



The counterfeit drugs business continues to grow at an alarming rate. Andrew Jackson, Novartis, explains to Jim Banks what measures are in place and what needs to be done to secure the future of legitimate pharmaceuticals.

THE DARK TRADE

Counterfeiting, the epidemic of modern pharmaceuticals, has evolved from 'bathtub' small-time operations to multinational criminal syndicates, reaching even the highest levels of government. Though much is being done to help identify fake products, understanding where they enter the supply chain and establishing effective deterrents is essential to protecting customers and ultimately brand reputation.

According to Andrew Jackson, Vice President of Security, Novartis US Corporation, supply and distribution channels offer the easiest access for counterfeit medications. 'The pharmaceutical distribution system is incredibly complex,' he says. 'Medicines are no different from apples and oranges: they will change hands many times between the point of manufacture and when they are dispensed, particularly in Europe, due to the parallel import system operating there.'

Security issues

Another entry point is the internet, which is unregulated and difficult to control. 'Even if a government agency can

Contributor profile



Andrew Jackson has been vice president, Corporate Security, Novartis Corporation since June 2008. He oversees Novartis' global anti-counterfeiting programme. Jackson was previously executive director and deputy head of Global Corporate Security with Novartis International AG. Novartis Corporate Security has regional offices in Asia, Latin America, US and Europe.

COUNTERFEIT ISSUES

- The pharmaceutical distribution chain is complex and products can pass through many hands before reaching the end user.
- Internet sales are growing and difficult to regulate.
- Fake holograms and packaging are used on counterfeit goods.
- The counterfeit drugs business is a more attractive option for criminals than other nefarious activities, because, in some countries, the sentence for selling cocaine is a life sentence, while selling counterfeit medicines results in as little as six months in jail.

take down an internet site that is selling questionable products, the same site can just pop up the next day under a different website address. The internet bypasses almost all of the security obstacles that are in place,' Jackson explains.

These issues, together with a 'quick fix' government mentality, have resulted in an over-reliance on technology as being the miracle cure. However, technology can only be used to validate drugs in

legitimate supply chains and does little to prevent alternative routes to market. For example, a counterfeit drug can move from China to the US, go twice around the world, and never once enter the legitimate pharmaceutical supply chain.

'That tells you a lot of things,' says Jackson. 'Firstly, that the counterfeiting of pharmaceuticals is increasingly international in nature. Secondly, that criminals are able to bypass legitimate supply chains with ease. Thirdly, that there is a huge criminal investment in organising the supply and distribution of fake drugs. For example, there could be transport companies, warehouse facilities and fulfilment

centres in one country and logistics/forwarding operations in another, which all require a considerable degree of sophistication and organisation, not to mention finance, to set the whole thing up. There is no quick fix to this.'

Security features in packaging can provide a false sense of security. For example, affixing a hologram on a box will have no effect at all in the scenario Jackson outlined. Conversely, it could have a completely counter-productive effect. When patients or health professionals see a hologram on the box they could be led to believe it contains a genuine product, when nothing could be further from the truth.

'In fact, we have some examples from several different countries, including Russia, where we have products that are completely counterfeit including the cardboard box, patient leaflet, blister and the tablet,' he explains. 'On those boxes there is a hologram, which is also counterfeit, that says "this product is protected against counterfeit". Technology is a double-edged sword.'

Subjective data

Despite the bleak picture often painted through statistics, such as the figure that 50% of all drugs traded via internet pharmacies are counterfeits, Jackson warns that these numbers are seldom based on fact. Counterfeiting is by definition an illegal, underground activity, and reliable data are therefore hard to come by. Many statistics that are widely quoted are not supported by empirical data and are often cited by entities with a vested interest in exaggerating the extent of the problem.

Manufacturers of life-style drugs are the hardest hit by counterfeiters who favour erectile dysfunction drugs as their main sources of income.

Jackson says Novartis has had a very different experience. 'We frequently buy our own products from the internet and the amount of counterfeit Novartis products that we discover this way is minimal,' he says. 'Most of the products we recover have either been diverted, stolen or are near to expiry because people will shift products cheaply when goods are near to their expiration date, and a lot of that ends up on the internet.'

Summarising the statistical issue, Jackson believes counterfeiting is growing, and is attracting serious organised crime. 'Bad guys are drawn to it because they are willing to target all forms of therapeutic categories, not just life-style drugs,' he says. 'All the signs are that counterfeiting will continue to grow and it will become very difficult to get back under control.'

PSI intelligence

The most comprehensive set of statistics about counterfeiting is kept by the Pharmaceutical Security Institute (PSI). Twenty-six pharmaceutical manufacturers, including Novartis, participate by providing their own

intelligence and investigative data, which PSI tabulates against its own research gathered from open sources.

'The PSI publishes an annual report and that data clearly shows that, despite all the efforts by industry and increasing efforts by all the law enforcement around the world, the amount of cases and the quantity of counterfeit products on the market continues to increase,' says Jackson. 'You could argue that the industry is getting better at identifying counterfeiting, but I'm sure much still goes unreported and undetected. The ease with which people can counterfeit products, the lure of making a lucrative profit and the lack of an effective deterrent will continue to attract more criminals who want to get involved in the counterfeit business.'

Legal disparities

Jackson believes that one of the reasons why pharmaceutical counterfeiting is so attractive is because the law in many jurisdictions is very weak. He gives two examples.

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'If you manufacture, sell and distribute cocaine in Columbia and are caught, you'll go to prison for 20 years, which is effectively a life sentence,' he says. 'But if you manufacture, sell and distribute a pharmaceutical product and get caught, you'll be sentenced to two years and you'll probably be back on the streets within six months. So, sanctions are not effective. If you are a recent graduate from the "Bogota university of crime" considering your career options, which is the most attractive career path?'

The other example occurred in 2008 when Novartis worked with authorities in a Middle East country and four people were arrested for handling counterfeit Novartis products in the Middle East. 'Released on bail, they were subsequently prosecuted, found guilty and sentenced to six months' imprisonment and a hefty fine,' says Jackson. 'The problem is, while the wheels of justice were turning, these guys had absconded because they weren't remanded into custody during the trial. They were tried in absentia. Even if the authorities catch up with them, which is unlikely, they're only going to serve six months.'

Education and preparation

For Novartis, awareness is the cornerstone of its strategy to combat this growing problem. The company recently participated in a National Geographic TV documentary, *Illicit: The Dark Trade*, which examined cross-industry counterfeiting. Novartis contributed undercover film footage showing the unsanitary and unhygienic conditions in which some counterfeiters operate. The WHO anti-

counterfeiting task force, IMPACT, is using the same visual approach, putting together its own films of counterfeiters for government education programmes.

‘We spend a lot of time talking to governments, training law enforcement authorities, customs police and regulatory authorities – anyone who will come into contact with medicines,’ explains Jackson. ‘But because we live post-9/11, law enforcement teams have many other issues on their plate, such as narcotics, illegal immigration, regular customs issues and terrorism, so resources to combat counterfeiting are hard to secure. What we tend to do, in many parts of the world, is initiate many investigations ourselves. We will do our own intelligence and investigative work and once we have identified individuals involved in counterfeiting or counterfeit manufacturing facilities, pass this information to law enforcement who will take the necessary action. This methodology of industry working in close collaboration with law enforcement has proved very effective in many countries and has resulted in many seizures of counterfeit medicines, packaging materials and illicit manufacturing equipment, and the prosecution and imprisonment of offenders.’

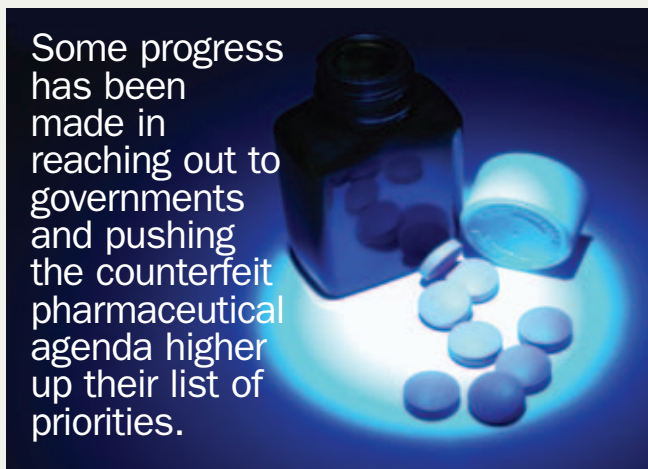
Jackson believes that some progress has been made in reaching out to governments and pushing the counterfeit pharmaceutical issue higher up their list of priorities in terms of organising task forces and introducing legislation to help deter criminals.

‘One example took place in November 2007, when there was an EU customs seminar entirely devoted to this issue,’ says Jackson. ‘Several pharmaceutical companies, including Novartis, gave presentations. On the basis of that, EU customs identified pharmaceutical counterfeiting as one of their key priorities for intervention and enforcement action in Europe in 2008. That kind of commitment from government would have been inconceivable a few years ago. However, there is no room for complacency, and there remains a huge amount of work to be done.’

Institutional attitudes

One of the features of counterfeiting in many parts of the world is that, like any high level professional lucrative criminal activity, it attracts government corruption.

‘In some countries there is absolutely no question that the government colludes or at the very least turns a blind eye to what’s going on,’ says Jackson. ‘In China, there are local economies in small towns and villages that are entirely dependent on counterfeiting, not just pharmaceuticals but



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also designer shoes, T-shirts and handbags. Many suspect the involvement of the Chinese military (PLA) in counterfeiting and civilian authorities have indicated that they do not regulate the PLA.’

Collaborative goal

For Jackson, the antidote to this epidemic of fake goods begins with increased worldwide coordination. ‘One of the frustrations shared by many industry colleagues is the inability of

governments to talk to each other in a joined-up way,’ he says. ‘This is an international problem that doesn’t respect boundaries.’

Jackson calls for greater international coordination and meaningful exchanges of information, joint operational activity and joint investigations involving industry.

‘We have a lot of information about individuals and organisations involved in this and we are only too willing to share,’ he says. ‘A dedicated task force in every country that is able to devote resources – intelligence people, police, customs, health ministry and regulatory people – in a coordinated and collaborative fashion would be the ultimate goal. But I suspect that this is still a long way from coming to fruition.’ **WPF**

AUTHENTICATION LIBRARY

Industry leaders have been investing heavily in extending the reach of their authentication centres around the world so they can collaborate with local authorities and create significant barriers to counterfeit drugs entering legitimate supply chains. To this end, sanofi-aventis announced the launch of its Central Anti-Counterfeiting Laboratory at the Tours pharmaceutical plant in September 2008. The new laboratory will provide expert analysis and identification of counterfeit sanofi-aventis products, as well as:

- create global testing methods that can be used to verify the authenticity of sanofi-aventis medicines
- create traceability reports on counterfeit products
- monitor internet activity associated with counterfeiting
- monitor distribution chains
- instigate and carry out independent investigations
- identify counterfeiting

- networks, enabling authorities to dismantle these organisations, leading to the seizure and destruction of counterfeit sanofi-aventis products
- maintain an ‘identity card’ database of confiscated fake goods, which can be used by regulatory agencies, police, customs and courts worldwide for prosecution.

According to sanofi-aventis, the introduction of its facility in France has already ‘spectacularly increased’ the rate of counterfeit identifications. The company is also investing in tamper-proof packaging systems as well as visible and invisible authentication systems. The sanofi-aventis security label, which uses bank note technology, is being applied to ‘high risk’ products. In 2011, barcodes called Datamatrix will be used to monitor the movements of sanofi-aventis products from manufacturing to end-user dispensing.