

THE PHARMACY

Tackling the challenge of counterfeit drugs

Simon Gallant of law firm Mishcon de Reya and Dr Mike Tremblay of Tremblay Consulting look at some legal and policy options.

Unlike other counterfeit products, fake drugs are not just bad for business – they can cause death, serious illness or the failure to improve the health of otherwise treatable patients.

But getting patients to take their medicine is enough of a problem without frightening them into non-compliance, especially when the vast majority of medicines in the Western world are legitimate. Governments and pharmaceutical companies around the globe have therefore been understandably cautious in tackling counterfeit products.

Undoubtedly there is a serious worldwide problem. The World Health Organization estimates that 8-10 percent of global medicines are fake, with levels as high as 25 percent in some countries and illicit earnings alleged to be running at some US\$35 billion annually. The problem is compounded by the different ways that individual countries enforce counterfeiting laws, hampering cross-border surveillance, tracking and prosecutions against counterfeiters. The growth of distribution over the internet adds another layer of complexity.

Encouragingly, there is a real sense that concerted action is being taken to tackle the problem on a number of levels. At the level of the EU, the European pharmaceutical industry (through EFPIA) have a position paper forthcoming, as do the ABPI in the UK through the work of the Coding and Patient Safety Group. The Council of Europe has undertaken a multi-nation study of counterfeit medicines with results to be reported to European countries at a conference in September 2005.

The UK government has also started to take a more coherent approach, developing the Intellectual Property Crime Group within the Patent Office. It is hoped that this Group will grow to coordinate action by the industry and criminal enforcement agencies. With the UK holding the Presidency of the European Union from July to December 2005, patient safety will be a priority with counterfeit drugs expected to feature prominently.

In addition to activity at the policy and structural level, a number of drug companies are starting to look at the problem in a highly proactive fashion – not just in the context of parallel imports that hurt the bottom line, but also in the more murky sphere of truly counterfeit products. Pfizer and GSK have been particularly active in addressing the counterfeiting of their products, but virtually all manufacturers' products are at some risk – including branded drugs for erectile dysfunction, weight loss, cholesterol lowering agents, antibiotics, anti-malarials, vaccines and HIV drugs.



A lot of work is being done on the engineering side, deploying packaging and track-and-trace technologies, such as RFID tags to track shipments, as well as forms of barcoding technology to track individual packets of medicines. The US FDA is promoting the use of RFIDs by 2007.

Public education is in its infancy but it is expected that this will become an increasingly important element in the mix. Successful deployment of the coding systems is, for example, something that the industry will want to promote in the near future.

In terms of legal responses, criminal enforcement can often be slow and ineffective; it is hoped that the Patent Office may improve the position. But there are other options – in particular, pursuing wrongdoers through the civil courts.

Drawing on experience of tackling counterfeit products in other sectors, it is believed that pharmaceutical companies can take heart from the prospects of achieving a satisfactory outcome – not just in terms of seizing counterfeiting product but also in adding to their bottom line through financial recoveries made from distributors. Achieving the virtuous circle of recoveries to finance ongoing investigations is a highly realistic option, but it requires careful planning and commitment.

Initially, a pharmaceutical business must assess the type and scale of the counterfeiting issue that it faces. How much damage is the problem causing (or could it cause) in terms of, for example, lost sales, potential claims and brand diminution? The best tack here is to work with experienced investigators to provide the best possible assessment of the particular problems faced by the individual business.

Once the wrongdoers have been identified, civil proceedings can be launched. Often this will mean seeking emergency orders from the court to seize and freeze the assets of distributors. Once executed, a settlement will often quickly follow. The emphasis should always be on identifying the pharmaceutical company's loss of profit as the measure of damages (rather than the counterfeiters' own profits or some notional royalty payment). This approach of 'turning losses into profits' has been highly effective in other sectors – ranging from software and computer games to tobacco and fashion. It ought rapidly to become the enforcement method of choice for drug companies looking to seriously tackle this problem. Instead of regarding enforcement as a drain on resources, those working within the legal function should come to be viewed as a profit centre for their businesses.

In summary, the outlook is promising. There is much to do, but both governments and industry are starting to adopt a coherent, multi-layered approach to tackling the problem of counterfeit drugs. ■

Simon Gallant, Consultant Solicitor, Mishcon de Reya, UK, with Dr Mike Tremblay, Tremblay Consulting, advisor on counterfeit drugs to industry.