

Falsified Medical Products Strategy

2012-2015

Foreword

I am very pleased to introduce the MHRA's second Anti-Counterfeiting Strategy.

The first was launched in November 2007 as a response to the most serious infiltration of falsified medical products in the UK regulated supply chain which followed a number of previous incidents. On these occasions, the visual appearance of the products concerned convinced dispensers that they were genuine. It was not until expert analysis of the packaging and chemical analysis of the product were conducted that they were found to be falsified.

These serious incidents provided the trigger for the development of a comprehensive strategy aimed at minimising this tangible and worrying threat to public health. The first strategy set out a three strand approach drawing together *communication* with the public and healthcare professionals, *collaboration* with relevant stakeholders and a range of *regulatory* activities to mitigate the threat.

As a result of implementing the strategy in 2007, the MHRA has seen a marked reduction in known incidents of falsified medical products which have penetrated the regulated UK supply chain. In 2009 the MHRA recalled one batch of falsified product on one occasion. In 2008 and 2011 respectively, there were individual incidents of authentic products packed in falsified packaging reaching the UK market which were intercepted at wholesale level before being sold on to pharmacies.

However improved international collaboration has revealed clear evidence that the UK pharmaceutical market is still attractive to counterfeiters. Consignments of falsified high value medical products have been seized en route to the UK and this has shown that those engaged in this activity have employed sophisticated methods of concealment to transport the product across the world. There is no room for complacency; high value medical products with a high turnover combine with large and complex supply chains to maintain the UK as an attractive and lucrative market for falsified medical products.

Incidents of falsified medical products reaching pharmacies are mercifully rare; access to falsified medical products is more common through unregulated websites. This strategy also details the measures taken by the MHRA to tackle this complex aspect, bringing together relevant stakeholders and international partners to combine efforts in raising public awareness and carrying out proportionate enforcement activity.

Efforts to combat falsified medical products call for partnership working and extensive international collaboration. There is clear evidence to show that producers of falsified medical products who have historically targeted their products against the developing world, now also target a broad range of medical products and therapeutic categories across developed markets.

Combating the real and present threat posed by falsified medical products will continue to remain a priority for the MHRA. The Agency remains committed to providing leadership in dealing with this issue to enhance public health and maintaining public confidence in the way we obtain our medical products.

Gerald Heddell
Director Inspection, Enforcement & Standards
MHRA

March 2012

Introduction

The first MHRA Anti-counterfeiting strategy was launched in 2007 against a backdrop of increasing incidents where falsified medical products had breached the UK regulated supply chain. A range of falsified medical products purporting to treat life threatening diseases had reached pharmacies and patients. In addition, MHRA investigators and UK Border Agency (UKBA) officers are increasingly seizing falsified products destined for supply through unregulated websites.

The scale and volume of falsified medical products available throughout the world is unknown and little reliable data exists. Pockets of data suggest very serious situations in some developing countries but due to the lack of an agreed international definition of a falsified medical product and an often reluctance to publicise, no meaningful estimation can be made. The picture in developed countries is also unclear as falsified products are very difficult to detect. However, in the UK significant effort has been expended on assessing the threat and a number of cases have been identified.

In early 2007, 2.1million doses of falsified medicines labelled for the treatment of prostate cancer, heart disease and schizophrenia were imported into the UK and entered the regulated supply chain purporting to be parallel traded products. 700,000 doses reached pharmacies and patients; the remainder was traced and seized by the MHRA or recalled from the market. Following a 3½ year international investigation and a 4 month criminal trial, a former wholesaler / parallel importer was prosecuted successfully and sentenced to 8 years imprisonment.

The overall picture has changed somewhat. The MHRA has issued one recall since June 2007 for one batch of falsified product prescribed for the treatment of chronic asthma. This product was intercepted at a wholesaler's warehouse and no evidence emerged to show that it had reached patients. The wholesaler was investigated, prosecuted and convicted. He was sentenced to 12 months imprisonment.

In 2008 and 2011, there were individual incidents respectively where authentic products were illegally diverted into the EU and packed in falsified outer packaging. These falsified medicines were intercepted at wholesale level before being sold on to pharmacies.

The economic climate has changed drastically since 2007 with exchange rates influencing a reduction in parallel imports of medicines. Parallel exporting has become more evident, bringing a different set of challenges in its wake. In the 2008 and 2011 incidents, the falsified medicines were sold into the EU from the UK, which lends some support to this theory.

Vigilance has increased significantly across the supply chain and at UK ports of entry. Co-operation with UKBA has proved to be particularly effective.

However, MHRA seizures of falsified medicines for supply through the unregulated supply chain (principally through unlicensed websites) have continued. Enforcement activity has intensified and the implementation of co-ordinated international initiatives against those operating illegal websites offering falsified medical products has made an impact. An initiative developed and pioneered by the MHRA has been hugely successful - in 2008, the annual “International Internet Week of Action” known as Operation Pangea was launched and has evolved to become a truly global, multi-sector operation. The 2011 operation was co-ordinated by INTERPOL and involved over 80 countries. The initial exercise was designed primarily as an awareness raising initiative to tackle the *demand* for the online supply of medical products through informing patients and consumers of the increased risks in obtaining medical products from unregulated websites. The initiative has also led to tackling the *supply* aspect through the seizure of millions of doses of illegal medical products, closure of thousands of websites offering medical products illegally and the investigation, arrest and prosecution of hundreds of people across the world.

Since publication of the first MHRA Anti-counterfeiting Strategy, the European Parliament has announced new legislation designed to secure supply chains in Member States and the Council of Europe has finalised the “Medicrime” convention, encouraging its member states to put in place legislation to criminalise falsified medical products. The MHRA has also carried out two public consultations on recommendations drafted as a result of the review of the UK supply chain which was tasked under the previous Anti-Counterfeiting Strategy.

On a global level, there is continuing debate on the future role of the World Health Organization in tackling falsified medical products and a universal definition of what constitutes a falsified medical product. The MHRA will continue to contribute to this debate.

All of these initiatives have a common aim; to deliver a proportionate response to the threat posed by falsified medical products by striking a balance between imposing unnecessary burdens on stakeholders within the supply chain while ensuring public health is properly protected.

Executive Summary

This strategy describes the MHRA approach to combating falsified medical products by building on the success of the first Anti-counterfeiting Strategy (2007) and specifically tackling the issue through three key areas: *prevention*, *incident management* and *investigation* of all reports of falsified medical products.

Incidents of falsified medical products entering the UK regulated supply chain have reduced since 2007. A combination of factors may have contributed to this reduction:

- Fluctuations in the exchange rate - medical products are more expensive in other EU countries and therefore those markets are more attractive to those supplying falsified medical products.
- The MHRA implemented a comprehensive Anti-counterfeiting Strategy in 2007 which raised awareness of the issue.
- Vigilance has been increased throughout the supply chain and at UK ports, the focus being on the medical products known to be at most risk of being falsified.
- The MHRA has embarked upon an aggressive long term public communication strategy highlighting the risks from falsified medical products.
- The MHRA has pursued a number of high profile and successful prosecutions which have resulted in lengthy terms of imprisonment and hefty confiscation orders for those convicted, serving as a deterrent to others.

These factors have also served to markedly increase the risks to those perpetrators involved in the manufacture, distribution and supply of falsified medical products in the UK.

Falsified medical products are more commonly available through unregulated websites. UKBA and MHRA are seizing record levels of falsified medical products destined for supply through unregulated websites. The UK is being used as a transit and fulfilment centre for orders placed on websites hosted and operated from other countries, thereby giving the impression to the end consumer that the product supplied originated in the UK.

A review of the UK medicines supply chain was launched with the first Anti-Counterfeiting Strategy which called for a root and branch review of medicines supply from the point of importation through to the point of dispensing (see Appendix A for more details).

New European legislation designed to strengthen EU/EEA supply chains and minimise the risks to consumers has now been published. This legislation must be implemented by 2013 (see Appendix B for more details).

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Definitions

World Health Organisation

There is currently no agreed international definition of a falsified medical product and this issue continues to be the subject of debate at the World Health Organisation.

European Parliament

The European Parliament in their new Falsified Medicines Directive (Directive 2011/62/EU amending Directive 2001/83/EC) defines a falsified medicine as:

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.*

The definition does not include unintentional quality defects and is without prejudice to infringements of intellectual property rights.

The European Directive (see Appendix B) uses the term 'falsified medicinal product' in order to distinguish falsified medical products from other illegal medical products, as well as products infringing intellectual property rights.

Council of Europe

The Council of Europe defines counterfeit within the Medicrime convention as meaning:

'A false representation as regards identity and/or source'

extending this definition to include both human and veterinary medicines and medical devices (see Appendix C for more details).

MHRA

No specific definition of counterfeit medical product exists within English law and the MHRA adopts the definition contained within the European Falsified Medicines Directive. As a rule, the MHRA will look for clear evidence that there was an intention to deceive a consumer, patient, healthcare professional and/or operator within the supply chain, into believing that the medical product being manufactured offered or supplied was the genuine article when in fact it was not.

The Life Cycle of a Falsified Medicine

The Manufacturer

- Falsified medicines are not manufactured to internationally recognised standards of Good Manufacturing Practice (GMP)
- They are typically produced in very poor conditions in terms of cleanliness and hygiene
- Those engaged in their production rarely have any relevant qualifications but may have some previous connection with the pharmaceutical supply chain.
- Falsified medicines are very rarely manufactured in the UK, with one known case since 2003
- Finished falsified medical products seized in the UK have one or other of the following characteristics:
 - no active pharmaceutical ingredient (API)
 - the wrong API
 - too much API
 - too little API
 - always contain a range of unknown impurities
 - may use inappropriate excipients
 - often fail to dissolve at the correct rate when taken
- The blisters, patient information leaflets, outer packaging and overt security devices are often almost indistinguishable from the genuine article, suggesting access to professional or high quality printing facilities
- They frequently advertise their products on-line
- Access to cheap, often patent infringing APIs determines the ability to manufacture
- They can produce tablets, capsules, injectables, creams and gels
- They frequently interact with brokers who place orders dependent on the demand and their knowledge of the markets in different countries

The Broker

- Brokers frequently act as the middleman between the manufacturer of the falsified medical products and their intended market
- Often contact between the manufacturer and broker is achieved initially via on-line business to business trade forums
- Brokers will acquire genuine product and send to manufacturers to be reverse engineered
- They will sometimes dictate the batch/lot number and expiry date required
- They understand the demand for specialist products in various countries and markets
- They have contacts with licensed wholesalers, but will not normally hold wholesale licences themselves
- They will sometimes supply forged laboratory analysis reports for the falsified product
- They can supply in unusually large quantities and with high regularity
- Prices are often just below market prices but not necessarily unusually so
- Brokers arranging the supply of falsified medicines can be based outside of the EU

The Importer / Wholesaler

- The UK has a large and complex supply chain attractive to those manufacturing and distributing falsified medicines
- Falsified medical products are sometimes smuggled into the UK mis-declared as a range of other articles including vitamins and food supplements
- On other occasions, they enter member states of the European Union, receive Customs clearance and are then transhipped to the UK
- Falsified medical products have entered the UK purporting to be parallel traded medicines
- The most common method of importation is via the post in parcels often containing thousands of doses of falsified medicines destined for supply through unregulated internet websites

- In most cases the holder of a wholesale dealer licence is required to facilitate falsified medicines into the regulated supply chain, this is done either unwittingly or intentionally
- In virtually all of the UK incidents involving falsified medicines entering the regulated supply chain importers / wholesalers have failed to conduct sufficient due diligence concerning the broker or source of the product
- In a number of UK incidents importers/wholesalers have failed to report suspicious offers to the MHRA

The Pharmacy

- Since August 2004 batches of falsified medicines have reached pharmacy level in the UK on 10 known occasions, each time leading to an MHRA recall
- Pharmacists have unwittingly dispensed falsified medicines to patients
- On each occasion the product being dispensed was visually indistinguishable from the genuine product
- There was no means of authenticating the product at the point of dispensing
- There was also no means of establishing if the individual packs of medicine had been tampered with
- It is often very challenging to trace the suspect batch back through the supply chain to point of insertion

The Patient

- A patient being dispensed a medicine by a healthcare professional through the regulated supply chain deserves to have complete confidence that the medicine being dispensed is a genuine product
- Failure to protect the regulated supply chain leads to a loss of confidence in the way medicines are obtained and in the medicines themselves
- Where falsified medical products have reached patients through pharmacies, a patient would have been unable to distinguish the genuine product from the falsified
- Patients sourcing their medicines from websites need access to reliable information concerning the increased risks of products supplied by potentially

unscrupulous website operators in order to make an informed decision on the safest way to obtain their medical products

- The practice of remote prescribing of prescription only medicines via on line consultation questionnaires is open to widespread abuse
- With very few exceptions, it is impossible to identify individual patients who have been dispensed a falsified medicine following an MHRA recall

MHRA Falsified Medical Products Strategy

Aim

The overall aim of this strategy is to reduce the risks to patients and consumers in the UK from the threats posed by falsified medical products while increasing the risk to those behind this illegal activity.

This aim will be achieved through the following approach;

1. **Prevention** - implementing measures to prevent falsified medical products reaching patients.
2. **Incident Management** - ensuring a timely and professional response to incidents involving falsified medical products focused on safeguarding public health.
3. **Investigation** - to use the law proportionately against those involved in the manufacture, distribution and supply of falsified medical products.

1. Prevention

Objective

To reduce the number of falsified medicines entering the UK regulated supply chain

The UK market for medical products is immense (£8,000 million¹ in 2009) and the supply chain to service this demand is complex and diverse. Preventing falsified medical products designed specifically to convince a healthcare professional that they are genuine from entering the market is a difficult task. A combination of communicating the threat, market surveillance and testing, vigilance at UK ports, pharmacovigilance and establishing the public and private, national and international networks to facilitate the exchange of information and co-operation are some of the methods adopted by the MHRA to prevent falsified medical products penetrating our supply chains.

¹ Source: ONS Annual Business Inquiry, Sections C – Manufacturing, Release Date 16/11/2010

Communication

The MHRA will continue to use all appropriate channels to communicate the threats posed by falsified medical products to the public, healthcare professionals and other stakeholders.

Providing the public with sufficient information to make an informed choice as to the safest way to obtain medical products is seen as the key component of this strategy.

The MHRA has used a range of methods to achieve this, including participation in television and radio programmes of a news, current affairs or documentary format. The MHRA has also been involved in television and cinema campaigns highlighting the risks of obtaining medical products from unregulated websites and has issued guidance to pharmacists jointly with the General Pharmaceutical Council.

Raising public awareness of the dangers of sourcing medical products from unregulated websites is aimed at reducing demand from this type of retail outlet and consequently curtailing this marketing route for the supplier of falsified products.

The MHRA will continue to raise public awareness through the provision of accurate and balanced information concerning falsified medical products and how they affect the public in the UK.

An example of an MHRA initiative aimed specifically at raising public awareness of the risks involving unregulated websites is described below in a case study (see also page 26 for more details regarding illegal supply over the internet).

Case Study - Operation Pangea

Operation Pangea is an MHRA initiative which, since its earliest inception as a UK operation in 2006, has grown to involve over 80 countries in 2011 taking measured co-ordinated enforcement action against illegal websites offering to supply falsified and other dangerous medical products. The principal objective of this operation is to raise public awareness and to do so through widespread enforcement activity involving a range of stakeholders.

In 2006 the MHRA began a series of initiatives known as 'Internet Days of Action'. These involved enforcement action being taken simultaneously against a number of active UK based illegal websites. The broadcast and print media was invited to accompany MHRA investigators during investigations which resulted in widespread coverage of the threats to public health from counterfeit and illegally supplied medicines. Four similar initiatives followed. During 2008, the MHRA engaged 8 other countries and invited them to participate in an 'International Internet Day of Action' known as Operation Pangea. This had the effect of extending the activity to these 8 countries and heralded very positive international media coverage.

In 2009 INTERPOL offered to co-ordinate Operation Pangea II from their headquarters in Lyon, France, with the MHRA providing the international secretariat to administer the operation. The

continued/...

operation was extended to a week of action and 25 countries took part with corresponding international media coverage, seizures and arrests.

Operation Pangea III in 2010 saw 44 countries participating with the World Customs Organisation providing support, INTERPOL maintaining the co-ordination function and the MHRA providing the secretariat. Over 2 million doses of illegal medicines were seized across the world, almost 500 websites were taken down and 90 individuals arrested or placed under investigation. Media coverage extended across 17 languages and over 500 television, radio and print broadcasts and articles.

The largest operation (at the time of going to print) took place in 2011, Operation Pangea IV, with over 80 countries participating with the common aim of protecting public health in their respective countries. Over 13,500 illegal websites were removed or suspended and 2.5million doses seized. The pharmaceutical industry, electronic payment providers, domain name registrars and internet service providers together with Police, Customs and medicines regulators have joined together to take effective action against the illegal supply of medicines on the internet.

In the UK, MHRA partnership working with the Metropolitan Police Central e-Crime Unit and the UK Border Agency has proved to be particularly effective.

Whilst the international nature and challenges of the Internet call for collaboration between different agencies and countries, the principal objective of Operation Pangea is to deliver a clear, consistent and accurate message to consumers in terms that outline the significantly increased risks to individual health and personal security when medical products are purchased from unregulated websites.

Regrettably, there have been fatalities which can be attributed directly to medical products purchased on the internet. These are sometimes caused by dangerous products, and sometimes through the unintentional or intended overdose by patients. Enforcement activity alone will not solve this problem, but it is an important component in a range of measures aimed at deterring those persons intending to engage in this illegal activity by targeting their products at UK consumers.

Operation Pangea acts as a catalyst for attracting public interest and allowing targeted public health messages to be delivered to vulnerable groups.

The MHRA will continue to support this successful initiative as a tangible means of communicating a complex and challenging international issue using enforcement activity as a means of raising public awareness.

Collaboration - Anti-Counterfeit Stakeholders Group

Since 2006, the MHRA has convened and chaired a twice yearly meeting of the Anti-Counterfeit Stakeholders (ACS) group whose membership comprises of trade associations for manufacturers (ABPI), wholesalers

(BAPW), parallel traders (BAEPD), generics manufacturers (BGMA) and the Pharmaceutical Security Institute (PSI). UKBA, HM Revenue and Customs (HMRC), Police, and the

General Pharmaceutical Council (GPhC) are also represented.

The objective of this regular forum is to share information and intelligence concerning the seizure of falsified medical products in the UK and overseas, reports of falsified medical products to the MHRA and other regulators, unusual or suspicious market activity and information from industry concerning demand. The MHRA provides an overview of counterfeiting activity primarily seen in the UK and EU in the previous 6 months.

The meeting updates a maintained 'Watch-list' of the medical products determined to be most susceptible to counterfeiting activity based upon the most recent information and intelligence. This Watch-list is circulated to law enforcement

MHRA Market Testing Scheme

The MHRA conducts a testing scheme of medicines that are marketed in the UK. This scheme extends across pharmacies and wholesalers.

MHRA Inspectors and GPhC Inspectors gather samples during routine inspection programmes and submit them to the MHRA laboratory for examination.

agencies, ports, postal hubs, regulators and the pinch points within the supply chain with the intention of increasing vigilance on these specific products. MHRA market and internet surveillance is also focused upon these medical products.

The Watch-list is circulated within the supply chain but is not published more widely. Evidence has emerged that counterfeiters of medical products in other parts of the world have been monitoring the MHRA website and downloading recall notices and information on anti-counterfeiting initiatives to better inform themselves.

The MHRA is committed to continue the Anti-Counterfeit Stakeholders (ACS) Group and develop further methods of identifying those medical products most at risk from counterfeiting.

The products tested align to the Watch-list of products identified during the ACS meetings.

This ensures that vigilance and resources are focused on the products which represent the greatest degree of risk based upon the most recent information available.

The Yellow Card Scheme

The Yellow Card Scheme provides a facility for the public and healthcare professionals to report any side effects and other problems suffered by patients whilst taking a medicine.

The Watch-list of medical products most at risk of being falsified is

provided to the administrators of the Yellow Card scheme for additional vigilance in relation to unusual signals which may indicate that falsified medical products have reached the regulated supply chain.

International Partnerships

World Health Organization

The World Health Organization (WHO) is currently engaged in negotiations with member states as to its future role in tackling the issue of what is currently referred to as substandard/ spurious/ falsely labelled/ falsified/ counterfeit medical products (SSFFC).

The World Health Assembly called for the formation of a member state inter governmental working group to examine the WHO's future role in SSFFC medical products and agree a universal definition. Two meetings have been held in 2011 and some progress has been made. However, an agreed definition of what constitutes an SSFFC medical product has not yet materialised.

The WHO originally provided the secretariat function for the

International Medical Products Anti-Counterfeiting Taskforce (IMPACT). This Group was set up in 2006 and brought together all private and public sector stakeholders to tackle falsified medical products.

Some member states have challenged the WHO mandate to be involved with such an initiative and those discussions are continuing.

The Italian Medicines Agency has held the secretariat of IMPACT on a temporary basis since 2010.

The MHRA supported the aims of the IMPACT initiative and will continue to participate in negotiations at the working group of member states to agree the definition and help ensure the future role of the WHO in this important issue.

Permanent Forum on International Pharmaceutical Crime (PFIPC)

The Permanent Forum on International Pharmaceutical Crime is an international enforcement forum aimed

at protecting public health and safety through the exchange of information and ideas to foster mutual co-

operation. The forum consists of members from 15 countries worldwide and its goal is to enhance the protection of public health by combating pharmaceutical crime.

Membership of PFIPC comprises Medicines Regulatory Agencies and Law enforcement personnel responsible for combating the issue in their respective countries.

Council of Europe

The Council of Europe (CoE) was responsible for the formulation of the “Medicrime” convention (see Appendix C) which was opened for signature in October 2011. The MHRA supports the principle of the Convention and played an active role in its development. CoE has progressed a number of other initiatives to tackle falsified medical products under their European Directorate for the Quality of Medicines and Healthcare (EDQM).

The MHRA has actively engaged with a number of other member states in the delivery of training to over 150 Police, Customs and Regulatory officials within the Council of Europe

European Heads of Medicines Agencies Working Group of Enforcement Officers (WGEO)

The WGEO consists of the 27 Member States of the European Union (EU) in addition to European Economic Area (EEA) countries and a number of international partners and observers.

PFIPC members are active in co-ordinating and participating in international initiatives and providing training in this area.

The International Laboratory Forum on Counterfeit Medicines (ILFCM) is a partner group of PFIPC and specialises in laboratory technology and expertise in testing for falsified medical products.

community who were involved in the investigation of cases concerning falsified and illegal medical products.

This training to front line staff has delivered tangible benefits in raising awareness, increased vigilance, co-operation and investigation of falsified medical product cases.

The MHRA will continue to engage with EDQM in specific projects to tackle falsified medical products and will be delivering an enforcement training program to medicines regulators, police and customs in 2012 during the UK’s Chairmanship of the Council of the European Committee of Ministers.

The working group reports to the European Heads of Medicines Agencies group.

Delegates are a combination of Medicines Regulators, Police and Customs.

The working group meets twice yearly, hosted by the country holding the EU Presidency.

This working group is concerned with fostering closer co-operation and collaboration between member states and tackling the issue of falsified and illegal medical products.

The MHRA provides the secretariat for this group and co-ordinates a Rapid Alert System to highlight detection of

medical products discovered in illicit supply chains.

The WGEO host 5 separate work streams focused on a range of topics aligned to the aims and objectives of the overall group.

The WGEO comprises of the national experts and practitioners in the field of falsified medical products from across Europe and provides an effective network that facilitates rapid response and international co-ordination when incidents of falsified medical products are discovered.

2. Incident Management

Objective

To ensure reports of suspected falsified medical products are investigated in a timely and efficient manner, with the primary focus on minimising the risks to public health

The first priority of the MHRA is to safeguard public health and it is this objective that determines the Agency's actions on receiving a report concerning falsified medical products. Immediate action involves gathering the relevant experts to carry out an initial assessment as quickly as possible. Prioritising actions with a focus on minimising risks to public health is critical. Establishing effective working relationships with other relevant public or private entities is vital, and providing clear, consistent and logical advice to the public are the foundations of managing an incident successfully.

Incident Handling

When a report of a falsified medical product entering the regulated UK supply chain is received by the MHRA,

an Incident Management Team is convened under the chair of the

Director of the Inspection, Enforcement and Standards Division.

This team will comprise of representatives from the Enforcement, Inspectorate, Laboratory Group, Defective Medicines Recall Centre, Press Office, Policy Division and other experts relevant to the type of incident and product involved.

Minimising risk to the Public

The first priority of the MHRA is to protect public health and immediate steps will be taken to quarantine or seize any suspected falsified medical products and to minimise the risk to the public by preventing any further product from entering the supply chain.

Laboratory Analysis

Samples of the suspicious product will be submitted to the MHRA laboratory for forensic analysis and, wherever practicable, also to the manufacturer (Marketing Authorisation Holder) of the genuine product to complete their own analysis.

Medical Assessment

On receipt of laboratory analysis, if results suggest the product is falsified, an assessment will be carried out of the medical risks associated with the falsified product. This will contribute to the level of recall to be conducted if one is deemed necessary.

Assessment of availability

An assessment will also be made in relation to the extent of supply of the falsified product - if it has entered the

regulated supply chain and if so has it reached pharmacy and patient level.

If evidence suggests that the falsified product has reached pharmacy level within the supply chain, a decision to recall the affected batch or batches from the market is likely to be made.

If there is no evidence that falsified products have reached pharmacies, but information suggests that falsified products may be circulating or being offered to wholesalers, the MHRA will contact all licence holders within the supply chain to establish the situation before considering a recall.

Communication Plan

At this stage a comprehensive communications strategy will be drawn up involving the manufacturer (of the genuine product that has been falsified), MHRA and any other relevant stakeholder. The objective of the strategy is to provide clear and consistent information and advice to patients, carers, healthcare professionals and those involved in the supply chain regarding action to be taken in the event that they have handled the affected batches or have doubts or suspicions about medical products which they have been offered, may have taken or are in their possession. Providing an accurate, balanced and clear message is key in reducing confusion, fear and panic – all of which requires careful handling.

Investigation

Whilst steps are being taken to protect public health through the withdrawal of the falsified medical products,

immediate enquiries will also be conducted to investigate the audit trail and supply route of the falsified products. Evidence will be gathered as soon as possible nationally and internationally in order to ascertain who was involved in the distribution and supply of the product. Financial enquiries will also be carried out to trace the payment for the falsified products and evidence obtained to show who has benefited from the sale of the falsified products.

Prosecution

All evidence gathered will be assessed and, where sufficient evidence relating to UK entities exists, a prosecution file will be submitted to Government

Recall of Medicines

The Defective Medicines Report Centre (DMRC) is a unit within the MHRA whose role it is to minimise the hazard to patients arising from the distribution of defective medicines. DMRC provides a 24 hour emergency assessment and communication system between manufacturers, distributors, regulatory authorities and consumers.

In all falsified medical product cases in the UK, the decision to recall a batch of medicines is made following consultation between the DMRC and the marketing authorisation holder (of the genuine product). The MHRA has regulatory powers to enforce a recall; these powers are rarely used provided that the licence holders work openly and closely with the MHRA. The

prosecutors for a decision regarding potential prosecution.

Debriefing

There are inevitably lessons to be learnt from every incident. A careful analysis is conducted of each case involving falsified medical products, identifying areas for improvement in practices, policies and any weaknesses in procedures, regulation and legislation. It is the lessons learnt from these cases that have informed the UK supply chain review and fuelled the negotiations in the European Union Falsified Medicines Directive.

responsibility for managing the logistics of a product recall is usually that of the licence holder.

The MHRA uses an internationally recognised classification system for medicine recalls based upon the perceived level of risk:

Classification

Class 1 - The defect presents a life threatening or serious risk to health.

Class 2 - The defect may cause mistreatment or harm to the patient, but is not life threatening or serious.

Class 3 - The defect is unlikely to cause harm to the patient, and the recall is carried out for other reasons, such as non-compliance with the

marketing authorisation or specification.

In addition there is a 'caution in use notice' which is known as a class 4 drug alert. This is issued where there is no threat to patients nor serious defect likely to impair product use or efficacy. These are generally used for minor defects in packaging or other printed materials.

It is important to ensure close communication, co-ordination and co-operation between the licence holder and the MHRA when conducting a recall. It is a priority for the Agency to

ensure that a clear and consistent message is delivered throughout the supply chain and to patients in a timely and efficient manner.

Any recall involving falsified medical products is undertaken in conjunction with a press release to reach as wide an audience as possible.

3. Investigation

Objective

To thoroughly investigate and where appropriate use all available legislative powers to prosecute those responsible for the manufacture, distribution and supply of falsified medical products

All cases involving reports of falsified medical products to the MHRA are thoroughly investigated. There are two principal avenues of enquiry. Firstly, the origin of the products, which usually involves tracing the product back through the supply chain to the point of insertion. Secondly, tracing the payment for the product back through the various bank accounts through which it has passed. This results in investigations of a complex and international nature. The MHRA will continue to use all legislative powers available to investigate and prosecute those knowingly involved. Following successful conviction, the Agency will seek to confiscate the financial proceeds from the offences committed. Successful prosecutions serve as a deterrent to others but perhaps more importantly, robust investigations help identify the weaknesses in our systems, particularly those which have been exploited. Thorough investigations provide the necessary evidence to drive through proportionate changes to legislation which strengthen our supply chains and make the falsification of medical products a less attractive option for criminals.

Investigation and Prosecution

The MHRA has a well-developed Enforcement group comprising of a Case Referral Centre, Intelligence Unit, Operations teams and a Prosecution Unit. Appropriate legal powers including entry to premises, inspection and seizure are afforded to appropriately trained and authorised staff. The approach to investigations concerning falsified medical products discovered in the regulated supply chain is robust. A thorough investigation is conducted into each incident and, where evidence exists to suggest knowing involvement in the manufacture, storage, distribution or supply of falsified medical products into the regulated supply chain, a prosecution file will be submitted to Government lawyers for a decision on potential prosecution.

Where evidence exists to suggest the knowing involvement by or negligence on behalf of any licensed entity or licensed individual, consideration will also be given to the suspension or revocation of the appropriate licences, removal of *responsible persons*, in addition to possible prosecution.

The MHRA investigates all cases involving allegations of falsified medical products and the illegal supply of medical products through websites that are either hosted in, supplying medical products, accepting payments or fulfilling orders from within the UK.

The MHRA receives reports from the public, healthcare professionals, industry and through its own pro-active investigations. The MHRA will usually conduct a test purchase and arrange subsequent laboratory analysis of any product received. The method of payment will be researched and the recipients traced.

In cases where there is sufficient evidence, the MHRA will use its powers to conduct any necessary inspections and seizures. Routine detailed computer forensic examinations and financial investigations are undertaken to establish the scale, scope and value of illegal activity that has been taking place. Profits accrued from illegal activity will be pursued, restrained and confiscation sought.

The MHRA has successfully prosecuted numerous individuals for supplying falsified medical products through wholesalers, pharmacies and websites and has restrained and confiscated significant assets. The courts have taken a firm line with many offenders receiving custodial sentences.

The table below outlines a UK case involving the largest falsified medicine penetration of the legitimate UK supply chain, which resulted in an 8 year prison sentence for the individual responsible for the illegal operation.

Case Study - Operation Singapore

Between January and March 2007 nine separate importations into the UK of over 2.1 million doses of falsified medicines took place. Seven batches of three medicines for the treatment of prostate cancer, heart disease and psychosis were affected. Although all of the products were contained in French packaging and appeared visually identical to the genuine product, they had in fact originated from the Far East. The MHRA seized 1.3million doses but already over 700,000 doses reached pharmacies, hospitals, care homes and patients.

The MHRA was notified of the incident in May 2007 when a licensed repackager raised the alarm over a suspicious pack of an anti-psychotic medicine. There followed a 3½ year investigation which revealed the extent of a £4 million fraud to flood the UK market with falsified medicines.

The investigation involved 13 countries, resulted in 17,000 pages of evidence and 93 witnesses from 6 countries were required to give evidence at a 4 month Crown Court trial.

The medicines entered the UK supply chain purporting to be manufactured and packaged for the French domestic market, they were posing as parallel traded products and once in the UK were further altered through the addition of a small label known as a vignette, peculiar to the French market, but a detail that had been omitted by the counterfeiter. Through the addition of this vignette, UK wholesalers were convinced that the product had originated in France.

Analysis of the medicines showed that they were all sub-potent with between 50% and 80% of the active pharmaceutical ingredients; they also contained a number of unknown impurities. The MHRA assessed the medical risks as high and instigated class 1 recalls of all seven batches of the three medicines.

The audit trail showed the medicines had been shipped from Hong Kong to Singapore, before being sent on to Belgium where they received customs clearance to enter the European Union. Trucks from the UK would then collect the consignments and deliver them to the warehouse of a licensed wholesaler in Basingstoke where the French vignettes would be applied and the product re-packed into large cardboard boxes. The falsified products were now finished and improved to such an extent that they were now marketable in the UK. From here the medicines were sold via two further licensed wholesalers into the UK supply chain.

The movement of the medicines was being controlled by two 'off the shelf'² companies in Mauritius and a company in Luxembourg. They would also receive payment for the falsified medicines via banks in Belgium, Luxembourg and Mauritius.

Completely independently, the United States Immigration and Customs Enforcement (US ICE) were conducting their own investigation in South East Asia in relation to a Chinese businessman offering to supply medicines in industrial scale quantities. He supplied samples of his product which corresponded to the falsified medicines and batch numbers recalled in the UK. The US authorities then notified the MHRA of the link. The Chinese businessman travelled to the United States to negotiate supplying to the US market and on his arrival was arrested. In his possession was his laptop computer, a copy of which was immediately sent to the MHRA in the UK. Forensic examination proved links with the various 'off the shelf' companies, the falsified medicines, freight documents and photographs of the products subject of the UK investigation.

² 'off the shelf' company refers to a readily purchasable - limited and registered company that meets the necessary legal requirements to be a company in name where the named company officers have no actual direct involvement in the operational running of the company

continued/...

The Chinese businessman, was tried in the United States, convicted of supplying falsified medicines and sentenced to 6½ years imprisonment. MHRA investigators gave evidence at his trial.

In the UK a number of arrests were made and following a 4 month trial the principal offender was convicted of conspiracy to defraud and sentenced to 8 years imprisonment. US investigators of the Kevin Xu case travelled to the UK and gave evidence at the MHRA trial.

This investigation was large and complex by any standard and clearly demonstrated the MHRA response to incidents of this nature. The sentences handed down to those convicted were designed to deter others contemplating similar activity.

Falsified Medical Products and the Internet

Patients and consumers in the UK are much more likely to obtain falsified medical products through illegal websites than through high street pharmacies.

Currently there are no known cases of fatalities in the UK attributed to falsified medical product obtained from the internet, but websites supplying falsified medical products have led to deaths around the world.

However, the threat remains and the MHRA has made frequent seizures of falsified medical products in the UK destined for supply through the internet to consumers here and abroad.

Illegal websites offering falsified medical products are difficult to monitor, quick to disappear, hosted all over the world and the beneficiaries are hard to identify. See table below for further details of how the internet is used a crime facilitator.

Frequently websites appear to be hosted in the UK when in fact they are not. The site may be hosted on a

server in one country, sending the customer order to another, the product will be received from a third and the payment accepted in a fourth. This business model is difficult to deal with, necessitating close co-operation amongst the relevant international stakeholders.

The most common types of products available through illegal websites are so-called “life-style” medicines for the treatment of erectile dysfunction, obesity and depression but a number of other therapeutic categories are also seen, dependent upon demand. Whilst this demand exists and huge profits are a possibility, it is unlikely that counterfeiters will ignore this lucrative opportunity.

Falsified steroids misused by body builders have been seized during MHRA investigations, together with human growth hormones.

The MHRA has successfully investigated and prosecuted a number of persons supplying falsified medical products through illegal websites and has participated in international

investigations to combat this illicit trade. In some cases, financial investigators have uncovered a web of transactions amounting to millions of pounds which have been funnelled offshore.

The MHRA does not believe that enforcement activity alone will solve this problem. A focus on increasing public awareness in the risks posed by unregulated websites and undermining demand, coupled with proportionate enforcement activity is seen as the most effective way forward.

The Internet as a facilitator for the illegal supply of medical products

The internet has provided counterfeiters with a number of important opportunities which have been exploited fully, these include:

- Access to consumers and patients through a global marketplace
- Access to business to business forums enabling the manufacturers of falsified products to advertise the supply of vast quantities
- The ability for counterfeiters and suppliers to communicate across the world through a number of different technologies quickly, easily and confidentially
- Advertisement through SPAM e-mail to millions of individuals
- Ability to establish infinite numbers of websites quickly and easily to provide resilience in their business and avoid disruption by law enforcement
- Relative anonymity in registering websites
- Wide geographic spread of internet infrastructure, causing jurisdictional difficulties to law enforcement
- Access to electronic payment systems to facilitate credit card payments
- Use of global mail and courier networks to deliver and track goods both to suppliers and end users
- Ability to monitor law enforcement and regulatory measures to combat falsified medical products, and alter quickly the flow of product and payments to avoid detection
- The use of offshore companies and bank accounts to launder the financial proceeds of their crimes
- The opportunity for credit card fraud, identity theft and the downloading of malicious software to consumers' personal computers

Test Purchase and Internet Monitoring

The Intelligence Unit within the Enforcement Group of the MHRA deploys specialist software configured to identify websites illegally supplying medical products within the UK or to UK consumers.

The software is also configured to research automatically any products currently listed on the MHRA Watch-list of medical products most at risk of being falsified.

When sites are identified the Intelligence Analysts will conduct test purchases. This can result in a range of outcomes ranging from the receipt of no product, the wrong product, falsified or other unlicensed medicine or the supply of medicines without prescriptions. Often the credit card details used for payment are overcharged, identity stolen and computer malware secretly downloaded on to the computer compromising security.

Once a product is received it is sent to the MHRA laboratory for analysis.

Difficulties arise when servers, internet service providers, hosting companies and payment providers are situated in a number of different countries.

When evidence is obtained of the illegal supply or supply of falsified medical products, and jurisdiction permits action the MHRA will, and often does, prosecute.

When an overseas website is identified with no UK nexus, where the UK is targeted as a customer, the MHRA works closely with the Metropolitan Police Central e-Crime Unit to have the websites closed and locked down or the MHRA refers the case to counterparts in the respective country(s).

MHRA test purchase activity from suspicious websites is funded entirely from the proceeds of crime confiscated from those offenders convicted.

International Law Enforcement

Due to the international nature of investigations involving falsified medical products, the MHRA has found it necessary to engage with several international law enforcement organisations.

INTERPOL

This Police network has a designated unit to tackle pharmaceutical crime and has become the coordinator of

Operation Pangea. INTERPOL coordinates operational activities, provide training and facilitates the exchange of information between the 190 member countries.

Europol

This Police organisation conducts analysis and assists in coordinating joint investigations between European Union member states.

Eurojust

Eurojust facilitates and fast tracks requests for mutual legal assistance between European member states, and convenes case conferences between investigators and prosecutors.

amongst the 177 member Customs administrations.

The MHRA will continue to work closely with any relevant law enforcement agency and develop bilateral working relationships in pursuit of the objectives of this strategy.

World Customs Organisation

The WCO has also become a key stakeholder in Operation Pangea coordinating Customs initiatives focusing on falsified medical products

Conclusion

Falsified medical products is a global issue which requires a global response. The MHRA is committed to tackling the issue of falsified medical products through working with stakeholders in the UK and internationally. This is a crime which presents a real and present threat of harm to patients and consumers. The MHRA will ensure that it continues to pursue and promote initiatives that will minimise the risk of falsified medical products reaching patients in the UK, while increasing the risk to criminals engaging in this illegal activity.

The MHRA calls upon all players and stakeholders to maximise efforts in taking responsibility for ensuring a secure and safe supply chain to best safeguard public health.

MHRA UK Supply Chain Review

In 2008 the MHRA, working together with all relevant Government Departments and the Royal Pharmaceutical Society of Great Britain, conducted a thorough review of the UK supply chain for medicines.

The result of this review was the subject of the first public consultation in December 2008. This consultation was well received and comments assisted in a second, more refined set of proposals which was issued for consultation in November 2009.

Some of the proposals overlapped with negotiations taking place in respect of the European Falsified Medicines Directive. Following agreement to the new directive in European Parliament in 2010, the UK supply chain proposals were amended to avoid duplication and overlap.

The remaining proposals under the supply chain review are now in the latter stages of negotiation. They include:

- Introducing a more rigorous application process for a wholesale dealer's licence, with the right for the MHRA to check on relevant previous convictions and to refuse a licence to anyone who is not a 'fit and proper' person.
- Introducing a new obligation for licence holders to apply appropriate standards in trading in medicines and to report any suspicious events to the MHRA.
- Introducing a more rigorous application process for responsible persons with the right for the MHRA to check on previous criminal convictions and to refuse to register anyone who is not a fit and proper person
- Introducing a new obligation for Responsible Persons to apply appropriate standards in trading in medicines and to report suspicious events to the MHRA.
- Establish clear standards to be developed as a training scheme for Responsible persons and a national public register of qualified Responsible persons which the MHRA will maintain.
- Provide a 2 year transitional period for existing responsible persons to obtain the necessary competence qualification.
- The removal of a current exemption in UK regulations that allows importers of medicines from outside of the European Economic Area (EEA) for export outside of the EEA without an appropriate authorisation.

European Commission Falsified Medicines Directive

The European Commission had concerns with the rise of falsified medicines infiltrating the regulated supply chains and the increase in seizures of falsified medicines carried out at the EU borders. The Commission submitted a set of proposals which have been subject of negotiations and discussions in which the MHRA has participated fully. Lessons learnt from incidents involving falsified medicines in the UK have been shared with EC and EU colleagues and have helped shape the finalised legislation.

Following adoption by the Council and European Parliament the new legislation on falsified medicines was published on the 1st July 2011 in the Official Journal of the European Union.

The legislation will be applicable on the 2nd January 2013.

The legislation focuses upon the following areas:

Brokers

- A broker is defined as a person who engages in all activities relating to the sale or purchase of medicines except for wholesale distribution as defined in the Directive which does not include physical handling of the product and consists of negotiating independently and on behalf of another legal entity or person. Brokers must register their details with the competent authority in the member state where they are established. The register of brokers must be publicly accessible. Persons removed from the register may not broker medicines in the future and new Good Distribution Practice Guidelines will be drafted for brokering.

Wholesale Dealers

- A requirement to report to the competent authority (and MA holder) if they suspect medicines they are trading may be falsified. They will also be required to record the batch numbers of medicines (at least those requiring a safety feature). They must maintain a quality system setting out responsibilities, processes and risk management in relation to their activities. They must verify that wholesalers from whom they purchase medicines hold a valid wholesale dealers licence and comply with Good Distribution Practice.

Active substances and excipients

- Strengthened requirements for control and inspections of facilities manufacturing active pharmaceutical ingredients and certain excipients. Manufacturers of pharmaceuticals will need to verify compliance with Good Manufacturing and Good Distribution Practice of suppliers of APIs and certain excipients through the conducting of audits.

Medicines imported into the EU for export to third countries

- Persons importing medicines from a 3rd country outside of the EU for re-export to a 3rd country outside of the EU must hold an authorisation, or registration if brokering, with the competent authority. A new term of 'introduced' is used to describe medicines imported into the EU but not intended to enter free circulation within the EU.

Safety features

- There is a requirement for the application of an obligatory authenticity feature on the outer packaging of the medicines. This feature is a unique identifier which allows verification of the authenticity of the medicinal product. The obligation applies to all prescription medicines with the possibility of exceptions if a risk assessment has shown that the particular product is not at risk. Over the counter medicines will normally be excluded unless evidence exists to show a specific product is at risk from counterfeiting.

Internet Supply of Medicines

- Internet supply will only be undertaken by persons entitled to supply medicines to the public. They must be registered to do so and have a permanent address. The website must include details of the supplier and link to a national website bearing an EU logo. Member states may restrict internet sales of medicines under national legislation. Each member state must have its own national website listing those entitled to supply medicines to patients and consumers. There is an obligation placed upon member states to conduct information awareness campaigns on the dangers of falsified medicines and of illegal internet sales.

Strengthening Inspections and appropriate penalties

- Closer co-operation between member states and the European Medicines Agency is encouraged in respect of inspections. A clear obligation is made for the inspection of brokers, wholesalers and manufacturers of active substances and excipients in the EU and 3rd countries. An EU database containing GMP and GDP certificates, registrations of importers, manufacturers and distributors of active substances will be established. There is also an explicit obligation on Member States to introduce penalties for infringements of the Directive's provisions that are effective, proportionate and dissuasive.

The MHRA is now working on the implementation of the Directive and will work together with stakeholders to ensure a smooth transition from January 2013.

Council of Europe Medicrime Convention

The Council of Europe convention on the counterfeiting of medical products and similar crimes involving threats to public health has been published and offered to the 47 member states and some observer countries for signature in October 2011.

The UK has not yet in a position to sign the Convention but is working with Government lawyers and other Government Departments to resolve any outstanding issues.

The Convention is designed to address counterfeit medical products through penal sanctions, preventative measures, the protection of the rights of victims and promotion of international co-operation on counterfeiting and similar crimes.

The focus of the convention is specifically on the protection of public health and does not cover infringements of intellectual property rights, it includes:

- The manufacturing of counterfeit medical products
- Supplying, offering and trafficking in counterfeit medical products
- The falsification of documents
- Co-operation amongst authorities
- Preventative measures

This Convention is designed to encourage member states to ensure that they have adequate legislation in place to combat the threat of counterfeit medical products and is part of a series of Council of Europe initiatives targeted at this issue (see International partnerships).

The Convention applies to human and veterinary medicines and medical devices and will be open to signature from non-member states at a later date.

The MHRA participated in the negotiations during the development and drafting of this Convention and sees it as an extremely useful tool both for countries developing a response to this issue and those that have been dealing with the problem but have inadequate legislation in place.

Frequently Asked Questions

- **Are falsified medical products dangerous?**

Toxic ingredients leading to poisoning and sub potent products failing to treat the disease for which they were dispensed have led to thousands of deaths worldwide. No known fatalities attributed to falsified medical products have occurred in the UK.
- **What do they contain?**

Falsified medical products in the UK typically contain a reduced amount of the active pharmaceutical ingredient. They are therefore sub potent and are often contaminated with other unknown impurities and do not dissolve properly.
- **Where are they made?**

It is very rare for falsified medical products to be produced here in the UK. Most falsified medical products discovered in the UK originated in Asia and particularly the Far East.
- **How are they made?**

Cases around the world demonstrate consistently the unhygienic and poor conditions in which falsified medical products are produced. This has also been seen in the rare cases of manufacturing discovered in the UK.
- **Are they only available on the internet?**

They are more commonly supplied through unregulated websites, but more unusually they have been discovered in the UK supply chain at wholesaler and pharmacy level.
- **How can I be sure an on line pharmacy is safe?**

Some on-line pharmacies bear the green cross logo of the General Pharmaceutical Council. This means that the pharmacy is registered and is associated with a physical pharmacy subject to regulation. Websites concealing their physical address or offering prescription only products without a prescription should be avoided.
- **Do falsified medical products get into high street pharmacies?**

On 10 known occasions since 2004 falsified medicines have reached pharmacy and patient level.
- **How do they enter the supply chain?**

The UK has a very large, complex, and strictly regulated supply chain. For a falsified medicine to enter the supply chain the holder of a wholesale dealers

licence has either been deceived, acted deliberately or negligently to facilitate the product's entry onto the market.

- **How much of this is out there?**

There are no reliable global statistics available; some specific studies in developing countries have highlighted certain types of medicines and the level of falsified products. The WHO is embarking upon a global monitoring and surveillance project in an effort to measure the scope, scale and extent of the issue.

- **What types of medicines are affected?**

The most commonly falsified products found in the UK are medicines for erectile dysfunction and weight loss, However heart, cancer, anti-psychotic, anti-depressants, anti-cholesterol products have also been discovered by the MHRA in the UK.

- **How can you tell the difference between genuine and fake?**

Falsified medical products come in many shapes and forms, some are easily recognisable but others are visually identical to the real thing. Only laboratory analysis will determine the genuine from the fake.

- **What can be done to prevent this happening?**

The MHRA launched an Anti-counterfeiting strategy in 2007 and has published a new edition in 2012 called the Falsified Medical Products strategy setting out the measures taken to reduce the risk from falsified medical products.

- **Are medical devices falsified?**

Yes, falsified diabetes and HIV test kits, as well as condoms and contact lenses are known to have been falsified.

- **What should I do if I have a suspicion a medical product is falsified?**

Firstly consult with your pharmacist, there may be an explanation.

Secondly if still suspicious contact the **MHRA Anti Counterfeit hotline on +44 (0)20 3080 6701 or e-mail counterfeit@mhra.gsi.gov.uk**

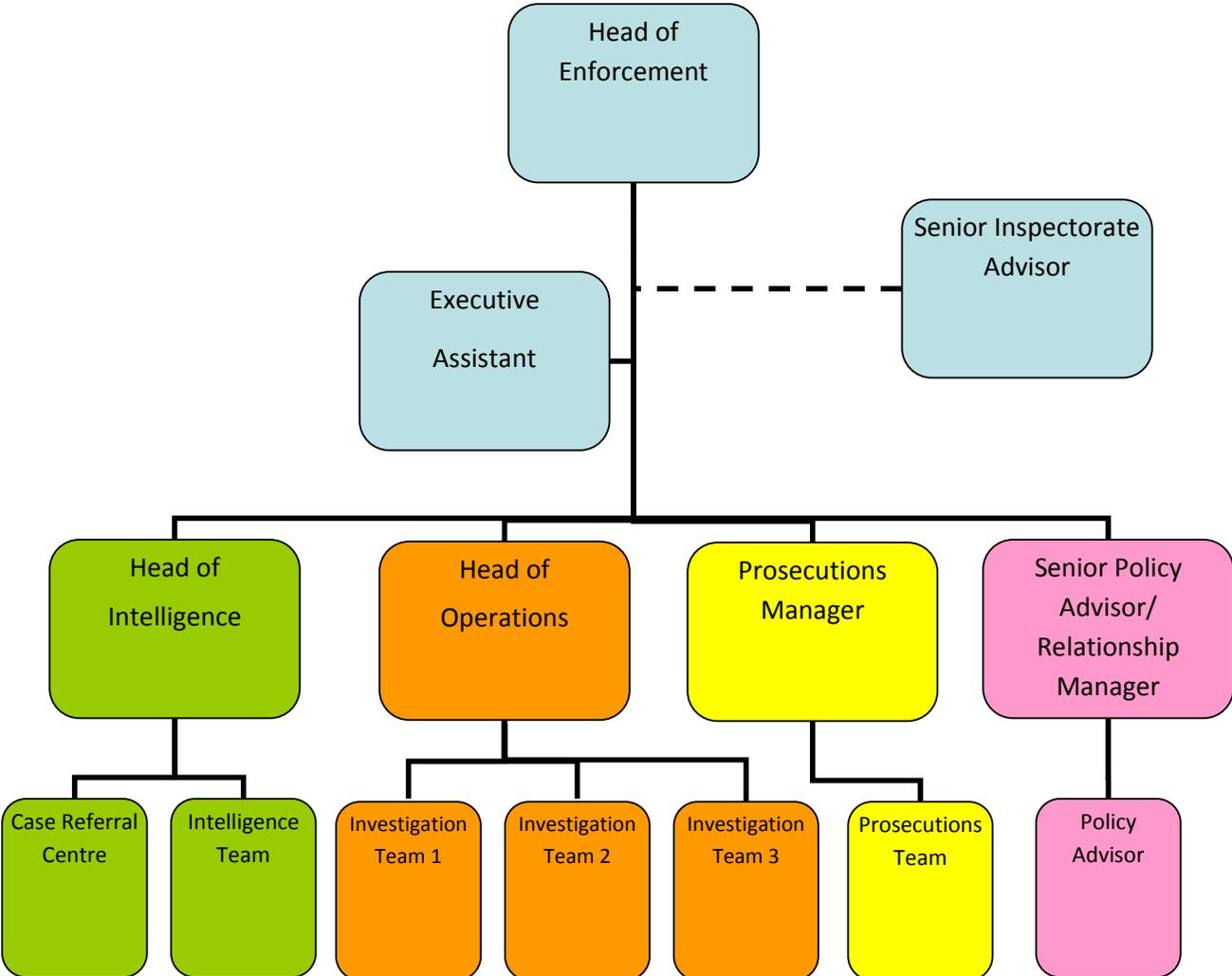
Falsified Medicines recalled in the UK 2004-11

	Date	Product	Indication	How discovered	Action
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 a 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 repackager	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
10	2009	Seretide Evohaler	Asthma	Information from a European Customs office	Batch Recalled

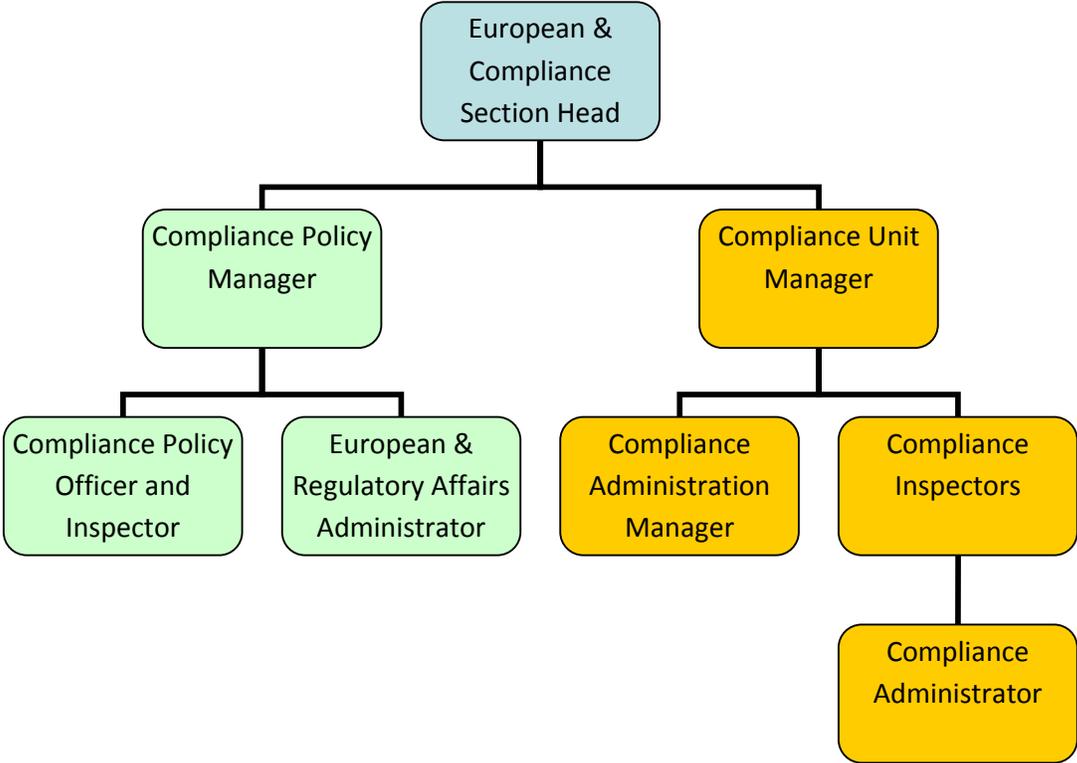
**Other Falsified Medicines in the UK regulated supply chain 2004-11
(did not reach patients in the UK and therefore not recalled)**

	Date	Product	Indication	How discovered	Recall	Comments
1	2005	Cialis/Viagra	Erectile Dysfunction	MHRA	N	Seized before reaching patients
2	2005	Lipitor	Anti-cholesterol	MHRA	N	Seized before reaching patients
3	2005	Celebrex	Arthritis	MHRA	N	Seized before reaching patients
4	2006	Propecia	Hair Loss	Wholesaler	N	Seized before reaching patients
5	2007	Plavix	Anti-platelet	Industry Laboratory	N	Seized before reaching patients
6	2008	Enbrel	Rheumatoid Arthritis	Marketing Authorisation Holder	N	Seized before reaching patients. Diverted authentic product in falsified packaging
7	2011	Truvada and Viread	HIV	Licensed re-packager	N	Seized before reaching patients. Diverted authentic product in falsified packaging

Enforcement Group (medicines)



European & Regulatory Affairs Compliance Section (devices)



MHRA Anti-Counterfeiting Hotline

To report a suspected falsified medical product or suspicious approach relating to the sale/supply of falsified medical products, please contact by email or telephone:

MHRA 24 hr Anti-Counterfeiting Hotline:

counterfeit@mhra.gsi.gov.uk

+44 (0) 203 080 6701

www.mhra.gov.uk

Glossary

ABPI	Association of the British Pharmaceutical Industry
ACS	Anti-counterfeiting Stakeholders Group
API	Active Pharmaceutical Ingredient
BAEPD	British Association of European Parallel Distributors
BAPW	British Association of Pharmaceutical Wholesalers
BGMA	British Generic Manufacturers Association
DMRC	Defective Medicines Report Centre
EC	European Commission
EDQM	European Directorate for the Quality of Medicines
EEA	European Economic Area
EU	European Union
EUROPOL	European Police Organisation
GDP	Good Distribution Practice
GMP	Good Manufacturing Practice
GPhC	General Pharmaceutical Council
HMA	Heads of Medicines Agencies
HMRC	Her Majesty's Revenue and Customs
IMPACT	International Medical Products Anti-counterfeiting Taskforce
INTERPOL	International Police Organization
MA	Marketing Authorisation
MHRA	Medicines and Healthcare products Regulatory Agency
PFIPC	Permanent Forum on International Pharmaceutical Crime
PSI	Pharmaceutical Security Institute
SSFFC	Substandard/Spurious/Falsely labelled/Falsified/Counterfeit
UKBA	United Kingdom Border Agency
US ICE	United States Immigration and Customs Enforcement
WCO	World Customs Organisation
WGEO	Working Group of Enforcement Officers
WHO	World Health Organization