



Profiles

(Left) Since 1992, Dr Jonathan Harper has worked as a pharmaceutical regulatory consultant across the world and is the author of the 2006 *Counterfeit Medicines – Survey report* for the Council of Europe.

(Right) Andrew Jackson has been deputy head of corporate security at Novartis since 2002. In this role, he oversees Novartis' global anticounterfeiting programme.

The sale and trade in counterfeit pharmaceuticals is substantial and does considerable harm to governments, manufacturers, distributors and wholesalers, while exposing patients to a variety of serious threats to their health and well-being. The World Health Organisation (WHO) calculates that one in four packets of medicine sold at street markets in developing countries could be fake, and that a quarter of the medicines consumed in such places could be counterfeit, rising to half in some areas. Africa, South East Asia, South America, India and China are all booming markets for counterfeits.

A WHO study between 1999 and 2000 found that 60% of all counterfeit medicine cases occurred in poor countries, against 40% in industrialised nations. Another WHO study found over a third of 104 anti-malarial drugs on sale in pharmacies in South East Asia did not contain any active ingredients.

Worldwide problem

To dismiss counterfeits as purely a developing-world problem would be dangerously complacent, warns Dr Jonathan Harper, author of the Council of Europe's 2005 counterfeit medicines survey report. 'It is a global issue,' he says. 'The drug supply chain crosses the whole planet. It is wrong to say it is a developing-world problem and therefore does not concern us.'

Russia and the Balkans, with well-established and particularly ruthless organised crime networks, are becoming hot-spots for counterfeits, both branded and generic. Similarly, lifestyle drugs such as hormones, steroids, anti-impotence and anti-obesity drugs, and antihistamines are becoming the most commonly produced counterfeits, with the West targeted as the main market.

DEADLY TRADE

The global counterfeit drugs market is stronger than ever and poses a great risk to public health worldwide. Nic Paton asks Dr Jonathan Harper, and Andrew Jackson of Novartis what governments, regulatory bodies and the pharma industry are doing to stop this dangerous fraud.

DRUGS TARGETED BY COUNTERFEITERS

- Lifestyle drugs, such as Viagra
- Drugs for tuberculosis
- Drugs for HIV/AIDS
- Anti-cancer treatments
- Anti-virals

Drugs for tuberculosis, HIV/AIDS and, as genuine drugs become more expensive, anti-cancer drugs and antivirals, are all being targeted by the counterfeiters. In the UK, for example, the Medicines and Healthcare products Regulatory Agency reported that in early 2007 it had seen five incidents in the past two years where fake medicines had reached patients through the NHS, compared with no incidents since 1994. The US FDA, too, in early 2006, issued an alert about fraudulent flu remedies, including counterfeit prescription oseltamivir, widely known as Tamiflu.

'It is a big issue and it is getting worse,' agrees Andrew Jackson, deputy head of corporate security at Novartis. 'However, industry and governments are getting better at quantifying the issue. There is growing recognition that it is a global problem that does not respect borders. The counterfeiters will target any product regardless of its therapeutic category and cost. We see some inexpensive over-the-counter and generic drugs being counterfeited, even though margins are slim. It's anywhere that counterfeiters can make money quickly. In some cases this is a sophisticated operation, in others it is as basic as two men making it in a garage in Colombia.'

The internet has exacerbated the problem, with many people receiving junk mail advertising pharmaceutical products that are undoubtedly counterfeit. Ironically, there is a strong suspicion that the success in recent years of various global anti-narcotics drives, and better coordination by anti-drugs

Supply Chain

agencies, may now be having an impact on the counterfeit pharmaceuticals market. 'The people who are involved in drug trafficking will often also be involved in the fake medicine business,' adds Jackson. 'In Colombia, for example, if you get caught manufacturing, selling or distributing cocaine you will get 20 years. For a pharmaceutical product, the penalty is two years with parole in six months. But the margins in some cases are higher, so it is not surprising why it can be an attractive proposition to an enterprising criminal.'

Varied response

So, what is being done? The response can be broken down into two areas: technological and non-technological. One key response was the launch of an International Medical Products Anti-Counterfeiting Task Force by WHO at the end of 2006 to coordinate the response among governments, law enforcement agencies and the pharma industry.

The response from governments around the world, and the seriousness with which it has been tackled, has varied widely. Authorities in the UK and US have been very proactive, as has the Colombian Government and China. 'In Russia, the biggest counterfeiter is a well-known public figure and little has been done to stop him,' says Jackson. 'But there has been a growing recognition that this is an issue that must be tackled.'

HOT OFF THE PRESS

Jonathan Harper writes: 'The recently published UN INCB 2006 report provides a good example of the level of global incoordination in tackling the problems with pharmaceutical counterfeiting. It places the blame at the feet of national authorities, when in fact it would be better if the INCB could be an active partner, contribute to designing a global solution and pass on its valuable knowledge on how to tackle a global public health and crime problem. After all, the fake drug business is just an extension of the illicit narcotics and psychotropic business.'

Within Europe, the response has been tentative, says Harper, although the European Parliament made a statement acknowledging counterfeiting as a serious problem that must be addressed. 'Europe should be taking more of a lead in this and in providing technological solutions to developing countries.'

There needs to be tougher sanctions and better communication of the dangers from fake drugs. 'But care must be taken not to overstate the risk,' Harper adds. 'This could undermine the health system. You don't want people to stop taking their medicines, but you don't want to understate the risk either.'

Technological solutions

Some technological solutions are relatively low-tech, such as simple colorimetric assays developed for artemisinins to identify fake artesunate antimalarials. In Germany, the German Pharma Health Fund has developed a mini-lab for analysing the authenticity of a wide range of drugs.

Some countries now require drug companies to confirm the authenticity of their product by creating a pedigree that vouches for a medication's origin and how it has subsequently been handled. This can be as simple as a barcode or as complicated as the radio frequency identification technology (RFID) being developed by the US FDA. Several pharmaceutical companies are experimenting with RFID, optically variable devices and other technologies to help track and authenticate drugs.



Undercover photographs of counterfeiting practices in Colombia, showing that producing fake medicines is not necessarily a sophisticated process.

With the increasing sophistication of counterfeit packaging as much an issue as the drugs themselves, some companies are testing holograms, colour-shifting inks and watermarks. Others are experimenting with inks or dyes and using tamper-resistant packaging tape. Jackson warns there is a big danger that each EU member state is developing its own technological system, which will probably make things more complicated.

'It has the potential to become unmanageable,' he says. 'Technology can help authenticate and track and trace products, but it is unlikely to help delete or suppress counterfeit products. 'There are many technology vendors who are anxious to sell their products to the pharma industry purely for commercial reasons. But my concern is that, by focusing solely on technology, we run the risk of not doing the other things that we should be doing to tackle this scourge.'

The key to any anticounterfeiting strategy, says Harper, is to have an effective risk management and coordination structure in place, good cross-sectoral coordination and cooperation in terms of regulation and enforcement, a strong regulatory system and tough sanctions.

Regulatory recognition

While there is a lot to be gloomy about when it comes to the counterfeit market, at least one positive is that the issue does, finally, appear to be creeping higher up the political and regulatory agenda.

'Even just a year ago, there was less recognition that there was a problem out there,' says Harper. 'But in the past year we have seen a lot more interest and motivation by the regulatory authorities. It is incredibly difficult to check every medicine, and the quality of some counterfeits is very high. But it is incumbent that pharmaceutical retailers are able to ensure that what they are selling, as far as possible, is a legitimate product.'

Wholesalers, agrees Jackson, need to be ever more diligent when it comes to sourcing products, and pharmacists need to ensure they know their products well. 'If there is anything strange or unfamiliar, if there is a printing or spelling error or something appears odd, then it must be reported,' he warns. 'And never buy anything over the internet - it is amazing how many people do, but all they are doing is gambling with their health.' **END**