



ASSOCIATION OF THE BRITISH PHARMACEUTICAL INDUSTRY

ABPI White Paper on Counterfeiting

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1 Executive Summary

The issue of counterfeit medicine has emerged as a serious and potentially damaging issue for patients, industry, the National Health Service (NHS) and the Department of Health (DH). It is likely that the problem of counterfeit medicine in the supply chain is far deeper and more insidious than we anticipate. Lilly's experience in 2004 and Pfizer's in 2005 demonstrated that counterfeit products can go undetected for some time and often discovery is a case of luck rather than detection.

The issue of counterfeit medicines has implications for the good name of the industry and significant consequences for patients.

Patient groups support the position of the industry that counterfeits are a threat to patient safety and would like industry and the MHRA to tighten the supply chain and develop policies and procedures that will help eliminate counterfeit products entering the supply chain.

Developed countries are being targeted by counterfeiters as medicines command a high price and counterfeiting is therefore a highly profitable operation with low risk.

The pharmaceutical industry is deeply concerned about the threat posed by counterfeit medicines. The most obvious danger is the risk to patient safety. Counterfeits do not always contain the appropriate levels of active ingredients and are often produced in shockingly substandard manufacturing operations. If deaths or serious illness in patients is linked to counterfeits that have been dispensed through the legitimate supply chain, the impact on public confidence in the entire health system – in pharmacies, GPs, hospitals as well as pharmaceutical wholesalers and manufacturers - could be huge and long lasting. The industry, through the ABPI, has established a working group on Illegal Trade in an attempt to focus the industry's response to this issue.

The UK supply chain has few restrictions and is inadequately protected (or policed). Combined with the (legal) free movement of goods throughout the EU suppliers are able to obtain fraudulent product from any unscrupulous source for trading, unchecked throughout Europe.

In recognition of the problem the ABPI has set up an Anti-Counterfeiting Group to examine the issues involved and make recommendations for industry. This group is working with other stakeholders and taking evidence from all parts of the supply chain in order to formulate "advice to industry" that will form the basis for this document.

2 Patient safety

Medicines are designed to alter the course of a disease and improve patients' quality of life. It goes without saying that anything that compromises this is incompatible with the highest standards of ethics that the industry imposes on itself.

The risks to patients from illegal trade vary from the inconvenient to fatal. At one end of the scale medicines that have been illegally diverted but contain active ingredient may only marginally affect the patients' immediate wellbeing in a very minor way. At the other end of the scale are manufactured fakes that contain no active ingredient and may contain something that is actually harmful. As the seriousness increases, the effects can be catastrophic. In this paper we have highlighted the cases of patients with malaria dying because they are not getting any active treatment. This is all the more serious because they are paying for medicines that they think are effective.

The pharmaceutical industry is constantly seeking methods to counteract counterfeit trade in medicines.

3 Overview of the Illegal Trade Problem

3.1 Definition

The World Health Organisation defined counterfeits as:

Old Definition

"Counterfeit medicines are part of the broader phenomenon of substandard pharmaceuticals - medicines manufactured below established standards of safety, quality and efficacy. They are deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit medicines may include products with the correct ingredients but fake packaging, with the wrong ingredients, without active ingredients or with insufficient active ingredients"

See: <http://www.who.int/mediacentre/factsheets/fs275/en/>

WHO Background Paper: <http://mednet3.who.int/cft/>

New Definition (2006)

"• counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging."

See: <http://www.who.int/medicines/services/counterfeit/overview/en/index.html>

Counterfeiting, which can apply to both brand name and generic medicines, means that a product is deliberately and fraudulently labelled in a way that suggests that it is the authentic, approved product made by the genuine manufacturer. Counterfeit products may include medicines made:

- without the active ingredient
- with an insufficient or excess quantity of the active ingredient
- with the wrong active ingredient
- with fake packaging
- with incorrect labelling or administration instructions

Counterfeit drugs are unlikely to be as effective as genuine products. A patient who takes a counterfeit medication may be at risk from a number of dangerous health consequences. Patients may experience

allergic reactions, unexpected side effects, or a worsening of their medical conditions. In the worst cases, these drugs could be hazardous to human health or even fatal.

The World Health Organisation (WHO) estimates that up to 10% of medicines worldwide may be counterfeit, costing the pharmaceutical industry about \$2 billion annually.

Well over 100 cases of counterfeit medicines are investigated each year by the MHRA.

3.2 Background

The estimation by the World Health Organisation of up to 10% of medicines worldwide might be counterfeit could cost industry around \$2 billion a year. This estimate has however been reassessed in 2006 and the WHO now says:

“Analysis shows that counterfeiting is greater in those regions where regulatory and legal oversight is weaker, and therefore:

- § *Most developed countries with effective regulatory systems and market control (e.g. USA, EU, Australia, Canada, Japan, New Zealand) currently have a very low proportion, i.e. less than 1% of market value. However, we must keep in mind that indications point to an increase in the prevalence of counterfeit medicines even in developed countries;*
- § *Many developing countries of Africa, parts of Asia, and parts of Latin America have areas where more than 30% of the medicines on sale can be counterfeit. Other developing markets, however, have less than 10%; overall, a reasonable estimate is between 10% and 30%;*
- § *Many of the former Soviet republics have a proportion of counterfeit medicines which is above 20% of market value -this falls into the developing country range;*
- § *Medicines purchased over the Internet from sites that conceal their actual physical address are counterfeit in over 50% of cases.“*

This is money that could be invested in discovering new medicines. The patient is exploited by these traders twice over.

Counterfeiters are not constrained by the type of product although they do concentrate on areas where they can make as much money as possible. Products of counterfeiters have included:

- § antibiotics,
- § hormones,
- § analgesics,
- § steroids,
- § antihistamines,
- § anti malarial
- § anti obesity drugs
- § lipid lowering products

In fact it would appear that no product area is immune from counterfeiting.

Counterfeiting hits the developing world most because they lack any sophisticated detection or prevention measure and therefore perpetrators are less likely to be caught. It has been estimated that as much as 40% of medicines in these countries can be illegal. However developed markets suffer too as

demonstrated by the recent cases of counterfeit medicines discovered in the US supply chain including Lipitor, Neupogen, Serostim, OxyContin and others

This is a highly lucrative activity. The counterfeiting of this high value, high volume products provide an economic incentive for criminal activity with little or no consequences for the perpetrator. Their activities in the United States of America have affected patient confidence. Some patients are actually taking out lawsuits against distributors and pharmaceutical manufacturers.

Applying the WHO statistics (of 10%) to the UK would have equated to 82 million packs of medicines that are not genuine. This is clearly not the case. Inspections by the MHRA indicate that the incidence in the UK is a lot lower (probably under 1%).

However based on a very small percentage of 0.1% that still amounts to 825,000 packs a year and rising. The main targets of the counterfeiters are the high value products and we have seen several examples over the last few years. Taking the top 50 UK products and their relative UK sales at an average price of £50 per package, the counterfeiters are defrauding the NHS and taxpayer of £42.5million pounds per annum.¹

Illegal trade embraces direct copying of real product to hijacking of product on its journey to the patient and includes the following:

- Copies attempting to look like the genuine product
- Illegal imports, either from a non-approved supplier or manufacturer or where the active ingredient has not yet been approved for use in another country
- Illegally relabelled products: sometimes this is to extend the shelf life of short-dated products or to re-label the product with a label indicating a higher strength, which can be sold for more
- Substituted or diluted product: increasing the quantity in the original batch by addition of counterfeit product
- Diverted product includes: product supplied overseas (at reduced cost) under access to medicines schemes. These do not reach intended patients but are diverted to a market commanding a higher price. In other markets pharmaceutical manufacturers supply free samples to hospitals which can end up being sold to patients
- Stolen product: here the product is genuine but not legally owned by the seller. Problems can arise from storage and shelf life of the product especially if the product should be kept a low temperature as is the case with products such as vaccines.

Each of these methods is used by the fraudsters to capitalise on the opportunity to make money.

3.3 Sources of illegal trade

Counterfeit medicines come from a wide variety of sources. Some product is manufactured directly by factories in India, China and the former Soviet Republics and even locally for example the recent case of Viagra which was found in an illegal factory in Wembley in the UK. These factories sometimes produce copies of the real ingredients exploiting the originators intellectual property, most do not. All of these so called factories however are uncontrolled and do not have the same standards of hygiene and good manufacturing practice that govern the originators.

¹ Source, IMS Data

Much of the product destined for the 3rd world however does not even contain original ingredients and a recent BBC programme entitled bad medicine highlighted how the unscrupulous traders were supplying vials which should have contained adrenalin and contained nothing more than water. Doctors literally watched their patients die in front of them.

Often the trade in pharmaceuticals is carried out by offenders who literally make up the product in their garage or garden shed. In a recent case involving fake Viagra, the fraudster was making the product in his so called laboratory. Allen Valentine was convicted of running one of the biggest counterfeit drug rings in Europe. When his Wembley “factory” was raided, police found fake medicines worth £6 million and a laboratory capable of producing half a million pills each day.

The Internet Pharmacy is providing counterfeiters with an unfettered outlet for fake medicines. Internet pharmacies are simple to set up and difficult to police. Patients seeking their medicines through these websites are knowingly putting themselves at risk.

Parallel trade can be a conduit for illegal medicines entering the supply chain since the law allows traders to repackage the products. Either the medicines can enter via this channel or the empty packaging can be sold and used to mask counterfeit medicine. It is recognised that parallel trade is legitimate and their trade body has developed guidelines for good practice. Nevertheless all precautions must be taken to ensure that parallel trade does not become the main route for illegal trade.

The process of parallel trade, whereby medicines originally intended for use in one country e.g. Spain, are diverted to another country e.g. the UK, may significantly undermine the integrity of the supply chain. Commercial middlemen trade 140 million medicine packs across borders every year in the European Union.² 70% of these re-packaged medicines are destined for the UK³. All of these medicines are opened, any tamper-evident packaging removed and the foreign patient information leaflet (PIL) is discarded. The medicine blister strips are also removed and stickers are placed on them identifying the product in English (for the UK, Swedish in Sweden etc.). The blister strips are then repackaged with a new PIL in a new box or the original manufacturer’s box, which is often 'over-stickered' identifying the product in the destination language. There are three principle concerns:

- § Human error in the re-packaging process.
- § Batch re-call is hindered by the movement of these medicines around Europe.
- § Counterfeits are given a vehicle to enter the legitimate supply chain.

There are a number of ways in which counterfeits can enter the supply chain. Products will enter the supply chain at any point of weakness between the manufacturers and the patient. This may involve Web Pharmacies, short line wholesalers or even major wholesalers who may believe they have purchased legitimate product.

Parallel trade whilst being a perfectly legitimate business is also recognised as a conduit for counterfeits to enter the legitimate supply chain as revealed in an article published in the Netherlands in October 2004⁴. This article involved the Dutch Regulatory Authorities, the parallel trader and the pharmaceutical company involved building a definitive case study. A case study provided by Pfizer also indicates this potential.⁵

² MacArthur, D., European Association of Euro-Pharmaceutical Companies, quoted in ‘Parallel Trade in Medicines’, Social Market Foundation, June 2004.

³ Haigh, J., IMS Global Consulting, quoted from SMF seminar

⁴ **Nep-Cialis bevat sildenafil**, 1 oktober 2004 • Jaargang 139 Nr. 40 • Pharmaceutisch Weekblad

⁵ Pfizer case study (see annexe

3.4 Consequences

The consequences of illegal or counterfeit trade can be devastating. As the BBC programme “Bad Medicine” highlighted in the case of the children undergoing heart surgery (for which their was an excellent prognosis) the doctors and parent had the heart breaking experience of watching their children die in front of them because the medicine (in this case adrenaline had been exchanged for something inactive.

In Africa and India thousands of patients are dying from malaria because, according to the WHO, up to 40% of their antimalarial drugs are counterfeit. The further devastating consequence of this is that substandard drugs build up resistant strains of the disease which is then almost impossible to eradicate using the standard drug regimens.

At best, the regular use of substandard or counterfeit medicines leads to therapeutic failure or drug resistance; in many cases it can lead to death.

In Niger in 1995,⁶ during a meningitis epidemic, over 50 000 people were inoculated with fake vaccines, received as a gift from a country which thought they were safe. The exercise resulted in 2,500 deaths.

Haiti 1995; India in 1998⁷ Paracetamol cough syrup prepared with diethylene glycol (a toxic chemical used in antifreeze) led to 89 deaths in Haiti in 1995 and 30 infant deaths in India in 1998.

Worldwide⁸ Of the one million deaths that occur from malaria annually, as many as 200,000 would be avoidable if the medicines available were effective, of good quality and used correctly.

South-East Asia in 2001⁹ a study revealed that 38% of 104 antimalarial drugs on sale in pharmacies did not contain any active ingredients and had resulted in a number of preventable deaths.

Cambodia in 1999¹⁰, at least 30 people died after taking counterfeit antimalarials prepared with sulphadoxine-pyrimethamine (an older, less effective antimalarial) which were sold as Artusenate.

Nigeria 1990: A cough mixture “diluted” with poisonous solvent. Over 100 children die.

Mexico 1991: Thousands of samples of an ointment for burns contain sawdust.

Bangladesh 1992: The quality of 37 out of 137 allegedly branded products is doubtful.

Turkey 1993: In 1993, a pharmacist is arrested after attempting to export drugs to Africa. The active ingredient in his “drugs“ is baking powder.

Cameroon 1994: 20 percent of the drug samples analysed were substandard drugs.

Niger 1995: According to information provided by “Physicians without Frontiers”, a meningitis drug contains water only.

⁶ Source WHO <http://www.who.int/mediacentre/factsheets/fs275/en/>

⁷ Source WHO <http://www.who.int/mediacentre/factsheets/fs275/en/>

⁸ Source WHO <http://www.who.int/mediacentre/factsheets/fs275/en/>

⁹ Source WHO <http://www.who.int/mediacentre/factsheets/fs275/en/>

¹⁰ Source WHO <http://www.who.int/mediacentre/factsheets/fs275/en/>

Haiti 1996: At least 59 children die after taking a counterfeit syrup used to treat fever.

China 1997: Test series show that 10 percent of the drugs tested are substandard or counterfeited.

Kenya 1998: So-called malaria drugs turn out to be completely ineffective. The number of persons adversely affected can only be roughly estimated.

Malawi 1999: The renowned Africa Health journal reports a genuine flood of counterfeited drugs all over the country.

Cambodia 2000: At least 30 deaths result from counterfeited malaria drugs.

China 2001: The Shenzhen Evening News reports more than 100.000 people died of faked drugs in China this year.

Nigeria 2002: 60% of our drugs are either counterfeit, substandard or expired, says the head of the country's drug control agency.

International 2003: WHO declares, on average, 10-20% of medicines in developing countries markets are substandard. ¹¹ See footnote

As we can see from the examples above the direct consequences for the patients can be devastating. A further effect on patients is the amount of money diverted from research and development on new treatments for tomorrow's patients.

3.5 Potential Escalation

The scope of illegal trade is worldwide. It appears that the developing nations are most affected, but it is by no means confined to these areas. Indeed the trade is increasing in the developed nations because of higher prices attained in those countries.

Fraudulent supply of pharmaceuticals to the EU is likely to dramatically increase with the extension of EU membership. The accession of an additional 10 countries means that the EU has grown from 15 to 25 members. Cyprus, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, the Slovak Republic and Slovenia joined on 1 May 2004; and a further 2 Bulgaria and Romania hope to join by 2007.

This exposes thousands of miles of unprotected borders to the illegal entry of medicines into the pharmaceutical supply chain from former Soviet states where a recognised and significant counterfeit drugs problem already exists. In addition the accession countries are still developing their infrastructures and do not have the resources to adequately police their borders.

Additionally the nature of the movement of goods across the world facilitates the trade and organised crime syndicates are taking advantage of this to move into counterfeiting medicines because they see bigger profits and lower risk from these activities.

4 Packaging and Labelling

¹¹ GPHF (German Pharmaceutical Health Fund) http://www.gphf.org/web_en/projekte/minilab/hintergrund_arzneimittelaelschungen.htm

Packaging and labelling of medicinal products is a highly regulated activity. Manufacturers have to submit all aspects of their packaging and Patient Information Leaflets to the MHRA (Medicines and Healthcare Regulatory Authority) / EMEA (European Medicines Evaluation Agency).

Packaging is part of the intellectual property of the license holder which means that it is illegal to duplicate or copy in any way shape or form. Manufacturers include many anti-counterfeiting measures both overt and covert such as holograms, tamper evident seals, security inks and hidden markings. Packaging also includes critical information such as batch number, expiry date, date of manufacture and bar codes, product description etc. Batch numbers are important for events such as a product recall. Expiry dates and storage instructions are important guarantee that a product is supplied to the patient with the right potency to ensure successful treatment.

Parallel traded products can be legitimately repackaged. Traders must comply with the MHRA guidelines for packaging and labelling. However this activity invariably removes all of the original manufacturers' security measures. Repackaging creates a potential supply of discarded original manufacturers' packaging that could be used as a conduit for counterfeit medicines to reach the supply chain. See the following website for further details on these regulations.

http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=105

http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=200

It is worth noting that all PI packs go through a process of assessment by the MHRA PLPI unit in order for the PI company to obtain an import licence. Parallel traders must comply with the MHRA guidelines for packaging and labelling. However there is insufficient resource provided by the MHRA for monitoring of packaging quality and they are reliant on manufacturers to report non compliance. Many manufacturers report these breaches to the MHRA, but find that there is often insufficient follow up, thus allowing sub standard packaging to enter the supply chain.

5 MHRA and EMEA as the Industry's Regulators

5.1 MHRA

The MHRA is the government agency which is responsible for ensuring that medicines and medical device work, and are acceptably safe. Their work ensures that all products are as safe as it is possible to make them by rigorously scrutinising all aspects of a products discovery, development and subsequent marketing. They oversee all medicines and devices and take any necessary steps to inform and protect the public.

As part of their work, the MHRA conduct inspections of all aspects of a pharmaceutical company's value chain, this involves inspection of research, development and quality control laboratories, clinical trials, manufacturers, wholesalers and Pharmacovigilance systems. These inspections are carried out by the Inspectorate Group of the Inspection and Standards Division.

This group monitors systems under a recognised standard for each system being inspected. These are:

- **Good Laboratory Practice.** The inspectors verify that test facilities which conduct non-clinical safety studies on pharmaceuticals, agrochemicals, industrial chemicals, food and cosmetics meet GLP requirements to the standards necessary for regulatory purposes. (monitored by The Good Laboratory Practice Monitoring Authority (GLPMA))
- **Good Clinical Practice.** Which monitors all aspects of Clinical Practice and is carried out by the (GCP) Compliance Unit

- **Good Manufacturing and Distribution Practice (GMP/GDP)** Medicines Inspectorate assess manufacturers' compliance with the provisions of their manufacturing authorisation and the principles and guidelines for GMP as detailed in the appropriate European Directives. GDP Inspectors assess Wholesale Dealers compliance with the provisions of their Wholesale Dealers license and the principles and guidelines for GDP.
- Pharmacovigilance (GPvP) Inspectorate assesses pharmaceutical companies' compliance with UK and EU legislation relating to the monitoring of the safety of medicines given to patients. See below for link the MHRA website

http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=135

5.2 EMEA

- EMEA is the body which is responsible for the protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use. The EMEA coordinates the evaluation and supervision of medicinal products throughout the European Union. The Agency brings together the scientific resources of the 25 EU Member States in a network of 42 national competent authorities. It cooperates closely with international partners, reinforcing the EU contribution to global harmonisation. Further details can be found at: <http://www.emea.eu.int/>

The MHRA and EMEA bodies ensure that all aspects of a pharmaceutical company's activities comply with regulations and are regularly monitored to ensure they are in compliance. These bodies however are under resourced and do not necessarily have the means to carry out all the inspections that they would like to conduct.

6 Weakness in the UK and European Supply Chain.

Originally the pharmaceutical supply chain was very simple and secure because product was shipped from manufacturer to wholesaler to dispenser and then to patient. This process was both simple and direct leaving no opportunity for counterfeits to enter the supply chain. This model is still considered to be the ideal.

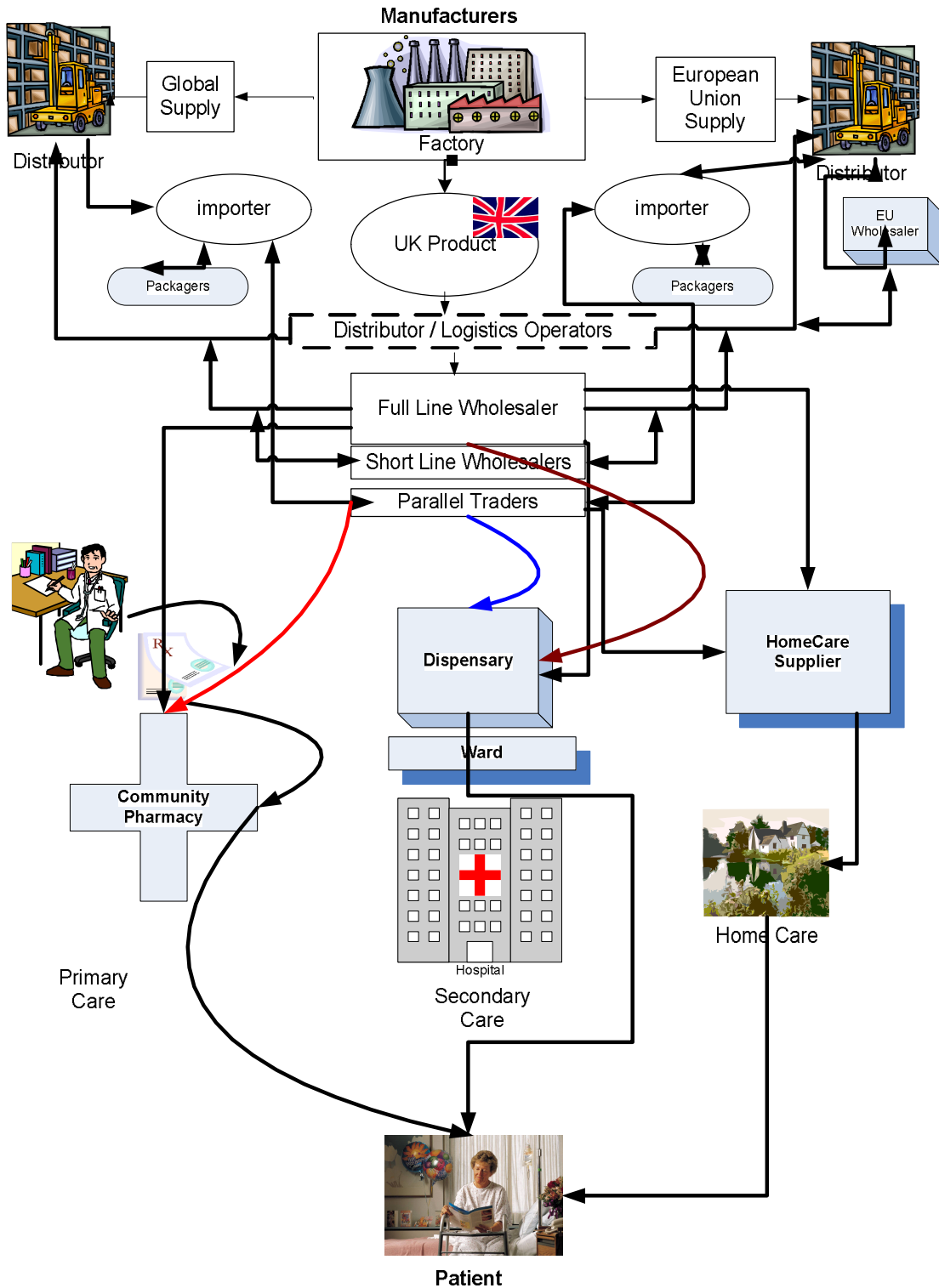
In today's complex environment distribution has become much more fragmented largely because EU law enshrines the free movement of goods across the borders of member states.

Increased pressures on profits and prices within the distribution system over the last decade has increased willingness for parties in the supply chain to make price its prime consideration and seek out the lowest deals. This has compromised the relationship between quality, safety and security of supply.

This situation has created the opportunity for new players to enter the market which has been created by their ability to gain wholesalers' dealers' licenses relatively easily. Inevitably the large number of applications and new license holder has placed significant burdens on the MHRA.

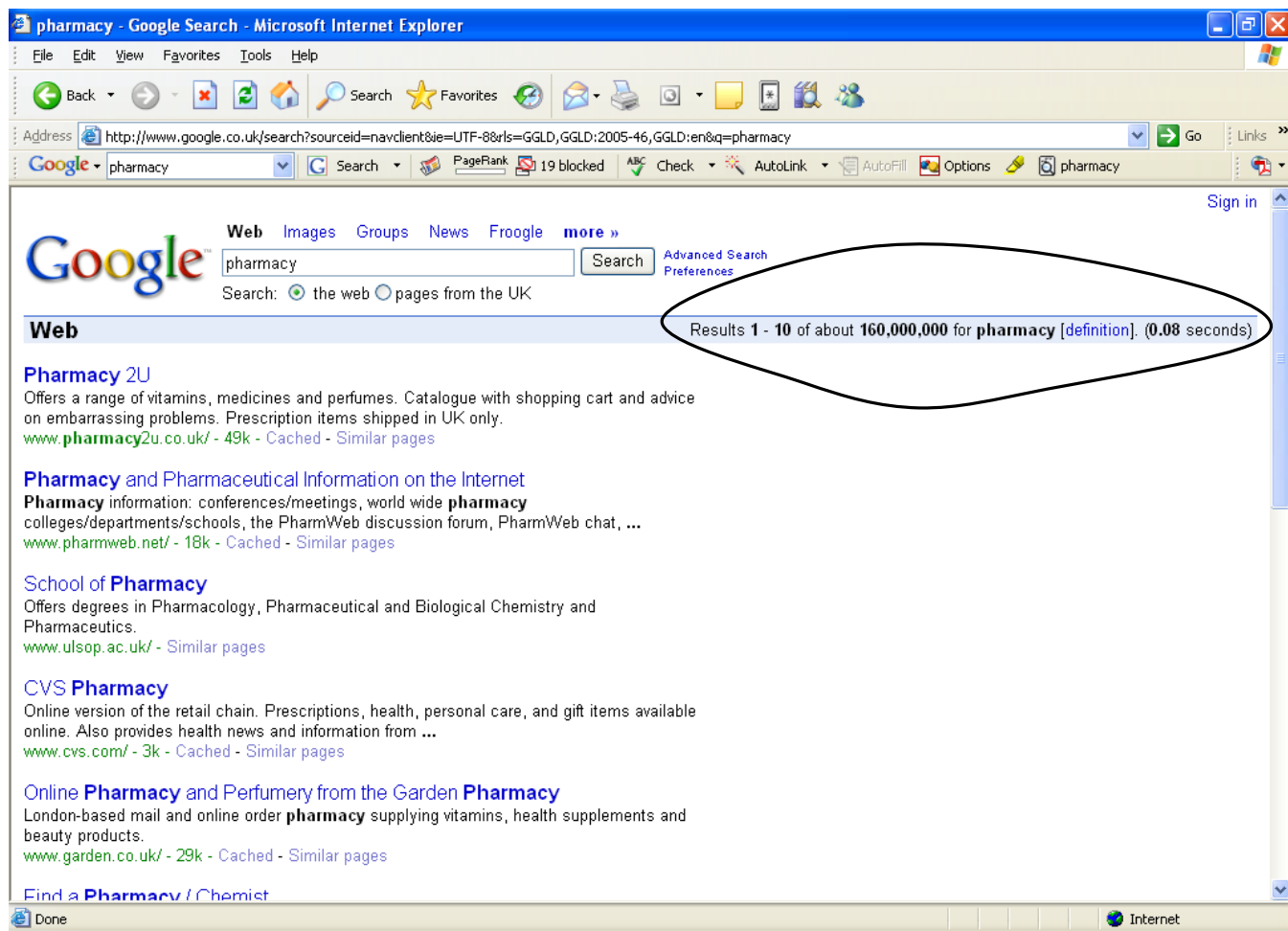
The multitude of participants in the supply chain has increased the number of stages and points of access that a products moves through. This means that it is harder to control product movement or track product within the supply chain.

See below:



6.1 Internet Pharmacy

An internet pharmacy is an online store accessible through a web browser from any computer that is attached to the World Wide Web. Internet pharmacies can be set up by anyone in any country worldwide and as such they are difficult if not impossible to control. Using a search facility tool to search for internet pharmacies returns 160,000,000 results. This demonstrates how easy it is to set up these sites and how pervasive they have become.



Many people use internet pharmacies to obtain prescription only medicines without a prescription. Either because they do not wish to visit a doctor or they are too embarrassed to obtain a prescription for problems such as erectile dysfunction. Price too may be an issue whereby someone on medication may think that they can avoid prescription charges for their particular medicine.

The problem for patients is that they cannot guarantee that the medicine they receive is genuine and may well be a counterfeit.

7 Prevention & Solutions

7.1 Technologies and packaging

The industry currently uses a variety of methods to tackle counterfeit products. These include:

- Detection
- Supply chain management
- Covert and visible forensic packaging technologies
- Tracking technologies
- Enforcement

Using all of these methods has kept the UK supply chain relatively free from counterfeit medicines reaching the patient. However as we have seen over recent years, counterfeiting of medicines is a relatively risk free and therefore attractive crime. The industry, government and NHS need to collaborate to reduce this risk even further.

7.1.1 Detection

An ounce of prevention is worth a ton of cure so the saying goes. The aim of all anti counterfeit measures is aimed at preventing counterfeits in the first place. Counterfeit medicines are produced in many countries with Russia, India and China being among the major suppliers. These counterfeits enter the supply chain by many and various routes. The simplest method of protection is to identify these products at the borders. Customs and Excise have the powers to detain suspicious cargoes at the point of entry. However they are not experts in pharmaceutical packaging and they work with manufacturers to identify whether the medicine is genuine. Customs and excise run a registration scheme for intellectual property and many manufacturers have registered their products. This enables the Customs officers to carry out port side investigations into suspicious cargoes.

Some counterfeits will elude detection and not all counterfeits enter the UK from abroad. These products may well enter the supply chain and a few will reach the patient. Industry provides bar coding on their packaging to help wholesalers and pharmacists identify product within their automated systems. However, industry has been looking to strengthen the coding to allow authentication at the points of dispensing. In addition they are investigating the use of Radio Frequency Identification tags. These use radio signals to confirm the identity of the package.

New technology, Laser Surface Authentication TM, allows manufacturers to take a fingerprint of their package or blister strip and provide a unique identifier for every package they produce. This fingerprint will allow pharmacists to validate the pack as original at the point of dispensing to patients. As an added bonus the database can carry other critical data such as strength of tablet, batch number and expiry date enabling tracking of the product throughout the supply chain. This data will also help to reduce medication errors.

7.1.2 Supply Chain Management

The risk from counterfeits arises from forged or copied medicines entering the supply chain. The most secure supply chain system is when a product is sent straight from the manufacturer to the consumer. Pharmaceutical manufacturing and distribution is so complex that this scenario rarely if ever takes place. The shorter the supply chain the more secure it is. A product produced in the UK and distributed via a recognised major wholesaler to a pharmacist probably represents the safest supply chain. Manufacturers are examining other possibilities such as supplying pharmacists direct, or vendor inventory management to see if this can improve the supply chain security.

Additional complexities arise from the trading of medicines across Europe know as parallel trading. Whilst this is perfectly legitimate, it adds unnecessary risk to the process of distribution for no clinical or financial benefit to the patient.

7.1.3 Covert and visible forensic packaging technologies

The package in which the medicine is supplied will contain a variety of features that are used to demonstrate their authenticity. These features can include:

- Tamper evident seals (to show a product has not been tampered with)
- Holograms
- Colour Shifting Inks
- Security Labels
- Security Papers
- Digital Watermarks

- Security Graphics
- Bar Coding
- Radio Frequency Identification
- Tablet Marking
- Hidden Identity Marking

These measures may be present in any combination such as Bar Coding together with Tamper Evident Sealing. However these measures are made redundant if the product is repackaged.

7.2 Working with regulators - Legislation and Penalties

7.2.1 Working with Regulators

The activities of the UK pharmaceutical market are overseen by the MHRA. The **Medicines Act 1968** brought together the main rules for medicines and regulates drugs that are used for medicinal purposes, there are three main categories.

- Prescription only medicines
- Pharmacy Medicines
- General

A pharmacist can only sell 'Prescription Only' drugs if they have been prescribed by a doctor. The 'General' category allows the medicines to be sold without a prescription in any shop, and a pharmacist can sell 'Pharmacy Medicines', without the need for a prescription.

Possession of 'Prescription Only' medicines without a prescription is a serious offence.

The medicines act introduced a number of legal provisions for the control of medicinal products. It was an enabling act that provided a system of licensing that applied to manufacturers, and all parties in the supply chain including importers. The act made it illegal to pursue any activities relating to medicines except under an appropriate license.

The MHRA (and in a European context the EMEA) set the framework within which these activities are conducted and as such bear a large responsibility for ensuring the integrity of medicines so that the patient can receive the maximum benefit.

The relationship between the Pharmaceutical Industry and the MHRA is complex, but there are regular meetings to discuss problems and mechanisms for improving processes so that activities such as counterfeiting can be minimised or eradicated.

The ABPI's anti-counterfeiting task force holds regular meetings with the MHRA's intelligence unit to share information and propose new ways of tackling this issue.

7.2.2 Legislation and Penalties

There is no specific crime of counterfeiting of medicines and prosecutions are aimed at actions under the Medicines Act (1968) or within copyright infringements. There are other Acts of Parliament that can be used and this includes:

- **Medicines Act (1968)**
- **Drug Traffickers Offences Act 1994**
 - Gives police the power to seize the assets and income of anyone who is found guilty of drugs trafficking, even if that income isn't related to the trafficking of drugs.

- It also makes it illegal to manufacture or sell equipment for the preparation or use of controlled drugs.
- **Customs and Excise Management Act 1979**
 - In conjunction with the Misuse of Drugs Act:
- Makes it illegal to import or export controlled drugs without authorisation.
- A successful conviction leads to the same penalties as under the Misuse of Drugs Act, although the fines can be more substantial, based on the value of the drugs seized.

Actions under the Medicines Act (1968) attract a penalty with a maximum of 2 years and an unlimited fine. The penalties for infringing copyright are often much lower than other similar crimes and considerably lower than penalties for supplying class Narcotics. This is one reason why criminals are attracted to counterfeiting because if they are caught, they are unlikely to receive such severe sentences. See below.

Drug Classification

Class of drug	Possession	Dealing
A Ecstasy, LSD, heroin, cocaine and crack, magic mushrooms (if prepared for use), amphetamines (if prepared for injection).	Up to 7 years in prison or an unlimited fine. <i>Or both.</i>	Up to life in prison or an unlimited fine. <i>Or both.</i>
B Amphetamines (speed), Methylphenidate (Ritalin), Pholcodine.	Up to 5 years in prison or an unlimited fine. <i>Or both.</i>	Up to 14 years in prison or an unlimited fine. <i>Or both.</i>
C Cannabis, Tranquillisers, some painkillers, GHB (Gamma hydroxybutyrate).	Up to 2 years in prison or an unlimited fine. <i>Or both.</i>	Up to 14 years in prison or an unlimited fine. <i>Or both.</i>

In a November 2004, Allen Valentine, of Harrow, pleaded guilty to conspiracy to supply Class C drugs between January 1, 2001 and April 21 this year, as well as two similar charges involving contraventions of the Trade Marks Act and Medicines Act. He was sentenced to 5½ years in prison. This case was unusual in that the penalty handed down was severe, but the prosecution used “*conspiracy to supply Class C drugs*”.

The trading of counterfeits endangers the lives and wellbeing of patients and the pharmaceutical industry believes that there should be specific legislation to cover the counterfeiting and supply of fake medicines.

7.2.3 Working with Stakeholders – Education - Safety Chain

7.2.4 Stakeholders

There are a large number of stakeholders with an interest in counterfeit prevention:

- Patients
- Patient Groups
- Doctors (and their professional bodies)
- Nurses
- Pharmacists
- MHRA (Medicines and Healthcare Regulatory Agency)
- Manufacturers
- Prescription Pricing Authority
- Pharmaceutical Industry suppliers
- National Health Service
 - National Patient Safety Agency
 - Connecting for Health
 - NICE
 - PCT's
- Department of Health
- Treasury
- Wholesalers and Distributors
- Medical Device Companies
- Vaccine Manufacturers
- Generics Manufacturers
- Parallel Importers
- Retailers
- Logistics and transportation
- Trade associations
- Home office

The main objective of these stakeholders is to supply medicines that help control, alleviate and cure illness in patients. It is in the best interests of all stakeholders to prevent counterfeits reaching the patient and thus avoiding any harm that may result.

The pharmaceutical industry already has a robust working relationship with the majority of these stakeholders.

All of these play a role in the process of prevention. The aim of the ABPI is to collaborate with these groups to gain consensus on mechanisms for prevention and deterrence. The ideal is to create a seamless process such as the Pharmaceutical Safety Chain where a product's pedigree is validated throughout its passage to the patient. This will require the use of modern technology and the utilisation of authentication at the point of dispensing.

7.2.5 Education

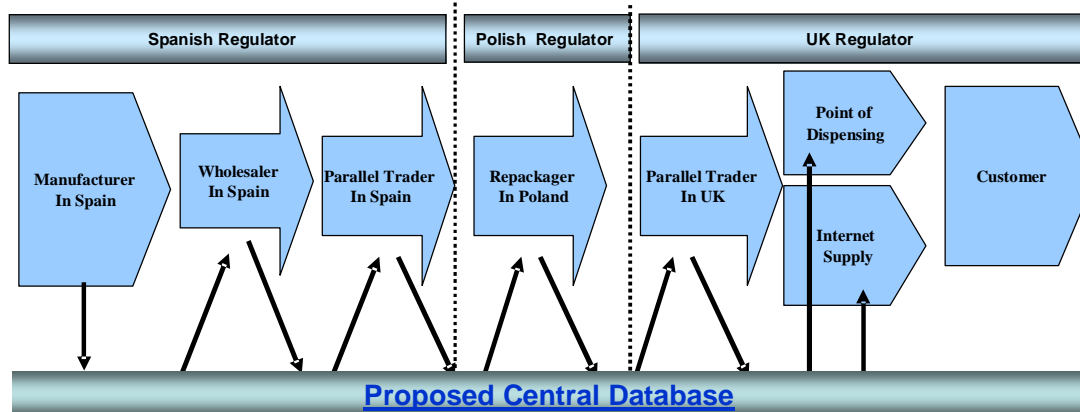
Education is one of the components in combating fraud. Patients, doctors, nurses and other people who have a physical connection need to understand how to recognise and deal with counterfeits. It is interesting to note that, of the counterfeits that were identified in 2005, one incident was spotted by a patient who noticed that the tablet crumbled when broken in half unlike her previous medication. Another incident

was identified by a wholesaler spotting a discrepancy with batch numbers. There is much that can be done to reduce counterfeiting through an education programme.

7.2.6 Pharmaceutical Safety Chain

Create a pan-EU central record of batch numbers of product moved within the EU

This will ensure that product batches entering and leaving a country will be recorded with regulatory authorities thus enabling full track and trace, product recall, and supply chain security



Enables full visibility by the regulator of all batches of products within its jurisdiction. The database allows each participant within the supply chain to authenticate:

- a) the genuine source of medicines
- b) the proper licensing of the person it buys from and sells to and
- c) assists with track and traceability, product recall and supply chain security

Figure 1 - Pharmaceutical Safety Chain

The safety chain concept provides product in the supply chain with a pedigree in much the same way as was used in the food industry to prevent BSE passing into the food chain. Here the concept was credited with preventing and eradicating BSE.

Medicines often travel across international borders because of the location of manufacturing plants and parallel trading. Using unique identifiers products can be verified by all parties who touch the product against a database. In this way a products pedigree can be validated.

8 Conclusions

Pharmaceuticals are becoming targets for professional criminals for the supply of counterfeit drugs. These criminals are sophisticated and have the means to produce and package fake products that are nearly indistinguishable from the original. The only difference being that the fake medicines rarely contain actual medicine and are a potential risk to patients well being and health. This crime is particularly pernicious as it exploits vulnerable people and puts their lives at risk.

There is a groundswell of opinion that all stakeholders need to take action to eradicate this trade by making it difficult if not impossible to pursue.

There are a number of actions that can be taken by government, manufacturers, wholesalers, pharmacists and doctors to reduce or eliminate counterfeits, some of these include:

- Better legislation (e.g. prevent repackaging)
- Ensure that existing legislation on quality of packaging is rigorously enforced

- Increases penalties
- Creating product pedigree
- Authentication at the point of dispensing
- Unique identifiers for medicinal packs
- Fingerprinting products (Laser Surface Authentication)

In order to be successful all parties in the supply chain and the health services need to collaborate to produce the best anti counterfeiting strategy possible. The strategy relies on international collaboration and setting consistent standards across Europe and the other pharmaceutical markets.

Experts consider that the UK could be a big target for organised crime syndicates who believe that the trade is profitable and low risk. The prime target for counterfeit medicines is the so called lifestyle products as these products have high individual pack value and high sales volumes. However counterfeiters are perfectly happy to target any product that will produce a good return on their investment.

Manufacturers include overt and covert techniques to help make copying more difficult and thus prevent this trade. Whilst these physical methods are helpful, combating the trade requires an holistic approach that includes securing the supply chain, inspection of products, physically identifying products with holograms, batch numbers, expiry dates and coding and legislation to prevent traders from repacking medicinal products and eliminate online pharmacies. Legislation is also needed to punish perpetrators and act as a deterrent.

If all stakeholders work together to eliminate counterfeit medicines, thousands of patients will be able to take their medicines in the full confidence that they are safe

Appendices

Appendix A

1 Best Practice in the Supply Chain

Recent events have demonstrated the vulnerability of the UK pharmaceutical supply chain to attack from fraudulent or unscrupulous traders. Counterfeit product was found by chance by a patient because the counterfeit product broke up more readily than the branded product. The consequent investigation found considerable, hitherto unsuspected, quantities of fake product in the supply chain.

The pharmaceutical industry has a responsibility for ensuring the safety and quality of the medicines that it manufactures and supplies. Commitment is required from all parties through the supply chain to ensure that this inherent quality is not compromised prior to the product reaching the patient. Industry recognises its responsibilities to work collaboratively with all parties in the supply chain and with the MHRA to ensure patient safety.

There is awareness by industry of a number of weak links that have been identified in the supply chain, which potentially compromise patient safety. These include:

- § poorly labelled and packaged parallel traded products being supplied to patients
- § risk of counterfeit and illegally and fraudulently traded goods entering distribution channels
- § actual counterfeited product reaching patients.

1.1 Product Labelling and Packaging

Patient safety must be paramount and equally high standards should be applied for all manufacturers and wholesalers operating in the UK. All steps should be taken to encourage a good flow of information from industry to the MHRA about products that are distributed with inappropriate labelling or inadequate patient information. Manufacturers often become aware of concerns relating to such products following customer enquiries and complaints.

In order to maintain high quality safety standards, manufacturers should consider adopting the guidance below:

1.2 Monitoring the Quality of Parallel Traded Medicines Entering the UK Market

Companies should:

- § Monitor all new PLPI licences granted for their own products.
- § Request samples of all internal and external packaging from the parallel importer once a licence has been granted, or at least before actual importation occurs. The importer is obliged to provide this according to the current case-law of the Court of Justice of the European Communities (ECJ). The trademark owner must be given advance notice that the repackaged product is to be put on sale. The ECJ has defined 'repackaging' as including operations such as 'removal' of blister packs from the original external packaging and their insertion into new external packaging' or 'addition to packaging of new user instructions or

information or the fixing or self-stick labels' (ECJ 11 J 1996, MPA Pharma GmbH vs. Rhone Poulenc Pharma GmbH (C-232/94) and BMS vs. Paranova A/S (C-427/93, C-429/93, C-436/93) and joined cases C-71/94, C-72/94, C-7394.

- § Develop a management process for collection and checking of parallel import packs in order to ensure legal requirements are fulfilled.
- § Develop a management process for the handling and control of samples of parallel imports.
- § Quality control parallel import samples to ensure that they meet the current leaflet and labelling requirements and regulations. See Council Directive 92/27/EEC of 31 March 1992 (attached as Appendix 2).
- § Ensure that any breaches of leaflets/labelling regulations, issues relating to patient safety and other general complaints are forwarded to the MHRA with evidence, in a timely manner, for further action.
- § Follow up on the notification to the MHRA to check on the actions taken by the MHRA in respect of the complaint.
- § Ensure that departments which receive patient complaints and queries regarding parallel imports e.g. Medical Information, are fully briefed on the subject, including briefing by the Legal Department if required.

1.3 Counterfeit and Illegally and Fraudulently Traded Pharmaceuticals

Recent press coverage has highlighted the fact that counterfeit and illegally and fraudulently traded medicines have occurred in the UK market. The ABPI's policy on this can be found in Paragraph 10 entitled '**Guide to Manufacturers' and Paragraph 12 'Illegally and Fraudulently Traded Pharmaceuticals'**.

In order to maintain high quality safety standards, manufacturers should consider adopting the guidance below:

2 Illegal and Fraudulently Traded Pharmaceuticals

2.1 Reducing the Risks of Entry into the UK Market

- Companies can and should protect their own interests by exercising vigilance in accepting orders for goods which are suspicious in the context of the alleged destination in terms of (for example) the nature of the product, the size of the order, the payment terms, the shipping route, non-standard packaging, or the unfamiliarity of the customer. At a recent UK trial the defence made great play of the fact that the manufacturer had sold goods to what was in effect a personal trading company with no history of pharmaceutical sales and was not the holder of a wholesale dealers licence.
- The need for such vigilance should be included in the training of all personnel who handle export orders.

- The MHRA publish lists of manufacturers licence and wholesale dealers licence holders. This enables licence holders to meet their obligation to supply medicines only to persons authorised to receive them. In the case of doubt about the genuineness of customers, a check should be made e.g. via the MHRA.
- Companies should have systems in place in order to sample materials from the supply chain, including retail and returned goods and to examine these to ensure that they have not been illegally or fraudulently traded. Such a sampling system may well also be used to assist with the detection of counterfeits.
- In the event that a product is confirmed to be counterfeit or to come from an illegally or fraudulently traded batch, the original manufacturer should report the facts to the MHRA who will advise on the next steps.
- Recall notices and public statements concerning counterfeit, illegally or fraudulently traded products are agreed between the MHRA and the importer or trader. The original manufacturer will always be notified by MHRA particularly in the case of a defect inherent in the product as supplied by them, however, any communications and their timing with respect to the actual recall will be discussed with MHRA first.
- The company has the right to issue an advance public statement if it considers this necessary to protect the public and the reputation of its products. Any such statement should be discussed with the MHRA prior to its distribution.
- Where the authorities intend to issue a statement or recall notice, the company should agree to the wording of such statements as soon as possible.
- Any notices should include information, wherever possible, as to how the counterfeit or illegally or fraudulently traded product can be differentiated from the authentic or legitimately traded product. The company should endeavour to arrange a fully supported information line to handle enquiries from the professions and public.
- Depending on the exact circumstances of individual cases, the company will need to define its policy on whether the goods are to be returned, exchanged or credit notes issued.

It is also suggested that manufacturers should have the following in place:

A. A Policy and Training Document

This should address the following issues as a minimum:

1. Does the pharmaceutical manufacturer have a clearly stated policy available to staff regarding product diversion?
2. Does the manufacturer have incorporated in their training programme for staff, methods for educating them about the risks of diversion?
3. Are members of staff working within Export Sales Departments, educated with regard to recognition and examination of export documents, bills of lading etc?

4. Where more than one member of staff is involved in a transaction, or a new employee takes over a partially transacted sale, does the company have methods for ensuring they are fully briefed on what others are doing, or have done?
5. Are all employees fully aware of the importance of and legal requirements to retain certain documents and company records? and have:

B Operating Procedures Which Address the Following:

When a manufacturer receives an order for products for export from a new customer, they should:

Check that the customer is the holder of a current wholesale dealer's licence?

Check that there is no public or industry record of the customer being guilty of past illegal activities?

Check that the product is a suitable one for the country in question?

Check that the quantities ordered are in keeping with the market?

Ensure that the original product supplied for export is packed in compliance with the marketing authorisation of the recipient country and hence be easily recognisable.

Appendix B

1 A policy document and action plan on Counterfeiting.

1.1 Summary of Position

Counterfeiting is an established problem of the pharmaceutical industry world-wide. Historically, however, there is little evidence of counterfeit medicines being traded within and between countries where there are short, highly regulated distribution channels between manufacturer and user.

The prime responsibility for prevention and control of counterfeiting lies with government regulation of the healthcare infrastructure and distribution chain. The Medicines Control Agency (MHRA), Royal Pharmaceutical Society of Great Britain (RPSGB) as well as the industry all have reason to be concerned about the potential risk to patient welfare and have a duty to prescribers and patients alike to take all reasonable steps to eradicate risk.

The industry's main concern is that the inadequate control of imports by third parties provides the opportunity for counterfeit products to enter the distribution chain. These can arrive in container loads of mixed batches from different parts of the world. A smaller but not insignificant amount of goods for so-called "personal use" also enters the country via the "suitcase trade" through the facility of the "green channel" at Customs.

It is acknowledged that the MHRA is the lead enforcement agency in the UK and it actively works together with all interested parties in investigating suspect products in the market place. However, a number of government agencies and statutory bodies have a role in the detection of counterfeit medicines and prosecution of offenders - namely the Department of Health, RPSGB, the police, HM Customs and Trading Standards Officers - and the pharmaceutical industry is keen to co-operate with them.

Insofar as the entry of counterfeit medicines into the distribution chain is concerned, it should be pointed out that the present system of reimbursement to pharmacists acts as an incentive to purchase cheap products. This is evidenced by the "Schaffer" cases where several pharmacists have been disciplined for purchasing illegally imported medicines at low prices supplied via an unlicensed wholesaler.

1.2 Recommendations

- The ABPI should work with the MHRA to seek improvements that would enhance the monitoring, inspection and checks on importers. The Agency publishes lists of licence holders.
- The industry should reinforce its stated position that batch references need to be recorded to pharmacy, or preferably, at patient level.
- Each imported consignment should be accompanied by documentation, which clearly records the audit trail back to the original manufacturer.
- Companies should be vigilant and report instances of suspect product to the MHRA.
- In revising its Code of Ethics originally issued in May 1992, the RPSGB should take the opportunity to require pharmacists to report, to the authorities and the holder of the marketing authorisation,

offers of supply of suspect products, and to report, isolate and withhold from sale any such stock that is received. It is the responsibility of the RPSGB to follow up reports expeditiously and to apply appropriate sanctions to those found in breach.

- Wholesalers should report and isolate suspect stock similarly and should apply due diligence to satisfy themselves of the legitimacy of the source of the products. They should ensure that they are fully in a position to co-operate in a recall and to provide information as to the destination of their supplies.

1.3 Industry's Rights and Obligations

- Companies have a duty to protect the security of their medicines against counterfeit, by the use of “intelligent packaging” devices such as tamper evidence, coding of packs and, where warranted, trace markers within the product material itself.
- A company which suspects a product is counterfeit should carry out appropriate visual inspection and chemical analysis as quickly as possible.
- The company must be fully satisfied that a product is counterfeit before informing the authorities and, if appropriate, the professions and public, in order to avoid unnecessary public alarm.
- If the authorities suspect that a product is a counterfeit, the information should be communicated immediately to the company producing the genuine product. Whilst the primary responsibility for analysis in this case rests with the authorities, the company will offer appropriate co-operation. Any inspection and analysis should be completed as quickly as possible.
- Recall notices and public statements concerning counterfeit products are agreed between the MHRA and the trader. The original manufacturer may have a role to play, e.g. in the case of a defect inherent in the product as supplied by them, however, any communications and their timing must be agreed with the MHRA first.
- The company has the right to issue an advance public statement if it considers this necessary to protect the public and the reputation of the genuine product. Any such statement should be discussed with the MHRA prior to its distribution.
- Where the authorities intend to issue a statement or recall notice, the company should agree to the wording of such statements as soon as is practically possible.
- Any notices should include information, wherever possible, as to how the counterfeit can be differentiated from the authentic product and all relevant details as to the likely danger to, or effect on, the patient brought about by the use of the counterfeit version. The company should endeavour to arrange a fully-manned information line to handle enquiries from the professions and public.
- Since by definition the company did not put the counterfeit product on the market, it will not be obliged to accept returned counterfeit goods or to exchange them, or to issue credit notes in respect of them.
- Since the manufacturer of counterfeit products is generally unknown, the appropriate authority (the MHRA Defective Medicines Report Centre) will generally issue a recall notice. In the interests of patients, the company producing the genuine product will co-operate in any recall.

- A company maintains the right to undertake its own investigation and/or to take direct legal action to protect all aspects of its business.

1.4 Trafficking in Counterfeits as a Criminal Offence

Having regard to the potential threat to human life posed by counterfeit medicines, the industry urges that Section 300 of the Copyright, Designs and Patents Act 1988 (“Fraudulent application or use of trade mark an offence”) should be rigorously enforced and that there should be rapid international adoption and implementation of Article 61 of the GATT TRIPs Agreement of December 1993 (“Criminal Procedures”).

In addition, the Medicines Act 1968 should be amended to ensure that it contains provisions such that the MHRA is empowered to rigorously pursue alleged counterfeiters and anyone dealing in such products. Further, the provisions should include penalties to ensure that the courts can deal effectively with offenders.

ABPI First issued: February 1992.

Reviewed: October 1997. Revised July 2000, updated March 2006.

Appendix C

Case Study: Counterfeit Lipitor in the UK supply chain

In July 2005 counterfeit Lipitor 20mg was found in the UK supply chain resulting in a recall of a batch of 120,000 packs of Lipitor 20mg. MHRA issued the recall after 70 counterfeit packs of medicine claiming to be Lipitor 20mg and using the same batch number as the genuine product were found in two separate licensed UK wholesalers, one a short-line wholesaler (parallel trader) and the other a full-line multinational wholesaler. It is understood that the short line, parallel trading wholesaler imported the counterfeit Lipitor 20mg from outside the EEA, an illegal activity in its own right, and subsequently sold these medicines to the large full line multi-national wholesaler who in turn supplied the counterfeit medicines to pharmacies across the UK. The extent to which the counterfeit Lipitor 20mg had penetrated the UK pharmacy system is clearly demonstrated by the fact that over 50% of the medicines returned from pharmacy following the MHRA recall notice were proven to be counterfeit. Only days after this incident a second batch of counterfeit Lipitor, this time 40mg, was found on the same premises of the UK licensed short-line parallel trader. The UK regulator, the MHRA, was alerted to the possibility of counterfeit Lipitor 20mg being available in the UK by the Dutch regulator, after the Dutch seized a significant quantity of the same counterfeit Lipitor in the same UK livery in a Dutch pharmacy.