# WorldPharma

World Pharmaceutical Frontiers 2008 Vol. 2

www.worldpharmaceuticals.net

AN SPG MEDIA PUBLICATION

Published in association with

Deloitte.



# **Flawed**

Dr Susanne Keitel on APIs, impurities and the need for regulatory change

Official ICSE & CPHI supporting publication





## **Brand protection: time for action**

Pharmaceutical counterfeiting is increasing, resulting in millions of dollars lost in tax revenues and sales, with potentially lethal consequences for consumers. Now is the time for a comprehensive approach from industry, government, legislators and law enforcers to fight this illegal trade.

lobal product counterfeiting has reached a dimension never seen before, targeting everything from software to life-saving medicines. Hardly a week goes by without disturbing news of yet another counterfeit pharmaceutical product that has resulted in severe and often deadly consequences for consumers.

The scale of the problem has grown so rapidly that governments and multinationals are scrambling to find ways of stopping the flood of counterfeit products infiltrating markets and supply chains. National economies are losing millions of dollars in tax revenue and legitimate manufacturers are losing millions of dollars in sales due to the manufacture and sale of counterfeit goods. The WTO estimates that approximately 10% of the world trade is in counterfeit products, which means the global counterfeit market is worth around \$350-500 billion a year.

Some of the latest developments also indicate that counterfeit medicines are infiltrating legitimate distribution channels and an increasing percentage of counterfeit drugs are sold next to legitimate products on the shelves of pharmacies or through the national healthcare system.

## An effective anti-counterfeiting strategy requires more than the right technological security features.

### Ready to protect

The response of the pharmaceutical industry to the growing problem of counterfeit drugs may be late, but much can still be done. Five years ago, there was a tendency in the industry to avoid public discussions about the subject; that has clearly changed. Today, all major companies are in the process of finding the right strategy on how to tackle the problem.

Pharmaceutical companies have begun to proactively protect their products throughout the value chain to mitigate the risks from counterfeiting. Both companies and regulators publicly acknowledge the existence of fake medicine and try to educate consumers and patients, but identifying and implementing the right brand protection and authentication technology is not easy.

Compared with many other products, medicinal goods pose a significant challenge to the application of anticounterfeiting technologies. For one, the products do not allow the use of all available technologies and any anticounterfeiting technology used on healthcare or pharmaceutical products

must meet the stringent criteria of regulators and prove to be harmless to the consumer and patient. In the past most anti-counterfeiting efforts almost exclusively focused on protecting the packaging material. Protecting the packaging alone might not be sufficient in the future.

The disadvantages are obvious. Firstly, the quality of counterfeit packaging material today is so good that consumers and patients are usually unable to distinguish real from fake. Secondly, a genuine packaging does not necessarily guarantee that its contents are genuine. The industry has seen numerous cases of repackaged goods containing fake products.

#### Comprehensive strategy

Recent technological advancements may offer solutions to the dilemma. providing brand protection and security solutions directly on or in the product. Specific laser and nanotechnology solutions for the pharmaceutical industry are in development - and in some cases already in use - that can provide protection of the individual tablet, pill or dosage. Furthermore, these new anti-counterfeiting

applications open possibilities to combine brand protection and track and trace aspects by linking and authenticating the item-level product with the corresponding packaging material, adding a new layer of security. Owners of highvalue brands are likely to use these newly available laser and nanotechnology applications for their most valuable brands.

Designing an effective anticounterfeiting strategy requires more than finding the right technological security features: brand owners and manufacturers need to take a more holistic approach and incorporate brand protection aspects into the overall business process and complete value chain from product design, sourcing and the manufacturing process to the control of the supply and distribution chain.

Combating the problems of pharmaceutical counterfeiting is hardly an effort that can be mastered by any stakeholder alone: it requires a joint and coordinated approach by brand owners, the industry, government authorities, legislators and law enforcement. WPF

Company profile

Frank Schurgers is founder and CEO of Integris International, a leading consultancy for the design and implementation of global anti-counterfeiting strategies. For more information, contact: fschurgers@integris-intl.com.