Protecting Critical Care Drugs

Securing the Most Susceptible Products from Counterfeiting

The growth of injectable critical care therapeutics requires multi-layer protection and authentication solutions.
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Patient Safety at Risk

It was thirteen years ago when San Francisco AIDS patient Rick Roberts noticed a burning sensation while injecting Serostim, a human growth hormone that helps prevent AIDS wasting syndrome. Roberts purchased Serostim regularly from a nearby location of a national pharmacy chain. By checking with his pharmacist, he learned that counterfeit Serostim had been showing up in pharmacies in several states. Further investigation revealed that although the Serostim packaging looked real, the medicine in the vial was not. Roberts had unwittingly been injecting himself daily with the female pregnancy hormone HCG (human chronic gonadotropin), which is meant to be taken once a week. The Serostim pedigree (a record of where the drug was manufactured and its supply chain stops along the way to the pharmacy) had been falsified. That made the counterfeit Serostim appear to be an authentic drug from a reputable distributor.¹

Recent cases of newer injectable drugs such as Avastin continue to make headlines today.² Avastin is an injectable medicine used to treat cancer used in clinics, hospitals, and doctors’ offices. The counterfeit version of the drug contained none of the medicine’s active ingredient, bevacizumab. This likely resulted in patients not receiving their prescribed anti-cancer therapy.

² https://www.fda.gov/drugs/drugsafety/ucm291960.htm
A Growing Problem

The trafficking of fake and altered drugs, including injectable hormones and vaccines, has reached epidemic levels in some parts of the world and is a growing problem in the United States. The problem also includes genuine drugs stolen from the supply chain. Such drugs run the risk of being mishandled, making them ineffective and potentially dangerous if they are used. These problems are especially relevant for injectable medicines which often have increased requirements for cold chain or other special handling. The global Injectable drug delivery market, in terms of value, is projected to grow from $362 billion in 2016 to $624 billion in 2021, a CAGR of 11.5% during the forecast period. This agrees with the growth in the global vial market which has a projected CAGR of 11.73% between 2016 and 2020.

Fake injectables began showing up in the United States drug supply in 2001, causing drug companies to seriously consider the best ways to protect their consumers — and their brands — from fake or altered products. Drug manufacturers sought help from companies such as Authentix that specialize in anti-counterfeiting technology. Key to a solid anti-counterfeiting plan is a drug maker’s first evaluation of its manufacturing process. Sponsors need to look at how and where their drugs are manufactured, then evaluate the way products are put together — and where the controls of related packaging components reside. That information can be used to create a strategy dictating where anti-counterfeiting features should be implemented to ensure that the product supply is protected from compromise, theft, or abuse as it travels from the point of manufacture through the distribution system to various points of sale.

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3 MarketsandMarkets “Injectable Drug Delivery Market by Type (Device, Formulation), Therapeutic (Cancer), Usage Pattern (Immunization), Administration (Skin, Musculoskeletal), Distribution Channel (Hospital), Patient Care Setting (Hospital, Home Care) - Forecast to 2021”

4 Research and Markets “Global Vials Primary Packaging Market 2016 – 2020”
http://www.researchandmarkets.com/research/frmf tb/global_vials
Multilayered Solutions for Positive Identification

Anti-counterfeiting features that can authenticate injectable drugs are both overt and covert, and they can be applied in numerous ways: on labels, onto closure seals, on cartons where vials of injectable drugs are stored, into plastic caps of individual vials, and onto the glass vial itself.

The different types of features all serve a different purpose, from enabling end users to quickly identify a branded product as genuine, to covert markings that enable a manufacturer or inspector to identify the source of diversion or other illicit activity. When combined with the careful design and production quality controls used in authentic product manufacturing, these features raise the bar of complexity for counterfeiters and make the product a less attractive target.

Visible security features serve a valuable purpose in the authentication stack. They offer a way for individuals to inspect packaging without any specialized tools, and these elements are often difficult to reproduce using scanners or reprographic methods. Specialized color-shifting inks (similar to those used on currency) are used on both labels and packaging. Color-shifting inks appear to be a different color depending on the angle from which they are viewed. They are difficult to manufacture and difficult for counterfeiters to duplicate. There are other types of optically variable features as well, including holograms, micro-optics (like the blue stripe found on the current US $100 bill), and reflective features. Many of these non-ink elements are affixed either to the drug packaging or to the vial closure seal during the packaging steps.

Visible security features are a starting point, but drug companies need to rely on additional features to create layers of security. Counterfeiters are extremely creative and clever. Even if a visible authentication feature is hard to recreate perfectly, a counterfeiter only needs to copy it closely enough to confuse someone who just gives a package a quick glance. A good counterfeit is an excellent copy of the genuine product — so even the injectable drug’s manufacturer may not be able to tell if a product is counterfeit or authentic. High-security covert features add an extra level of protection and assurance because they are difficult for counterfeiters to detect but easily verified by field inspectors who check drug authenticity.
Covert markers can be embedded into labels, closure seals, or other features of injectable drug packaging. Although such markers are invisible to the naked eye, they can be detected using specialized handheld surface spectrophotometers. Field instruments use proprietary excitation and detection optics and detection algorithms for rapid, secure field authentication. Additional forensic layers of security are also embedded into the materials and can be confirmed through more extensive laboratory analysis.

One innovative feature developed at Authentix is the incorporation of covert authentication into the non-reusable metal ferrule of injectable vials. Since the ferrule is broken during administration, this part of the package cannot be reused and therefore can’t be collected by counterfeiters to create fake vials. The Authentix technology allows reading of the covert markers through the plastic vial cap, even when this cap is not visibly transparent. This marker family and associated readers are part of our Sherlox™ brand protection offering, that includes services, markers, readers, and an information management system to form the basis of a complete brand protection and inspection program.

Case Study:

A large CPG company had a problem with a beauty product being sold in China. The product represented ~$100M of annual sales to the company, and they suspected there might be counterfeiting in the marketplace. Authentix was able to quickly supply security inks that made no visible difference to the packaging, but allowed inspectors to quickly identify counterfeit goods. The first survey of product found a counterfeit rate of approximately 30%. After a campaign of distributor and retailer education, repeat inspections estimated US$5.0M worth of counterfeit product had been removed from the marketplace just by the implementation and education, indicating a tremendous ROI was possible with the program. Continued spot checks by their sales teams, combined with eliminating some wholesalers, warning letters to other offenders, and reporting of lesser offender wholesalers to their security team has led to the latest check finding the incident rate dropping to just under 10%. This is an incredible amount of revenue recovery in less than a 24-month period.
Tracking

Authentication of injectable drugs is only part of the solution when it comes to curbing drug counterfeiting. It’s also important to track products at various points along the supply chain. Manufacturers can keep tabs on drugs as they travel through distribution with field monitoring and barcoding.

**Field monitors** inspect drugs as they travel through the supply chain. For example, a field inspector might visit a drug distributor’s warehouse to use a reader that quickly checks for a marker’s spectral profile. Absence of the proper spectral profile would immediately “raise a red flag” and act as an early warning before fake drugs could get further along through the distribution channels. In addition to actually checking for authentication features, the mere presence of inspectors acts as a deterrent. Their regular visits can discourage distributors from obtaining injectable drugs through questionable sources.

An effective anti-counterfeiting solution contains multiple, layered components.

**Serialization:** In the serialization process, a company marks individual units at the point of manufacture (giving each a unique serial number) and implements stations to read those markings, capture the tracking data, and drop that information into a managed database that allows authorized personnel to monitor where products go after they leave the manufacturing facility. You’re probably most familiar with this process as it applies to shipping a package overnight, when you can track it on the Internet until it reaches its destination.
Recently a number of technologies have become available that allow a manufacturer to uniquely identify their product or package by measuring some inherent properties of the product. These technologies usually involve some manner of high speed and high resolution scanning of the product under specific conditions that allow unique optical patterns that are created by the randomness of the manufacturing process. The technologies offer the benefit of not having to add any additional features to the packaging, but the imaging requirements on the production lines can be quite demanding and difficult to implement at speed. Once captured, the identification of the package can take place with conventional cameras, allowing widespread authentication and tracking by inspectors, retailers, or even consumers.
An Ounce of Prevention

Historically, drug companies have implemented anti-counterfeiting strategies in response to an urgent counterfeiting problem. Such a strategy can be put into place relatively quickly, within a matter of weeks. It is better, however, to implement a well-planned, overarching strategy that encompasses manufacturing, monitoring, and supply chain considerations before any trouble arises.

As counterfeiting becomes a mounting concern, drug sponsors are to taking a proactive approach to the problem. Many companies are thinking more broadly about how to implement coordinated anti-counterfeiting, anti-diversion strategies across their brands and throughout different regions of the world. Just as tamper-evident seals on bottles of pills and liquid formulations became more common due to a tampering scare in the 1980s, attitudes toward anti-counterfeiting technologies are beginning to evolve now. Once viewing such measures narrowly as an “extra feature” that only “added cost” to the bottom line, drug makers are beginning to realize the importance of protecting the integrity of their brands and the most important part of the equation: protecting the safety of consumers. As serialization requirements continue to evolve, the tracking of individual units through the supply chain could enable very secure and traceable evidence of authentic drugs being supplied by manufacturers and distributors to end users that take the steps to use this information.

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About Authentix:

Authentix is a leading global authentication and information services company announces. Authentix develops and markets Authentix Sherlox™, an end-to-end authentication offering for brand owners that includes an integrated system of security markers and readers, a powerful data information system, and robust services.

Learn more about what Sherlox can do for your brand protection program at http://authentix.com/offerings/sherlox/