

Counterfeit drugs set alarm bells ringing

This week's recall of a counterfeit drug found in the UK medicines supply chain is the second such case in as many weeks. **Debbie Andalo** reports

The two cases of counterfeit drugs that have found their way into the legitimate medicines supply chain in the UK in just 10 days have set alarm bells ringing throughout the pharmacy profession and the pharmaceutical industry.

Both the Royal Pharmaceutical Society and drugs manufacturers have expressed some anxiety that the counterfeit lifestyle drugs available on the internet have somehow found a route into the official UK medicines chain.

Although the two cases are the only ones of their kind in the UK in the past 10 years, they have come at a time of heightened global awareness in the pharmacy profession and industry of the risks of counterfeit drugs.

Only last month at a conference in London John Theriault, vice-president of global security for drug manufacturer Pfizer, referred to counterfeiting as "the emerging crime of the 21st century". His comments came as Pfizer announced it was setting up an advice website to help patients who believe their prescribed medicines may be counterfeit. Although the website has been established by its international headquarters in the US its core information is useful to patients anywhere in the world.

The two counterfeit cases in the UK involve "lifestyle" drugs — Reductil (sibutramine), which is prescribed for obesity, and Cialis (tadalafil), which can be used in cases of erectile dysfunction (see p335).

Investigation

The Society's director of practice and quality improvement, David Pruce, says his gut reaction is that the two cases are linked, although he adds this was only supposition as the two investigations into the cases being carried out by the Medicines and Healthcare products Regulatory Agency are still ongoing.

He says: "It wouldn't surprise me if the two cases were linked because they have both occurred over a period of only a couple of weeks. But if the drugs counterfeiting, which we have seen happening on the internet, has got into the legitimate supply chain in the UK this would be extremely worrying."

Counterfeit drugs in some parts of the world, especially South East Asia, can account for more than half the medicines in the official supply chain, he says. But it is not only developing countries that are at risk. In America last spring the cholesterol-lowering statin Lipitor, produced by Pfizer, was targeted by counterfeiters. And the number of cases of suspected counterfeit prescribed drugs investigated in the US by the Food and Drug Administration is reported to have gone up fourfold in the past four years to more than 20 a year.

Mr Pruce comments: "Until now this is something which we have been able to keep

out of the UK. In the UK the checks and balances are in place but in other parts of the world counterfeiting is a huge problem."

He says that one of the most widely counterfeited drugs is a common antibiotic, which suggests that "astronomical" amounts of money could be made from this kind of fraud.

He adds: "Counterfeiting is big business out there and I think the fact that the MHRA has been able to overcome it until these two cases is a credit to the authorities."

Pfizer, whose erectile dysfunction drug Viagra has also been targeted by drug counterfeiters in the past, says it is concerned about the two UK cases. In April this year the Metropolitan Police seized millions of counterfeit drugs, including counterfeit Viagra, following raids in London and the Home Counties.

A spokesman for the company says: "It appears that counterfeiters are now targeting the legitimate supply chain, therefore it is imperative that this supply chain is as secure as possible. In the first instance Pfizer is calling on the Department of Health and the regulators to examine the weakest point of the European supply chain — repackaging of original manufacturers' medicines by parallel traders."

Two cases

The first case of a counterfeit drug in the UK medicines supply chain in a decade came to light on 25 August. It involved Cialis which is produced by Lilly ICOS UK Ltd.

The fake product was discovered after a patient reported to Lilly that the 20mg tablets he was taking were crumbly when he tried to break them in half.

The company called in the MHRA, which discovered that tablets were in circulation in the supply chain bearing two batch numbers that did not match any used by Lilly for genuine product.

The second counterfeit case was discovered last week, on 2 September, when a wholesaler noticed an unusual batch number associated with Reductil, which is produced by Abbott Laboratories Ltd. The wholesaler called in the MHRA, which confirmed the batch was counterfeit.

Abbott Laboratories and Lilly ICOS UK Ltd, are both assisting the MHRA with its investigations.

A spokesman for Lilly says: "We are waiting until the outcome of the investigation before making any future statements. Until the investigations are complete we are not in a position to say where in the supply chain the product is coming from."

He says that pharmacists wishing to be sure they are dispensing genuine Lilly medicines should look on the back of blister packs



Have counterfeit drugs found a route into the official medicines supply chain?

for a hologram-type company logo which changes colour from red to gold and back to red. This guarantees authenticity.

Abbott Laboratories has confirmed that it is helping the MHRA with its investigation and is advising patients who have unknowingly been dispensed counterfeit Reductil to return the drugs to either their pharmacist or GP.

A company spokesperson says: "Abbott Laboratories takes the counterfeiting of drugs very seriously and we are committed to protecting patient safety. In this case patients should talk to their pharmacist first to ensure that they are taking genuine Reductil."

Speedy action

The Association of the British Pharmaceutical Industry says the integrity of the medicines supply chain in the UK is "of the utmost importance."

A spokesman says: "These cases are in some way good news — not that they are happening, but that the cases are being picked up. I think the fact that speedy action has been taken on this is reassuring. Things can go wrong in the best regulated systems.

"I don't think the system is at fault. Action needs to be taken to track down the perpetrators of this fraud and to stop their activities and lead them to justice — whether they are in this country or not."

The MHRA was unable to say when it would complete its two investigations, which it launched immediately it became aware of the cases.