



ANTI-COUNTERFEITING STRATEGY

2007-2010

**MEDICINES AND HEALTHCARE PRODUCTS
REGULATORY AGENCY**

Foreword

Professor Kent Woods

It is my pleasure to publish the first Medicines and Healthcare products Regulatory Agency's (MHRA) Anti-Counterfeit Strategy. This document clearly sets out the MHRA's approach to combating the availability of counterfeit medicines and devices in the UK for the next three years.

Evidence suggests that the availability of counterfeit medicines and medical devices is a growing threat worldwide, with the World Health Organisation (WHO) leading the International Medical Products Anti-counterfeiting Taskforce (IMPACT) to combat the problem.

Tackling this important issue is a key priority for the MHRA. The overriding aim of the Agency is always to safeguard public health, this is partly achieved through the removal of counterfeit medicines and devices from the market. It is also achieved through ensuring an infrastructure is in place to deal with these incidents efficiently and effectively, balanced communication of the threat to all stakeholders, and the thorough investigation and prosecution of those involved.

In the UK there have been nine recalls of specific batches of counterfeit medicines in the past three years. On each of these occasions the counterfeits had reached pharmacy and patient level, four of these recalls were conducted following a single incident this year. There has also been a number of reports of counterfeit medical devices discovered in the UK, or seized on their way to the UK.

The MHRA have been working hard to investigate each of these incidents, and where appropriate prosecute those engaged in the supply of counterfeit medicines, with a number of notable successes.

Recent cases have uncovered sophisticated international networks of individuals, some operating within the UK, engaged in the distribution and supply of counterfeit medicines.

Much has been learnt from these cases, it is important to identify the underlying factors which encourage the counterfeiters to target the UK and put in place systems to make the UK a less attractive environment for them. With this in mind the MHRA is conducting a thorough examination of the current arrangements for the supply and distribution of medicines in the UK, and will report the findings to Government.

This strategy describes the MHRA approach to a global problem; no single regulator, company or indeed country can tackle the disease of counterfeit medicine alone, a holistic approach is required.

I hope this document is of use to all those engaged in the manufacture, supply and distribution of legitimate medicines and medical devices, and most importantly consumers, in demonstrating the commitment of the MHRA to minimising the risk of counterfeit medicines and medical devices reaching patients.

Professor Kent Woods
Chief Executive
MHRA

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Introduction

Michael Deats

The UK represents a lucrative market for counterfeiters of medicines and medical devices. High prices, a large market, widespread internet connectivity and a complex supply chain all conspire to encourage those engaged in the manufacture and supply of counterfeit medicines and devices to target the UK.

Counterfeit medicines and devices are not normally manufactured in the UK, with only a few isolated medicine cases coming to light in the past 10 years. However the UK is a transit point, distribution hub and end user of counterfeit medicines.

Counterfeit medicines are most commonly distributed through on-line pharmacies, most of which are hosted outside of the UK. The WHO estimates that up to 50% of medicines sourced from websites that conceal their physical address are counterfeit. This is known as the unregulated supply chain. It should be clearly understood that there are no guarantees of the safety, quality or efficacy of medicines purchased in this way. Many of these websites are advertising and supplying the medicines illegally, with inadequate consultation, no prescriptions and often no involvement of qualified healthcare professionals.

Counterfeit medicines are less frequently, but perhaps more worryingly, discovered in the regulated supply chain, that is through licensed wholesalers, parallel traders and pharmacies. Incidents have steadily increased since 2004, with counterfeit medicine reaching patients on 9 occasions necessitating batch recalls, and discovered at wholesale level on a further 5 occasions. Despite the relatively few occasions when this has occurred, when compared to the enormous scale of the UK market, any incident of a counterfeit medicine being supplied unwittingly to a member of the public by a pharmacist is dangerous and unacceptable.

This strategy sets out the MHRA approach to tackling the availability of counterfeit medicines and medical devices in the UK. It identifies a programme of activities designed to make the UK a less attractive market for those engaged in supplying counterfeit medicines and devices.

This strategy describes how the MHRA will ensure effective communication of the threat to the public and stakeholders, collaborate with international counterparts, relevant areas of industry and law enforcement and regulate proportionately to tackle the issue.

Michael Deats
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Executive Summary

This is the first Anti-counterfeit strategy published by the MHRA tackling the availability of counterfeit medicines and medical devices in the UK. The strategy sets out a three year plan to combat counterfeit medicines and devices through a sustained programme of communication, collaboration and regulation.

The MHRA has developed and implemented strategic and operational measures designed to minimise the risk of counterfeit medicines and medical devices reaching patients through both the regulated and unregulated supply chains. The Agency is approaching the issue on three broad fronts, and eight separate streams of work;

- **Communication**

Ensuring 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. This will include the launch of a 24hour anti-counterfeiting hotline.

- **Collaboration**

The MHRA will ensure full participation in all relevant International initiatives to tackle counterfeit medicine and medical devices which impact upon the UK. This will include the World Health Organisation (WHO) International Medical Products Anti-Counterfeiting Taskforce (IMPACT).

The Agency will continue to forge close working relationships with law enforcement agencies and other regulatory bodies to ensure an awareness and recognition of the threat from counterfeit medicines and devices, and encourage collaborative working where appropriate.

The MHRA will continue to work closely with all relevant sectors of the pharmaceutical industry, to encourage a focus on the threat posed by counterfeiters.

The Agency will continue to host the Anti-counterfeiting Stakeholders (ACS) meeting between Regulators, Law enforcement and Industry.

- **Regulation**

The Intelligence unit within the MHRA will conduct a continuous threat assessment of the risk from counterfeit medicines and devices, based on all known incidents in the regulated supply chain.

Maintain targeted market surveillance projects throughout the supply chain on the medicines most at risk from counterfeiting.

Thoroughly investigate all reports of counterfeit medicines, and wherever appropriate prosecute and confiscate the assets of those involved.

The MHRA will thoroughly examine all aspects of the supply chain in view of recent incidents of counterfeits reaching patients and make any necessary recommendations for change.

MHRA – An Overview

The Medicines and Healthcare products Regulatory Agency is the Government Agency which is responsible for ensuring that medicines and medical devices work and are acceptably safe.

The MHRA keep watch over medicines and devices and we take any necessary action to protect the public promptly if there is a problem.

AIMS

- Protecting public health through regulation, with acceptable risk benefit profiles for medicines and devices.
- Promoting public health by helping people who use these products to understand their risks and benefits.
- Improving public health by encouraging and facilitating developments in products that will benefit people.

OBJECTIVES

- Maintain rigorous authorisation and inspection programmes
- Maintain and develop pro-active surveillance and enforcement programmes
- Communicate authoritative and reliable information and advice to improve public and professional awareness
- Engage with and influence other Government bodies and European and worldwide regulators concerned with medicines and medical devices.
- Support innovation and product development, offering constructive and impartial advice to scientific communities and health services
- Minimise the cost of regulation so far as is compatible with our public role
- Run a successful business with a skilled and equipped workforce dedicated to the Agency's aims.

Counterfeit Medicine – The Facts

- The World Health Organisation estimates that up to 1% of medicines available in the developed world are likely to be counterfeit. This figure rises to 10% globally, although in some developing countries they estimate one third of medicines are counterfeit.
- Counterfeit medicine is now a truly global phenomenon, at first thought to only affect developing countries, now known to impact upon developed countries.
- Counterfeiters now also target the most lucrative markets, copying high value, high turnover, high demand medicines.
- The UK is not typically a manufacturer of counterfeit medicine, however the UK is a transit point and end user market.
- There have been nine recalls of counterfeit medicines in the UK in the past 3 years, which had reached pharmacy and patient level (Appendix A).
- A further five cases were discovered at wholesale level and seized before they reached the market (Appendix B)
- Counterfeit medicine is more commonly available to consumers via on line pharmacies, the WHO estimate 50% of medicines available from sites which conceal their physical address are counterfeit.
- Counterfeit medicine available in the UK originally focused upon 'lifestyle' medicines, including erectile dysfunction and weight loss medicines. Counterfeiters are now also focusing on 'lifesaving medicines' including Cancer and Heart medicines.
- No fatalities have been attributed to counterfeit medicine in the UK, although numerous fatalities have occurred around the world.
- Counterfeit medicine found in the UK regulated supply chain is frequently designed to deceive pharmacists and patients that it is genuine, often only laboratory analysis reveals the counterfeit product
- Counterfeit medicines discovered in the UK typically contain a reduced amount of the active pharmaceutical ingredient, although the wrong ingredient or no ingredient at all have been found less frequently.
- All counterfeit medicines are dangerous

Medicines - Enforcement and Intelligence Group

The Enforcement and Intelligence (E & I) Group at the MHRA comprises of an Intelligence, Investigations, Prosecutions and Support unit of 42 staff based in London, Welwyn Garden City and York.

The Group has responsibility for the investigation of breaches of the Medicines Act and associated legislation, including the MHRA response to counterfeit medicines available through the regulated and unregulated supply chain.

Enforcement group staff have statutory powers under the Medicines Act 1968 to enter business and private property in the furtherance of their duties and seize articles suspected of being concerned in breaches of the Act and associated legislation.

The Group conduct investigations in accordance with all relevant legislation and submit recommendations for prosecution to Department of Work and Pensions(DWP) solicitors.

The E and I Group are usually engaged in approximately 30 prosecutions at any one time for a range of offences, in addition to this the Group provides support to the Police for any prosecutions they are conducting which also include breaches of the Medicines Act.

Prosecutions can range from cases relating to illegal advertising or sale of unlicensed products heard at Magistrates Courts, through to large Crown court trials concerning global conspiracies to supply counterfeit medicines.

Investigations concerning counterfeit medicine are usually complex, involving networks of companies and bank accounts, often overseas. The individuals concerned have a thorough knowledge of the markets and different countries supply arrangements, procedures and laws. They will often try to exploit perceived weaknesses in supply chain arrangements. The extent of this type of criminal activity is serious and these types of cases are invariably referred to DWP solicitors recommending prosecution.

The MHRA has had to adapt to this rising challenge. The E and I Group now employs specialists in conducting International investigations, financial investigations, crime analysts, internet investigators, disclosure officers, test purchasers, and specialists in the use of the Regulation of Investigatory Powers Act 2000.

The Enforcement and Intelligence Group principally relies upon the offences contained within the Medicines Act 1968, which carry a maximum 2 year sentence and/or unlimited fine. Cases involving counterfeit medicines are also prosecuted using the Trademarks Act 1994 carrying a maximum sentence of 10 years imprisonment and the Proceeds of Crime Act 2002 with a maximum sentence of 14 years. Consideration will now be given to using the Fraud Act 2006 for these types of cases. Civil injunctions have also been relied upon where appropriate.

Counterfeit Medical Devices - The Facts

- The term 'medical device' covers all products, except medicines, used in healthcare for the diagnosis, prevention, monitoring or treatment of illness or disability. The range of products is very wide: it includes contact lenses and condoms; heart valves and hospital beds; resuscitators and radiotherapy machines; surgical instruments and syringes; wheelchairs and walking frames.
- Counterfeiters concentrate on low cost, high turnover, high demand products.
- There are no known cases of counterfeit devices being manufactured in the UK.
- The UK is an end user market or transit point for the products.
- Most UK cases have involved the supply of counterfeit devices direct to consumers rather than healthcare professionals, through small retail outlets.
- Counterfeit medical devices have been seen as commodities used in VAT carousel fraud.
- Cases in the UK that are known to have reached consumers include condoms, and dental material for use in fillings.
- Incidents of counterfeits intercepted before reaching consumers include glucose test strips for use in conjunction with Insulin, and corrective contact lenses.
- Counterfeit devices seized within the UK are usually packaged to a high standard and are difficult to distinguish from the genuine article.
- In the past 12 months there have been 10 reported incidents all concerning counterfeit condoms.
- Counterfeit devices are also supplied through Internet websites
- Unlike medicines, wholesalers do not require a licence to trade in medical devices.
- Counterfeit medical devices are dangerous, they are deficient in terms of quality and performance.

Medical Devices - Compliance Unit

The Medical Devices Compliance Unit has responsibility for implementing and enforcing the Medical Devices Regulations in an effective and efficient way taking appropriate and proportionate action where necessary to correct any breaches identified. In particular:

- a. Complete reviews of a programme of manufacturers and products selected by the Agency for inspection; and
- b. Complete investigations into suspected breaches to the Regulations reported to us by third parties.

Where non-compliances are identified we, will work with the manufacturer to resolve the problem. However, where necessary and justified the MHRA has the powers detailed below to take formal enforcement action against manufacturers (subject to fulfilling various EU obligations).

The Medical Devices Regulations are made under the Consumer Protection Act 1987 and the majority of the powers that can be used in carrying out the enforcement function are also derived from the Act. These include the power to inspect goods, enter premises, require records to be produced, seize and detain goods in order to find out if there has been a contravention of the safety regulations. Then if a contravention is found, to issue notices suspending or prohibiting the supply of the product or as mentioned above if the manufacturer fails to bring the product into compliance voluntarily or adhere to formal enforcement measures to prosecute the offence. We also have additional powers for consumer products available direct to the public under the General Product Safety Regulations which include the power to require a manufacturer to recall faulty product. A successful prosecution under the Medical devices Regulations carries a maximum penalty of a £5,000 fine per offence or six months imprisonment and under the General Product Safety Regulations of a fine of £10,000 per offence or 12 months imprisonment.

MHRA Anti-Counterfeiting Strategy

Objectives

The MHRA will develop and implement strategic and operational measures to minimise the risk of counterfeit medicines and medical devices reaching patients through both the regulated and unregulated supply chains.

Programme of Activity

- To provide reassurance to the public through the provision of balanced accurate and timely information enabling informed choices to be made on how to obtain safe medicines and medical devices.
- To establish and maintain in collaboration with Industry and law enforcement a watch list of the medicines and devices most likely to be counterfeited that target the UK, and focus resources throughout the supply chain against the products most at risk.
- To encourage reporting and continue to investigate thoroughly all referrals to the MHRA of suspected counterfeit medicines or medical devices.
- To enhance and broaden the targeted market surveillance scheme.
- To deliver and constantly update a strategic threat assessment of the availability of counterfeit medicines and medical devices in the UK
- To fully participate in WHO, European Commission and other international initiatives to combat counterfeit medicines and medical devices.
- To disrupt the market for counterfeit medicine and devices in the UK
- To increase the risk of prosecution to those involved in counterfeiting medicines
- To identify the drivers behind this criminality and influence changes in domestic and International legislation to increase the risk to counterfeiters and reduce the market.

Part 1

Communication

It is the over-riding aim of the MHRA to safeguard public health, in achieving this aim effective communication is a critical component.

The provision of easily accessible accurate, timely and specific information is key to the success of this strategy. The public, healthcare professionals, supply chain, Industry and other stakeholders need to be aware of the risks, extent, and availability of counterfeit medicine and devices. Through highlighting the issue and risks involved to both the public and distributors it is possible to undermine the market for counterfeit medicine in the UK.

The MHRA has recently published a communications strategy for the next 3 years, where it sets out the Agency approach to communicating with stakeholders. The aim of the strategy is:

“To help maintain confidence in the regulation of medicines and medical devices by providing timely, necessary and helpful information to healthcare professionals, to the public and to industry, and by ensuring that people know who to turn to if they are concerned”

Counterfeit medicine is an emotive subject, unsurprisingly attracting intense media interest. It is vital to any anti-counterfeiting strategy that a balanced message is communicated to the public. It is easy to alarm patients to the extent that they stop taking medicines that in the vast majority of cases are perfectly safe, with the resulting detrimental effect upon their health. This situation is of course completely counterproductive, however it is important to raise awareness, provide appropriate advice and encourage the reporting of any suspicions in a measured way. A delicate balance has to be carefully reached in conveying a clear message, in a manner that protects patients without causing undue distress. To this extent the MHRA will use all appropriate opportunities through its Communications Division to disseminate information to assist in raising awareness of this issue.

Public Awareness

This strategy does not attempt to educate the public to identify a counterfeit medicine or device, sometimes the counterfeits are poor and easily detectable, but more often they are extremely good copies designed to deceive the patient, visual examination is unlikely to identify the fake and only laboratory analysis will make that determination. The strategy is designed to give the public sufficient information concerning the existence of counterfeits, advice on how best to avoid them and what to do if you are suspicious about any medicine or device.

Media Coverage

- The MHRA will publicise the recall of a counterfeit medicine or medical device when it is suspected of reaching patient level.
- When considering publicity of a recall the MHRA will collaborate with all stakeholders to ensure a clear consistent message is delivered to the public.
- In order to act as a deterrent and provide reassurance that action is being taken, Television, Radio and Newspaper coverage will be actively sought in relation to seizures, arrests, investigations, court proceedings and sentences concerning counterfeit medicine and devices wherever appropriate.
- The Enforcement and Intelligence Group at the MHRA will actively participate wherever possible in contributing to balanced articles identifying the threat posed by Counterfeit medicine
- Consideration will always be given to participating in any documentaries, programmes or articles reporting counterfeit medicine in a balanced and proportionate manner.

Advice

- The MHRA will publish advice and information concerning Counterfeit medicines and devices on their website.
- Any recall of a counterfeit medicine will be published on the website and more widely if necessary
- The MHRA will continue to work together with other regulators and professional bodies in developing and publishing advice for public and key stakeholders, for example, joint guidance is already published by the Royal Pharmaceutical Society of Great Britain and the MHRA.
- Particular audiences will be targeted to increase awareness, for example, specific patient groups or demographic sectors that may be at risk.
- Internet users using auction sites to obtain medicines will be provided with information to understand the increased risks involved in obtaining medicines through the internet.

Reporting Counterfeit Medicine and Devices

- The MHRA have launched a 24 hour hotline to enable the public, healthcare professionals, those engaged in the supply chain and Industry to report directly, and where necessary confidentially to the MHRA, via telephone or through the MHRA website any suspicions that they may have concerning counterfeit medicines or medical devices.

Healthcare Professionals

The MHRA clearly recognises the importance of ensuring that those engaged in caring for patients are aware of the risk posed by counterfeit medicine, and that sufficient guidance is provided in the event that they are faced with such a suspicion.

- Advice concerning counterfeit medicine will be made available to all healthcare professionals through the MHRA website and specialist press.
- The MHRA will continue to support awareness raising by other regulatory agencies and professional bodies, particularly the issuance of guidance to healthcare professionals on what to look for and how to deal with suspected counterfeit medicine.
- The MHRA enforcement group will continue to participate in Healthcare professional conferences to increase awareness to diverse audiences who are most likely to encounter counterfeit medicines.
- The MHRA will continue to encourage healthcare professionals to report suspicions to the Agency for further investigation.

MHRA Combating Counterfeit Medicines Conference 2007

The MHRA is hosting an international conference in London at which this strategy will be launched. The event will be opened by the Government Minister responsible for the MHRA, and has attracted speakers from the WHO and European Commission, law enforcement and regulators. The purpose of the conference is to raise awareness of the International and domestic efforts to tackle this issue.

Part 2

Collaboration

The manufacture and supply of counterfeit medicines and devices is a truly global phenomenon, often facilitated through the internet acting as a worldwide distribution and communication channel with no political or geographic boundaries. Those engaged in this trade are not constrained by international and legal protocols, allowing rapid and effective co-operation between counterfeiters and distributors situated in diverse countries enabling them to maximise the profit generated through the widest distribution of their illicit products.

Close, co-ordinated and active collaboration is required with International and domestic stakeholders in both the public and private sector. This collaboration should deliver both strategic and tactical outcomes ranging from legislative and regulatory review to operational results focused upon safeguarding public health

The issue requires far more than one Government Agency, one pharmaceutical company or one country to attempt to undermine the market in counterfeit medicine and devices. The MHRA will continue to actively participate within the relevant international community, encouraging the flow of information and full co-operation wherever possible.

Equally the MHRA will engage, consult and where appropriate work with industry, particularly in support of targeted market surveillance, awareness seminars, and the sharing of information in support of investigations.

International Engagement

Global

- **World Health Organisation (WHO).** The MHRA will support the newly formed International Medical Products Anti-Counterfeiting Taskforce (IMPACT) primarily through the enforcement working group, in its identified mission to promote and strengthen international collaboration to combat counterfeit medical products.
- **Permanent Forum on International Pharmaceutical Crime (PFIPC).** This Global forum represents regulatory law enforcement practitioners and responsible for the enforcement of medicine legislation, meeting annually to share identified best practice, information, intelligence and emerging global trends in counterfeit medicine activity and other forms of pharmaceutical crime. The forum contributes directly to the WHO, IMPACT enforcement working group
- **Interpol.** The MHRA works closely with the Intellectual property crime programme, and all details of UK counterfeit incidents and investigations are passed to Interpol. The MHRA looks to Interpol to provide a level of co-ordination when faced with investigations and incidents involving numerous countries.
- **Other international programmes.** The MHRA will contribute to any other relevant International initiative focusing upon counterfeit medicines and medical devices which may have an impact on the UK.

Europe

- **European Commission.** The MHRA will support the European Commission in the review of the current legislative framework, concerning counterfeit medicines, medical devices and parallel trade. With a particular focus in relation to enforcement systems, co-operation and communication structures and activities concerning awareness raising. The MHRA will share the lessons learnt from UK investigations involving counterfeit medicines and devices with the Commission, and the trends identified from the intelligence received from all sources.
- **Council Of Europe.** The MHRA actively supports the Council of Europe Committee of Experts on Pharmaceutical Questions through its multi-sectoral Ad hoc group on counterfeit medicines. The overall objective of the committee is to minimise public health risks posed by counterfeit medicines. The MHRA chairs the training sub-group, focusing upon the delivery of training to practitioners engaged in investigative activity. MHRA personnel are preparing training material to be delivered to drug regulatory, police and customs staff from a number of Council of Europe member States in December 2007.
- **The Heads of Medicines Agencies Working Group of Enforcement Officers (HMA, WGEO).** This group reports directly to the European Union Heads of Medicines Agencies Group and comprises of the European practitioners engaged in the enforcement of medicines regulation, including the investigation of counterfeit medicine. This group meets twice annually under the holder of the presidency of the European Union. The MHRA provide the secretariat function to this group. This group co-ordinates joint initiatives, training, risk assessment, research, co-operation, project work and the sharing of information.

Bilateral Cooperation

- The MHRA will continue to develop close bi-lateral relationships with those countries recognised as producers of counterfeit medicine, developing memorandums of understanding with both regulators and law enforcement, focusing on co-operation and information exchange, and wherever possible encouraging operational activity against those engaged in the production and distribution of counterfeit medicines.
- The MHRA will fulfil all obligations in complying with formal International mutual legal assistance requests received from competent authorities for evidence supporting prosecutions against those engaged in counterfeiting medicine.

Industry Participation

Close and effective collaboration with the private sector engaged in the manufacture, distribution and sale of medicines is a vital strand of this strategy. The MHRA Enforcement and Intelligence Group will continue to develop close links with all relevant areas of industry engaged in supplying pharmaceuticals in the interest of safeguarding public health.

The MHRA will continue to develop participation with Industry, meeting with trade associations and individual manufacturers and wholesalers to develop bi-lateral relationships, ensuring communication channels are open and effective.

Anti-counterfeit Stakeholders Group

- The MHRA will invite UK industry trade associations and law enforcement to participate in a twice yearly Anti-Counterfeit Stakeholders (ACS) meeting to share information and intelligence gathered concerning counterfeit medicine and the

threat posed to the UK supply chain. This meeting will result in a watch list of the counterfeit medicines most at risk of being encountered in the UK. This list will be used to increase vigilance and market surveillance of these products from ports of entry through to pharmacies.

Manufacturers

- The Association of the British Pharmaceutical Industry (ABPI) is the largest trade association representing pharmaceutical manufacturers in the UK. The MHRA will continue to participate in the ABPI Anti counterfeiting Group whenever appropriate.
- The Pharmaceutical Security Institute (PSI) represents a number of manufacturers and concentrates efforts upon co-ordinating Industry anti-counterfeiting activity globally. The PSI is a key organisation in plotting global trends, and provides a focal point for information sharing. The MHRA will continue to work closely with the PSI wherever appropriate.

Wholesalers

- The British Association of Pharmaceutical Wholesalers (BAPW) represents the 10 of the largest full line wholesalers in the UK, supplying 90% of medicines to the UK population. Large wholesalers represent a significant link in the supply chain, occupying a critical point prior to distribution to community pharmacies, hospitals and dispensing doctors. The MHRA will continue to work closely with the BAPW, supporting their gold standard of distribution practice, and encouraging continued increased vigilance in their purchase and supply of medicines.

Parallel Importers

- The British Association of European Pharmaceutical Distributors (BAEPD) is the trade association representing 14 of the most active parallel trade companies in the

UK. The MHRA will continue to engage with the BAEPD and support the development of their code of practice, encouraging vigilance within their own operations.

Generic Medicines Sector

- There are no known incidents of counterfeit prescription only generic medicine in the UK regulated supply chain. However this is a common phenomenon elsewhere in the world. The MHRA Intelligence Unit will conduct a study into the likelihood of counterfeit generic medicine entering the UK regulated supply chain, and will seek to liaise closely with the generic medicine sector to assist in this work through the British Generic Manufacturers Association (BGMA).

Postal Services

- The MHRA will continue to develop working relationships with the Royal Mail, in an effort to raise awareness and increase vigilance on the movement and supply of illegal medicines through the various postal services.
- The MHRA will seek to develop liaison with other postal service providers and freight couriers to encourage the reporting of suspicious activity and develop appropriate information sharing agreements.

Security Technology Providers

- The MHRA will continue to monitor the development of new security technology enabling the track and trace of medicines down to individual pack level. The Agency believes that any solution would need to be at a European agreed standard both within Industry and at Governmental levels.

- The Agency continue to support steps taken by manufacturers to protect their product lines which are known to be at risk from counterfeiting with a layer of covert and overt security devices.
- Whilst recognised that the licensed re-packaging of product is permitted, this should be achieved whilst maintaining the integrity of the product and confidence of the consumer.

Devices Sector

- The Devices compliance unit will work closely with the devices Industry to share information, raise awareness and monitor the threats from counterfeit devices.
- A watch list of the devices most susceptible to counterfeiting will be developed and shared with appropriate stakeholders, and used to increase vigilance in respect of these products.

Law Enforcement and Regulatory bodies

The MHRA will continue to engage and enhance co-operation with law enforcement agencies and regulatory bodies. It is important for law enforcement to recognise and understand the threat from counterfeit medicines and to allocate resources where appropriate and necessary. The MHRA work closely with the Police, HM Revenue and Customs (HMRC), and the Serious Organised Crime Agency (SOCA), to ensure that the most recent information and intelligence is made available.

Serious and Organised Crime Agency

- The MHRA will continue to share appropriate information and intelligence with the Serious and Organised Crime Agency, and support any initiatives

concerning those engaged in the counterfeiting and distribution of counterfeit medicines and medical devices.

HM Revenue and Customs

- The MHRA have developed information exchange agreements with Her Majesty's Revenue and Customs to enhance partnership working when combating the availability of counterfeit medicine and devices.
- The MHRA will seek to develop awareness training to HMRC staff concerning the use of the information sharing agreement, the medicines most at risk of counterfeiting, global routes of transit, target profiles and trends of manufacturing, to enable a more focused, risk based approach to vigilance at ports of entry.
- The MHRA encourage joint inspection and visits of those companies suspected of involvement in supplying counterfeit medicines and being engaged in other Customs and Revenue related offences.

Police

- Memorandums of Understanding exist between the Association of Chief Police Officers (ACPO), various Police Forces and the MHRA to facilitate information exchange and where appropriate joint working.
- The MHRA will continue to liaise with the Association of Police controlled drug liaison officers, sharing relevant information, and attending awareness raising conferences and seminars.
- The MHRA will continue to provide in-house training through annual Law Enforcement Officer open days, targeting Police Intelligence Bureaux from all

Police Forces, HMRC, SOCA, Trading Standards, and other appropriate regulatory bodies.

Royal Pharmaceutical Society of Great Britain

- The MHRA has close links with the Royal Pharmaceutical Society of Great Britain (RPSGB) who have responsibility for the licensing, registration and inspection of community pharmacies within the UK. A memorandum of understanding is being developed to facilitate the exchange of information, joint working and increased co-operation. The RPSGB and MHRA have already collaborated on the publication of advice to pharmacies and patients concerning counterfeit medicine.

Trading Standards

- The MHRA, from both the Medicines and Devices groups regularly collaborates with local Trading Standards offices in joint investigations and prosecutions. The MHRA will ensure that Trading Standards offices are aware of the products most at risk of counterfeiting.

Intellectual Property Office

- The MHRA will continue to support the Intellectual Property office in completion of their annual report, and share information concerning counterfeit medicines and devices.

Strategic Threat Assessment

The MHRA Intelligence Unit has the task of assessing the threat from counterfeit medicines and devices to the UK. The unit draws on information provided from a wide range of sources including the public, healthcare professionals, Industry, law enforcement and International counterparts.

MHRA analysts monitor international activity of medicine counterfeiters and assess the potential impact upon the UK. Detailed research is conducted into links with other types of crime, and unusual trends in licence applications.

Each incident in the UK is analysed carefully to understand the modus operandi, identify the methods of manufacture, distribution mechanisms, preferred routes and any weaknesses in the current regulation and legislation.

This research results in evidenced based recommendations for proportionate changes to current arrangements.

- The MHRA Intelligence unit will develop a strategic assessment concerning the threat of counterfeit medicine and devices to the UK.
- Scope the risk to public health from counterfeit medicine and devices
- Scope the economic impact from counterfeit medicine and devices
- The assessment will address the extent of counterfeit incidents and their impact upon the UK regulated supply chain.

- Identify any vulnerabilities or weaknesses in the current system and regulations, and make the necessary recommendations to take forward to Government.
- Research the vulnerabilities arising from the availability of counterfeit active pharmaceutical ingredients (API).
- Analyse in detail why the UK is a target of counterfeiters and how this compares to other European Union (EU) and non-EU countries.
- Conduct thorough analysis of counterfeit medicine incidents to identify the drivers influencing this type of criminality.
- Monitor and identify trends relating to the supply of counterfeit medicine through websites, auction sites and on-line forums.
- Anticipate future trends and emerging threats to both the regulated and unregulated UK supply chain.
- Strategic Threat Assessment findings will influence the future shape of the MHRA Anti-counterfeiting strategy

Targeted Market Surveillance

The identification and monitoring of the medicines most at risk from counterfeiting already on the market ensures a focused, risk based approach to the proportionate monitoring of the regulated and unregulated supply chains.

Following consultation with pharmaceutical manufacturers, wholesalers, distributors, law enforcement, and regulators, a watch list of medicines most likely to be counterfeited for UK supply is compiled. The list takes into account the most recent intelligence available

from around the world, particularly but not exclusively relating to seizures of counterfeit medicines contained in packaging designed for the UK market.

The list is distributed to HMRC, MHRA, RPSGB, Police Controlled drugs liaison officers, and the manufacturers and distributors trade associations. Vigilance is increased in relation to these medicines at ports and throughout the supply chain. Samples will be taken during inspections of wholesalers and pharmacies and tested in the MHRA laboratory.

Regulated Supply Chain – Wholesalers and Pharmacies

A programme of pro-active surveillance of the UK medicines supply chain for the presence of counterfeit medicines was initiated in 2005. To date six market surveys have been completed and a further two are in progress.

Samples are taken from community pharmacies by Royal Pharmaceutical Society of Great Britain Inspectors. Manufacturers participating in the programme have agreed to cover the costs of the samples by providing a stock replacement free of charge. MHRA Good distribution practice inspectors (GDP) also provide samples from wholesale distributors.

Prior to the survey commencing, three reference batches of the sample product from each manufacturing site supplying product into the UK market are provided by the UK licence holder.

The samples are analysed using near infra-red (NIR) spectroscopy and principle component analysis to compare data from the sample analysis with the reference library data of the authentic batch. NIR is a non-destructive analytical technique that has been demonstrated to differentiate the site of manufacture of identical solid oral dosage forms. Irregular or anomalous results from the NIR screening are discussed with the company and followed up with further laboratory investigations where necessary.

Six product surveys have already been undertaken, one of which was a European wide project. Further surveillance programmes targeting the medicines featuring on the watch

list are planned. When the survey of all of the 'at risk' products are completed a rolling programme of surveillance will continue.

Un-Regulated supply chain – The Internet

The products that feature on the watch list are also subject to monitoring on the internet by the MHRA Intelligence Unit, through automated search tools configured to focus on any UK websites supplying the watch list medicines.

Following identification of a website a covert test purchase and analysis is carried out. The test purchase programme is funded from assets confiscated from convicted offenders.

Enforcement Activity

Regulated Supply Chain - Incident Handling

Every report of a suspected counterfeit medicine or medical device is treated as a serious incident and none more so than a report of a suspected counterfeit product within the regulated supply chain.

Reports to the MHRA are directed to the Enforcement and Intelligence Group or devices compliance unit, and will trigger an immediate response, where they are assessed and allocated as a matter of urgency, with the clear emphasis placed upon protecting public health through the seizure, quarantine, analysis and if necessary recall of the counterfeit product.

A cross agency group are immediately convened under the Director of the Inspection and Standards Division. The group comprises of senior representatives from the Enforcement and Intelligence group (E&I), Defective Medicines Recall Centre (DMRC), Inspectorate,

MHRA Laboratory and the Communications Division (Press office). Other specialists or experts are called in depending on the individual circumstances of the case.

Close liaison from the outset is critical with Industry, and any suspected product will urgently undergo laboratory analysis by the genuine manufacturer as well as the MHRA.

Once the suspicious product is confirmed as counterfeit, the extent of penetration in the supply chain is assessed, as is the medical risk to patients. Any counterfeit product which is assessed as reaching pharmacies or patients will be the subject of recall. The DMRC will then issue a rapid alert throughout the supply chain, and to our international counterparts. The MHRA press office will develop a communication strategy in close liaison with stakeholders to engage with the media to ensure a clear, unambiguous, balanced message is delivered to the public and healthcare professionals offering advice and guidance.

Investigation

In parallel with the primary objective of protecting public health the Enforcement and Intelligence group will commence a thorough investigation. The first steps involve establishing the audit trail of the counterfeit product. This invariably requires early consultation with our international counterparts, law enforcement, Interpol and Europol.

This type of investigation is prioritised within the agency with a very clear focus on identifying those persons knowingly engaged in the manufacture, distribution and supply of counterfeit medicines. Investigations into counterfeit medicine are characterised by their complexity, scale, international nature and financial profit. Where individuals are identified the MHRA will work together with the Police and HM Revenue and Customs whenever appropriate. However the MHRA will not hesitate to prosecute alone where sufficient evidence exists.

Any businesses or individuals identified who are suspected of being involved in the distribution and supply of counterfeit medicines who hold a licence issued by the MHRA

will be referred to the Inspection Action Group (IAG). Consideration will be given to the immediate suspension of their licence to trade in pharmaceuticals, pending the outcome of any investigation and subsequent prosecution, and revocation of their licence on successful prosecution. Details of suspensions and revocations will be made available on the MHRA website.

During the course of an investigation concerning counterfeit medicines, MHRA financial investigators will embark upon the task of establishing the scale of profits accumulated during the criminal activity and the identification, restraint and confiscation of offender's assets. Qualified MHRA financial investigators are now attached to regional asset recovery teams in London and Manchester. The confiscation of assets is a strong deterrent against those counterfeiting and supplying medicines and will be pursued in all appropriate cases.

The MHRA Enforcement and Intelligence Group will continue to thoroughly investigate all referrals, information and Intelligence concerning counterfeit medicines occurring within or impacting upon the UK.

Wherever possible and appropriate, evidence will be forwarded to solicitors for consideration of prosecution using the most appropriate legislation. This includes the Medicines Act 1968 and the Trademarks Act 1994 the Proceeds of Crime Act 2002 and the Fraud Act 2006.

At the conclusion of any successful prosecution an application for full recovery of costs is made, and always vigorously pursued.

Unregulated supply chain incidents – Internet

The intelligence unit has responsibility for tackling the availability of counterfeit medicine through on-line pharmacies and internet websites. Specialist search tools are configured to continuously monitor the internet for websites hosted in the UK, or fulfilling orders from within the UK that are supplying suspicious product. These factors bring the case within

the Jurisdiction of the MHRA, sites identified that are operating overseas are referred to the relevant jurisdiction.

Links have been established with on-line auction sites to facilitate the removal and investigation of suspicious product.

Internet Investigation

On receipt of information or identification of a suspicious website, enquiries are commenced to establish who is responsible for the management and control of the site. A test purchase will be made, and on receipt of any product it will be immediately submitted for chemical analysis. If a product is identified as counterfeit liaison will be established with the genuine manufacturer. A criminal investigation will then be launched into identifying the person(s) supplying through the site. The intelligence unit will contact the Internet Service Provider to remove the offending site. Where necessary the MHRA will also pursue civil injunction against persistent offenders.

Internet Days of Action

The MHRA have conducted three internet days of action which have resulted in co-ordinated activity against those websites most active within the UK suspected of breaches of medicine regulation, including counterfeit medicines. During this initiative the Agency has been accompanied by observers from European counterparts and the media in an effort to raise awareness of the increased risk in obtaining medicines from unlicensed websites operated by unqualified individuals supplying sub-standard product illegally.

The MHRA will continue to take action against those websites based in the UK suspected of supplying counterfeit medicines.

Medical Devices

The devices compliance unit will investigate any report of a counterfeit medical device. On receipt of a report any suspect product is removed from the supply chain. An investigation then commences to establish who has handled the product and how it arrived in the UK.

Where appropriate the unit will continue to prosecute those knowingly engaged in the distribution and supply of counterfeit devices to serve as a deterrent to others considering engaging in this type of criminal activity.

Conclusion

Reducing risks to patients – increasing risks to counterfeiters

The success of this strategy is quite simply a reduction in the risk to patients of suffering an adverse reaction to a counterfeit medicine or medical device, and an increase in risk to those engaged in manufacturing, distributing and supplying counterfeits.

Combating counterfeit medicines and devices will remain a priority for the MHRA. Progress in undertaking the programme of activities described in this strategy will be subject to audit.

Appendix A

World Health Organisation Definition of a Counterfeit Medicine

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 correct ingredients, wrong ingredients, without active ingredients, with insufficient quantity of active ingredient or with fake packaging.

Appendix B

Recalls of counterfeit medicines in the UK

1	2004	Cialis	Erectile dysfunction	Discovered by patient	Batch recalled
2	2004	Reductil	Anti obesity	Discovered by large wholesaler	Batch recalled
3	2005	Lipitor	Cholesterol reduction	Information from European Regulator	Batch recalled
4	2006	Lipitor	Cholesterol reduction	Discovered during MHRA investigation	Batch recalled
5	2006	Lipitor	Cholesterol reduction	Discovered during MHRA investigation	Batch recalled
6	2007	Zyprexa	Anti psychotic	Discovered by re packager	Batch recalled
7	2007	Casodex	Prostate Cancer	Discovered during MHRA investigation	Batch recalled
8	2007	Plavix	Anti Platelet	Discovered during MHRA investigation	Batch recalled
9	2007	Plavix	Anti Platelet	Discovered during MHRA investigation	Batch recalled

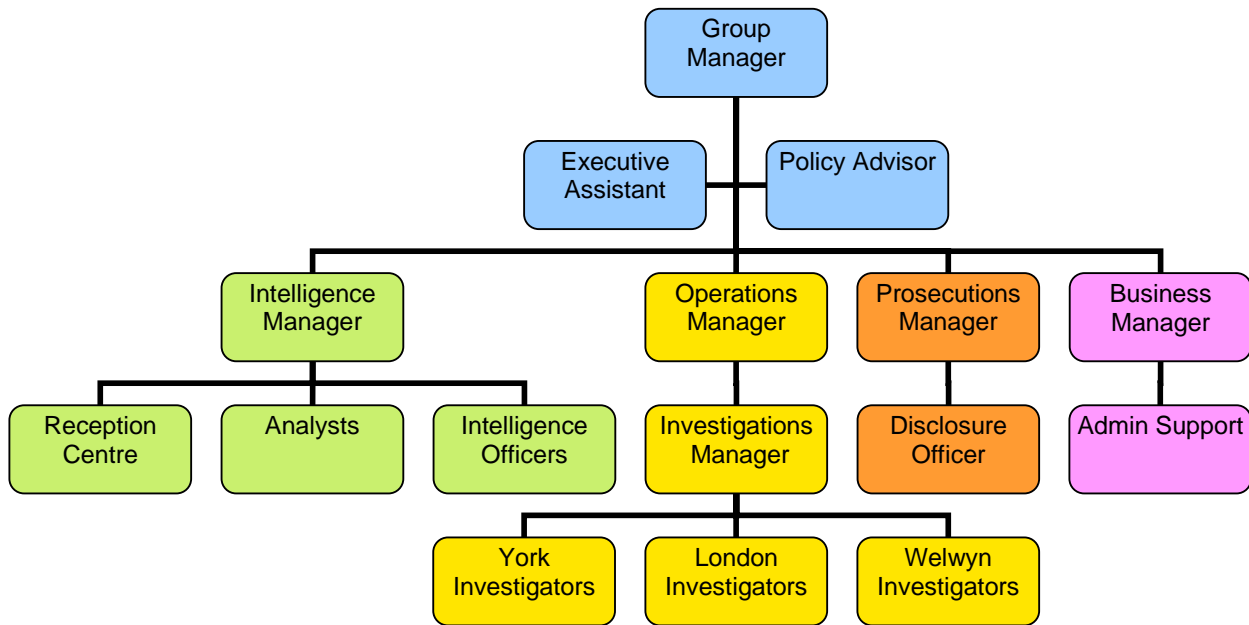
Appendix C

Counterfeits discovered within wholesale chain before reaching patients

1	2005	Cialis and Viagra	Erectile Dysfunction	Discovered during MHRA inspection	Product seized
2	2005	Lipitor	Cholesterol Reduction	Discovered during MHRA investigation	Product seized
3	2005	Celebrex	Arthritis	Discovered during MHRA investigation	Product seized
4	2006	Propecia	Hair loss	Discovered by full line wholesaler	Product seized
5	2007	Plavix	Anti-platelet	Discovered by Industry laboratory	Product seized

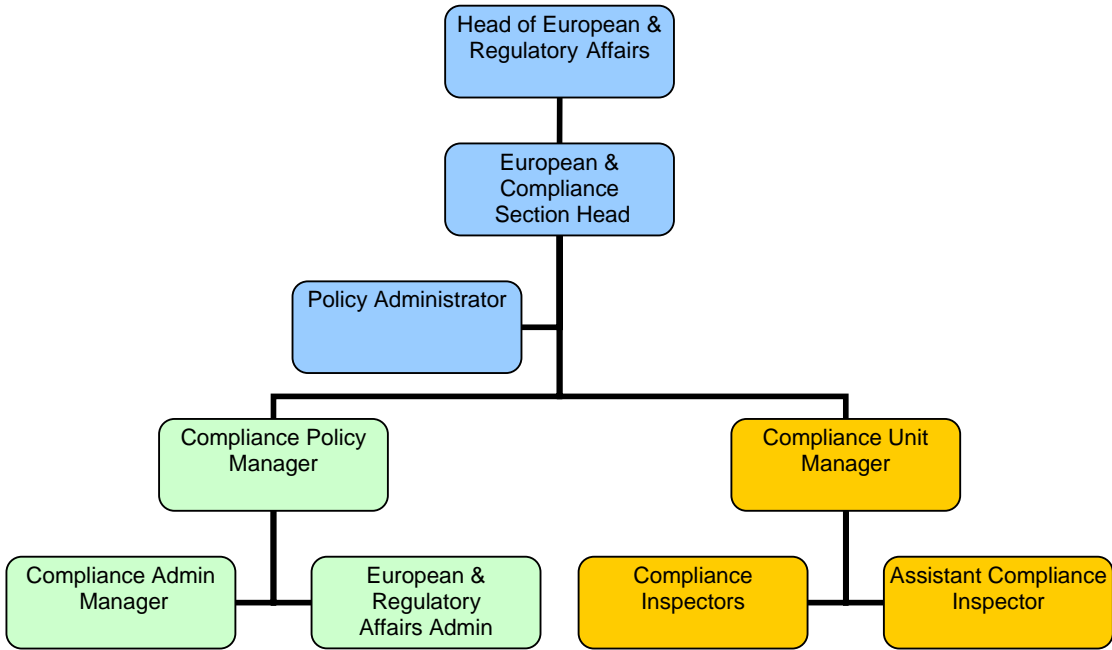
Appendix D

MHRA Enforcement and Intelligence Group



Appendix E

Medical Devices Compliance Unit



Appendix F

MHRA 24 hr Anti-counterfeiting Hotline

www.mhra.gov.uk

+44 (0) 203 080 6701

Glossary

MHRA	Medicines and Healthcare products Regulatory Agency (MHRA)
WHO	World Health Organisation (WHO)
IMPACT	International Medical Products Anti-counterfeiting Taskforce (IMPACT)
ACS	Anti-counterfeiting Stakeholders (ACS)
E & I	Enforcement and Intelligence (E & I) Group
DWP	Department of Work and Pensions (DWP) solicitors
Medical Device	'Medical device' covers all products, except medicines, used in healthcare for the diagnosis, prevention, monitoring or treatment of illness or disability.
HMA, WGEO	Head of Medicines Agencies (HMA), Working Group of Enforcement Officers (WGEO)
ABPI	Association of the British Pharmaceutical Industry (ABPI)
PSI	Pharmaceutical Security Institute (PSI)
BAPW	British Association of Pharmaceutical Wholesalers (BAPW)
BAEPD	British Association of European Pharmaceutical Distributors (BAEPD)
BGMA	British Generic Manufacturers Association (BGMA)
HMRC	HM Revenue and Customs (HMRC)
SOCA	Serious Organised Crime Agency (SOCA)
ACPO	Association of Chief Police Officers (ACPO)
RPSGB	Royal Pharmaceutical Society of Great Britain (RPSGB)
API	Active pharmaceutical ingredients (API)
EU	European Union (EU)
GDP	Good distribution practice inspectors (GDP)
NIR	Near infra-red
DMRC	Defective Medicines Recall Centre (DMRC)
IAG	Inspection Action Group (IAG)