research showed that the first action that GPs said they would take when encountering counterfeit medicines in the future would be to report it to the medicines regulatory agency. In contrast, the pharmacists would report it to their medicine supplier as a first choice with the medicines regulatory agency only their third choice. This could have been because GPs were trained to report any adverse patient effects to the

medicines regulatory agency (via the UK's Yellow Card Scheme) so for GPs, counterfeit medicines would fall within that reporting procedure. On the other hand, the pharmacists might be more aware of the counterfeit medicines issue because of their past experiences but they might need more training on best practice in reporting a suspected counterfeit medicines case to the medicines regulatory agency.

In relation to education and training programmes, the research raises significant concerns because of the very low numbers of health professionals reporting receiving such education and training. Indeed no GPs in this study reported having attended any such programmes. This might be why the GPs reported having had less experiences of counterfeit medicines than the pharmacists. The lack of previous education and training programmes might have had an impact on the pharmacists' and GPs' reported future action if they suspected a counterfeit medicines case. Furthermore, if GPs are unaware of the counterfeit medicine problem and particularly that from online purchases they are unlikely to consider it as a possible cause of a patient presenting with therapeutic failure or adverse event. Also, the lack of specific education and training programmes might be the reason for the majority of pharmacists in this research to report that they do not follow good dispensing and purchasing practices that have been recommended by the MHRA and the RPS to protect patients from counterfeit medicines.

The lack of past education and training programmes for pharmacists and GPs might also be a reason why there was no majority view as to the timing of training and education programmes in the future, with broadly equal support for holding it within the undergraduate degree, during the pre-registration/foundation year and post-registration/post-foundation year. Nonetheless, this research reported distance learning as the first choice for GPs to deliver a training programme with workshops as the second choice, which could be because of the GPs' busy work schedule. In contrast, the pharmacists preferred workshops as their first option and distance learning as the second option; which is understandable as they are dealing physically with medicines on a daily basis.

Pharmacists were found to be slightly more inclined to see it as part of their role to report incidents of counterfeit medicines to the medicines regulatory agency than the GPs. However, only half of the GPs agreed with having the roles of raising patient awareness and providing advice to patients regarding counterfeit medicines, whereas most of the pharmacists agreed this was their role. This could be explained by the



pharmacists having had relatively more experience with counterfeit medicines as well as some education on this in contrast to GPs. These results could also suggest that those roles identified were not sufficiently well communicated to either GPs or pharmacists which would be reflected in their normal work practices. The only role agreed by a majority of both pharmacists and GPs was reporting suspicions to a medicines regulatory agency.

Findings showed the need for more educational activities targeted at health professionals (GPs and pharmacists) based on their preferences which could help them to protect the public from counterfeit medicines. Findings also could help decision-makers within the medicines regulatory agency to identify where and how to plan its education activities for the health professionals. Both studies may help decision-makers at the medicines regulatory agency to appreciate the importance and feasibility of engaging GPs and pharmacists more in efforts to combat counterfeit medicines by increasing their understanding of their roles. Likewise, the decision-makers could be informed about the communication methods preferred by the GPs and pharmacists.

Overall a number of the findings from the pharmacist and GP studies, including low levels of past experiences of counterfeit medicines, low or non-existent reported training and education about counterfeit medicines and their different views with the regulatory agency concerning what roles they should carry out in implementing the anti-counterfeit medicines suggest that there is a need for greater awareness raising and communication between the regulatory agency, the health professionals and their professional bodies. In turn this may increase the awareness raising and communication between these healthcare professionals and their patients.

### **8.3 Findings related to the processes of developing, implementing and evaluating an anti-counterfeit medicines strategy.**

In addition to recognizing the findings of this research with respect to areas of agreement and disagreement among the four study groups; it would be important also to recognize the overall research contribution to understanding the way different groups

may engage in the processes of developing, implementing and evaluating an anti-counterfeit medicines strategy. The feasibility of strategy development, the organisational demands of developing a strategy in this area and the challenges of including health professionals in the implementation need to be understood.

First, it should not be surprising that both MHRA representatives and stakeholder participants recognised the threat posed by counterfeit medicines on a range of levels. It is also understandable that having a strategy to combat counterfeiting was seen as a prerequisite. Such agreement is a first step in developing a strategy. Nevertheless effective implementation is an altogether more complex task not least because of the number of actors involved in such an implementation and the different characteristics of their organisations, as such a strategy will have an effect on the public sector, private sector, government agencies and professional associations. Also, the health dimensions, the law enforcement dimensions and the commercial dimensions will all have an effect on the complexity of such a strategy. Therefore, by involving many of the significant actors in this study a picture of this complexity has been highlighted and confirmed.

Secondly, with regards to the different actors' engagement in a strategy, this research has shown that stakeholders are keen to engage in such a strategy from the drafting stage. Though it should be recognised that the motivations of stakeholders vary from one type to another. There would, for example, be a great contrast between the priorities of a law enforcement agency and a multi-national pharmaceutical manufacturer. Therefore, such contrasts may make multi-lateral cooperation more problematic for the medicines regulatory agency in developing the strategy. Nevertheless, this study confirmed that those stakeholder groups included in the study appeared to be fully engaged in the strategy. On the other hand, the engagement of the health professionals was less easy to determine as this research showed lack of past experience of counterfeit medicines, absence of education and training, inconsistent application of best practices and lack of agreement over roles all of which revealed the scope for greater engagement. Although, it perhaps equally revealed the workload pressures and priorities of both GPs and pharmacists.

Thirdly, it should consider that the MHRA is a pioneer in the field of developing an anti-counterfeit medicines strategy. However, this study has revealed that there are substantial organisational demands on the agency and that there appear to be areas which can yield further strategy improvements in the future. These include discussing

and agreeing the nature and timing of the input that stakeholders should have at the drafting stage, the communication and agreement of precisely what roles healthcare professionals have in the implementation of a strategy and an overall re-evaluation of communication activities and the MHRA's role in developing training programmes or materials for healthcare professionals as such programmes seem largely lacking at present. Furthermore, term-based strategies require evaluation which improve the overall strategy process over time. However, there appears to be no evaluation process in place in the case of the MHRA which could be drawn from both their own publications and the findings of this research. Therefore, this research showed this is an important area for the MHRA to consider in the future.

Fourthly, this research highlighted the organisational demands of implementing such a strategy in this area with pharmacists and GPs. A number of gaps emerged between what the MHRA might hope for in regard of the position of health professionals in regard to implementing an anti-counterfeit medicines strategy and what the results of this research indicate. Low awareness arising from lack of past experiences and lack of relevant training would appear to be a major challenge as does the more effective communication of the desired roles these healthcare professionals should have in the overall effort to combat counterfeiting of medicines.

There are also significant findings concerning the practices of pharmacists and GPs in securing the supply chain and reporting cases of counterfeiting to the agency which suggests that there is more work to be done in this area. It is also important to recognize that health professionals usually have busy schedules and they are responsible for delivering a range of health messages to patients. Also, pharmacists and GPs are dealing with so many demands and guidelines already set for their patient consultations; therefore, it should be considered how they view the risks of counterfeit medicines to their patients and they may have a low priority which could account for some of the findings in this study. To raise this priority would require a major effort which probably cannot be done by the medicines regulatory agency only and need contributions from other parties like professional bodies.

Pharmacies want to protect their reputations by supplying only legitimate medicines but they might have a range of commercial considerations and pressures on resources which may mitigate against prioritizing the advising and educating of patients and even the reporting of counterfeit cases to the MHRA. Overall, this research has provided

evidence that there are major challenges facing a medicines regulatory agency in fully and appropriately engaging health professionals in the implementation of an anti-counterfeit medicines strategy.

## **8.4 Research limitations**

While the findings of this research combine to contribute new knowledge to the field of study, several limitations need to be considered. The researcher's background as a pharmacist working with another country's national medicines regulatory agency and past working experience and knowledge of the counterfeit medicines topic may have had an influence of being subjective during the design stages of the studies and might have imposed a bias during data analysis. Additionally, the views of participants as expressed in the interview studies might have been affected by the fact that they knew that the researcher was working for another national medicines regulatory agency and that therefore they might have presented partial or less authentic descriptions of their real perceptions and interpretations of the issues being discussed.

The selection of participants for this research has been affected by the decision-makers at the MHRA making changes to the proposed participants list for the MHRA study should be recognized as it might have introduced some recruitment bias to the sample. However, the researcher's efforts to overcome any possible bias should also be noted by explaining to the participants at the beginning of each interview that the study was not aimed at evaluating the MHRA's work; also, the researcher tried not to ask questions that could be directly linked to the MHRA's performance. Similarly, in the stakeholders' study, not all stakeholder groups were represented and many of the participants did not have direct involvement with the MHRA's activities in combating counterfeit medicines. It is entirely plausible that those stakeholder groups were not represented may have expressed different views than those who were.

When considering the results from the two survey studies, it is important to consider that the relatively low response rate for pharmacists and GPs questionnaires might limit the generalizability of the research findings. Also, the percentage of pharmacists and GPs who had had past experiences of counterfeit medicines was surprisingly low as was

the number reporting prior education and training regarding counterfeit medicines, something which would have affected the results.

The final limitation for this research was related to the lack of existing literature on anti-counterfeit medicines strategy, particularly empirical studies, but also literature which explored the views of pharmacists or GPs on the counterfeit medicines issue. While this is not so pertinent in an exploratory study such as this, having a literature base to refer to can assist a researcher in identifying appropriate methodologies and in providing some context in which to discuss the findings.

## **8.5 Research implications and recommendations**

This research was the first aiming to understand the process of developing an anti-counterfeit medicines strategy by drawing on the perspectives of a medicines regulatory agency and the agency's stakeholders together with two groups of health professionals, pharmacists and GPs in order to build a multi-dimensional, triangulated conceptualisation of the processes of developing, implementing and evaluating an anti-counterfeit medicines strategy and so address the research problem.

The findings of this research would therefore help highlight to the decision-makers in many national medicines regulatory agencies the reasons that having such a strategy is important. Also, it will provide an understanding of the processes of the drafting, implementing, and evaluating the strategy through this research into the case of the UK, its regulatory agency and the experience of having already developed such strategies.

This research was also the first to attempt to understand the current knowledge, experience and practices of pharmacists and GPs in relation to counterfeit medicines, enabling these health professionals to express their views on the roles they should play in combating counterfeit medicines. Therefore, this research should be useful for the decision-makers within national medicines regulatory agencies when planning to engage pharmacists and GPs in activities aimed at combating counterfeit medicines and the methods of communicating with them. It also highlighted to the decision-makers the need for working collaboratively with pharmacists' and GPs' professional bodies and organizations in education and communication about counterfeit medicines.

The findings from this research indicate several recommendations which provide evidence to underpin a guidance framework for the decision-makers of a national medicines regulatory agency who wish to develop an anti-counterfeit medicines strategy. This framework is set out below.

**I. Evaluating and understanding the agency's environment in respect to counterfeit medicines**

1. Identify the scale of counterfeit medicines
  - i. Via the medicines supply chain
  - ii. Via online websites
2. Identify the requisite agency's strengths
  - i. Well-developed departmental and divisional structure
  - ii. Supportive agency senior management
  - iii. Support from other government agencies
  - iv. Support from the agency's stakeholders
3. Recognise the agency's limitations
  - i. Resources and capability.
  - ii. Resistance for any change from agency's staff.
  - iii. Overall government regulations and legislation.

**II. Pre-drafting stage of an anti-counterfeit medicines strategy**

1. Identify the agency's departments/divisions that will be part of the drafting process.

Recommended departments/divisions are the enforcement department, the inspection department, the laboratory department and, the department responsible for dealing with defective product reports (Defective Medicines Report Centre), the pharmacovigilance department/division, the policy department/division, and the communications department/division, the licensing department/division and the legal department or government lawyers.

2. Identify the agency's stakeholders that might be part of the drafting process.

Recommended agency's stakeholders are the pharmaceuticals manufacturers (branded and generic), wholesalers, distributors, brokers, and the pharmaceuticals importers, police and customs.

3. Formulate an internal drafting committee from those departments/divisions, which could be led by either enforcement department or the policy department/division.

### **III. Drafting process of an anti-counterfeit medicines strategy**

1. The agency's internal drafting committee write a first draft of proposed activities and actions that will be the core of the strategy. The committee might need to consider and propose initial desired strategy outcomes and the evaluation process, including specific performance metrics, at this stage.
2. The first draft is shared with the agency's stakeholders for comments and feedback which might be in written format or via a meeting with the internal drafting committee.
3. The internal drafting committee write the second draft of a proposed strategy.
4. Share the second draft with agency's stakeholders for feedback, which will be in writing.
5. The internal drafting committee finalize the strategy, and then the agency may or may not share it with the general public for consultation.
6. The internal drafting committee send the strategy to the agency's senior management to be reviewed and approved.
7. The agency publish the strategy.

### **IV. Implementing process of an anti-counterfeit medicines strategy**

1. Identify a department/division to lead the strategy implementation process from those involved in the drafting process.

Recommended to be led by the head of the enforcement department or an agency's senior manager.

2. Identify departments/divisions that will be part of the implementation stage.

Recommended departments/divisions are the policy, the communications, the pharmacovigilance, the laboratory, the Good Distribution Practice (GDP) department, inspection department and finance department and possibly the legal department or government lawyers.

3. As part of the department/division roles in the implementation, setting an anti-counterfeit medicines objectives for each department/division which will be part of its overall department/division objectives.
4. Identify the agency's stakeholders that might be part of the implementation process.

Recommended agency's stakeholders are: the pharmaceuticals manufacturers (branded and generic), wholesalers, distributors, brokers, and the pharmaceuticals importers, police and customs.

5. Allocate specific roles to the stakeholders

Recommended stakeholders' roles are: securing the supply chain, collaboration, cooperation and sharing information with agency, being vigilant, reporting to the medicines regulatory agency any suspicions and educating and raising awareness among their own members and the general public.

6. Ensure good communication of the stakeholders' roles which might be achieved via regular agency-stakeholders meetings.
7. Identify the roles of pharmacists and GPs in the anti-counterfeit medicines activities.

Recommended pharmacists and GPs roles are being vigilant for any suspicion of counterfeit cases, to report any suspicion to the medicine regulatory agency, to provide awareness and advice to the patients, and to source their medicines from a secured supply chain.

8. Ensure good communication of the pharmacists and GPs roles which might be achieved via their professional bodies.

## **V. Strategy outcomes and evaluation process**

1. Set the desired outcomes of the anti-counterfeit medicines strategy at the drafting stage.



Recommended outcomes are changing people's behaviour and perceptions to counterfeit medicines, more securing of the supply chain, increased collaboration and sharing of information among stakeholders, increased public health protection from counterfeit medicines, decreasing the number of counterfeit medicines cases that reach the supply chain, more tightening of the legislation and regulations, more convictions of people involved in this crime, growth in the incidences reported to the agency and improvement in international cooperation.

2. Set quantitative metrics criteria for evaluation the strategy.

Recommended criteria are the number of counterfeit medicine incidents that reached the supply chain, the number of inspections carried out by agency inspectors, the number of reports to the agency regarding suspicion of counterfeit medicines from stakeholders, pharmacists, GPs and patients, and number of prosecutions and sentences for people trading in counterfeit medicines.

3. Assign responsible person for conducting the evaluation which might be from within the agency or an external audit.
4. Review the strategy based on the evaluation outcome for improving the future anti-counterfeit medicines strategy.

Moreover, this research presents three recommendations which might be considered by agency decision-makers aimed at improving the involvement of pharmacists and GPs in the overall effort to combat counterfeit medicines:

- I. The agency needs to work with universities in order to increase the awareness and education of the counterfeit medicines topic for pharmacists and GPs from undergraduate degrees and assist in incorporating relevant modules within degree courses.
- II. The agency needs to collaborate with pharmacists' and GPs' professional bodies to develop education and training programs about counterfeit medicines which may be in workshop format for pharmacists and distance learning for GPs.
- III. The agency needs to work with pharmacists' and GPs' professional bodies as well as pharmacists' and GPs' work organizations to develop the best method to communicate with pharmacists and GPs regarding counterfeit

medicines information which might be via professional journals or via their organizations.

## **8.6 Future research**

This research was conducted within the UK context with participants from the UK's medicines regulatory agency and its stakeholders as well as pharmacists and GPs practising in England. This might limit the applicability of the findings to the UK context. Therefore, further studies that examine strategy development in other contexts and tests the relevance of the guidance framework developed in this research would be valuable. A comparative study investigating one developed country (such as USA or Canada) and one developing country (such as Saudi Arabia) is therefore needed to extend both researchers and agencies' decision-makers understanding the key components that are involved in the development, implementation and evaluation of an anti-counterfeit medicines strategy.

A limitation of this research related to the recruitment of MHRA's stakeholders, as a relatively small numbers of participants were involved in this research and certain stakeholders groups were not represented. Therefore, further research might be needed to involve more participant from all stakeholders groups and to re-examine their views on the guidance framework developed in this research.

Further interview-based research with pharmacists and GPs could help in gaining a more in-depth understanding of their views related to their knowledge and experiences of counterfeit medicines and their roles in combating them. This would also enable the survey study to be redesigned in order to capture wider views of pharmacists and GPs related to their knowledge and experiences of counterfeit medicines and their roles in combating them.

Patients' views on anti-counterfeit medicines strategy and their perceptions of the counterfeit medicines issue were not part of this research. Therefore, further research may be needed to understand the patients' knowledge, experience and attitudes to counterfeit medicines something which would help the national regulatory agency in its efforts to combat the problem.

## **8.7 Conclusion**

This research examined key components in the process of developing a national anti-counterfeit medicines strategy from the perspective of a national medicines regulatory agency and the stakeholders of that agency together with the views of pharmacists and GPs on their roles in combating counterfeit medicines. An anti-counterfeit medicines strategy was identified as essential for a national medicines regulatory agency to successfully combat this problem. This research recommended that to develop such a strategy, the decision-makers at the national medicines regulatory agency need to evaluate and understand the agency's operating environment in respect to counterfeit medicines as this would help identify the scale and nature of the problem in the country and also to identify the agency's own strengths and limitations in being able to deal with it. Those decision-makers also need to evaluate which departments/divisions would be best to involve in drafting the strategy and how stakeholders can best provide consultation and feedback. This research also recommended that these decision-makers identify which departments/divisions should implement the strategy and where the responsibility for leading the strategy should lie. Stakeholders were found to have an important role in implementing such a strategy through securing the supply chain, being collaborative and co-operative, and sharing information with their agency, being vigilant, reporting any suspicions and having a role in educating and raising awareness of their own groups and the public. Decision-makers should appreciate that defining the strategy's outcomes and evaluating them would be a challenging task; and few outcomes might be seen as results from an anti-counterfeit medicines strategy. However, this research recommended likely outcomes of a strategy as changing people's behaviour toward counterfeit medicines, securing the supply chain, increasing collaboration and information-sharing among stakeholders, increasing public health protection from counterfeit medicines, decreasing the number of counterfeit medicines cases, tightening future legislation and regulations, more punitive convictions for those involved in counterfeit medicines, increasing levels of incidence reported to the agency and improving international cooperation. Results suggested that the agency could use metrics criteria for evaluation of some of those outcomes such as numbers of incidents that reached the supply chain, the number of inspections, the number of reports to the agency from stakeholders, pharmacists, GPs and patients, and the number of prosecutions and sentences for people trading in counterfeit medicines.

Also, this research showed pharmacists and GPs might help in combating counterfeit medicines by being vigilant for any suspicion of counterfeit cases, reporting any suspicion to the medicine regulatory agency, providing awareness and advice to the patients, and sourcing medicines from a secured supply chain. However, not all pharmacists and GPs in this research were agreed on those roles. Therefore, this research raised a concern about the degree of knowledge and awareness of pharmacists and GPs with respect to counterfeit medicines and their roles in combating the problem. This research showed that only a small percentage of pharmacists and GPs had had past experience of counterfeit medicines and only a limited number of pharmacists had had past education or training about counterfeit medicines. This research recommended that regulatory agencies need to work more closely with universities, the pharmacists' and GPs' professional bodies and work organizations to increase the awareness and education of counterfeit medicines topic and to improve communication methods with pharmacists and GPs.

# *Publications and conference presentations*

- **Conferences publications**

**B. M. Alwon**, D. J. Wright, F. Poland (2014) The roles of UK pharmacists and GPs in combating counterfeit medicines from the medicines regulatory agency perspective. *International Journal of Clinical Pharmacy*, 22 (Suppl. 2), 47, (Poster at RPS 214)

- **Conferences presentations**

**Alwon BM**, Solomon G, Hussain F, Wright DJ. Evaluating the quality and safety of online pharmacy websites from the perspective of the UK consumer, 8<sup>th</sup> Saudi Student Conference, January 31 – February 1, 2015, London, Poster presentation.

**B. M. Alwon**, D. J. Wright, F. Poland, The roles of UK pharmacists and GPs in combating counterfeit medicines from the medicines regulatory agency perspective, Royal Society of Chemistry, JPAG symposium, 19 March 2015, London, Poster presentation.

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# *Appendices*

## **Appendix 1 MHRA's Study**



## Appendix 1.1 UEA ethical committee approval letter

Faculty of Medicine and Health Sciences Research Ethics Committee



Bassam Alwon  
School of Pharmacy  
University of East Anglia  
Norwich Research Park  
NR4 7TJ

Research & Enterprise Services  
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20<sup>th</sup> December 2012

Dear Bassam

**Project title: Qualitative Study of Key Members from the National Medicines Regulatory Agencies in the United Kingdom and Saudi Arabia**  
**Reference: 2012/2013 - 22**

The amendments to your above proposal have been considered by the Chair of the Faculty Research Ethics Committee and we can confirm that your proposal has been approved.

Please could you ensure that any further amendments to either the protocol or documents submitted are notified to us in advance and also that any adverse events which occur during your project are reported to the Committee. Please could you also arrange to send us a report once your project is completed.

The Committee would like to wish you good luck with your project

Yours sincerely

A handwritten signature in blue ink that reads 'Yvonne Kirkham'. The signature is written in a cursive style.

Yvonne Kirkham  
Project Officer

## Appendix 1.2 Interview questions topic guide

### Research Questions Topic Guide

#### Project 1 - Phase 1 (MHRA Interviews)

1. Can you please tell me about your role in the MHRA?
  - Name and responsibilities
2. How do you think the MHRA viewed the problem of counterfeit medicines in the UK at the time when the strategy was being developed?
  - What do you think the factors that influenced this perception are?
  - How may these factors have been reflected in the areas for action identified by the MHRA for addressing the problem of counterfeit medicines in the UK?

Probe: more explanation for each factor mentioned.
3. Can you tell me how the MHRA came to put together its Anti-Counterfeiting Strategy 2007-2010?
  - What were the departments involved in developing this strategy and why?
  - What was the basis for selecting the elements (Collaboration, Regulation, and Communication) of this strategy?
  - Can you tell me what the process for designing this strategy was?
4. Can you tell me about the process involved in the MHRA implementing this strategy?
  - Which departments were allocated to the implementation?
  - How appropriate do you think each department was for being involved in the implementation of this strategy?
  - What do you see as the reasons for these allocations being made to these departments?  
(Probe: reasons for each department in turn)
  - How do you think the department's managers did in implementing their tasks?  
(Probe: what each department's manager did, in turn)
5. How did you specify the roles of GPs, pharmacists and patients (or Patient Care Trusts and Hospital Trusts) in this strategy?
  - What did you need to consider in order specifying appropriate roles?
  - How well do you think these roles were communicated to them?

6. What do you think the MHRA was expecting to see as outcomes from this strategy?
  - How did the MHRA formulate these expectations?
  
7. How did the MHRA evaluate those outcomes?
  - What were the criteria for evaluating them?
  - How were these criteria chosen?
  - Which department(s) was responsible for the evaluation?
  - What do you think were the reasons this department was selected?
  - What were the results of the evaluation?
  
8. Is there anything you would like to add?

## Appendix 1.3 Participant's invitation letter

### MHRA member invitation Letter

Dear .....

My name is Bassam Alwon and I work for Saudi Food & Drug Authority (Saudi-FDA).  
<http://www.sfda.gov.sa/En/Home/>

I am the Director of Quality Control of Pharmaceuticals Department, in which one of my tasks is to manage the Anti-counterfeiting section of the Saudi -FDA.

Counterfeit medicines are an important topic for medicines regulators and are becoming a serious threat to global healthcare. For this reason, I am undertaking a period of study leave which is sponsored from Saudi-FDA, to undertake a PhD degree in the field of counterfeit medicines.

I have started my PhD study at the University of East Anglia, School of Pharmacy (<http://www.uea.ac.uk/pha>) and I am working with Prof David Wright (Deputy Head of School) as my PhD supervisor (<http://www.uea.ac.uk/pha/dw>).

My research title is "Developing a national strategy to combat counterfeit medicines".

The aim of this research is to gain a better understanding of the MHRA's Anti-Counterfeiting Strategy, and to evaluate the relationship of this strategy with other stakeholders, like for example the health professionals, patients, distributors.

This will help me when I go back to my work to develop a strategy for Saudi-FDA to combat counterfeit medicines by adding to a wider understanding of strategies for combating counterfeit medicines. To achieve this object my research will use mixed research methods.

An important part of this study will be to conduct a number of interviews with members from MHRA and to learn from their experience how to develop and implement improved anti-counterfeiting strategies on my return to the Kingdom of Saudi Arabia.

These interviews will be confidential (as required by university ethical committee) and will only be used for this research.

The outcome of this research will be:

1. Submitted for my doctorate thesis.
2. Results will be summarized and sent to MHRA as feedback.
3. This research will help Saudi-FDA to develop a strategy to combat counterfeit medicines benefiting from the experience of one of the leading medicine regulators in the world.

4. Help to foster a spirit of co-operation between the Saudi-FDA and the MHRA in the global fight against counterfeit medicines.
5. The outcome and results of the study might be published as scientific papers, taking rigorous account of all issues relating to anonymity of research participants and confidentiality in the presentation of data.

From my initial research I have identified you, along with a number of your colleagues, as a key opinion leader within the MHRA. Therefore, can I please ask if you would be prepared to be interviewed by me on this topic interviews will be conducted at your place of work and would take no more than 90 minutes and will be in a time that fitting with your calendar. If you are not able to help me with this research or you feel you are not the correct person within the agency to talk to, perhaps you could advise me as to whom I should contact.

Thank you for your cooperation

Regards

Bassam ALWON  
Research Pharmacist  
Pharmacy Practice  
School of Pharmacy  
University of East Anglia

Tel: 01603 591996  
Mob: 07538737292  
E.mail: [B.Al-Won@uea.ac.uk](mailto:B.Al-Won@uea.ac.uk)

## Appendix 1.4 Participant's information sheet

### MHRA members' Information Sheet

#### **Invitation**

You have been invited to be part of a research study. Before you decide to do so, it is important that you understand why this research is being conducted and what you will be involved in if you take part. Please take time to read the following information carefully.

#### **What is the purpose of the study?**

The aim of this study is to explore the knowledge, experiences and opinions of members of national medicines regulatory agencies in the United Kingdom and Saudi Arabia, as key elements in a strategy to combat counterfeit medicines. As you know, counterfeit medicines are an important topic for medicines regulators and are becoming a serious threat to global healthcare. Therefore, this research will help the researcher to propose elements in order to develop an effective anti-counterfeiting strategy.

#### **What will the study involve?**

If you take part, you will have a short interview of up to 90 minutes with the researcher (Mr Bassam Alwon, a research pharmacist); the interview will be on your knowledge, experience and opinions on the current counterfeit medicines strategy.

#### **Where will the interview take place?**

The interview will take place in a private room in the MHRA building during your regular office hours, unless it is agreed that an alternative would be more suitable for you. Any travel expenses involved will be covered by the researcher.

#### **Why have I been chosen?**

You showed interest in this study after being informed of this research through the invitation letter or through your manager where you work in the MHRA. Your experience is highly relevant to this study.

**Do I have to take part?**

No. It is up to you whether or not you take part. If you choose to take part in the study, you will be asked to sign a consent form before you are interviewed. Even after you have signed a consent form, you are still free to withdraw from the study at any time and without giving a reason. If you choose not to take part, this will not affect your employment or other rights in any way. If you wish to obtain independent information or advice about your rights regarding being involved in this research study, you can do so by contacting Prof David Wright, School of Pharmacy at the University of East Anglia, who is the primary supervisor for this study, on 01603 592042 or email [D.J.Wright@uea.ac.uk](mailto:D.J.Wright@uea.ac.uk), University of East Anglia, Norwich NR4 7TJ.

**What will taking part in this study involve for me?**

The researcher (Mr Bassam Alwon) will ask you some questions about your knowledge, experiences and opinions about your strategy to combat counterfeit medicines. The interview questions are designed to identify your views about the development process, the implementation and the evaluation of your strategy to combat counterfeit medicines. We also wish to record the interview if you are willing, to help the researcher review and analyse the conversation.

**What are the possible benefits of taking part?**

There are no direct benefits for you in taking part. However, you will be helping share and highlight the experiences of combating counterfeit medicines; consequently, this will help to protect patients from the harm of these medicines.

**What are the possible disadvantages of taking part?**

There are no particular disadvantages. If for any reason you do not wish to answer a question you may decline without saying why; this will not affect the value of the answers that you do give, and there will be no consequences for you whatsoever.

**What if there is a problem?**

If for any reason you have a complaint about how you have been dealt with during the study, or any worries or possible harm that you might suffer, this can be addressed through Prof David Wright,

who is the Deputy Head of the School of Pharmacy at the University of East Anglia, and who is a supervisor for this study, on 01603 592042 or email [D.J.Wright@uea.ac.uk](mailto:D.J.Wright@uea.ac.uk).

**What happens after the project comes to an end?**

The data will be analysed by the researcher and his supervisory team, and a copy of results will be summarized and sent to the MHRA as feedback without naming any of the participants.

**Will my taking part in the study be kept confidential?**

Yes. As required by the ethics committee of the University of East Anglia, all information about your participation will be kept confidential. Thus, all the information about you will be anonymized so that you cannot be individually identified. All personal information and your consent form will be stored by the researcher in a locked filing cabinet in an office at the School of Pharmacy, University of East Anglia, Norwich. These will only be viewed by the researcher and the research assistant. The data will only be analysed by the research team (Mr Bassam Alwon and his academic supervisors) and will be stored on a password-protected computer. All confidential documentation will be destroyed five years after the interview.

**What will happen to the results of the research?**

The findings of this study will form part of my doctoral thesis, and accordingly a copy will be lodged in the library of the University of East Anglia. The findings may also be sent to academic and professional journals for publication to add to the body of scientific knowledge and to share any relevant data or recommendations pertaining to the administration of medicines with other professionals in the field.

**Who is organizing and funding the research?**

The research is being organized and funded by the School of Pharmacy at the University of East Anglia. The information is being used for the researcher's doctorate research degree, supervised by a multi-disciplinary team of experienced researchers.



**Contact details:**

For any further information about this research, please contact the main researcher Mr Bassam Alwon on 01603 591996, at [B.Al-Won@uea.ac.uk](mailto:B.Al-Won@uea.ac.uk), or by writing to the Medicines Management Research Group, School of Pharmacy, University of East Anglia, Norwich, NR4 7TJ.

**Thank you for taking the time to consider  
becoming involved in this project**

## Appendix 1.5 Participant's Interview Consent Form

### MHRA members' Interview Consent Form



Director/Manager Name: \_\_\_\_\_

Office Phone Number: \_\_\_\_\_

Email: \_\_\_\_\_

Mailing address: \_\_\_\_\_

Date: ...../...../.....

Bassam Alwon  
[B.Al-Won@uea.ac.uk](mailto:B.Al-Won@uea.ac.uk)  
Medicines Management Research Group  
School of Pharmacy,  
University of East Anglia,  
Norwich, NR4 7TJ  
Norfolk

Re: Developing a national strategy to combat counterfeit medicines

Dear Bassam,

I have read and considered the information that you sent to me about taking part in this study on "Developing a national strategy for combating counterfeit medicines".

I understand that any information I provide will be treated in complete confidence.

I also know that I am free to withdraw from the study at any time without a reason.

I agree to take part in the study.

I am happy for you to contact me to agree a time and place for the interview.

Yours sincerely,

Name:

## **Appendix 2 Stakeholders' Study**

## Appendix 2.1 UEA ethical committee approval letter

Faculty of Medicine and Health Sciences Research Ethics Committee



Bassam AlWon  
Medicines Management Research Group  
School of Pharmacy  
University of East Anglia  
NR4 7TJ

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Web: [www.uea.ac.uk/researchandenterprise](http://www.uea.ac.uk/researchandenterprise)

29<sup>th</sup> January 2014

Dear Bassam,

**Title: A Qualitative Study of Key Stakeholders of the UK-Medicines and Healthcare Products Regulatory Agency with respect to developing of an anti-counterfeit medicines strategy.**  
**Reference: 2013/2014 - 17**

The amendments to your above proposal have been considered by the Chair of the Faculty Research Ethics Committee and we can confirm that your proposal has been approved.

The Committee has asked that you make it clear that the boxes on the consent form are for initialling.

Please could you ensure that any further amendments to either the protocol or documents submitted are notified to us in advance and also that any adverse events which occur during your project are reported to the Committee. Please could you also arrange to send us a report once your project is completed.

The Committee would like to wish you good luck with your project.

Yours sincerely,

A handwritten signature in blue ink that reads 'Yvonne Kirkham'. The signature is written in a cursive style with a large initial 'Y'.

Yvonne Kirkham  
Project Officer

**CC Supervisors by email**

## Appendix 2.2 Interview question topic guide

### Research Questions Topic Guide

1. Can you please tell me about yourself?
  - a. Name, education back-ground, work experiences.
2. Who do you think are the stakeholder groups who should be involved in preventing counterfeit medicines alongside the agency?
  - a. Do you think a medicines regulatory agency should have an anti-counterfeiting strategy? If so, why?
3. Can you please describe the roles of stakeholders in the developing an anti-counterfeiting strategy?
  - a. What do you think could be done to make it better?
  - b. What do you think the development process should be?
4. What is the general role of MHRA's stakeholders in carrying out an anti-counterfeiting strategy?
  - a. How should these roles be communicated to them?
  - b. What could be done to make it improve?
  - c. What are the barriers the stakeholders could face?
  - d. How you think the MHRA has taken these roles into account in the strategy?
5. What do you think the roles of pharmacists and GPs are in an anti-counterfeiting strategy?
  - a. How should these roles be communicated to them?
  - b. How you think the MHRA has taken these roles into account in the strategy?
6. What do you think is the best way for a medicines regulatory agency to implement an anti-counterfeiting strategy?
  - a. What do you think is the process of implementation?

- b. What do you think is the role of stakeholders in the implementation?
- c. What do you think the MHRA actually did in implementing its strategies here?
- 7. What outcomes should be expected when an anti-counterfeiting strategy is implemented?
  - a. How could those outcomes be formulated?
  - b. What outcomes do you think the MHRA expected to follow from its strategies?
- 8. How do you think a medicines regulatory agency could evaluate the outcomes of this strategy?
  - a. What should be the methods for evaluating them?
  - b. What do you think the stakeholders could do to help in such an evaluation?
  - c. How do you think the MHRA evaluated its strategies?
- 9. Is there anything you would like to add?

## Appendix 2.3 Participant's invitation letter

### Participants' Invitation Letter

Dear .....

My name is Bassam Alwon and I am PhD student conducting research in the field of counterfeit medicines. I have now started my PhD study at the University of East Anglia, School of Pharmacy (<http://www.uea.ac.uk/pha>) and I am working with Professor David Wright (Deputy Head of School) as my PhD supervisor (<http://www.uea.ac.uk/pha/dw>).

Counterfeit medicines are an important topic for medicines regulators and are becoming a serious threat to global healthcare.

My research title is "Developing a national strategy to combat counterfeit medicines". The aim of this research is to gain a better understanding of developing an anti-counterfeiting strategy and to evaluate the relationship of this strategy with agency stakeholders from the pharmaceuticals industry, for example, manufacturers and distributors.

This will help me, when I return to my work, to develop a strategy for to combat counterfeit medicines by adding to a wider understanding of strategies for combating counterfeit medicines. To achieve this objective my research will use mixed research methods.

An important part of this study will be to conduct a number of interviews with key members of the UK-MHRA's stakeholders and to learn from their experience how to develop and implement improved anti-counterfeiting strategies on my return to the Kingdom of Saudi Arabia. These interviews will be confidential and will only be used for this research.

The outcomes of this research will be:

1. Submitted for my doctorate thesis.
2. Summarized and sent to the MHRA as feedback.
3. Used to assist to develop a strategy to combat counterfeit medicines, benefiting from the experience of one of the leading medicines regulators in the world.
4. Possibility sent for publication as scientific papers, taking rigorous account of all issues relating to the anonymity of the research participants and to all aspects of confidentiality in the presentation of data.

From the initial research the gatekeeper (Mr. Robert Lowe) and I have identified you, along with other key members of the UK-MHRA's stakeholders, as a key opinion holder in respect to the counterfeiting issue in the UK. Therefore, I would like to ask if you would be prepared to be interviewed by me on this topic. Interviews will be conducted at your place of work (or any other place that is convenient for you) and will take no more than 90 minutes at a time fitting in with your diary. If you are not able to help me with this research, or you feel you are not the correct person to talk to, perhaps you could advise me as to whom I should contact.

Thank you for your cooperation

Regards

Bassam Alwon  
Research Pharmacist  
Pharmacy Practice  
School of Pharmacy  
University of East Anglia  
Norwich, NR4 7TJ

Tel: 01603 591996  
Mob: 07538737292  
E.mail: [B.Al-Won@uea.ac.uk](mailto:B.Al-Won@uea.ac.uk)



## Appendix 2.4 Participant's information sheet

### Participants' Information Sheet

#### Invitation

You have been invited to participate in a research study. Before you decide to do so, it is important that you understand why this research is being conducted and what it will involve for you if you take part. Please take time to read the following information carefully.

#### What is the purpose of the study?

The aim of this study is to explore the knowledge, experiences and opinions of key members of the UK-MHRA's stakeholders from the pharmaceuticals industry in respect to the counterfeiting issue in the UK and the MHRA's anti-counterfeiting strategies, as key elements in a strategy to combat counterfeit medicines. As you know, counterfeit medicines are an important issue for medicines regulators and are becoming a serious threat to global healthcare. Therefore, this research will help the researcher to identify key elements for developing an effective anti-counterfeiting strategy.

#### What will the study involve?

If you take part, you will attend an interview which would last no more than 90 minutes with the researcher (Mr. Bassam Alwon, a research pharmacist); the interview will cover your knowledge, experience and opinions on the counterfeiting issue in UK and the MHRA's anti-counterfeiting strategies.

#### Where will the interview take place?

The interview will take place in a private room at your workplace during your regular office hours, unless it is agreed that an alternative would be more suitable for you. Any travel expenses involved will be covered by the researcher.

#### Why have I been chosen?

You showed interest in this study after being informed of this research through the invitation letter or through your manager at your place of employment. Your experience relating to your work role is highly relevant to this study.

**Do I have to take part?**

No. It is up to you whether or not you take part. If you choose to take part in the study, you will be asked to sign a consent form before you are interviewed. Even after you have signed a consent form, you are still free to withdraw from the study at any time and without giving a reason. There is no pressure on you to take part in this research, you have the right to choose at any time not take part. If you choose not to take part, this will not affect your employment or other rights in any way. If you wish to obtain additional information or advice about your rights regarding being involved in this research study, you can do so by contacting Professor David Wright, School of Pharmacy at the University of East Anglia, who is the primary supervisor for this study, on 01603 592042 or email [D.J.Wright@uea.ac.uk](mailto:D.J.Wright@uea.ac.uk), University of East Anglia, Norwich, Norfolk, NR4 7TJ.

**Do I have to answer all the questions?**

No, during the interview if you feel any distress or discomfort in answering any question, you have the right not to answer it without any justification of your decision to the researcher. You can also withdraw from the study at any point if you wish to do so without giving a reason.

**What will taking part in this study involve for me?**

The researcher (Mr. Bassam Alwon) will ask you some questions about your knowledge, experiences and opinions about the counterfeiting issue in the UK and the MHRA's anti-counterfeiting strategies to combat counterfeit medicines. The interview questions are designed to identify your views about the counterfeiting issue in the UK and the development process, the implementation and the evaluation of a strategy to combat counterfeit medicines. We also wish to record the interview, if you are willing, to help with subsequent review and analysis of the conversation.

**What are the possible benefits of taking part?**

There are no direct benefits for you in taking part. However, you will be helping share and highlight the experiences of organisations in combating counterfeit medicines; consequently, this may help to protect patients from the harm of these medicines.

**What are the possible disadvantages of taking part?**

There are no particular disadvantages. If for any reason you do not wish to answer a question you may decline without saying why, this will not affect the value of the answers that you do give, and there will be no consequences for you whatsoever.

**What if there is a problem?**

If for any reason you have a complaint about how you have been dealt with during the study, or any worries or possible harm that you might suffer, this can be addressed through Professor Mark Searcey, who is the Head of the School of Pharmacy at the University of East Anglia, on 01603 59 2026 or email [m.searcey@uea.ac.uk](mailto:m.searcey@uea.ac.uk).

**What happens after the project comes to an end?**

The data will be analysed by the researcher and his supervisory team, and a copy of the results will be summarised and used for researcher's PhD thesis, without naming any of the participants.

**Will my taking part in the study be kept confidential?**

Yes. All information about your participation will be kept confidential. Thus, all the information about you will be anonymised so that you cannot be individually identified. All personal information and your consent form will be stored by the researcher in a locked filing cabinet in an office at the School of Pharmacy, University of East Anglia, Norwich, UK. These will only be viewed by the researcher and the research assistant. The data will only be analysed by the research team (Mr. Bassam Alwon and his academic supervisors) and will be stored on a password-protected computer. All confidential documentation will be destroyed five years after the interview. However, if a participant reveals something that might cause concern to the researcher or information that might cause harm to the participant or to someone else, the researcher will raise these concerns with his supervisory team to decide if confidentiality should be breached at this level in order that the concerns may be raised with the appropriate authority.

**What will happen to the results of the research?**

The findings of this study will form part of my doctoral thesis, and accordingly, a copy will be lodged in the library of the University of East Anglia. The findings may also be sent to academic and professional journals for publication to add to the body of scientific knowledge and to share any relevant data or recommendations pertaining to the administration of medicines with other professionals in the field.

**Who is organizing and funding the research?**

The research is being organized and funded by the School of Pharmacy at the University of East Anglia. The information is being used for the researcher's doctorate research degree, supervised by a multi-disciplinary team of experienced researchers.

**Contact details:**

For any further information about this research, please contact the principal researcher, Mr. Bassam Alwon, on 01603 591996, at [B.Al-Won@uea.ac.uk](mailto:B.Al-Won@uea.ac.uk), or in writing to the Medicines Management Research Group, School of Pharmacy, University of East Anglia, Norwich, NR4 7TJ UK.

## Appendix 2.5 Participant's Interview Consent Form

### Participants' Interview Consent Form



Name: \_\_\_\_\_  
Office Phone Number: \_\_\_\_\_  
Email: \_\_\_\_\_  
Mailing address: \_\_\_\_\_  
Date: \_\_\_\_\_

Bassam Alwon  
[B.Al-Won@uea.ac.uk](mailto:B.Al-Won@uea.ac.uk)  
Medicines Management Research Group  
School of Pharmacy,  
University of East Anglia,  
Norwich, NR4 7TJ  
Norfolk  
UK

**Re: Developing a national strategy to combat counterfeit medicines**

- I have read and considered the information that you sent to me about taking part in this study on "Developing a national strategy for combating counterfeit medicines".
- I understand that any information I provide will be treated in complete confidence.
- I also know that I am free to withdraw from the study at any time without a reason.
- I agree to take part in the study.
- I am happy for you to contact me to agree a time and place for the interview.

Yours sincerely,

Name:

Version No. 2

Date: 13/12/2013

## **Appendix 3 Pharmacists' Study**

## Appendix 3.1 UEA ethical committee approval letter

Faculty of Medicine and Health Sciences Research Ethics Committee



Bassam Al Won  
Medicines Management Research Group  
School of Pharmacy  
University of East Anglia  
NR4 7TJ

Research & Enterprise Services  
West Office (Science Building)  
University of East Anglia  
Norwich Research Park  
Norwich, NR4 7TJ

Telephone: +44 (0) 1603 591720  
Email: [fmh.ethics@uea.ac.uk](mailto:fmh.ethics@uea.ac.uk)

Web: [www.uea.ac.uk/researchandenterprise](http://www.uea.ac.uk/researchandenterprise)

01 September 2014

Dear Bassam,

**Project Title: A survey study to describe the views of England's community pharmacists and GPs regarding their role, experience and practice with respect to counterfeit medicines**  
**Reference: 2013/2014 - 85**

The amendments to your above proposal have been considered by the Chair of the Faculty Research Ethics Committee and we can confirm that your proposal has been approved.

Please could you ensure that any further amendments to either the protocol or documents submitted are notified to us in advance and also that any adverse events which occur during your project are reported to the Committee. Please could you also arrange to send us a report once your project is completed.

The Committee would like to wish you good luck with your project.

Yours sincerely,

A handwritten signature in blue ink that reads 'Yvonne Kirkham'. The signature is written in a cursive style.

Yvonne Kirkham  
Project Officer

cc Prof David Wright and Prof Fiona Poland

## Appendix 3.2 Pharmacists' questionnaire



# ***Counterfeit medicines Community pharmacist's role, experience and practice***

### Instructions to complete the questionnaire:

- This questionnaire consists of five sections.
- It should take between 5 and 10 minutes to complete.
- Please tick one box for each question unless stated otherwise.
- Please tick all that apply in questions 6, 7, 9, 10 and 37.
- Please use the pre-paid envelope provided to return the questionnaire.
- Please fill in the postcard provided.
- Please send the postcard separately in the pre-paid envelope provided.

For any enquiries please do not hesitate to contact:

Bassam ALWON

Tel: 01603 591996

E.mail: B.Al-Won@uea.ac.uk

Medicines Management Research Group

School of Pharmacy

University of East Anglia

Norwich, NR4 7TJ

Version 2

15/8/2014



Section 1: Experiences of counterfeit medicines			
	No	Yes	How many times
1. Have you had any experiences of a medicine being recalled due to a counterfeiting incident?	<input type="checkbox"/>	<input type="checkbox"/>	.....
2. Have you had any experiences of counterfeit medicines through your supply chain? (e.g. from your wholesaler or distributor)	<input type="checkbox"/>	<input type="checkbox"/>	.....
3. Have you ever been offered a product from your wholesaler or distributor which you suspected might be counterfeit?	<input type="checkbox"/>	<input type="checkbox"/>	.....
4. Have you had any experiences of a patient reporting or showing you a product that might be counterfeit?	<input type="checkbox"/>	<input type="checkbox"/>	.....
5. Have you had any experiences of a patient having an adverse effect that might be from a counterfeit medicine? (If your answer is NO please go to question 7)	<input type="checkbox"/>	<input type="checkbox"/>	.....
6. If you experienced a patient having an adverse effect from a counterfeit medicine, which of the following actions did you take? (Please tick all that apply)			
Did not do anything	<input type="checkbox"/>		
Gave the patient advice	<input type="checkbox"/>		
Used the Yellow Card Scheme to report the incident	<input type="checkbox"/>		
Isolated the item from my stock	<input type="checkbox"/>		
Communicated to someone else in my organisation	<input type="checkbox"/>	Their occupation.....	
Other	<input type="checkbox"/>	Please specify .....	
7. If you suspect that a medicine is counterfeit, which of the following would best describe your action(s): (Please tick all that apply)			
Do nothing	<input type="checkbox"/>		
Report it to my supplier	<input type="checkbox"/>		
Report it to the MHRA	<input type="checkbox"/>		
Isolate the item from my stock	<input type="checkbox"/>		
Communicate to someone else in my organisation	<input type="checkbox"/>	Their occupation .....	
Report it to my professional body	<input type="checkbox"/>	Please specify .....	
Other	<input type="checkbox"/>	Please specify .....	
Section 2: Educational experiences			
	No	Yes	How many times
8. Have you attended any education or training opportunity regarding counterfeit medicines? (If your answer is NO please go to question 11)	<input type="checkbox"/>	<input type="checkbox"/>	.....
9. Where did you receive it? (Please tick all that apply)			
Within undergraduate degree	<input type="checkbox"/>	Within pre-registration year	<input type="checkbox"/>
		Post- registration	<input type="checkbox"/>
10. Which of the following education or training opportunities have you undertaken regarding counterfeit medicines? (Please tick all that apply)			
Workshop	<input type="checkbox"/>	Conference	<input type="checkbox"/>
		Distance learning	<input type="checkbox"/>
Journal article	<input type="checkbox"/>	Other	<input type="checkbox"/>
		Please specify .....	

11. Where would you believe an education or training opportunity specifically about counterfeit medicines should be?

Within undergraduate degree       Within pre- registration year       Post- registration

12. Which type of education or training opportunity would you prefer to undertake regarding counterfeit medicines?

Workshop       Conference       Distance learning   
 Journal article       Other  Please specify .....

### Section 3: Your practice

For each of the following could you please select the option that matches your practice?

Dispensing practice	Never	Rarely	Some-times	Often	Always	Not applicable
13. Check the package seal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Look for an altered expiry date	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Compare the physical characteristics of the product (colour, tablet or capsule markings, shape and thickness) with previously purchased products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. Look for any signs of a removed or switched product label	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. Look for subtle changes in the product's package (compared with previously purchased products)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. Examine the package for changes in paper texture, size and thickness of the labels, also the gloss or finish on the paper	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. Look for changes in fonts and font sizes, print colour or raised print	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. Examine all printing on flaps and surfaces of the box in comparison with previously purchased products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. Look for overt security (e.g. hologram)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. Look for changes in the size of the container (length, diameter and shape) compared with previously purchased products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Purchasing practice	Never	Rarely	Some-times	Often	Always	Done by someone else
23. Establish integrity of the supplier prior to ordering	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24. Establish a list of approved suppliers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25. Develop a list of key products that can only be purchased from the manufacturer or its authorised distributors	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Purchasing Practice	Accept the offer	Treat it with caution	Reject the offer	Not applicable
26. If a product is being offered at an unusually cheap price, would you:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27. If a product is being offered in an unusually large quantity, would you:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
28. Please use this space if you want to explain any of your answers given above:				

**Section 4: Role of pharmacist**

	Yes	No	If No, who do you consider would be responsible for that
29. Do you believe the reporting to the regulatory agency of any suspicion of counterfeit medicines is one of the pharmacist's duties?	<input type="checkbox"/>	<input type="checkbox"/>	.....
30. Do you believe raising awareness for patients about counterfeit medicines is one of the pharmacist's duties?	<input type="checkbox"/>	<input type="checkbox"/>	.....
31. Do you believe providing advice to patients about counterfeit medicines is one of the pharmacist's duties?	<input type="checkbox"/>	<input type="checkbox"/>	.....
32. Through which method of communication would you prefer to receive information about counterfeit medicines?			
Professional journal	<input type="checkbox"/>	Professional bodies	<input type="checkbox"/>
Via your organization	<input type="checkbox"/>	Fax	<input type="checkbox"/>
Email	<input type="checkbox"/>	Press release	<input type="checkbox"/>
General media	<input type="checkbox"/>	Other	<input type="checkbox"/>
Please specify .....			

**Section 5: Personal Information**

33. Your gender: Male  Female

34. Your experience of working as a pharmacist (years)

0 - 5  6 - 10  11 - 15  16 - 20  21 - 25  Over 25

35. What is the postcode of the region you work in? (e.g. NR1) .....

36. What is your place of work?

Independent community pharmacy (5 or less)  Small chain community pharmacy (6 - 15)

Large chain community pharmacy (more than 15)

37. Which professional bodies are you registered with? (Please tick all that apply)

RPS  UKCPA  GPhC  Other  Please specify:.....

***If you are willing to participant in a 10-minute confidential interview to talk about your experience relating to counterfeit medicines, please complete the postcard provided***

***Thank you for your time and co-operation***

## Appendix 3.3 Pharmacists' invitation letter



Bassam ALWON  
Tel: 01603 591996  
E.mail: B.Al-Won@uea.ac.uk  
Medicines Management  
Research Group  
School of Pharmacy  
University of East Anglia  
Norwich, NR4 7TJ

Participant's address

### Counterfeit medicines: Pharmacist's role, experience and practice

#### Invitation Letter

Dear .....

My name is Bassam Alwon; I am a PhD student at the School of Pharmacy, University of East Anglia. As described during our recent telephone conversation, I am interested in the role of community pharmacists with respect to counterfeit medicines.

To date, I have undertaken interviews with senior managers from the Medicines and Healthcare products Regulatory Agency (MHRA) and its stakeholders to understand their views regarding the role of community pharmacists in combating counterfeit medicines. I am now surveying community pharmacists in order to capture their perspective.

Please find enclosed a brief questionnaire which allows you to report your role, experiences and practice regarding counterfeit medicines.

As stated during our telephone conversation, you have been randomly selected from the national database of community pharmacies and I am delighted that you have offered to take part.

This survey is designed to be completed by community pharmacists, and should take between 5 and 10 minutes. Your responses are confidential, will be kept anonymous, and the results will only be used as part of my PhD and for publication in relevant scientific journals.

Thank you in advance for your cooperation.

Yours sincerely,

Bassam ALWON

Version 2

## Appendix 3.4 Pharmacist's postcard

Dear Bassam

- **Taking part in a 10-minute follow-up interview**
  - I am willing to participate in a 10-minute confidential interview to talk about my experiences relating to counterfeit medicines. I would prefer to be contacted about the interview through:
    - Email, my email is .....
    - Phone call, my number is .....
  - I am not willing to participate in a 10-minute confidential interview to talk about my experiences relating to counterfeit medicines.

Thank you Participant's address

Yours sincerely,

## Appendix 3.5 Pharmacist's follow-up reminder letter



Bassam ALWON  
Tel: 01603 591996  
E.mail: B.Al-Won@uea.ac.uk  
Medicines Management  
Research Group  
School of Pharmacy  
University of East Anglia  
Norwich, NR4 7TJ

Participant's address

### Counterfeit medicines: Pharmacist's role, experience and practice

Follow-up letter

Dear .....

My name is Bassam Alwon and I am a PhD student at the School of Pharmacy, University of East Anglia. We had a telephone conversation few weeks ago regarding a surveying to community pharmacists in respect to counterfeit medicines.

Following that telephone conversation, I sent to you a brief questionnaire which allows you to report your role, experiences and practice regarding counterfeit medicines.

Please find enclosed a second copy of the questionnaire in case you did not receive it first time.

This survey is designed to be completed by community pharmacists, and should take between 5 and 10 minutes. Your responses are confidential, will be kept anonymous, and the results will only be used as part of my PhD thesis as well as for certain scientific publications.

Thank you in advance for your cooperation.

Yours sincerely,

Bassam ALWON

Version No. 2

## **Appendix 4 General Practitioners' (GP) Study**

## Appendix 4.1 UEA ethical committee approval letter

Faculty of Medicine and Health Sciences Research Ethics Committee



Bassam Al Won  
Medicines Management Research Group  
School of Pharmacy  
University of East Anglia  
NR4 7TJ

Research & Enterprise Services  
West Office (Science Building)  
University of East Anglia  
Norwich Research Park  
Norwich, NR4 7TJ

Telephone: +44 (0) 1603 591720  
Email: [fmh\\_ethics@uea.ac.uk](mailto:fmh_ethics@uea.ac.uk)

Web: [www.uea.ac.uk/researchandenterprise](http://www.uea.ac.uk/researchandenterprise)

01 September 2014

Dear Bassam,

**Project Title: A survey study to describe the views of England's community pharmacists and GPs regarding their role, experience and practice with respect to counterfeit medicines**  
**Reference: 2013/2014 - 85**

The amendments to your above proposal have been considered by the Chair of the Faculty Research Ethics Committee and we can confirm that your proposal has been approved.

Please could you ensure that any further amendments to either the protocol or documents submitted are notified to us in advance and also that any adverse events which occur during your project are reported to the Committee. Please could you also arrange to send us a report once your project is completed.

The Committee would like to wish you good luck with your project.

Yours sincerely,

A handwritten signature in blue ink that reads 'Yvonne Kirkham'. The signature is written in a cursive style.

Yvonne Kirkham  
Project Officer

cc Prof David Wright and Prof Fiona Poland



## Appendix 4.2 GPs' questionnaire



# Counterfeit medicines

## GP's role, experience and practice

### Instructions to complete the questionnaire:

- In this survey, the World Health Organization (WHO) definition of the counterfeit medicines is been used;

*"A counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging".*

- This questionnaire should take 5 minutes to complete.
- Please tick one box for each question unless stated otherwise.
- Please complete the questionnaire and the postcard; and use both pre-paid envelopes provided to send it separately.

For any enquiries please contact:

Bassam ALWON  
Tel: 01603 591996  
E.mail: B.Al-Won@uea.ac.uk  
Medicines Management Research Group  
School of Pharmacy  
University of East Anglia  
Norwich, NR4 7TJ

## Section 1: Experiences of counterfeit medicines

	No	Yes	How many times
1. Have you had any experiences of medicines being recalled due to counterfeiting?	<input type="checkbox"/>	<input type="checkbox"/>	.....
2. Have you had any experiences of a patient reporting or showing you a product which might be counterfeit?	<input type="checkbox"/>	<input type="checkbox"/>	.....
3. Have you had any experience of a patient having an adverse effect that could be the result of taking a counterfeit medicine?	<input type="checkbox"/>	<input type="checkbox"/>	.....

*If you answered 'YES' to either question 2 or 3 then please answer question 4  
If all of your answers are 'NO' then please go to question 5*

4. If you experienced a patient having an adverse effect from a counterfeit medicine, which of the following actions did you take? *(Please tick all that apply)*

- Did not do anything
- Treated the patient from this side effect
- Used the Yellow Card Scheme to report the incident
- Isolated the item from my stock
- Reported to someone else in my organisation  Their occupation.....
- Other  Please specify .....

5. If you suspect that a medicine is counterfeit, which of the following would best describe your action(s): *(Please tick all that apply)*

- Do nothing
- Report it to my supplier
- Report it to the manufacturer
- Report it to the MHRA
- Isolate the item from my stock
- Report to someone else in my organisation  Their occupation .....
- Report it to my professional body  Please specify .....
- Other  Please specify .....

## Section 2: Educational experiences

	No	Yes	How many times
6. Have you received any specific education or training regarding counterfeit medicines? <i>(If you answered 'NO' please go to question 9)</i>	<input type="checkbox"/>	<input type="checkbox"/>	.....
7. Where did you receive it? <i>(Please tick all that apply)</i>			
Within undergraduate degree	<input type="checkbox"/>	Within foundation year	<input type="checkbox"/>
		Post- foundation	<input type="checkbox"/>
8. Which of the following education or training have you undertaken regarding counterfeit medicines? <i>(Please tick all that apply)</i>			
Workshop	<input type="checkbox"/>	Conference	<input type="checkbox"/>
		Distance learning	<input type="checkbox"/>
Journal article	<input type="checkbox"/>	Other	<input type="checkbox"/>
		Please specify	.....
9. In your opinion where should education or training on counterfeit medicines be provided? <i>(Please tick one answer)</i>			
Within undergraduate degree	<input type="checkbox"/>	Within foundation year	<input type="checkbox"/>
		Post- foundation	<input type="checkbox"/>
10. Which type of education or training opportunity would you prefer to undertake regarding counterfeit medicines? <i>(Please tick one answer)</i>			
Workshop	<input type="checkbox"/>	Conference	<input type="checkbox"/>
		Distance learning	<input type="checkbox"/>
Journal article	<input type="checkbox"/>	Other	<input type="checkbox"/>
		Please specify	.....

## Section 3: Role of GP

GP's duty with respect to counterfeit medicines	Yes	No	If 'No', who do you believe should be responsible
11. To report to the medicines regulatory agency of any suspicion of counterfeit medicines?	<input type="checkbox"/>	<input type="checkbox"/>	.....
12. To raise awareness for patients about counterfeit medicines?	<input type="checkbox"/>	<input type="checkbox"/>	.....
13. To provide advice to patients about counterfeit medicines?	<input type="checkbox"/>	<input type="checkbox"/>	.....

14. Through which method of communication would you prefer to receive information about counterfeit medicines? (*Please tick one answer*)

- Professional journal       Professional bodies       Via your organization   
Fax       Email       Press release   
General media       Other  Please specify.....

15. Please use this space if you want to explain any of your answers given above:

### Section 4: Personal Information

16. Your gender:      Male       Female

17. Your experience of working as a registered doctor (years):

- 0 - 5       6 - 10       11 - 15       16 - 20       21 - 25       Over 25

18. What is the postcode of the region you work in? (e.g. NR1) .....

19. You work as:

- Non-dispensing GP       Dispensing GP

20. Which professional bodies are you registered with? (*Please tick all that apply*)

- RCGP       BMA       GMC       Other  Please specify:.....

**Would you please share your experience relating to counterfeit medicines and participate in a 10-minute confidential interview?**

*If 'YES', can you please complete the postcard provided*

***Thank you for your time and co-operation***

## Appendix 4.3 GPs' invitation letter



Norwich Medical School  
University of East Anglia  
Norwich Research Park  
Norwich  
NR4 7TJ  
Tel: 01603 591996  
E.mail: B.Al-Won@uea.ac.uk

### Counterfeit medicines: GP's role, experience and practice Invitation Letter

Dear «Name»

My name is Richard Holland; I am a Professor of Public Health Medicine, in Norwich Medical School, University of East Anglia. I work closely with our School of Pharmacy to develop knowledge and interventions in Pharmacy Practice. One of their PhD students (Mr Bassam Alwon) is interested in the role of General Practitioners with respect to counterfeit medicines.

In this study, the World Health Organization (WHO) definition of the counterfeit medicines is been used;

*"A counterfeit medicine is one which is **deliberately and fraudulently mislabeled** with respect to identity and/or source...."*

*"Counterfeit products may **include products** with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging".*

You have been randomly selected from the national database of NHS Clinical commissioning groups (CCGs) and we would be delighted if you could take part in this study.

Please find enclosed a brief questionnaire which allows you to report your role, experiences and practice regarding counterfeit medicines.

This survey should take 5 minutes. Your responses are confidential, will be kept anonymous, and the results will only be used as part of a PhD thesis and for publication in relevant scientific journals.

Thank you very much in advance for your kind help.

Yours sincerely

A handwritten signature in blue ink, appearing to read "RH", is written over a light blue rectangular background.

Professor Richard Holland

A handwritten signature in blue ink, appearing to read "Bassam", is written over a light blue rectangular background.

Bassam Alwon

Encs

Version No. 3

Date: 22/10/2014

## Appendix 4.4 GPs' postcard

Dear Bassam

- **Taking part in a 10-minute follow-up interview**
  - I am willing to participate in a 10-minute confidential interview to talk about my experiences relating to counterfeit medicines. I would prefer to be contacted about the interview through:
    - Email, my email is .....
    - Phone call, my number is .....
  - I am not willing to participate in a 10-minute confidential interview to talk about my experiences relating to counterfeit medicines.

Thank you Participant's address

Yours sincerely,

## Appendix 3.5 GPs' follow-up reminder letter



School of Pharmacy  
University of East Anglia  
Norwich Research Park  
Norwich  
NR4 7TJ  
Tel: 01603 591996  
E.mail: B.Al-Won@uea.ac.uk

### Counterfeit medicines: GP's role, experience and practice Follow-up letter

Dear «Name»

My name is Richard Holland; I am a Professor of Public Health Medicine, in Norwich Medical School, University of East Anglia. I work closely with our School of Pharmacy to develop knowledge and interventions in Pharmacy Practice. One of their PhD students (Mr Bassam Alwon) is interested in the role of General Practitioners with respect to counterfeit medicines.

A few weeks ago, we sent to you a brief questionnaire which allows you to report your role, experiences and practice regarding counterfeit medicines.

In this study, the World Health Organization (WHO) definition of the counterfeit medicines is been used;

*"A counterfeit medicine is one which is **deliberately and fraudulently mislabeled** with respect to identity and/or source...."*

*"Counterfeit products may **include products** with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging".*

Please find enclosed a second copy of the questionnaire in case you did not receive it first time.

This survey is designed to be completed by GPs, and should take 5 minutes. Your responses are confidential, will be kept anonymous, and the results will only be used as part of my PhD thesis as well as for certain scientific publications.

Thank you in advance for your cooperation.

Yours sincerely

Professor Richard Holland

Bassam Alwon

Encs

Version No. 2

## **Appendix 5 Counterfeit Medicines Advice for Healthcare Professionals**





# Counterfeit Medicines Advice for Healthcare Professionals

## Guidance for Pharmacists and Dispensing Doctors

### Introduction

Counterfeit medicines are those medicines that are described as *"deliberately and fraudulently mislabelled with respect to identity and / or source. Counterfeiting can apply to both branded and generic products. Counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients, or with fake packaging"* (WHO definition).

Counterfeit medicines can harm patients in two ways: individually and at the community level. Taking adulterated substances or lack of treatment can harm an individual, from unexpected adverse reactions to toxicity and / or anaphylaxis. Counterfeit medicines can also be life threatening and have caused deaths in Africa and Asia. For example inert antibiotics will not cure an infectious disease, nor will "vaccination" with a counterfeit vaccine protect from illness. Improper treatments are a risk to public health, either through increased disease transmission or through the development of antibiotic resistance.

In addition, the credibility of a national healthcare system can be harmed if counterfeit medicines get into the legitimate supply chain, which may lead to patients becoming irrationally fearful of perfectly safe treatments.

### UK Situation

Over 750 million prescriptions are written annually in the UK. Only a small number of counterfeit medicines have reached the legitimate pharmaceutical supply chain since August 2004. This guidance needs to be viewed in that

context. The Government, through the Medicines and Healthcare products Regulatory Agency (MHRA), takes each such case very seriously, investigating all allegations of counterfeit medicines in the UK, the vast majority of which are not associated with the legitimate supply chain. The MHRA will take regulatory action where breaches are identified – which may take the form of revoking licences and / or the instigation of criminal proceedings.

### Factors associated with increased counterfeiting:

- Blockbuster 'lifestyle' medicines that have created a demand for illicit use
- Globalisation of markets has made distribution of counterfeit products easier
- The internet provides counterfeiters with easy access to consumers and markets
- An increase in the self-prescribing culture and self care
- Technology to produce everything from labels to active pharmaceutical ingredients is now widely available
- Weak regulations, in terms of enforcement and penalties governing the medicines distribution systems in many countries which do not provide a strong enough deterrent for counterfeiters
- Cottage industries that use unemployed skilled labour
- Organised crime has become increasingly involved in counterfeiting as it becomes more profitable with lower risks than other drug crime

## Counterfeit Medicines Advice for Healthcare Professionals

### Guidance for Pharmacists and Dispensing Doctors

#### Consequences of counterfeiting:

Counterfeiting has significant social and economic consequences. Most importantly, patients may not get safe or effective products and consequently may be at significant risk. On the economic side, legitimate manufacturers of pharmaceutical products suffer from patent and copyright infringement as counterfeiting, in reality, 'hijacks' the brand. The Government is affected through loss of taxation revenue and undermining of the national healthcare system. Considerable resources are required to combat the practice of counterfeiting. In addition, health plans for the NHS are being defrauded and compromised.

#### Action to be taken:

Pharmacists or dispensing doctors worried about a counterfeit medicine need to do certain things to minimise / prevent harm to patients:

- Contact the MHRA on the counterfeit hotline by:
  - E-mail: [counterfeits@mhra.gsi.gov.uk](mailto:counterfeits@mhra.gsi.gov.uk)
  - Phone: on the 24 hour counterfeit hotline 0207 084 2701
  - Clicking the green icon on the MHRA website homepage: [www.mhra.gov.uk](http://www.mhra.gov.uk)
- Await MHRA instructions – conducting unilateral action may prove ill-advised, unnecessary, confusing and counter-productive
- If a drug alert and recall notice is received, be prepared to:
  - Check the current stock held in the dispensary and return any potential counterfeit medicines in line with guidance issued
  - If possible, interrogate the PMR systems to reveal which individual patients are on that particular medicine and when it was dispensed
  - Contact those patients who have been supplied with that particular medicine within the suggested timeframe to check on their medication

If a patient is concerned that they have a counterfeit medicine then the pharmacist or dispensing doctor should make a record of this (recording patient contact details, reason for patient's suspicion, product name, dosage, batch number and expiry date would be extremely helpful) and inform the MHRA immediately.

Dispensing doctor's practices are covered in the same alert system as pharmacies.

#### Tips for evaluating product sources & detecting counterfeit medicines

- Establish the integrity of the source prior to need. Where possible, establish a list of approved suppliers
- Require that any alternative source of supply provides the following as a minimum:
  - A pedigree back to the previous source
  - Certification that it is not a diverted product
  - Certification that any actions by the alternative source will not alter any original manufacture warranties or guarantees
  - Certification that the product has been stored and handled consistent with product labelling requirements
- If a product is being offered at an unusually cheap price and / or in unusually large quantities (particularly in a large quantity of the same batch number), treat with extra caution
- Consider developing a list of key pharmaceutical products that will not be purchased from sources other than the manufacturer, or authorised distribution channel
- Look for an altered expiry date. Counterfeiters commonly purchase 'short-dated' products and then alter the labels
- Compare the physical characteristics of the product. Look at colour, tablet or capsule markings, shape and thickness of the medicine. You can also weigh the product to see if there are wide variations
- Notwithstanding the obvious differences in the packaging of legitimate parallel imported products, look for signs of a removed or switched product label. One common practice by counterfeiters is to remove the original label and replace it with a counterfeit label. To do this, they use lighter fluid, acetone or some other solvent which may leave a tacky residue on the container. Also, the label may be faded or discoloured along the edges due to the solvent
  - Look for subtle changes in the product's package (compare with previously purchased products) Examine the package for differences in paper texture, size and thickness of the labels, also the gloss or finish on the paper. Look for differences in fonts and font sizes, print colour or raised print. Examine all printing on flaps and surfaces of the box in comparison with previously purchased products where possible. Look for overt security

## Counterfeit Medicines Advice for Healthcare Professionals Guidance for Pharmacists and Dispensing Doctors

features such as holograms or colour shifting inks. Finally, look for breaks or tears in the sealing tape and seals.

- Look for variations in the size of the container (compare with previously purchased products)
- Look for differences in container length, diameters and shapes. Examine for variations in diameters of bottle openings or lids. Examine for variations in the thickness of glass or plastic containers and for variations in container colour tints.

- Listen to patients  
Counterfeit medicines around the world are often first detected by patients

Report all suspicious approaches or known information on counterfeits to the MHRA through the counterfeit hotline:

- E-mail: [counterfeits@mhra.gsi.gov.uk](mailto:counterfeits@mhra.gsi.gov.uk)
- Phone: on the 24 hour counterfeit hotline 0207 084 2701
- Clicking the green icon on the MHRA website homepage: [www.mhra.gov.uk](http://www.mhra.gov.uk)

In 2007, one phone call to the MHRA from a suspicious wholesaler led to the interception and seizure of 15,000 packs of a counterfeit cancer medicine and nearly 20,000 packs of counterfeit anti-platelet medicines before they could reach pharmacies and patients.

Pharmacists and dispensing doctors should always purchase medicines from reliable, trusted wholesalers and suppliers – thorough due diligence checks should be conducted regularly and systems reviewed.

## What is being done to stop the business of counterfeit medicines?

### RPSGB

The RPSGB recognises the need to provide information to both pharmacists and patients around counterfeit medicines. Although the number of counterfeit medicines entering the legitimate supply chain in the UK is extremely small, pharmacists are very closely involved in the repercussions of counterfeiting so have an important role in helping prevent counterfeits reaching patients.

The RPSGB Inspectors are involved, in collaboration with the MHRA, in a UK wide targeted medicine surveillance scheme. Inspectors pick 'high risk' medicines off the shelves of community pharmacies which are then sent to the MHRA for testing and analysis.

The RPSGB has developed an internet pharmacy logo and more information on this can be found at [www.internetpharmacylogo.org](http://www.internetpharmacylogo.org). This logo will help the public identify bona fide internet pharmacy and indicates that a website is operated by a registered pharmacy in Britain. By clicking on the logo visitors will be taken to the RPSGB's website, where they can verify the registration details of both the pharmacy and the pharmacist(s) behind the site.

The logo looks like this:



Each individual logo contains the pharmacy's *unique seven digit registration number*, issued by the RPSGB.

A legitimate online pharmacy should:

- Clearly display the name, address and owner of the pharmacy business
- Have a physical address in the country where it claims to be located
- Require patients to provide a medical history evaluation before supplying them with a medicine
- Require a prescription signed by a UK-registered doctor for obtaining prescription-only medicines
- Have a telephone number that patients can call to speak to a pharmacist
- Have a privacy and security policy

British pharmacy premises are all registered with the RPSGB and are listed on its Register. You can check this here: [www.rpsgb.org/registrationandsupport/registration/seachourregisters/](http://www.rpsgb.org/registrationandsupport/registration/seachourregisters/)

## Counterfeit Medicines Advice for Healthcare Professionals Guidance for Pharmacists and Dispensing Doctors

### MHRA

Whilst the UK legitimate pharmaceutical supply chain is tightly regulated it is recognised that no supply chain is impenetrable – whatever the regulatory and surveillance safeguards that may be in place. The Minister of State (Public Health) launched the MHRA's Anti-Counterfeiting Strategy in London in November 2007.

This strategy sets out a three year plan to combat counterfeit medicines and devices through a sustained programme of *communication, collaboration and regulation*

#### Communication:

Ensuring both the public and healthcare professionals have sufficient information about counterfeit medicines, how to avoid them, and how to report any suspicions to the MHRA – this guidance is part of that effort.

#### Collaboration:

The Agency will continue to host the UK Anti-counterfeiting Stakeholders (ACS) meeting between Regulators, Law Enforcement and Industry / Trade which ensures an awareness and recognition of the threat from counterfeit medicines / devices whilst encouraging collaboration and increased vigilance.

The MHRA fully participates in all relevant international initiatives to tackle counterfeit medicines / devices which impact upon the UK, including the World Health Organisation (WHO), International Medical Products Anti-counterfeiting Taskforce (IMPACT), EU Commission work in this area, EU Heads of Medicines Agencies enforcement officers and the Council of Europe.

#### Regulation:

The MHRA is thoroughly examining all aspects of the supply chain with key stakeholders in view of recent incidents of counterfeits reaching patients and will make necessary recommendations for change.

The MHRA will maintain targeted market surveillance projects throughout the supply chain on the medicines most at risk from counterfeiting. They will thoroughly investigate all reports of counterfeit medicines, and where appropriate, prosecute and confiscate the assets of those involved.

### DDA

The Dispensing Doctors' Association (DDA) fully supports all action to eliminate counterfeit medicines. As the vast majority of medicines dispensed by doctors are sourced from wholly reputable wholesalers the DDA works closely with them to ensure that the highest standards are maintained and instances of counterfeit medicines being found in dispensing doctors' dispensaries are therefore extremely rare.

### Further Information

If you are worried about counterfeit medicines, or want more information, you can:

- Visit the MHRA website at [www.mhra.gov.uk](http://www.mhra.gov.uk) and click on the green icon on the right hand side of the screen labelled "Reporting a counterfeit product" – this will take you to the counterfeit information page
- Visit the RPSGB website at [www.rpsgb.org](http://www.rpsgb.org)
- Visit [www.internetpharmacylogo.org](http://www.internetpharmacylogo.org)
- Send an email to [counterfeit@mhra.gsi.gov.uk](mailto:counterfeit@mhra.gsi.gov.uk)
- Visit [www.dispensingdoctor.org](http://www.dispensingdoctor.org)

Telephone the MHRA 24 hour counterfeit hotline on 020 7084 2701

## **Appendix 6 An example of method of coding using NVIVO**

Project 1.nvp - NVivo

File Home Create External Data Analyze Query Explore Layout View

Go Refresh Open Properties Edit Paste Cut Copy Merge B I U Format Paragraph Styles Editing Proofing

Nodes Relationships Node Matrices

Look for: Search In: Nodes Find Now Clear Advanced Find

Name	Sources	References	Created On	Created By	Modified On	Modified By
1-Before the drafting of an anti-counterfeit medicines strategy	0	0	21/05/2013 15:51	B	17/06/2013 10:19	B
1-View of MHRA regarding the problem of counterfeit medicine in UK before the strategy	11	37	21/05/2013 15:52	B	17/06/2013 10:31	B
2-Motive factors to create anti-counterfeit medicines strategy	11	57	21/05/2013 15:52	B	17/06/2013 10:33	B
3-The reflection of these motive factors in the strategy	10	26	21/05/2013 15:53	B	17/06/2013 10:30	B
4-Changing in the motive factors between the two strategies	9	10	21/05/2013 15:53	B	17/06/2013 10:36	B
2-The pre-drafting stage for anti-counterfeit medicines strategy	0	0	21/05/2013 15:54	B	17/06/2013 10:20	B
1-Departments involved (should be involved) and reasons for this selection	11	62	21/05/2013 15:54	B	17/06/2013 10:49	B
2-Stakeholders involved (should be involved) and reasons for this selection	9	21	21/05/2013 15:55	B	17/06/2013 10:44	B
3-Reasons for the difference in main elements between the first and second strategy	6	18	21/05/2013 15:55	B	17/06/2013 10:57	B
4-The difference in the objective between the first strategy and second strategy	6	13	21/05/2013 15:55	B	17/06/2013 10:58	B
3-The drafting stage (drafting process) of anti-counterfeit medicines strategy	0	0	21/05/2013 15:56	B	17/06/2013 10:21	B
4-The implementation stage of anti-counterfeit medicines strategy	0	0	21/05/2013 15:57	B	17/06/2013 10:21	B

Interviewer 2

[Click to edit](#)

the Department of Health and became the DTOS and I moved into policy on, I don't know, about thirty years ago I suppose.

**Interviewer**

The first part I would like to focus on the view of counterfeit medicine from MHRA perspective. How do you think the MHRA viewed the problem of counterfeit medicine in the time when they decide to develop a strategy?

**Respondent**

Can I just ask you who else you've interviewed?

**Interviewer**

Sorry?

**Respondent**

Can I just ask you who else from here you've interviewed? Have you interviewed Nim o?

**Interviewer**

I will.

**Respondent**

You will do?

In: Nodes Code At

46 Items

14:45 01/02/2016