Tackling Track-and-Trace
An Overview and Pathway to a Solution
Introduction

Counterfeit medicines flooding the market are threatening the pharmaceutical industry on a global scale. In fact, it is believed that seven percent of all medicines worldwide are counterfeit. These random mixtures of harmful toxic substances are not only illegal, they are extremely dangerous to patients and damaging to the reputations of legitimate companies in the pharmaceutical supply chain.

What’s more, increased Internet sales, widespread demand for generic drugs and drug shortages in many countries and market segments have fueled the counterfeit drug trade. As governments worldwide scramble to respond, counterfeiters change their methodologies, moving operations or re-routing supplies to circumvent detection.

As a result, global legislation over pharmaceutical distribution has ramped up, calling for effective track-and-trace on drugs traversing the supply chain. Track-and-trace requirements will affect manufacturers, wholesalers, pharmacists, and in Europe, parallel distributors at the regional level.

In Europe, the EFPIA, EAEPC, GIRP, EDQM and PGEU are working toward a standardized identification solution for pharmaceutical products across the continent. In the United States, the FDA and DEA are working to institute a comprehensive track-and-trace system to monitor drugs throughout the production and distribution lifecycle.

From now through 2017, when a majority of these proposals are set to become law, pharmaceutical wholesalers and distributors will need to begin implementing systems to comply. This whitepaper will summarize the key regulations in play on both continents and suggest a compliance solution based on a combined process and technology approach to track-and-trace.

Why Track-and-Trace

The purpose of track-and-trace regulation in the pharmaceutical industry is to stem the flow of illegal and dangerous counterfeit medicines. These medicines represent a significant public health challenge. No central authority has all the information necessary to track-and-trace drugs across the global supply chain, much less quantify the extent of counterfeiting. Meanwhile, counterfeiters are extremely flexible in the way they mimic products and prevent detection.

In regions where regulatory enforcement systems are weak, counterfeiting thrives. Some figures show that 40 percent of the drugs circulated in South America are counterfeit; in West Africa, the figure jumps to 70 percent. Europe and the United States are attacking the problem through track-and-trace legislation, placing the burden for drug authentication on manufacturers, wholesalers, pharmacists and distributors.
The European Outlook

In Europe, the European Federation of Pharmaceutical Industries and Associations (EFPIA), along with the European Association of Euro-Pharmaceutical Companies (EAPEC), Groupement International De La Repartition Pharmaceutique (GIRP), the Pharmaceutical Group of the European Union (PGEU) and the European Directorate for the Quality of Medicines and Healthcare (EDQM) are all working toward a standardized identification solution for pharmaceutical products across the continent.

ESM Project

The European Stakeholder Model (ESM) is one such pan-European system, involving electronic product verification at the point of dispense for all prescription medicines. Manufacturers will be required to label medicine packages with a product code, including global trade item number, batch code, expiry date and serial number in both human-readable and machine-readable formats.

The machine-readable code will be a 2-dimensional datamatrix barcode. National databases connected through hubs will record the product codes and serial numbers and manage the exchange of data from across every Member State. Repackagers, or parallel distributors, will be required to assign a new serial code to the database in connection with the original product.

eTACT

Separately, EDQM is proposing an end-to-end coding system called eTACT, requiring manufacturers of prescription and over-the-counter medicines to assign a unified medicine identifier (UMI) on all packages. The UMI will include product numbers, non-sequential and unpredictable serial numbers, batch numbers and expiry data.

Initial plans call for machine-readable datamatrix labels on each package, with a possible switch to RFID labeling later. EDQM will manage the database, and provide online authentication of medicines to supply chain operators, including online pharmacies, as well as patients.

No clear model or implementation deadline has been set for either proposed system to date.

The American Outlook

In the United States, the FDA Safety and Innovation Act (FDASIA), signed into law July, 2012, gives the FDA authority to collect user fees from industry to fund reviews of innovator drugs, medical devices, generic drugs and biosimilar biologics; FDASIA is only the beginning of several new regulations under discussion. Here are the most pressing to date:

ARCOS Reporting

ARCOS is an automated drug reporting system, which monitors DEA (Drug Enforcement Administration) controlled substances from manufacturer through commercial distribution to point-of-sale, including hospitals, pharmacies, practitioners and teaching institutions. All Schedule I and II materials, Schedule III narcotic and gammahydroxybutyric acid (GHB) materials, and select Schedule III and IV psychotropic drugs are subject to report.
The American Outlook (continued)

Pedigree and ePedigree

Pedigree is a process that includes product serialization down to the lowest unit of sale, continuing through the supply chain with each trading partner authenticating receipt and transfer by way of interoperable electronic interchange. Since December, 2006, all drugs distributed by wholesalers, distributors or repackagers require Pedigrees, unless the seller is an Authorized Distributor of Record (ADR) for that drug. ePedigree is an electronic record of all data required by Pedigree laws; ePedigree data is exchanged using Electronic Product Code Information Services (EPCIS) standards.

National Drug Code (NDC) Number

NDC numbers are unique, three-segment numbers used for identifying human drugs listed in the FDA's Drug Registration and Listing System (DRLS). The FDA extracts data from the DRLS and publishes it in the NDC directory monthly.

DEA License Validation

This is the DEA's registration system, authorizing medical professionals, researchers and manufacturers who make, distribute, research, prescribe or dispense controlled substances. Distributors must verify customer license validation at entry and picking points. Various license types are issued at the state level, and each license must be verified to be “in good standing.”

CSOS (Automated Form) DEA Form 222 (Manual Form)

The Controlled Substances Act requires Schedule I and II controlled substances be distributed only by written orders issued in accordance with the DEA Office of Diversion Control. Order forms are presented in triplicate and must contain the DEA registrant’s name, address, date requested, number of packages ordered, size of package and name of substance. The purchaser retains one copy; the supplier retains one copy and sends the third to the local DEA agency. The purchaser and supplier must retain their copies for at least two years and make them available to DEA officials on request.

Suspicious Order

In 1998, the Suspicious Orders Task Force developed the “Suspicious Orders Identification Criteria,” voluntary guidelines for recognizing suspicious orders. The guideline supports 21 U.S.C. § 830(b)(1)(A), which requires regulated persons to report to the Attorney General’s office extraordinary quantities or uncommon methods of payment or delivery in relation to any listed chemicals.
A Reasonable Response

In light of the growing and various regulations and restrictions surrounding drug manufacturing, distribution and sales on both continents, supply chain partners in the U.S. and Europe must employ a proactive system of track-and-trace functionality to effectively survive and compete within this shifting compliance landscape.

However, track-and-trace solutions are not just about compliance; brand security and business vitality are also at stake. Where product diversion and theft may negatively affect the bottom line today, counterfeiting of any sort is damaging to the brand long-term and stand to erode customer base along with shareholder value.

View to a Solution

By employing effective product authentication across the supply chain, using appropriate track-and-trace solutions, the organization can protect against negative consequence down to smallest unit of sale.

For instance, electronic product codes (EPC) can track each unit from the manufacturer to the consumer and back to specific lot. As a result, the supply chain can be optimized as compliance is enhanced.

- Accurate handling can minimize chargebacks.
- Product recalls can be handled more efficiently and effectively.
- Pricing becomes more accurate.
- Liability in the event of product diversion or theft can be limited to unit vs. entire lots.
- Visibility can be improved, leading to more accurate forecasting and improved marketing decision-making.

Ideally, lot tracking and traceability should integrate all business processes, including purchasing, inventory management, production, sales, regulatory and financials in a single software solution. But, how do you implement the solution efficiently? How do you integrate track-and-trace with an existing enterprise system? Will it affect your warehouse system and operations? How will your supply chain partners react and interact? Are you using multichannel ecommerce as part of your business model? If so, is your software up to the challenge? How will you configure your packaging lines considering diverse products and markets? To be sure, many questions must be addressed.

Therefore, we suggest visualizing a solution before making fundamental changes. To institute an effective track-and-trace response capable of managing today’s changing pharmaceutical regulatory landscape, your goal should be to integrate all business processes through a single system that prohibits negative inventory and enables real-time transaction processing.
Essential Ingredients

Basic to the solution is a system that recognizes all of your regional standards for coding, capture and data exchange. This means you must be able to facilitate tracking and authentication, supported by the required documentation of all your activities, to the standards set by local authorities.

In addition, the system must be able to manage the process even when repacking and exceptions occur. Therefore, data access must be enabled across the supply chain through web portals and to the specific business-to-business standards used by your various supply chain partners. For maximum supply chain agility, mobile and fixed devices should also be functionally integrated to the solution.

Core capabilities to address include:

- Contract administration
- Rebates
- Chargebacks
- Pricing (Medicare/Medicaid in the U.S.)
- Recalls
- Expiration handling
- Non-saleable merchandise

Obviously, any automated system you select must be able to manage the serialization process cleanly. Here, your solution will need to generate lot data on barcode labels for real-time tracking through full-cycle receiving, quality control, put away, replenishment, counting, and pick, pack and ship operations. The data must be stored and formatted to record item, lot and warehouse history, as well detailed date, time and user information for any desired tracking reports.

A system that automatically alerts you of out-of-bounds instances (i.e., item doesn’t match batch ticket, product expirations, etc.) will also reduce your liability and enhance supply chain throughput. The ability to manage multiple expiration dates for the same product is also essential, if your operation is to support a first expiring first out (FEFO) picking sequence.

In short, a full system response should provide you with a functional controlled substance ordering system, including suspicious order monitoring, with the comprehensive electronic reporting and coding capabilities it takes to report all required data electronically, in compliance with regional regulations. To do this, appropriate RFID chip (non-line-of-sight technology) or 2-D barcoding (secondary data carrier) integration will be required.
The Payback

So, what is the payback for this business transformation, if not to ensure your right to stay in business and maintain the good graces of your local governing authorities? The answer is nearly as multi-faceted as the solution itself.

An automated, supply chain solution, specifically tailored to your pharmaceutical wholesale and distribution business, will deliver value on a number of fronts. In addition to holding your organization confidently within the boundaries of compliance, a reliable track-and-trace drug monitoring system will:

- Enhance your efficiency
- Speed delivery
- Reduce your cost-to-serve
- Eliminate waste
- Provide visibility into your expanded network inventory
- Improve forecasting
- Support sales
- Improve margins
- Build brand loyalty
- Create brand differentiation

View to a Solution

Growing threats to the global drug supply chain are driving regulatory requirements worldwide. Many laws are either in force currently or now in the trial stages. Your enterprise can benefit from compliance, beyond risk mitigation. A well-conceived track-and-trace capability will improve automation, visibility, efficiency and profitability across the supply chain.

The time to make your move is now, before complete legislation forces your hand. Contact IBS to discuss our singlesource ERP solution for pharmaceutical wholesale and distribution businesses – IBS Pharma. We can provide a fully integrated ERP track-and-trace solution that ensures compliance, as it also streamlines your complete supply chain operations.
## Contact Us

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