

Caught in the net

The internet has opened up a massive new market to counterfeiters, one that can be accessed at the click of a button. **Desmond Hunt** of US Pharmacopeia and Merck Serono's **Andreas Maack** explain how a global legislation effort combined with multilayered packaging protection can help catch the copies.

According to a report by internet security firm Commtouch Software, around 81% of spam sent during the first quarter of 2010 was pharmaceuticals-related. The internet has blown down the door for counterfeiters, their ability to bring products to market no longer hindered by geography and the need for a bricks and mortar base. At the same time, as manufacturing operations move east, the supply distribution chain is becoming stretched and weakened.

"Globalisation is definitely one of the main issues we are dealing with," explains Dr Desmond Hunt, of NGO US Pharmacopeia (USP), which sets standards governing the quality, purity, identity and strength of medicines. "A lot of products are going to multiple jurisdictions, each with their own regulations, frameworks and penalties. Counterfeiters, who aren't by nature the most ethical people, will look for holes in the system and these are growing in number."

Although counterfeit medicines make up less than 10% of pharmaceuticals for sale in the developed world, in some emerging markets they account for as much as 25% of the total, according to WHO figures. In the case of certain drugs, this figure is considerably higher.

"When we talk about drugs that are popular among counterfeiters, it's going to be high-price clear solutions, such as injectable products," Hunt says. "You get

a glass vial, a crimp – who can tell if something has been tampered with? Then there are the lifestyle drugs, the biggest of which is Viagra. Counterfeiters are very savvy and will often find a way to include the active ingredient in their product. You'll get an effect because, like a drug dealer, they want you to come back."

Counterfeit measures

The first line of defence is packaging. It is universally accepted that no single form of protection is effective enough and layered prevention methods must be used in combination to find the best solution. Many of the more advanced methods being developed by pharmaceuticals companies, particularly those that make use of forensic technology, are so confidential that even employees are unaware of how they work.

"When you start talking about forensics, that information is possibly more valuable and held more closely to the chest than even a company's patent secrets," Hunt says. "If something is suspected of being counterfeit it can be pulled right off the shelf, sent to the lab, and within a day or so they will have used forensic markers to decide on its authenticity."

Track and trace methods are also beginning to gain traction. Swiss biopharmaceutical company Merck Serono has introduced electronic radio frequency identification (RFID) tracking

technology on a number of its products in the US, allowing the company to monitor a package along the entire supply distribution chain.

"The gradual introduction of tamper-proof elements and the electronic pedigree of track and trace allow us to precisely track any drug package from production plant to pharmacy," explains Andreas Maack, the company's head of corporate security. "We are also currently developing a new type of tamper-evident seal. This will serve to protect against tampering and also help with product authentication."

Great gains have been made in the analysis and identification of fake pharmaceuticals. Merck Serono has developed a product known as the GPHF-Minilab, a mobile laboratory that is currently operational in 70 countries worldwide.

"The mobile laboratory was developed to identify counterfeit drugs quickly and cheaply," Maack says. "It provides drug quality verification and counterfeit medicines detection in a compact laboratory comprised of two suitcases filled with portable lab material. They are distributed through the Global Pharma Health Fund (GPHF), a charitable organisation initiated and funded exclusively by donations from Merck."

Both Maack and Hunt agree that these technological advancements can only be

fully effective in tandem with a global regulatory consensus.

"An issue we are having in the industry at large is how you define counterfeit," Hunt explains. "Just look at the discussions we've had around track and trace. Which technology do you use? How do you use it? If you opt for RFID, then at what frequency do you have it?"

"With the European Medicrime Convention of December 2010 we have for the first time among the EU member states a valid legislative instrument for the phenomena of counterfeit drugs," Maack says. "The Convention contains so-called 'dedicated acts', which call on industry to introduce anti-counterfeit measures on packaging as a way of increasing levels of security. A final decision on which technology is to be used for this legal requirement is still pending."

Education vs regulation

Even if a global regulatory solution emerged regarding packaging and distribution, trying to enforce restrictions

on the internet trade is another thing entirely. Not only does the worldwide web provide counterfeiters with a massive potential market, but a website closed by authorities can be back online within hours, under a new name and at a new address. However, Hunt is hopeful that as new generations grow up with the internet, a broader awareness will develop.

"When I go home and talk to my grandparents' friends, for them the internet is new," he explains. "They have no idea that illegal practices could actually be occurring. The website looks good, they appear to be asking the right questions, so the user doesn't think about the health consequences. When you say to consumers that they can buy their pills for 40% of the cost price, it is real."

As for USP, its general chapter on seminal good storage and shipping practices, 1079, has recently been updated for publication in the early part of next year. With money tight in the industry, it can be difficult to introduce new regulations in a way that isn't

perceived as burdensome or a hindrance to profitability. Constant cooperation is necessary if mutually desirable outcomes are to be achieved.

"The real dialogue occurs when a standard is actually written and published in Pharmacopeia form and we ask for feedback," Hunt says. "Sometimes companies have serious concerns about its impact on their product or operations, but our job is not to run people out of business. We try to make sure that quality drug products are being produced but at no extra cost. These companies have done nothing wrong; they just suffer from having a good product!"

For all the progress made in the fight against counterfeit pharmaceuticals, it is a war that can't be won. Anything that a manufacturer can do, a counterfeiter can learn to do as well. However, with well-enforced global regulations, continued advancement in packaging technology and improved education about the dangers of fake medications, the damage can be greatly reduced. ■

Constantia Flexibles

Big enough to dare,
small enough to care.

Constantia Flexibles develops, manufactures and supplies flexible packaging solutions for the pharmaceutical, food and beverage markets. We are a leading supplier of aluminium based packaging for products in the field of Pharma, Medical, Home & Personal Care.

- Blister Lidding Foil, also Child-Resistant
- High Performance Lidding Foil
- Coldform Foil
- Strip Pack, Suppository Foil
- Overwrap, Sachet Foil and Laminate
- Stick Pack Foil also with Child-Resistant Opening Aids
- Lidding and Sealing Foil for Cups and Cans
- Promotional and Retail Sachet Foil
- Wipe and Doypack Foil
- Anti-Counterfeiting Solutions

Constantia offers a number of innovative security technologies:

- Holograms
- Security foil
- Security pigments and inks
- Security graphics
- Tamper-evident opening systems



Constantia Flexibles

Mühlhofen, A-3200 Weinburg
T +49 7151 36904 - 34
F +49 7151 36904 - 35
Pharma@constantia-flexibles.com
www.constantia-flexibles.com

