SERIALIZATION: A GLOBAL CHALLENGE FOR PHARMACEUTICAL SUPPLY CHAINS

Governments are phasing in regulations mandating unique numerical identifiers for medicines. To comply, pharma companies must make changes now.

Counterfeit medications were long thought to be a problem only in developing countries. That’s no longer the case: The World Health Organization (WHO) estimates that about one percent of pharmaceutical sales in developed economies and more than 10 percent of sales in emerging markets are counterfeit products. Other international organizations believe the total percentage of counterfeit medicines could be as high as 30 percent.

No matter what the actual numbers may be, pharmaceutical counterfeiting is putting millions of lives at risk each year, and governments around the world are taking action to address this growing problem. For many, the principal weapon in that fight is track and trace regulations centered on product serialization—assigning and affixing a unique number to products and tracking them throughout the supply chain.
“It is expected that these [serialization regulations] will cover over 70 percent of global medicines by 2017,” said Andrea Charles of ColdChain IQ, an online community for pharmaceutical industry professionals, at a recent industry summit.

Compliance with these regulations will require companies to invest in new technology, make major process changes, and potentially restructure their supply chains. To ensure that such long-term, complex projects move forward as serialization requirements are being phased in over the next 10 years or so, pharma companies and their supply chain partners must begin making changes now.

Changes along the supply chain
Serialization regulations will push change all along the supply chain. For one thing, they require manufacturers, wholesale distributors, third-party logistics service providers (3PLs), and others to acquire the proper licenses and accreditations in each country that mandates serialization. For another, manufacturers will have to change the way they package, mark, and label their products, including redesigning packaging to accommodate new barcodes, serial numbers, and anti-tampering features.

At each hand-off (i.e., exchanges between manufacturer, wholesaler, distributor, and healthcare facility/pharmacy), companies will be responsible for the tracking, tracing, and documentation of drug shipments using identification numbers linked to items at the case, pallet, lot, or batch level. These numbers are most commonly applied as linear barcodes or data-matrix (2D) barcodes, but sometimes are included in radio frequency identification (RFID) tags.

One of the biggest challenges facing pharmaceutical manufacturers and their partners is how to generate, capture, verify, pool, share, and report specific pieces of data for each shipment. Depending on the country, that information may include drug name, strength, dosage, container size, number of containers, lot number, serial number, transaction date, shipment date, and names and addresses of trading partners. Manufacturers also must be able to access a complete transaction history for each sale.

That will make pharmaceutical companies responsible for extraordinary volumes of information, predicts Jonathan Blamey, Vice President, Global Products, Life Sciences & Healthcare, DHL Supply Chain. “If we are capturing 10 pieces of data for each of the 15 billion packs of pharmaceutical products in the EU, it gives you an idea of the sheer amount of data to be collected and managed,” he says. Add in all the other countries with similar requirements, and the magnitude of this challenge becomes clear.

Compliance will be expensive. To make all this possible, companies will need to acquire hardware and software, and integrate them with any existing enterprise resource planning (ERP) systems. Overall, the European Generics Association (EGA) estimates the cost to comply with the EU’s serialization regulations as:

- Printing and serialization — around US $331,000 to $397,000 (approximately €303,000 to €364,000) per packaging line

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• Anti-tampering — around US $199,000 to $265,000 (approximately €183,000 to €243,000) per packaging line, and
• Verification with repository information systems — around $53 million (approximately €49,000,000) per year.

Global scale
According to the consulting firm Accenture, some two-dozen countries have implemented serialization regulations or are in the process of doing so. They encompass a diverse range of nations, from economically developed markets like Canada, Germany, South Korea, and the United States to less-developed countries such as India, Nigeria, Saudi Arabia, and Turkey.

Experts expect there will be a consistent “core” regulatory structure across implementing nations, but each country will develop its own policies, serialization standards, and implementation timetable. Most countries are working toward some form of serialization regulations, with many of the large-volume markets implementing at least initial-stage laws by 2017.

In most cases, regulations will be phased in over a number of years, based on what actions must be taken (such as serialization, verification, traceability) and which entities must comply (manufacturers, wholesalers, 3PLs, and so forth). For example, the U.S. Drug Supply Chain Security Act has a 10-year phase-in for traceability, from January 2015, when lot-level traceability systems must be in place, to November 2023, when it mandates electronic, interoperable traceability systems at the package level. By the end of this decade, countries such as India, South Korea, Turkey, the United States, and the European Union will have expanded the number of supply chain participants that are required to comply with phased-in requirements.

This means supply chain partners must not only have a deep understanding of local markets and regulations, but also possess the necessary physical and IT infrastructure in place to enable compliance. A shared services supply chain model, in which a 3PL handles multiple manufacturers’ products in a shared facility, spreads risk and the costs of infrastructure, services, and personnel while providing access to leading-edge technology.

“Third-party logistics companies are already set up to capture a lot of supply chain data,” says Lisa Harrington, President of lharrington group, LLC and Associate Director, Supply Chain Management Center, University of Maryland. “It will have to be augmented, but they have the core systems to manage this level of data capture and processing.” In the United States, where manufacturers are responsible for storing the data, pharma companies can piggyback on their 3PLs’ systems and not have to make such a big investment themselves, she adds. In some countries, regulators store the data, but 3PLs will still be instrumental in capturing and processing the information at appropriate points in the supply chain.

It may prove difficult for pharmaceutical manufacturers to comply with serialization regulations given the aggressive timetables in many countries. That’s likely to lead to supply chain bottlenecks, at least initially. Establishing collaborations with expert supply chain

3 “Life Sciences & Healthcare Serialization—Capturing Data” (video), www.exel.com/serialization
partners to find efficiencies and develop compliance capabilities now will be key to minimizing the time to deploy and ongoing costs as regulations roll out in the future.

For more information about serialization’s impact on pharmaceutical supply chains, read the new white paper, Protecting products to save lives: Securing the pharma supply chain. You can download it here.