

# Cracking down on drug counterfeiters through anti-tamper and security labels



Drug counterfeiting is a growing problem both for pharmaceutical manufacturers and the patients they serve. In first-world countries, it is estimated that 1% of all pharmaceutical products are counterfeit, and a staggering 10% to 50% of drugs in developing nations fall into this category, according to the U.S. Food and Drug Administration. Not only do counterfeit drugs contribute to billions of dollars in global counterfeiting costs, they are also linked to thousands of deaths worldwide — though the exact number is unknown. Meanwhile, the original manufacturers of these drugs experience damage to their brand image, sales and revenue.

## Getting tough on counterfeiting

The Internet is the preferred distribution channel for counterfeit drugs globally. Approximately 50% of all drugs sold online are from non-approved FDA sources. To help pharmaceutical companies improve the security of their products, a number of national and global organizations, including the U.S. Food and Drug Administration, the World Health Organization, the World Customs Organization and Interpol have introduced new regulations to require more secure pharmaceutical packaging. New regulations encourage both anti-counterfeiting measures to improve accuracy in product authentication and anti-tampering measures to let end users know when product has been previously opened.

In 2014, a European Union directive for labeling and packaging also will be amended, requiring pharmaceutical companies to start including tamper-evident features in packaging for all prescription and some over-the-counter products. Designed to increase transparency, the amended EU directive will also extend liability for falsified medicinal products to manufacturers, repackagers, distributors, retailers and other relevant players in the pharmaceutical supply chain.

Compliance is a growing challenge for pharmaceutical manufacturers, whose products often travel long distances in their journey to the consumer. Deciding which security measures to implement for which products can be a drain on time and profits. Pharmaceutical packagers and manufacturers must ensure that their products are secure and can be authenticated in all phases of production. In addition, they now must also include security features that allow wholesale distributors and pharmacists to:

- Verify authenticity of drugs through overt, covert or forensic devices
- Track and trace individual packs or units
- Determine whether packaging has been tampered with
- Pinpoint fake or substandard products

Accordingly, more pharmaceutical companies are now looking to label developers to help them with anti-tampering and anti-counterfeiting strategies.

## Secure labeling options

Today's label technologies offer innovative and sophisticated solutions to defend against would-be counterfeiters and fraudulent activity. From 2-D and 3-D holograms to watermarks to tamper-evident void marks, labels can incorporate a wide range of overt and covert brand protection, giving companies a platform to implement multiple layers of product security.

Label technologies for brand protection are extremely versatile. Basic security features are provided by products containing security threads and holograms. Other options include low-resistance papers, destructible films and tamper-evident void labels. These off-the-shelf solutions are the most affordable and popular products for companies that want entry-level protection.

For a more advanced level of protection, additional features can be added and customized for additional brand protection. UV fluorescent prints, microprinting, color shift inks and customized holograms, voids and security papers such as watermarks are even harder for counterfeiters to duplicate. For manufacturers of drugs with a high-risk of counterfeiting, these solutions are worth the investment.

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Additionally, high-end solutions offer companies the greatest level of protection. Using unique and personalized security features, such as infrared detection and forensics, label developers can incorporate unique components into a label to identify and track products. A popular technology for product tracking and traceability is radio-frequency identification tags (RFIDs) for labels, which allow companies to track a product through its lifecycle by its label.

## Implementing a secure strategy

Today's pharmaceutical companies have the dual challenge of keeping inauthentic products out of the supply chain and keeping their own, authentic products insulated from security threats. While regulatory bodies have introduced guidelines to encourage action against counterfeiters, regulators have largely left it up to pharmaceutical manufacturers to determine how they will meet those guidelines.

Ultimately, which label technology or technologies are needed can vary greatly from company to company. Before implementing a protection strategy, all pharmaceutical manufacturers should consider questions such as:

- What level of security do we want to build in our packaging design?
- Do we want overt, covert or forensic solutions?
- How much do we want to invest in brand security?

Determining these needs will help manufacturers work better with packagers, label developers and printers to identify and implement solutions that ensure compliance while aggressively counteracting drug counterfeiting and tampering. >

