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Prevent Counterfeiting in the Pharmaceutical Industry

by Janice Abel

Many companies now deploy specialized packaging, applications, and other anti-counterfeiting technologies to help prevent counterfeit products, protect brands, protect customers, and allow rapid and effective response to counterfeit products. ARC would be interested to learn what steps, if any, your company takes.

Overview

The US Food and Drug Administration (FDA) estimates that counterfeit drugs account for 10 percent of all drugs sold in the United States. The World Health Organization (WHO) estimates that, globally, counterfeit drug sales will reach $75B by 2010. The Internet and gray market of distributors and re-packers represent real challenges to manufacturers trying to prevent counterfeit drugs from reaching consumers. As a result, drug manufacturers now deploy specialized packaging, applications, and other anti-counterfeiting technologies to protect brands, protect consumers, and allow rapid and effective response to counterfeit products. Manufacturers in other industries face similar challenges.

What Is a Counterfeit Drug?

The FDA (21 U.S.C. 321 (g)(2)) defines a counterfeit drug as a drug for which "…the container or labeling, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor."

Counterfeit drugs include those sold under a product name without proper authorization and those without the active ingredient, with an insufficient or excessive quantity of the active ingredient, with the wrong active ingredient, or with fake or mislabeled packaging. Some counterfeit drugs are packaged and labeled or re-labeled to look like real brand name or generic products designed to deceive consumers into thinking that they are buying the authentic product. Consumers, manufacturers, and wholesalers need to know with certainty where drugs have been, who has handled them, and through how many hands they have passed.

Counterfeit Cases

While counterfeiting occurs throughout the world, the percentage is much higher in developing countries. The WHO estimates that 10 percent of all pharmaceuticals in the global supply chain today are counterfeit and that sometimes the fake drugs contain toxic substances and chemicals that could cause death - *Figure 1*. Some counterfeit medicines contain heavy metals; cement, talcum powder, solvents, and even yellow road paint and floor wax (the latter to make them shine).

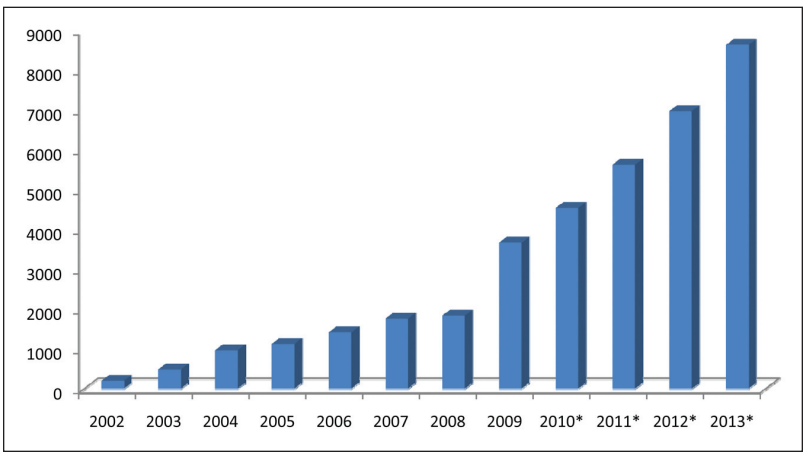

Figure 1. Recorded counterfeit incidents by year (Source: Pharmaceutical Security Institute).

The problem appears to be far less common in the industrialized world (such as in the United States, Australia, Japan, Canada,

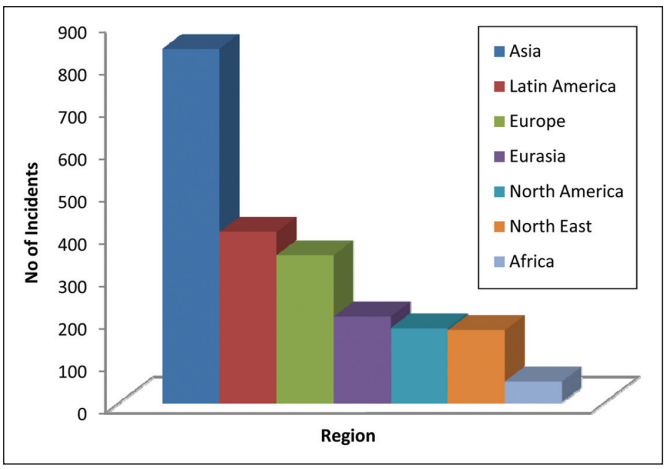

Figure 2. Recorded counterfeiting incidents by regions (Source: Pharmaceutical Security Institute).

New Zealand, and in the European Union), where estimates suggest that from less than 1 percent to 3 percent of medicines sold are counterfeit - *Figure 2*. However, the problem is growing everywhere.

Without a more secure supply chain, counterfeiting will continue to increase. There are several reasons for this. Counterfeiting drugs is a highly profitable activity and actually less risky than illicit drug trafficking. Under the current laws, narcotics traffickers view pharmaceuticals as a safer line of work, with fewer penalties if caught. Furthermore, counterfeiters can now access sophisticated technologies to copy the labels and packaging, including barcodes and other anti-counterfeiting devices. The common (legitimate) practice of repackaging and the existence of illegal drug marketing circuits/networks both facilitate counterfeiting activities. Well-organized counterfeiters have considerable resources. The ability for counterfeiters to sell drugs on the Internet and the willingness of buyers to purchase via this distribution channel also help foster a counterfeit culture.

Global Anti-Counterfeiting Regulatory Initiatives

The US FDA plans to increase prosecutions of pharmaceutical and food industry executives as part of an effort to refocus its criminal division, which has been under attack in Congress and criticized in a new government report.

The FDA released several Guidance draft documents over the past couple of years. The Agency released *Standards for Securing the Drug Supply Chain – Standardized Numerical Identification for Prescription Drug Packages* on 26 March 2010. Amendments to the FD&C Act in 2007 required FDA to take specific actions to secure the supply chain, including developing a Standardized Numerical Identifier (SNI). The guidance addresses SNIs for package-level identification. It provides flexibility in the type of data carrier, does not require incorporation of either batch number or expiry, and is compatible with the GS1 GTIN and AI-21 standards. The SNI is flexible in terms of the technology used. This can be a 2D barcode, Radio Frequency Identification (RFID), or use any other technology that secures the supply chain. However, the data carrier should be both human- and machine-readable.

The FDA also issued draft guidance on 13 July 2009 covering the use of inks, pigments, flavors, and other physical-chemical identifiers (PCIDs) by manufacturers to make drug products more difficult to counterfeit and to make it easier to identify the genuine version of the drug. PCIDs, inactive ingredients that can be detected and authenticated to deter counterfeiting, are added to coatings, capsule shells, encapsulated particles, or tablet layers of Solid Oral Dosage Forms (SODFs) for on-dose protection. PCIDs for SODFs include inks, molecular taggants, pigments, and flavors. The guidance recommends using PCIDs listed in the FDA's Inactive Ingredient Guide,

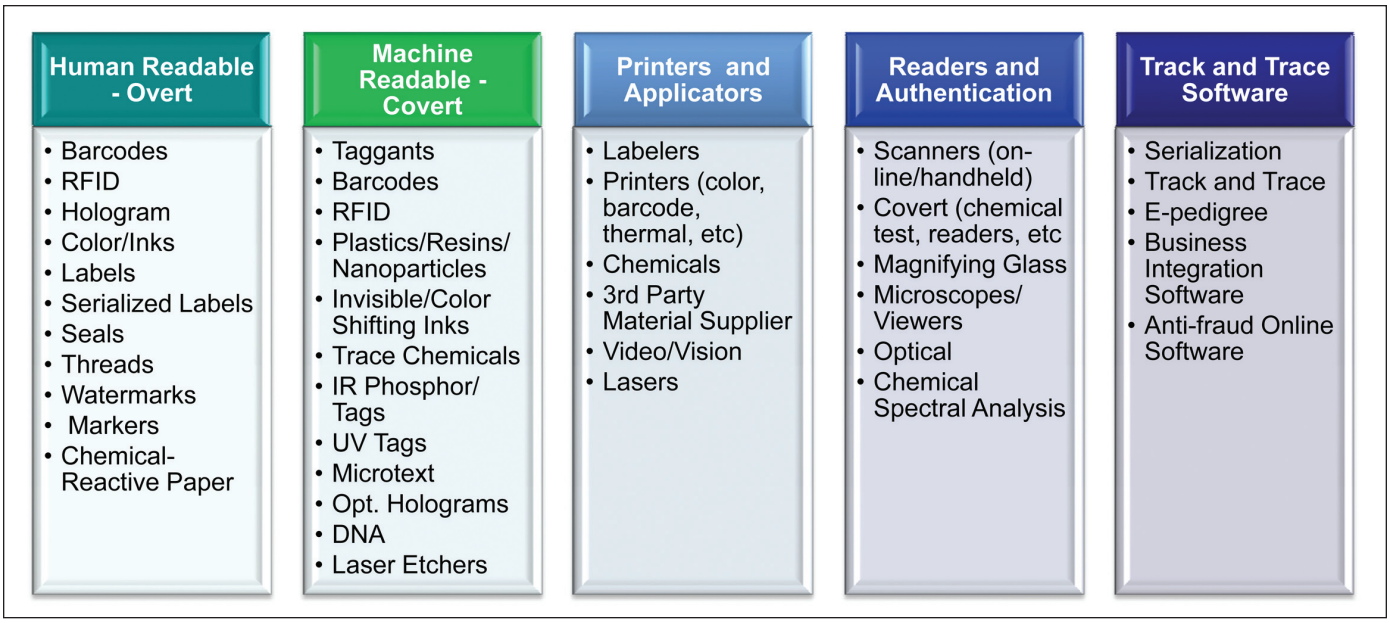

Figure 3. Anti-Counterfeiting technologies.

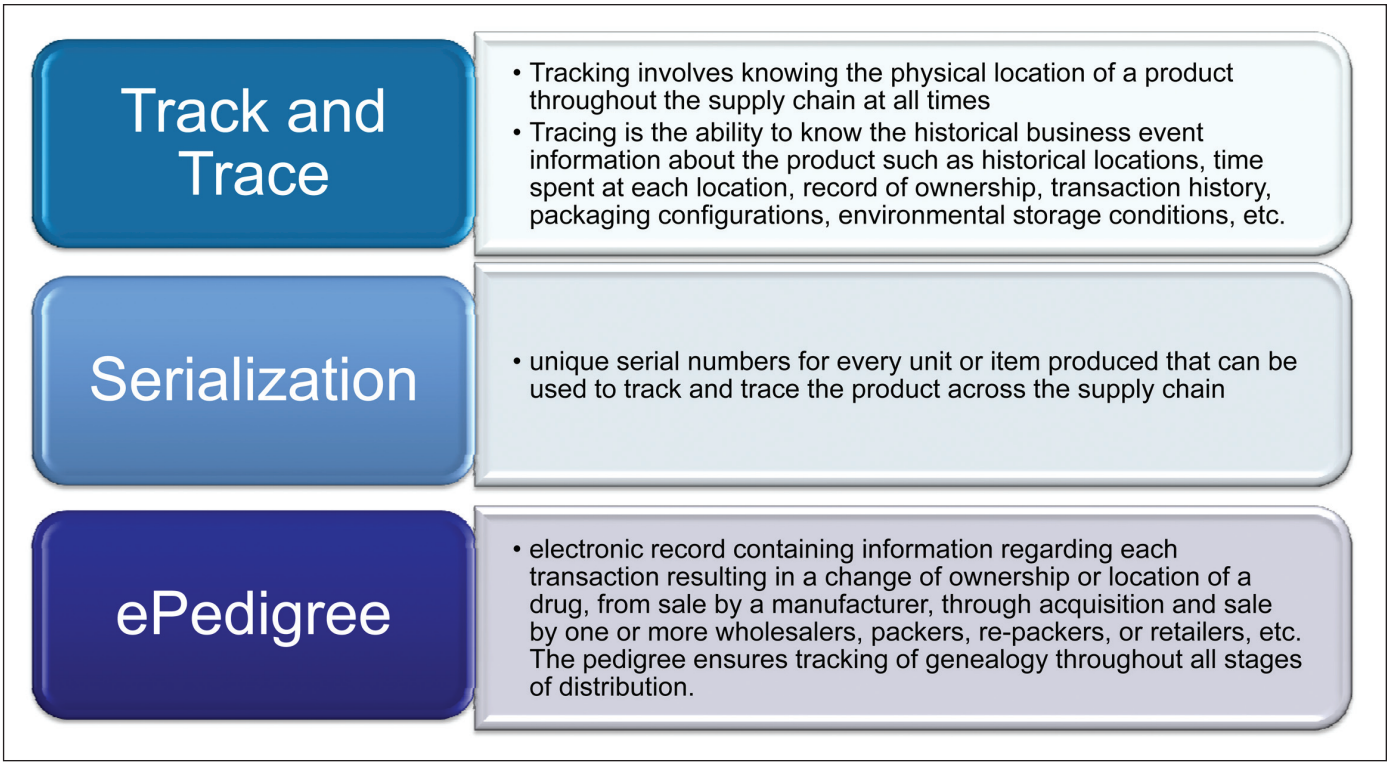

Figure 4. Definitions of epedigree, serialization, and track and trace.

adding the smallest amount possible and placing then on SODFs so that they do not interact with the API or interfere with the drug release.

In response to problems with excipient counterfeiting and a subsequent investigation uncovering the involvement of numerous distributors and brokers, the WHO developed the *Good Trade and Distribution Practices for Pharmaceutical Starting Materials* (GTDP) guidelines in 1998. That same year, the International Pharmaceutical Excipients Council of the Americas (IPEC–Americas) published a position paper on vendor qualification. IPEC-Americas, along with IPEC–Europe and IPEC–Japan, have since published numerous guidelines covering such topics as Good Manufacturing Practices (GMPs); Good Distribution Practices (GDPs), use of Certificates of Analysis (COAs), and significant-change notification to help manufacturers protect their excipient supply chains.

Despite these efforts, supply chain incidents involving excipients occurred again in China in 2005 and in Panama in 2006. These incidents prompted the US FDA to work with industry to develop three basic approaches to track chain of custody through the supply chain. These are paper trails, bar coding, and RFID. Because of the complexity of the excipient industry, the FDA determined that a paper trail would provide the fastest approach with the least disruption to the supply chain.

Although a single program cannot prevent fraud, a pedigree approach – using existing paperwork (or electronic paperwork) to the greatest extent possible – could provide a strong deterrent.

Anti-Counterfeiting Technologies

Most leading manufacturers implement technologies to secure the supply chain to prevent counterfeiting and protect their brands. The technologies range from high- to low-tech applications and solutions. Examples include sophisticated inks (Alpvision), advanced holograms (OpTec Security), taggants and markers (TopFlight Corporation, Microtrace, and 3S Simons Security Systems), labels (Zebra Technologies); lasers (Ingenia), RFID (Oat Systems and Kovia); serialization, authentication, traceability, and (ACSIS, Axway, Systech, Mobia Solutions, Siemens, Videojet, and Verify Brands); plus Internet sleuthing (OpTec Security and MarkMonitor) - *Figure 3*. Typically, these technologies utilize readers that input the data to a management system (SAP, Oracle/JD Edwards, Microsoft, and others).

Many technologies are available to help combat counterfeiting and secure the supply chain - *Figure 4*. Solutions must provide companies with the ability to trace lots all the way to the retail shelf and authenticate that products have moved through a legitimate supply chain. Automatic identification technologies, such as bar coding and RFID, have been touted as valuable assets for implementing effective track-and-trace systems. The FDA has been a driving force behind bar coding and RFID for carrying ePedigree information. New, easier to implement and less costly types of RFID are now hitting the market.

As the demand and volume increases for these technologies, the prices will decline and, in the future, most branded products will be equipped with anti-counterfeiting technologies.

Last Word

Resolving the global counterfeit drug problem requires common practices and a standards-based infrastructure that includes participation and collaboration by all trading partners across the supply chain, adequate legislation and enforcement, and implementation of emerging technologies. Although there is no single magic bullet against sophisticated counterfeiters, the supply chain needs to be more secure for all products.

Please participate in our confidential survey at: http://survey.constantcontact.com/survey/a07e31lwtw2gemvrn56/a01s1gemzx782/greeting.

The purpose of this survey is to develop a better understanding of the best practices being used by manufacturers, distributors and packers to manage the supply chain and address anti-counterfeiting and brand protection. The survey examines methods, technologies and solutions being used for preventing counterfeit product. Technologies that are being considered include various overt, covert, track and trace and epedigree. The survey will be used to better understand best practices for preventing counterfeit products from entering the supply chain.

About the Author

Janice Abel is a principal consultant in ARC's regulated industry group. In this capacity, Abel performs research and provides consulting services for ARC's clients in the pharmaceuticals, biotechnology, medical devices, and other regulated industries. Abel is a valued member of the Hybrid Team at ARC. Abel has been involved with the pharmaceutical and biopharmaceutical, consumer products, and other hybrid industries throughout most of her 25-year professional career. A longtime member of ISPE, she has served as chairperson for several ISPE committees, as well as president of the ISPE Boston Chapter. Abel is a frequent presenter and leader at ARC and ISPE conferences, and has authored numerous articles for *Pharmaceutical Engineering, Pharmaceutical Technology, Control Engineering,* and other industry publications throughout her career. Abel has been with ARC since November 2008. Prior to joining ARC, Abel was the Director of Pharmaceutical Industry Marketing at the Foxboro Company, Validation Technologies, and Invensys. Abel also worked on early cholesterol research at the Boston University Medical School Cardiovascular Institute. Abel has a BS in chemistry from Clark University, an MS in chemical engineering from Worcester Polytechnic Institute, and an MBA from Worcester Polytechnic Institute.

ARC is currently researching how companies deploy specialized applications and technologies, track and trace, epedigree and other solutions to help prevent counterfeit and stolen products from entering the legitimate supply chain. For further information or to provide feedback on this article or anti-counterfeiting solutions please contact jabel@arcweb.com.