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MHRA shifts counterfeit battle up a gear

By Selina McKee

The UK's Medicines and Healthcare products Regulatory Agency has published its first ever anti-counterfeit strategy, alongside the launch of a new 24-hour hotline for reporting suspected incidences of fake medicines and devices.

The move comes as criminal activity in the global counterfeiting arena continues to snowball, with the MHRA recently having to deal with an unprecedented number of phoney drugs entering the National Health Service supply chain.

In the UK, there have been nine recalls of specific batches of counterfeit medicines in the last three years, including Eli Lilly's antipsychotic Zyprexa (olanzapine) and Pfizer's cholesterol buster Lipitor (atorvastatin). These fake versions of medicines had made it all the way to the pharmacy and patient level, causing serious concern over the security of the supply chain and prompt batch recalls.

The Agency believes that the provision of easily accessible accurate, timely and specific information is paramount in the battle against this potentially lethal activity, and that the public, healthcare professionals, supply chain, industry and other stakeholders must be aware of the risks, extent, and availability of counterfeit medicine and devices in the UK. "Through highlighting the issue and risks involved to both the public and distributors it is possible to undermine the market for counterfeit medicine in the UK", it states.

Three-year battle plan

This notion forms a central vein in the MHRA's anti-counterfeit strategy, which sets out its comprehensive approach to fighting the availability of fake drugs and devices in the UK for the next three years. The group has developed a broad programme of activity, which, it hopes, will minimise the risk of patients coming into contact with counterfeits primarily by making the UK a less attractive target.

The Agency's war plan is very detailed but loosely based on three key fronts:

- Communication: to ensure that the public and healthcare professionals are well informed about the issue, including how to report any related suspicions to the MHRA, via its newly-launched hotline;
- Collaboration: to take part in "all relevant international initiatives" against counterfeit medicines and medical devices which impact upon the UK, including the World Health Organisation's International Medical Products Anti-Counterfeiting Taskforce (IMPACT). In addition, it plans to strengthen its ties with law enforcement agencies and other regulatory bodies as well as the pharmaceutical industry; and
- Regulation: the MHRA's Intelligence unit will conduct a "continuous threat assessment of the risk", and the group plans to keep a close eye on the supply chain and medicines

at a high risk via surveillance projects, investigate all reports of counterfeit medicines, and wherever appropriate, prosecute those involved.

Furthermore, it has promised a thorough examination of all aspects of the supply chain in view of the recent cases of fake drugs reaching patients, with a view to making recommendations for change, if necessary.

Attractive destination

The problem is certainly on the rise around the world and, as the MHRA points out, the UK offers a particularly attractive and potentially lucrative destination for fake medicines and devices, largely because of the high drug prices, sizeable market, extensive internet connectivity and a complex supply chain in the country.

Earlier this month, a woman who had £250,000 of counterfeit medicines stashed in her London home was sentenced to two and half years in jail by the Croydon Crown Court. Enforcement officers from the MHRA and the City of London Police discovered the fake drugs – which included more than 50,000 units of ephedrine, a selection of slimming and erectile dysfunction pills, painkillers and anabolic steroids - at thirty-nine year old Shazia Amjad's house in Uxbridge late last year. The drugs came from Pakistan and were sent to Amjad via mail.

Traditionally, criminal activity has been focused on the production of 'lifestyle' medicines, such as those to combat erectile dysfunction or induce weight loss, but it seems the focus is now shifting, with a growing number of 'lifesaving medicines' for conditions such as heart disease or cancer the next generation of counterfeiting targets.

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