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Be on the look out for counterfeit medicines in the supply chain

Strategies for preventing counterfeit medicines from entering the supply chain, and for detecting them if they do, were set out at the recent meeting of the Procurement and Distribution Interest Group. Dawn Connelly reports

Purchasers should be vigilant in order to help combat counterfeit medicines in the legal supply chain, Ged Lee, group manager, laboratories and pharmacopoeia at the Medicines and Healthcare products Regulatory Agency, told participants at the recent meeting of the Procurement and Distribution Interest Group.

He said that there are a number of things that purchasers can do to try to spot counterfeits. These are:

- Question large discounts
- Check batch numbers and expiry dates — often the expiry date on counterfeit products does not correspond with the batch number. If in doubt, contact the manufacturer to check
- Educate staff who handle the products of the risk of counterfeits and how to spot them, for example, to look out for faded packaging
- Contact the manufacturer and the regulatory authorities if you suspect that you may have found a counterfeit product

Dr Lee highlighted the fact that there have only been three cases in the past 10 years of counterfeit medicines penetrating the regulated UK supply chain (Zantac in 1994 and Cialis and Reductil in 2004), although there have been a number of instances in the illegal supply chain (including, those involving, for example, benzodiazepines, anabolic steroids, phosphodiesterase inhibitors and obesity treatments).

Since 1994, 26,500 samples of medicinal products have been taken randomly from the UK market and the MHRA has analysed them as part of its product quality surveillance programme and found no evidence of counterfeit medicines. "Therefore when people say that there are 5, 10 or 15 per cent counterfeit products in the legal supply chain I can't believe it, because, if there were, we would have found evidence of that in this programme," he said.

Ged Lee: purchasers need to be proactive to prevent counterfeits entering the supply chain

Dr Lee went on to discuss the case of counterfeit Cialis (tadalafil) in the legitimate supply chain, which was first reported to the MHRA on 10 August 2004 (*PJ*, 28 August 2004, p277). Within 13 days of this, samples of counterfeit batches in three different pharmacies had been detected and analysed by staff at the MHRA laboratory, the MHRA then issuing a rapid alert throughout Europe. He explained that the counterfeit Cialis tablets looked practically the same as the authentic product, with only slight differences in colour. The packets were also similar, with just slight differences in the printing — the batch number and expiry date for the counterfeit medicine were screen printed. In addition, the Eli Lilly logo on the strip packaging of the counterfeit did not fluoresce under ultraviolet light, as it did on the authentic product. Mid-infra-red analysis in a laboratory showed significant differences between the counterfeit and authentic products, he added.

"It became apparent to us with both [the] Cialis and Reductil [cases] that we needed to look at our strategy," said Dr Lee. He explained that the MHRA has always tended to be reactive, mainly because the legal supply chain is not something that can be sampled easily. "But now we need to think about our surveillance strategy and we have been looking at what we need to do in order to be proactive in identifying potential counterfeits in the supply chain," he admitted.

He continued by telling participants that the MHRA has already begun to do this with a pilot study that involves taking large numbers of samples from the end point of the supply chain, including community pharmacies, hospital pharmacies, wholesalers and internet sites. These products are rapidly screened using non-destructive techniques, such as infra-red technology, and reference authentic samples are collected from all manufacturing sites that supply the UK. Anomalous results are followed up with the companies concerned.

In the pilot study, 58 samples of Viagra have been analysed from one manufacturing site and 34 samples of Lipitor have been analysed from five manufacturing sites — in all cases the samples were compliant. "This shows that (a) the process works, and (b) we are able to take it forward and show that there is more we can do with it," he explained.

Another area in which the MHRA is being proactive is international collaboration. "We have set up an international meeting of regulatory authorities and are looking to collaborate and exchange information about analysis and surveillance," he said. Countries involved include the US, Canada, Australia, the Netherlands, Germany and Singapore, as well as the UK. It is an ad hoc group, Dr Lee explained — it means that the MHRA is notified of any counterfeits found in any of the markets within the group. "For example, counterfeit Cialis was found six months previously in the Australian market," he revealed.

The meeting of the Procurement and Distribution Interest Group of the Guild of Healthcare Pharmacists took place on 2 June in Coventry. **Dawn Connelly** is news and features writer with *The Pharmaceutical Journal.*

Collaborative procurement hubs need to have a clinical heart

The target for annual savings from collaborative procurement hubs is £270m by the financial year ending 2008, Zoe Greenwell, collaborative hub project lead at the NHS Purchasing and Supply Agency, told participants. There are three pathfinder collaborative procurement hubs, which started in February this year. Ms Greenwell said that the business cases for these have identified a £72m saving by the financial year ending 2008.

She went on to highlight the key characteristics of collaborative procurement hubs. All trusts within the relevant health authority own the hub — it is not centrally managed. The organisations own the targets and the delivery and they set the budgets and identify the resources they need to drive out savings for themselves, she said. "But they also look at the whole of their commercial spend, and that is different to the way in which the confederations have worked," she explained. They identify areas where they are happy that procurement is working, she said. "For pharmacy spend, the three pathfinders have said that [this] is clearly being managed well with existing collaborative procurement activity," she added.

Ms Greenwell also stressed that she has identified that, within the collaborative procurement hub scheme, there needs to be a clear clinical heart to the hub. "The hub needs to have clinical groups within it — including clinical directors and clinical procurement specialists — to ensure that the needs of the clinicians are built in to any of the sourcing contracts as they go forward." She added: "We cannot expect anyone to commit to contracts to change their practices if they are not involved at the beginning."

Ms Greenwell finished her presentation by looking at the future of collaborative procurement hubs. "Emerging hubs will work with the Pharmaceutical Market Support Group, PaSA and with existing purchasing groups to look at how [to] build the best relationships and move forward to improve purchasing in the NHS," she said.

Re-organised NHS PaSA is to focus on procurement

The NHS Purchasing and Supply Agency (PaSA) will have an increased focus on procurement as its core activity, Howard Stokoe, principal pharmacist at PaSA, told delegates. Its reorganisation comes as a result of the Government's review of arm's length bodies, he continued. PaSA will be taking on additional roles and is undergoing a complete restructuring, with the emphasis on more flexible ways of working. There will be five directorates: pharmaceuticals; clinical equipment; clinical consumables; non clinical items; and agency/services. Although the pharmacy team is smaller, a procurement enablement team, encompassing over a quarter of staff at the agency, will be involved in processing contracts and data analysis, said Mr Stokoe.

"PMSG (pharmaceutical market support group) and PaSA will be working closely with pharmacy purchasing groups and collaborative hubs. This will result in a joined up and consistent approach throughout the NHS," said Mr Stokoe.