Ensuring the Safety and Authenticity of Pharmaceutical Drugs with Innovative Packaging Technologies

**Introduction**
The World Health Organization (WHO) currently estimates the global trade in counterfeit drugs to be worth £75 billion, with continued growth predicted to be at a staggering rate of 13% a year. Criminals not only manufacture fake drugs, but some also seize authentic shipments and redirect them to other markets, reselling them for their own profit. In addition, diverters threaten the security of the pharmaceutical supply chain with ‘third shift’ production. This involves contractors or their staff carrying out extra, hidden production runs and selling the resulting genuine products into the grey market, which in turn confuses the consumer and can introduce weaknesses into the supply chain through which counterfeited products enter.

As the counterfeit trade grows, criminals are becoming increasingly sophisticated and capable in the way they package their products. As a result, global regulatory bodies have introduced strict legislation to ensure maximum security of pharmaceutical packaging.

The US Food and Drug Administration (FDA) enforces rule 21 CFR Part 2112, which specifies current good manufacturing practice for finished pharmaceuticals. The rule mandates that tamper-evident packaging should be used for over-the-counter (OTC) products. According to the regulation, a tamper-evident package has one or more indicators or barriers to entry which, if breached or missing, can reasonably be expected to provide visible evidence that tampering has occurred. It should not be able to duplicate the packaging using commonly available material or processes.

**Innovative Packaging Technologies**
Defeating the counterfeiters demands a multi-level approach, an element of which is secure packaging. However, in order to ensure optimal security of pharmaceutical packaging, both overt and covert technologies need to be used.

**Overt Technologies**
Overt features enable instant authentication of packaging through visual inspection by the user without requiring expert knowledge. Optically variable features such as holographic devices within the design, and colour-shift inks, are the most common
and effective overt security features, enabling packaging to be validated both quickly and easily.

Easily identifiable holograms are primarily used as first-level identification devices, and are designed to enable successful authentication at point of inspection. Another overt technology is colour-shift ink. Colour-shift inks appear as two or more distinct colours when viewed from differing viewing angles. Such features are easily verified by tilting the item carrying the colour-shift in order that the different colours can be seen. Supply of colour-shift inks is tightly controlled to ensure that the products are used only in genuine circumstances and under strict codes of conduct, including end use agreements.

Covert Technologies

Covert technologies such as infra-red (IR) and ultra-violet (UV) inks, microtext and microscopic tagging are invisible and difficult to detect and replicate without specialist detection equipment. Forensic solutions include molecular markers, and biological tracers offer another level of authentication, but these features can only be identified using laboratory equipment.

Images printed with UV inks are only visible under a UV light. UV inks are available in different frequencies, so depending on the formulation of the ink, the investigators will need to use either a long-wave or short-wave UV light in order for the printed images or text to become visible. As with colour-shift inks, the level of security with UV inks is determined by the ease of access to the inks and their component pigments – with special colours and alternative wavelengths more difficult to obtain.

Added security is ensured by incorporating taggants on packaging to ensure reliable identification of the product and its source of manufacture.

Pharmaceutical companies can integrate taggants to quickly protect and authenticate packaging in the market. Authentication is a key factor for the technology, which can reliably identify and distinguish genuine packaging from counterfeit ones. The most highly secure taggart systems can only be verified with special handheld readers that are in turn only available from a secure source, thus ensuring that any potential counterfeiter is not aware of the presence of an authentication technology.

To maximise security it is important to use both overt and covert design features which complement each other and are jointly used on packaging, such as security design and tear tapes.

Conclusion

With the use of increasingly sophisticated counterfeit methods, drug counterfeit criminals continue to advance and profit at the cost of public safety and company revenue. It is essential to implement overt, covert and forensic technologies to ensure that criminals are unable to re-use, copy or misappropriate pharmaceutical drugs or drug packaging. Anti-theft, tamper-evidence and authentication solutions enable inferior and potentially harmful counterfeit products to be reliably intercepted and stolen genuine products recovered. By implementing the new security techniques, robust and reliable protection from tampering, copying and brand infringement is enabled, and counterfeiting will become a less profitable and more challenging process.

References

1. WHO EXPERT COMMITTEE ON SPECIFICATIONS FOR PHARMACEUTICAL PREPARATIONS; Thirty-sixth Report, http://apps.who.int/medicinedocs/pdf/h3009e/h3009e.pdf

Richard Burhouse has been involved in the security industry for ten years, having joined Payne Security’s parent company, Filtrona in 2000 as part of their Graduate Management Development Program. During that time he has held various commercial roles within its Coated & Security Products line of business.

Prior to his current role, Richard was Marketing Manager for secure track & trace technology company FractureCode Corporation, based out of Copenhagen, Denmark. Richard holds a Bachelor of Science Degree in Chemistry and Business from Warwick University, a Post-Graduate Certificate in Management and has been awarded Chartered Marketer status by the Chartered Institute of Marketing. Should probably also add “Richard is a Director of the International Authentication Association” somewhere, but not sure where you should fit this in (might be better to say serves on the Board of the IAA).

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