The anticounterfeiting crossroads – where next?

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10% of medicines circulating globally are counterfeit, with levels as high as 25% in developing nations. Cambridge Consultants was recently commissioned to evaluate the market for anticounterfeiting products, as its senior research analyst Cornelia Thomas explains.

While alignment of legislation and supply chains is required in the short term, technology is expected to play an important role in combating counterfeiting in the future. The market for these technologies is difficult to estimate, but is believed to comprise about 1% of the global counterfeiting market, about $350 million. It is forecast to grow in line with the counterfeit market at approximately 13% per annum. Currently, barcodes and colour printing are the most commonly used anticounterfeiting measures in the pharmaceutical industry.

The most important attributes for anticounterfeiting technologies are simplicity of use and low cost. Others are the reliability of results, being tamperproof and their ease of application to a product. Being covert, associated with unpackaged product, having a flexible form, holding large amounts of information, or being exclusively linked to the detection system, are considered less important attributes. This explains why overt measures such as barcodes, colour printing, blister packaging and holograms are popular: they are all relatively cheap, easy to implement and simple to detect. However, they are also easy to counterfeit.

While not as frequently used, novel measures such as radiofrequency identification (RFID) tags, colour-shifting inks and molecular markers are more difficult to counterfeit, and are becoming increasingly popular for a variety of reasons.

RFID is the US FDA's technology of choice to combat counterfeiting. In early 2004, it called for the widespread use of RFID technology to track the manufacturing and distribution of prescription drugs. And indeed, some major pharmaceutical companies have introduced pilot RFID projects to track their most vulnerable drugs.

Purdue Pharma is using RFID to track shipments of its narcotic analgesic OxyContin (oxycodone), Pfizer is using RFID on its erectile dysfunction drug Viagra (sildenafil), and GlaxoSmithKline is testing the use of RFID tags on its HIV drug Trizivir (abacavir, lamivudine plus zidovudine). However, almost three years on from the initial FDA report, the industry has still not widely adopted the technology.

With individual tags costing more than five cents, RFID is still perceived as expensive, particularly if a tag is needed for every bottle of medication. In addition, there are a number of other unresolved issues, such as the need for RFID to be universally adopted for it to work most effectively, and the need to develop centralised standards on ownership, access and data security. RFID can also interfere with certain products, proteins for example, and there are also worries that tags attached to single bottles could lead to the infringement of consumer privacy and industrial espionage.

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...colour-shifting inks

Colour-shifting inks are currently mostly used on banknotes, but can also be found on packaging for some drugs – Pfizer now uses a colour-shifting logo. These inks contain very thin metal flakes, and depending on the angle of the incoming light the inks change colour. The colour combinations are almost infinite because different types and sizes of flakes can be combined to vary the reflective properties of the ink. Adding transparent pigments or dyes to the ink or overprinting with a second layer of coloured ink enhances specific colours.

However, since colour-shifting inks are overt and thus visible to the naked eye, they are still relatively easy to counterfeit compared with covert measures such as molecular markers.

...molecular markers

Molecular markers can be relatively expensive, difficult to implement and complicated to detect, and to be successful companies need to address these issues. Examples for molecular marker solutions are Microtrace's Microtaggant, Authentix's ingestible markers, Creo's Traceless and Identif's molecular fingerprint. All these companies offer customised solutions and work with companies to implement them.

The products are covert and can only be detected with proprietary readers. This makes them difficult to counterfeit, but it also makes it more complicated to authenticate them in the field. A customs official or pharmacist wanting to confirm the authenticity of medicines would have to know which reader to use. This is expensive and impractical.

Microtaggants are microscopic particles carrying a unique numeric code in a multiple coloured layer format which can be incorporated in products likely to be counterfeited. Microtrace

acquired the Microtaggant technology from 3M in 1985, and has since established a track record in anticounterfeiting measures.

Authentix was formed by the merger of Isotag and Biocode in 2003 and combines more than 17 years of experience in supplying anticounterfeiting services to a range of industries. It offers several technologies, including FDA-approved ingestible authentication markers, which could be used in pharmaceuticals.

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...authentication

These would allow authentication of pharmaceuticals at the single dose level, but many representatives of the pharmaceutical industry have rejected in-product technologies.

These are perceived to be expensive, and drugs containing them might have to undergo further clinical trials to show that the anticounterfeiting element does not affect efficacy or safety.

Creo was acquired by Kodak in 2005, giving it backing from a large company. Creo's technology involves producing a pattern of randomly distributed taggant particles in or on a product, and the specific pattern is then recorded in a database. Authentication is achieved by exposing an article to electromagnetic radiation such as infrared or visible light and confirming that the pattern read matches the pattern recorded.

Identif is a small company founded in 1996 offering an approach based on a synthetic DNA code which can carry information. The company has been providing its solution to Bristol-Myers Squibb since mid-2002 for use on packaging of anticancer and HIV drugs.

Unlike the other companies, Identif does not have a long track record of success, nor is it backed by a large international corporation. Representatives of the pharmaceutical industry stated that companies need testaments from people that have tried the product and say it is working well, and big names, as reputations are important when choosing a supplier.

The four solutions described can all contain information, making it possible to use them for both track-and-trace and authentication.

However, as for RFID, this raises issues of database creation, management and security, making these products less attractive to the pharmaceutical industry.

From the information gathered in our study it is possible to conclude that the market for molecular markers is perceived by the pharmaceutical industry as highly fragmented. Consolidation is expected, enabling the winners to benefit from economies of scale. This would bring down prices for molecular markers, making them more attractive.

A free PDF of *Scrip's* Pharmaceutical Anticounterfeiting Supplement can be downloaded from www.scripsupplements.com. It features editorials from the former FDA commissioner Peter Pitts, Ashley How from the Pharmaceutical Security Institute, the counterfeit medicines expert Graham Satchwell, and Jim Thomson from the Partnership for Safe Medicines.