

Curse of the counterfeit

It is estimated that business in counterfeits will be worth £75 billion this year. The 'Combating counterfeiting' conference held by the RPSGB highlighted major issues and techniques affecting the industry as well as procedures undertaken to fight against it...

Counterfeit medicines have become a growing global problem. According to the World Health Organisation, sales of counterfeit medicine range from approximately one per cent of sales in developed countries to 10 to 30 per cent in developing countries.

In a recent conference held at the Royal Pharmaceutical Society of Great Britain (RPSGB), industry experts highlighted the intensity of the problem as well as current status of new technologies in order to raise public awareness.

'The counterfeit drugs are now being made to order and for a range of products instead of a single product,' Dr John Kerridge, EU regulatory advisor, Eli Lilly & Company, observed at the conference. 'The trend has gradually moved away from lifestyle drugs a few years ago to life-saving drugs now and that change is of huge concern to everyone.'

Citing examples from raids undertaken frequently, Dr Kerridge emphasised the need for 'closer look' as although the ingredients and chemical composition may be far off the mark, the finer details that counterfeiters go through while packaging may make the products hard to identify from the genuine ones.

The same point was illustrated by Dr Tesh Patel, senior director of quality assurance at Astellas Pharma Europe UK, as he displayed striking images comparing genuine and counterfeit packaging. Dr Kerridge also raised the concerns surrounding the increase in the number of internet pharmacies that have cropped up in the recent past and although a lot of them carry icons – including VIPPS, RPSGB and Legit script logos – things may not always be what they seem.

Examples were provided by Jane Nicholson, executive director of the European Industrial Pharmacists Group, of purchases from an online pharmacy that have resulted in deaths. 'While there exist enforcement problems due to lack of sufficiently trained inspectors and funds for laboratories, we also need to look at legislation governing counterfeit drugs,' she said while noting that the United Kingdom Medicines Act is now over 40 years old.

Highlighting the Medicines and Healthcare products Regulatory Agency's (MHRA) battle against counterfeiters and counterfeit products, Nim Ahmed, head of Intelligence, Enforcement

Group at the MHRA, discussed how much importance is being placed on packaging. 'We have examined computers and found that people from the EU and UK have sent sample packs with details and requested them to be made to order.' The worrying thing according to Ahmed, however, was the amount of active ingredient in the counterfeit products which depended on the amount of money that was offered.

'Worryingly, we have seen a lot of professionals, wholesalers, pharmacists, people who have operated in the industry for a number of years and know the system and have observed where the gaps are have then tried to penetrate those gaps.'

Counterfeiters, as Ahmed pointed out, have a great understanding of how the supply chain worked and that has made their task easier. Picking on the same point, Dr Patel highlighted a risky assumption that if a package is secured through the supply chain to the pharmacist, it is assumed that the medication is secure.

Quoting Jim Chrisitan, VP Global Corporate Security at Novartis, Dr Patel said: 'In almost every case, the technology, be it a hologram, tamper-proof labels, embossing, thermochromic ink, RFID tags, DNA markers, and the likes, enables companies to track cardboard, not product. It is not unusual to find genuine product in counterfeit packaging and counterfeit product in genuine packaging.'

Ahmed also reminded the attendees – as



Close inspection should reveal whether something is right or wrong

well as wholesalers and pharmacists on the whole – of the MHRA's 24-hour hotline (020 7084 2701 or by emailing counterfeit@mhra.gsi.gov.uk) where discrepancies and irregularities can be reported.

According to Ahmed, counterfeit products are mostly manufactured in China and can then be dispatched to anywhere in the world. 'We have had to recall a lot of products targeting the parallel trade market and hence are implementing strategies that also includes speaking to healthcare professionals, doctors and nurses who deal with medicines regularly.'

With a network mapped across the world, Dr Patel admitted it was a difficult task preventing the trafficking of illegal drugs. 'If we cannot as yet prevent trafficking of illegal drugs why do we think we can prevent counterfeit medicines? However, we may not be able to prevent it, but we can be prepared for it.'

Preparation via vigilance, mass serialisation, and even an international convention, according to the speakers.

Counterfeit medicine statistics

- The global pharmaceutical market is worth \$620bn and an estimated 12 per cent of sales are counterfeit products
- 20 per cent of medicines sold in India are fake while 35 per cent of drugs sold worldwide by volume come from India
- In 2010, there will be \$75bn annual business in counterfeits
- In 2010, the global income generated from drug counterfeiting will be bigger than the GNP of the 80 poorest countries combined (1/3rd of the world)
- Bangladesh exports to 52 countries and have 80,000 unlicensed drug stores

Sources: IMS Health, Associated Chambers of Commerce and Industry in India