

Counterfeiting of Medicines

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Introduction

When Mrs X took her usual dose of Lipitor for Hypercholesterolemia she could hardly have anticipated that she would suddenly and unexpectedly collapse. She had been taking the medicine for some time and had not experienced any side effects. Unfortunately, she is one of the few people each year who receive a counterfeit medicine instead of her real medication and it could have had a disastrous effect because her Lipitor medicine was designed to lower her cholesterol levels and without it she could die from a heart attack or stroke.

The quandary of counterfeit medicines has emerged as a serious and potentially damaging issue for patients, the pharmaceutical industry and the NHS. It is likely that the problem of counterfeits in the supply chain runs far deeper and is more insidious than we anticipate. The discovery of fake Cialis in the supply chain demonstrated that counterfeit products can go undetected for some time and often discovery is a case of luck rather than detection.

The World Health Organisation (WHO) estimates that up to 10% of medicines worldwide may be counterfeit, at a value of about \$2 billion annually. Estimates for 3rd world and emerging economies are higher at around 40%. Applying the WHO statistics to the UK it would equate 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.

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 per annum¹.

Counterfeit (or illegal trade) in medicines may fall into a variety of categories:

- Copies which mimic the original so they appear to be the genuine product, they may or may not contain some of the original active ingredients.
- Substitution or dilution of the original product to increase the quantity in the original batch by addition of bulk such as chalk or other material.
- Illegal imports, either from a non-approved supplier or manufacturer or where the active ingredient has not been approved for use.
- Illegally relabelled products: this is often done to extend the shelf life of short-dated products or to re-label the product with a label indicating a higher strength so the trader can charge more.
- Diverted product includes: product supplied overseas (at reduced cost) under special schemes. Diverted products do not reach intended patients but are diverted to a market commanding a higher price. In the same category is stolen product which is original but the title is not owned by the trader.

Each year the Medicine and Healthcare Regulatory Agency (MHRA) investigates about 100 incidences of counterfeit medicine in the UK.

Why is counterfeiting a problem?

It is a particularly serious crime because it:

- Compromises patient treatment and could endanger life
- Reduces confidence of the medical profession in the quality, safety and efficacy of the medicines they prescribe
- Reduces public confidence in the entire health system
- Defrauds the tax payer
- Damages the pharmaceutical industry's ability to invest in future new medicines

There is a significant health risk to patients from counterfeit products. Counterfeit medicines often contain harmful ingredients, a different active compound or no active ingredient at all. They may also contain insufficient active compound than is required for therapeutic effect so the patient thinks they are being treated, whereas they may not experience any therapeutic benefit at all. Where they do contain active ingredient, the products will not be made to the same quality standards. Injectable products will probably not be sterile and may even be contaminated with human material, particularly where used vials are fraudulently recycled.

In a recent TV programme, children in Africa that were supposed to be injected with adrenalin to treat allergic reactions literally died in front of the camera because the adrenalin had been substituted with water.

Insecure Supply Chain

Pharmaceutical companies manufacture and package their products to extremely high and exacting standards which are regulated by the government through the MHRA. The regulations control everything from purity of ingredients through to the labelling of each carton or container. Even

¹ Source, IMS Data

missing a full stop on a pack can be reason enough for the MHRA to issue a product recall. Once the product has been manufactured, it only has a limited shelf life and the clock starts ticking immediately it leaves the production facility. The product enters the supply chain directly it leaves the factory and at that point the manufacturer loses control of the product as it is then passed through a variety of wholesalers, dealers and pharmacists before it reaches the patient. It is during this process that counterfeit product can be introduced.

Parallel Trade What is it?

Parallel-trading; the practice of buying medicines in one country for distribution in another country where the price of that particular medicine is higher, emerged as a result of the regulation of the EU pharmaceutical market, whereby member states dictate the price of the medicines they purchase.

The way in which pharmaceutical prices are regulated by each country across Europe leads to price differences in each EU country. These price differences allow traders to capitalise on the free movement of goods around Europe to buy medicines in a low priced country and sell the products to a higher priced country. This activity is perfectly legitimate. However this trade adds no value to the product or indeed the payer (usually the nation's health service) and in reality only really benefits the traders. A recent study by the London School of Economics concluded that parallel trade activity had no significant benefit to the health providers or patients².

Why is it a problem?

The manufacturing and distribution of pharmaceutical products is a highly regulated activity. It is strictly regulated in order to protect patients from any harm that might arise as a result of poor practices such as incomplete research, contamination of product, wrong information such as dosage or other problems that may lead to

iatrogenic disease (illness caused by medical intervention). The controls also include the way in which medicines are packaged and labelled and certainly include the storage of medicines so that they are kept at the optimum temperature. In this way doctors, pharmacists and patients can be assured that the medicines reach the patient in the optimum condition to treat the patients' illness.

All of these rules apply to parallel traders. However, medicines that are traded in this way can be repackaged and there are insufficient resources to inspect and oversee all these operations. This means that the original product is removed from the manufacturer's packing that contained all the anti-counterfeiting measures as well as tamper-evident seals and put into another carton. This situation may lead to counterfeit medicines entering the supply chain.

Once the patient receives their medicine from the pharmacist, they are confronted with unfamiliar packaging and patient information leaflets often leading to confusion, especially in the elderly.

Finally there is the economic impact. Manufacturers invest heavily in research and development facilities and manufacturing plants in order to be able to supply the best possible medicine for now and the future. Parallel trading takes value out of the system and puts it into the hands of the distributors whilst giving nothing back to the system. In the UK the Government assumes that pharmacists dispense parallel traded product and charges them a fee called clawback to take account of this trade and this actually encourages pharmacists to purchase parallel product because if they don't they will be financially penalised.

Internet Pharmacies

These are often used as a front to sell counterfeit medicines and a quick trawl of Google will generate many millions of hits. Drilling down to the websites quickly demonstrates that the legitimacy of

these sites is at best dubious. Statistics show that internet and health spam is fifth in the SPAM e-mail league³. A Google search returns millions of hits for these internet pharmacies and the vast majority are not legitimate.

Counteracting Counterfeit Medicines

Over the last year the UK has experienced several instances of counterfeit medicine reaching the patients. In all cases the product has passed through many hands including several short line wholesalers and across international borders before finally reaching the UK supply chain.

There is no single answer to preventing counterfeits and prevention must take a number of forms. Currently industry and government are addressing the situation with a range of measures:

- The prime attack on counterfeiters comes from the Government's regulatory authority, (Medicines and Healthcare Products Regulatory Agency [MHRA]) who police the supply chain infrastructure through their intelligence unit.
- The pharmaceutical industry is working with members of the supply chain and other stakeholders to tighten security in the supply chain.
- The pharmaceutical industry uses tamper evident seals and other packaging technologies to prevent copying in order to deter fraudsters and aid detection.
- The ABPI is working with the European Federation of Pharmaceutical Industry Associations to gain a Europe wide mechanism for combating counterfeiting.
- The pharmaceutical industry is co-operating with the Government's regulatory authority, (Medicines and Healthcare Products Regulatory Agency [MHRA]) as well as Department of Health, Royal Pharmaceutical

² The Economic Impact of Pharmaceutical Parallel Trade, a stakeholder analysis, LSE

³ <http://spam-filter-review.toptenreviews.com/spam-statistics.html>

Society of Great Britain, HM Customs and Trading Standards to develop and implement preventative measure such as inspection.

- The MHRA conducts field investigations to identify counterfeits that have entered the supply chain.
- Encouraging original pack dispensing so that substitution is made more difficult.
- The UK industry through the ABPI and EU industry through EFPIA are assessing additional methods of identifying products uniquely so that they can be readily identified as genuine packs at the point of dispensing.

New Initiatives

These measures go some way to addressing the problem, but new initiatives need to be added to these:

Primary initiatives: Securing the Supply Chain

The introduction of a more secure supply chain by creating a **product pedigree** in much the same way as was done in the BSE crisis so that all parties in the chain know where the product originated and its status.

The creation of a unique method of **identifying** each pack with a fingerprint using technologies such

as Laser Surface Authentication to provide each pack with its own identity so that product can be validated at the point of dispensing. This will require a database of all products which can hold batch number, expiry date and other critical information to enable track and trace. It is critical that the dispensing community take responsibility to have (and use) the scanning equipment to carry out the validation.

Legislation to prevent illegal internet pharmacies from advertising and selling products to patients. Provision of accreditation for legitimate internet pharmacies by the MHRA with a logo of accreditation which can be verified against a database held by the MHRA.

Legislation to introduce a specific crime of making and selling counterfeit and/or illegal medicines within the UK with penalties of up to 10+ years imprisonment and unlimited fines. (Current legislation under the Medicines Act, the standard way to prosecute such offenders, holds a maximum of 2 years in jail and or an unlimited fine)⁴.

Secondary Initiatives

Set up a **training initiative** (through the NHS) to provide a training and education programme

for all stakeholders to understand the problem and take necessary action to identify fake product. This includes patients, medical staff, pharmacists and even customs officers so that fake product is identified before it is taken by the patient.

Provision of more resources to **increase the inspection** on repackaging and handling of medicinal products so that all people who deal with medicines are working to the same standards.

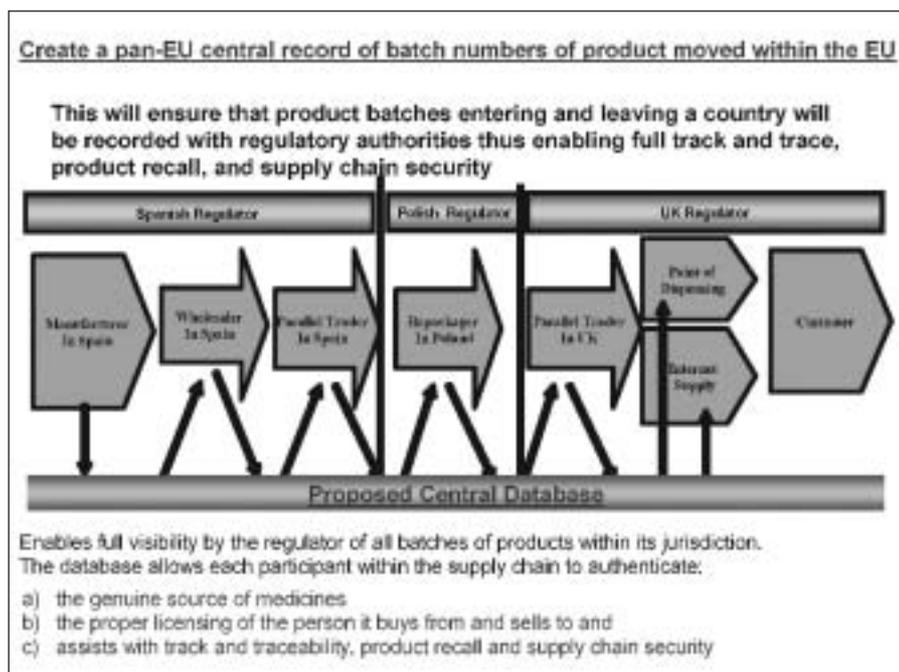
A 6 month study to examine all the tablets being taken by anyone who dies from whatever cause to test if they are genuine and provide statistical feedback on the penetration of counterfeits.

Conclusion

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, Mrs X and thousands of other patients will be able to take their medicines in the full confidence that they are safe.



⁴ MHRA Website, press release 30th November 2005 (Global counterfeiting organisation in court)