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DRUGS, LIES AND REGULATIONS

Pharmaceutical counterfeiting is increasing, potentially putting the safety, possibly lives, of millions of patients at risk. Julian Mount, senior director at Pfizer, explains what his company is doing to ensure and enhance patient safety.



Counterfeiting medicines are now highly sophisticated (counterfeit packet at the bottom)

In July 2005, counterfeit Lipitor® was discovered in the legitimate UK supply chain. It is the latest instance of counterfeit medicines found, and further evidence that counterfeiters and criminals appear to be targeting the legitimate pharmaceutical market. This type of activity can undermine the integrity of the medicines supply chain and can damage patient trust and confidence in their prescribed medication.

Illegal medicines have also been found in other European countries. In 2004, significant amounts of a counterfeit medicine were found in the Netherlands, after a patient complained of a crumbling tablet. Dutch pharmacy journal *Pharmaceutisch Weekblad* stated that the medicine 'arrived with the pharmacist [in the Netherlands] via parallel import'. The distribution was investigated by the Dutch Institute of Public Health¹.

Scale of counterfeiting

It is estimated that up to 15 per cent of the global medicines supply chain is illegal, rising to 25 per cent in some countries². The largest counterfeit market within close proximity to Europe is Russia, where it is generally accepted that 12 per cent of medicines are counterfeit³. Russian authorities have seized over 100 tonnes of illicitly manufactured pharmaceuticals in the last three years, according to the Federal Control Service. During this period, over 6000 drug-related crimes have been reported and over 136 illegal laboratories discovered.

Counterfeit drugs account for roughly 5–10 per cent of all drugs consumed in Russia, and the government is often criticised for failing to stem this tide. A recent UN survey ranked Russia as the fifth-largest producer of counterfeit

pharmaceuticals in the world, with around 70 per cent of these products produced domestically. From a global perspective, it is estimated that fraudulent medicines will become a \$75bn criminal industry by 2010, a 92 per cent increase on 2005 figures, according to the Pacific Research Institute in the USA.

Weak links

The rising incidence of the parallel trade of legitimate pharmaceuticals also has the potential to undermine patient safety and puts the integrity of the supply chain at risk⁴. Around 140 million packs of medicines are parallel traded every year within the EU as part of the free trade of goods, which is legal within the European Economic Area.

This trade of medicines is highly lucrative, with profits estimated as being in excess of €459m each year, and the number of parallel traders is growing rapidly (see Figure 1). Pfizer believes that this is not in the best interests of patients, as parallel trading has the potential to be exploited by criminals introducing counterfeit products into the supply chain.

Graham Satchwell, a former UK police detective superintendent, has argued that parallel trade may provide counterfeiters with an easy route for selling illegal products into the legitimate distribution chain. He warns that this high-volume and high-profit business activity, which poses a clear threat to patient safety, is not being sufficiently regulated and monitored⁵.

Repackaging threat

One of the potential problems with parallel trade is that medicine boxes are opened, the contents removed and the product repackaged. This introduces the

possibility of human error into the process. Pfizer has found numerous examples of human error in repackaged samples of parallel-traded pharmaceuticals that have the potential to compromise patient safety. For example:

- Different doses of medicine inside the packs from those stated on the outside
- The pack containing capsules when the box states tablets
- Expiry dates and batch numbers on the box not matching those of the medicines inside
- Patient information leaflets being in the wrong language or out of date

In a UK audit of parallel trade import samples, Pfizer found that over half of the samples had patient safety issues and over a quarter were serious enough to be referred to the MHRA, the UK regulator (see Figure 2). Of over 950 samples reviewed, more than one in five had patient safety issues serious enough to be referred to the regulatory authority. Even Boots, the UK's largest pharmacy chain, has been affected. It reported that it had identified five instances of problems with parallel-traded products, such as labelling errors and wrong pack size, one of which resulted in a batch recall⁶.

Batch recall

Parallel-traded medicines may go through as many as 30 pairs of hands before finally reaching the patient⁷. Inevitably, this hinders the ability to recall medicines efficiently and effectively. For example, if a batch of medicines sold in Spain is recalled, tracing where the entire batch may have been distributed is substantially more challenging once it has left Spain and moved across EU borders. Yet there is no regulatory requirement to record the batch numbers of imports and exports of medicines

Figure 1. Cumulative number of European PI licences

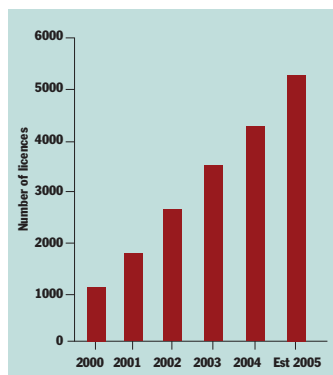
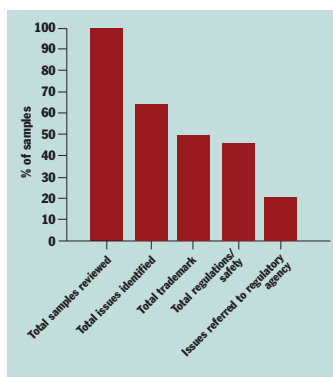


Figure 2. Extent of PI compliance/safety issues identified across Europe



with the regulatory authorities across the EU. This means that the systematic track and trace of medicines across the EU supply chain is made very difficult.

Undoubtedly, patient safety can be enhanced with a secure and safe medicines supply chain. At present, the European supply chain is fragmented, with no supra-national regulatory oversight. With the growing threat of counterfeit medicines entering the supply chain, the current system must be assessed and there is a need for even higher standards and greater responsibility on behalf of every stakeholder in the supply chain.

Protecting patients

Pfizer is committed to working with key stakeholder groups in order to help protect the integrity of the medicines supply chain and protect patients from counterfeit products. It is currently rolling out a series

Parallel-traded medicines may go through as many as 30 pairs of hands before reaching the patient

of security measures on its products that will help to deter counterfeiting activity, including the introduction of a unique Pfizer logo on packaging that uses colour-shift ink, a technology that is difficult to fake but easy to verify, and is similar to the ink used on bank notes. Tamper-evident packaging is also being introduced.

Pfizer believes that the parallel trading of medicines provides a potential vehicle for counterfeits to enter the legitimate supply chain and that the process of repackaging medicines is not in the interests of patients. The underlying principle whereby medicines can be opened and repackaged within the secondary medicines market can only benefit third parties, yet it can undermine the security of the medicines supply chain and put patients at unnecessary risk. Regulatory authorities at EU and Member-State level must act to ensure that the medicines supply chain is secure, and that patient safety is enhanced and protected. **END**

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