



Case Study: Lipitor® UK Recall



“My life depends on taking these pills as my condition is hereditary, my younger brother died at 31... I think it’s shocking that fake medicines are finding their way to our chemists.”

This is the response of a patient caught up in the scandal of counterfeit medicines reaching UK patients in July 2005. She was interviewed as part of an investigative programme (Tonight, ITV) in January 2006.

Up until summer 2004 the UK’s medicines and healthcare products regulator, the MHRA, had not seen evidence of counterfeit, or fake, medicines in the UK supply chain for over nine years. Since then however, over the last 18 months, nine cases of counterfeit medicines have been found in the legitimate supply chain, now under investigation. Of these, five were discovered on pharmacy shelves and had been dispensed to patients. Each incident involves a different type of medication and a different number of tablets. In the case of the patient quoted here it was a batch of counterfeit Lipitor® – a drug used to control cholesterol levels in patients at risk of heart attack and stroke.

The MHRA had discovered 70 counterfeit packs which had cleverly faked packaging and even used a genuine batch number.



The counterfeit tablets and packaging.

This meant that it was almost impossible to tell which packets were the real medicine and which were a dangerous imitation. The MHRA issued a recall for the 120,000 packs using the batch number which had been copied. One pack of Lipitor® contains 30 tablets, providing a month’s supply for a patient.

As is standard practice for a medicine recall, the drug’s manufacturer, in this case Pfizer, was required to manage, and cover the costs for the recall process. The company estimates that around half of all the packs returned were counterfeit. Pharmacies across the UK

participated in the recall, 106 in total, demonstrating how easy it had been for a fake medicine to infiltrate the legitimate supply chain.

So what had happened?

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.



240 pharmacies participated in the recall. 60% of returned medicines proved to be counterfeit.

It is understood that a short line, parallel trading wholesaler imported the counterfeit Lipitor® 20mg from outside the European Economic Area, an illegal activity in its own right, and subsequently sold these medicines to a licensed, large full line multi-national wholesaler who in turn supplied the counterfeit medicines to pharmacies across the UK.

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.

This was not via illegal or unauthorised routes – not Internet, Mail Order, or back street pharmacy – but because the counterfeiter penetrated the legitimate medicines supply chain.

“ The UK is not flooded with counterfeit medicines as some reports suggest, but the indicators suggest we are at significant risk.”

Nimo Ahmed, Head of Intelligence, MHRA



European Trade Group

