

CRIMINAL INTENTIONS

Counterfeit drugs are not just hitting pharmaceutical company profits, they are also costing lives. For producers, the shape of the challenge is clear but the scale is not. Andrew Jackson, deputy global head of corporate security at Novartis, tells Nigel Ash that real change can only come from the political landscape.

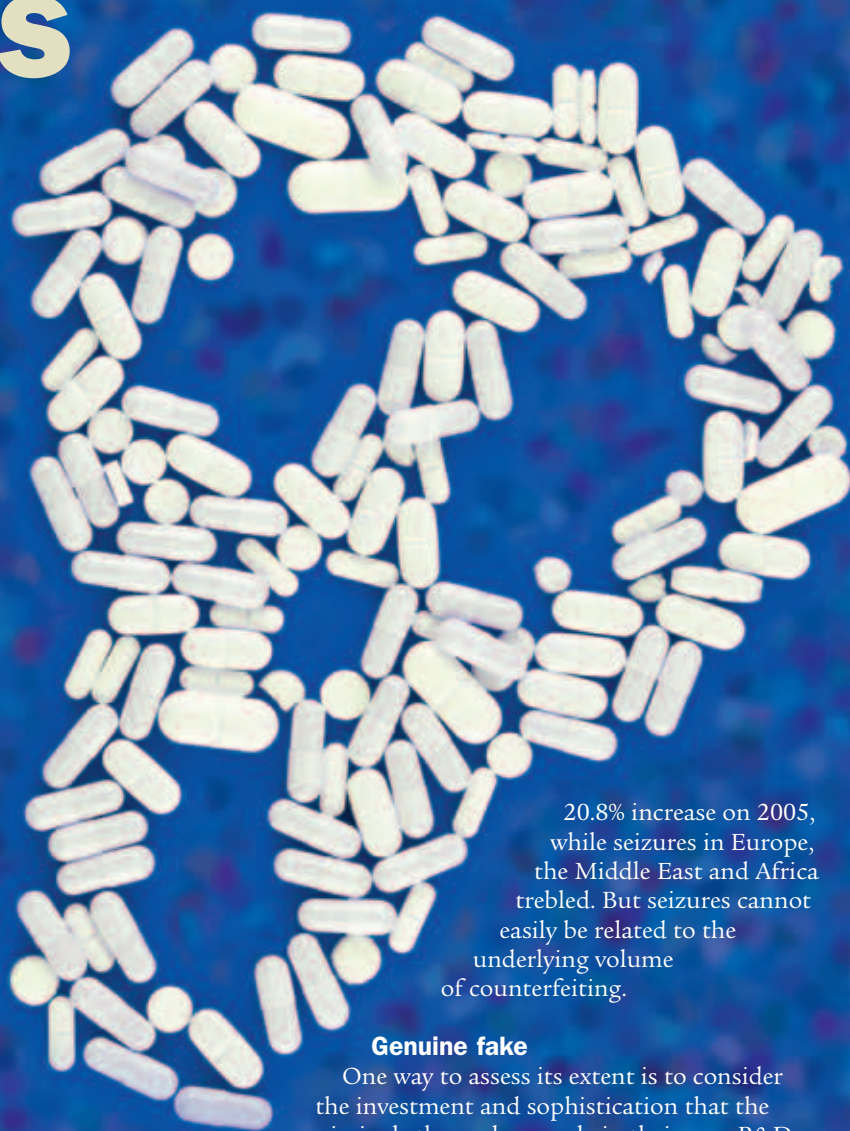
Counterfeit medicines represent an enormous health risk to the public. They may look like the real thing, but often they do not contain the correct ingredients or the right quantities of ingredients – and may even contain highly toxic ingredients. Even so-called ‘high quality’ fakes are unreliable because the source and what happens during the supply chain is unknown and illegal.

‘The figure that 10% of all pharmaceuticals globally are counterfeit is often attributed to the World Health Organization (WHO),’ says Andrew Jackson, deputy global head of corporate security at Novartis. ‘But the WHO cannot identify the original research on which that figure is based. The truth is that no one knows. By definition, counterfeiting is a criminal activity and statistics are inconsistent.’

If the number of fake pharmaceuticals being consumed is unknown, it is hard to assess how many people are dying because they have ingested these drugs and not the real medicines. ‘Nevertheless, there is a school of thought that a percentage of the deaths attributed to adverse drug reaction is caused by counterfeits,’ says Jackson.

This has been hard to prove since the patients have not only been consuming the evidence, but when they are dead, one of the first things grieving relatives invariably do is throw away the remaining medications.

The raw figures on counterfeit seizures, such as those given to US legislators in May last year, show that 8.1 million counterfeit tablets were seized in 36 countries during 2006, a



20.8% increase on 2005, while seizures in Europe, the Middle East and Africa trebled. But seizures cannot easily be related to the underlying volume of counterfeiting.

Genuine fake

One way to assess its extent is to consider the investment and sophistication that the criminals themselves apply in their own R&D: to create, package or repackage and then route their products to the market. Many drugs have different names in different markets. Re-boxing, re-leafleting and repackaging a stolen or diverted product, itself a technical challenge, can be a sophisticated operation.

One challenging recent development has been ‘co-mingling’, whereby the genuine product is packaged along with the

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fake. ‘They mix in counterfeit, stolen, diverted or adulterated products with genuine products at different levels and at different places in the supply chain,’ says Jackson. ‘This makes identification and authentication extremely difficult.’

For example, a box of three blister strips of pills, he explains, might have a single counterfeit strip. If a suspect shipment is examined, it may be a blister with the genuine medication that is analysed. Sampling now needs to be extensive.

‘If you think this through in terms of what it means to patients, one week they are getting a genuine product and with the second blister they are getting counterfeit,’ adds Jackson. ‘The medical implications of that scenario are horrendous.’

Parallel lines

In an ideal world, a short and secure supply chain cuts out the criminals. But with few exceptions, such as time-critical cold storage items where technology like RFID can be used for inventory and quality control rather than security and authentication, the supply chains are far from short. A major concern for Jackson is the consequences of EU Free Trade Rules, which have opened up a parallel market in pharmaceuticals.

‘In Europe, the situation is hugely complicated because of legitimate parallel trade,’ says Jackson. ‘What that means is that a drug can be sold in Greece, which is a low-price country,

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and that drug, provided it meets certain regulatory requirements in terms of packaging and labelling, can be legally re-packaged and sold in a higher-priced country within the EU.’

For example, when someone in the UK goes to the chemist to pick up a prescription, the chances are that the drug was originally sold in, say, Greece, so it will have changed hands several times quite legally. It will have been repackaged from its original Greek packaging, and the original Greek leaflet thrown away and replaced by an English language version and it will then be legally imported into the UK. Some research indicates that drugs that are sold in southern Europe can change hands between 20 and 30 times before ending up in a high street chemist. Every link in that supply chain makes it more vulnerable and susceptible to the entry of counterfeits.

Jackson highlights another danger that many, but not all, security or authentication features are in the cardboard

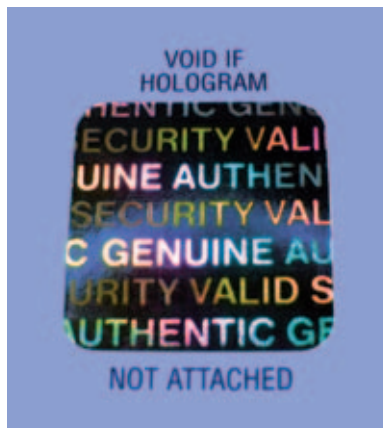
packaging, so they are not on the blister and it is very difficult from a regulatory point of view to get excipients on tablets.

‘Therefore, if you are a parallel importer in Greece and you get the necessary licences to repackage the product that you bought in Greece, and then sell it on to the UK, what happened to the cardboard that has all the security features that are designed to authenticate the product?’ he says. ‘Best case scenario is that they end up in the trash and are thrown away. Worse case scenario is that the genuine packaging with all those sophisticated security features is recycled and used to authenticate and conceal the counterfeit product.’

The main problem in Europe is the complexity of the supply chain and this perfectly legal repackaging. ‘You cannot repackage a Mars bar in Europe and export it to another EU country, but you can with medicines,’ comments Jackson. ‘It is totally bizarre.’

Jackson quotes a comment that EU commissioner for enterprise and industry Günther Verheugen made in January 2008: ‘Unfortunately, the first review of the study into parallel trade is that it brings considerable risk to the safety of the

patient,’ says Jackson. ‘The reasons for that are numerous. There are problems with the packaging and labelling of the products as well as product recalls; the complexity of distribution channels and its supply. Finally, it is difficult to effectively enforce the law.’



Holograms are effective if they are on the right packaging with the right product.

Jackson believes that ending the parallel market is a non-starter because it runs counter to EU Free Trade

principles. ‘But a major step would be to stop the repackaging and implement some form of over-boxing, which means that your original box is there with your original security features intact, albeit within a second box,’ he says. ‘It is pretty cumbersome, but it is an argument that has been put forward quite a lot. The counterfeiters could well over-box too, of course, but this way the integrity of the original packaging is maintained, whereas at the moment it is not – it is thrown away or recycled.’

Effective anti-counterfeiting

The Novartis anti-counterfeit team, which is organised regionally, is highly aggressive, says Jackson, and in his view runs one of the most effective anti-counterfeiting programmes in the industry. It works closely with the Pharmaceutical Security Institute (PSI), which was formed

in 2002 by leading producers to collect and coordinate counterfeiting data from members, in a database that allows the information to be shared. If necessary, affected producers may then launch joint investigations. The database is no doubt as powerful as Jackson maintains, but when *World Pharmaceutical Frontiers* visited the PSI website, its most recent posted events list was for 2006.

Routing checks

PSI was at Innsbruck, Austria, last year with eight producers, including Novartis, for a week-long conference for customs officials from the 27 EU states, focusing on how to spot counterfeit consignments. The routing of consignments is important, according to Jackson. The majority of Novartis products sold in Europe are made in Switzerland, so when consignments arrive from elsewhere – Russia, China, India and Latin America are major sources of counterfeit products – this should alert customs.

‘We have examples of our own products, which have holograms on them, in Russia,’ says Jackson. ‘But we don’t put holograms on them in Russia. The Russian products look legitimate and say they are protected against counterfeiting, but the whole product is counterfeit – the tablets, the cardboard, blisters and leaflet are all 100% counterfeit.’

The extent to which counterfeiters will go to improve the provenance of their fakes was, according to Jackson, highlighted by the investigation into an online pharmacy.

‘Some internet pharmacies source products from wherever they can get it cheapest,’ he says. ‘In this particular case, it started back in May 2006, when customs in the UK intercepted a huge shipment of pharmaceuticals at Heathrow airport. There were eight products involved belonging to five different companies, Novartis being one. Seven out of the eight products including ours, turned out to be counterfeit.’

The Novartis fake was manufactured in China, went by road to Hong Kong and flew to Dubai where it was warehoused. It would stay there until an order arrived and the product was flown from Dubai via Heathrow to the Bahamas where there was a fulfilment centre. This met orders for patients who had been foolish enough to buy their prescription drugs on the internet. In the Bahamas, individual patient orders were put together in Jiffy bags and shipped in bulk back to the UK. There were several little outfits in the UK whose job was

to put a stamp with the Queen’s head – a mark of legitimacy – on the bag and send all these packages in the post to unsuspecting patients in the US.

‘I have one of the orange plastic containers, which is what the patient would get through their letterbox,’ says Jackson. ‘Within the container, there is no cardboard, no patient information leaflet, simply three blister strips with tablets. In some of those plastic containers we recovered, one of the strips had counterfeit product and the others were genuine.’

Jackson’s team also regularly attends industry security technology conferences. ‘However, there is little to be learnt or gained by Novartis people going to these,’ he says. ‘The reason we go is primarily to counterbalance some of the more extravagant claims that are made by technology vendors.’

Quick fix challenge

Jackson says that one of his team’s responsibilities is assessing security technology and he is concerned that technology is sometimes presented as ‘the silver bullet’.

‘The Los Alamos National Laboratory tested RFID and defeated it with ease,’ he explains. ‘I am not saying that Chinese counterfeiters have the same expertise or same technology, but it proves that it can be done. It is very clear to me, working with this issue on a daily basis, that we are dealing with some very smart, sophisticated and organised criminals who invest considerable amounts of their own funds into counterfeiting – into their own R&D.’

Jackson feels strongly that for supply chain integrity to work, everyone has to prove their own professional integrity, which is a challenge given the complexity of the European supply chain and the legal parallel trade and repackaging. That integrity needs to be underwritten first by politicians and then by regulators.

‘Counterfeiting is now at last on the political agenda, but some politicians may be looking for quick fixes, such as sticking a hologram on the box or introducing RFID or 2D barcodes,’ he says. ‘These would be all well and good if they worked and actually solved the problem, but the real danger is that if there is over-reliance on technology. If people believe that there are magic bullets, politicians and regulators might buy into this misconception and do nothing else. They will not strengthen laws, will not devote law enforcement resources, will not support international coordination, and will not invest in raising public awareness about the dangers of buying product on the internet. So nothing else will be done.’ **WPF**

