

Research Article



An Overview of Track & Trace Regulations in Pharma Industry and its Impact on the Reverse Logistics of Medicines- Status in Regulated Countries and India

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ABSTRACT

Drug counterfeiting is an important problem addressed by several countries. This requires multiple measures to protect the supply chain. The implementation of anti-counterfeit technologies is an important strategy taken up by several drug manufacturers and regulatory authorities. The track and trace system and serialization are given importance and are widely used among all anti-counterfeit technologies in different countries. Developed countries like the USA have implemented RFID while the European trend is towards 2D barcodes. The Indian government is getting sensitised about the extent of the problem and has formulated rules mandating barcodes. Reverse logistics is a combination of product returns of expiring or overstocked product, and recalls initiated by manufacturers themselves or by regulatory authority for product defects. Extensive government regulations and reporting requirements, along with an increased focus on pedigree, have increased the need for good tracking, visibility and control measurements which are all critical components for any reverse logistics process.

Keywords: Counterfeit, Reverse Logistics, track and trace.

INTRODUCTION

Dispensing and dosing errors, reimbursement issues and cases of counterfeits in the legitimate pharmaceutical supply chain have highlighted the need to establish more clearly and effectively the identity of each individual medicine pack¹.

To tackle this issue effectively, there needs to be a united effort from the pharmaceutical industry, regulatory bodies, wholesalers and retailers to establish a standardized identification solution. A database where uniquely identifying bar codes on drug packaging can be verified at point of dispensing would significantly improve the ability to track pharmaceutical products on a global basis; there is an urgent need to improve traceability within the supply chain. Serialization technology provides the ideal solution to enhancing efficiency in the supply chain, reducing theft, counterfeit products and allowing manufacturers, distributors, retailers, pharmacies and end-users to ensure compliance with industry regulations. In order to sufficiently protect public health interests and the relationship of trust between patients and pharmaceutical suppliers, the entire production and supply chain needs to be closely regulated.²

The pharmaceutical industry operates on a global scale, and regulatory compliance across multiple geographies is fundamental to ensuring that the supply chain remains safe and secure.

Track and Trace (T & T) technologies are playing a main role in ensuring safe drug distribution chains and instituting quality / expiry recalls. T&T systems allow all stake holders where the product is at any time and see a record of where it had been previously. This is the process

of assigning a unique identity to each stock unit during manufacture which then remains with it through the supply chain until its consumption, and is called the track and trace system. Information is attached in the form of a unique pack coding, enabling access to the same information on a secure database.³

T&T systems rely on serialisation, the assigning of unique identification numbers to products. Products that lack identification numbers, or products with identification numbers that cannot be accounted for throughout the distribution chain, must be treated as falsified and removed from the market, even if they come from licensed manufacturers.

The unique identifier may be stored in a barcode, electronic product code, radio frequency chip or it may be a long-digit serial number.

Advantages offered by the track and trace system are :

- A reduction in medication errors
- Automated pharmacy billing
- Effective control of inventory
- Effectiveness in product recalls
- Detection of theft and product diversion.⁴

United States' Track and Trace Regulations Overview

In 2013, the Drug Supply Chain Security Act (DSCSA) was introduced, which requires all manufacturers to affix 2D barcodes on vaccine units of sale in the next couple of years.⁵



The Drug supply chain Security Act (DSCSA) mandates that manufacturers begin serializing all drug products at the saleable unit and case level for the US market starting in Nov.2017, with repackager deadlines beginning in 2018. It is also called Track and Trace Act.

DSCSA adds new sections in the Federal F & DC Act which include requirements for product tracing, identification and verification and standards for licensure of Third Party Logistic providers (3PLs).

The full complement of US requirements phases in between 2015 and 2023, with challenges for all supply chain companies at different points along the way.

DSCSA requires that manufacturers mark packages with a product identifier, serial number, lot number, and expiration date by November 2017. At the same time, wholesale distributors and other supply chain companies will perform end-to-end serialization testing with their manufacturing partners in advance of the deadline to allow time for any necessary adjustments.

By January 2015 pharmaceutical companies and wholesale distributors needed to achieve lot-based traceability, which involves sharing a Transaction History with every partner to whom you sell product. For many companies, establishing the necessary infrastructure for communication with partners at the level you need for regulatory compliance was the biggest challenge. In addition, the law does not prescribe standard formats for data exchange, so companies need to be equipped to receive transaction data in many configurations.

By July 2015, dispensers needed to be able to receive and archive T3 information, and be prepared to produce it in the event of an inquiry.

When serialization comes into play, product tracking will still be required but the nature of the requirement changes. Track and trace and serialization requirements will finally converge in 2023.⁶

In the event of a suspect product inquiry, supply chain companies must be able to produce the relevant transaction documentation within twenty-four hours (forty-eight hours for dispensers). During lot level preparation, the industry discovered that completing one transaction between two parties was challenging. When serialization with its end-to-end tracing takes effect, businesses will need to manage many transactions, involving billions of items, with tens to hundreds of partners, including outsourcing ones. So there is the supply chain communication challenge but there is also a data volume challenge as businesses generate, process, and store an unprecedented amount of data and transactions. In the US the smallest saleable unit and the sealed homogenous case need to be serialized.

Manufacturers must serialize by November 2017. The rest of the supply chain has more time before they need to make full use of the serial numbers, but there will be circumstances prior to that in which they need to interact

with the serial number, like for product returns and suspect product investigations.⁷

With the Drug Supply Chain Security Act (DSCSA) and the related implementation plan, new requirements were defined in the USA which aim at improving the traceability of prescription drugs within the supply chain.

The DSCSA is focusing more on each step in the supply chain, tracking the different stages on the way to the pharmacy.

On the FDA website, a graphic represents a summary of planned implementation timeframes for the Drug Supply Chain Security Act over a 10-year period. The major phases are:

- Lot-Level traceability and verification: Starting January 1 2015 for manufacturers, wholesalers and re-packagers; and July 1, 2015 for pharmacy (hospitals and retail): changes of ownership of a batch must be tracked.
- Unique Serialization:
From 2017 - 2019, single packages of drug products have to be marked with serialisation numbers and bar codes.
- Serialised Item-Level Traceability:
From 2023, information must be provided to allow supply chain partners to trace the transaction history back to the initial manufacturer or re-packager.⁸

California's e-pedigree Law and Drug Pedigree Requirements

On November 27, 2013, President Obama signed Public Law 113-54. This law contains provisions for a national track and trace system for prescription medication.

The pedigree is an important part of a series of provisions intended to address threats to the prescription drug supply from counterfeit, misbranded, adulterated or diverted drugs. The overall intent is to secure the drug distribution system and sustain and increase confidence in authenticity of prescription drugs in California by creating a track and trace system. Recalls, returns, drug take-backs will be greatly facilitated by electronic pedigree system.

Electronic Pedigree Requirements

- Prescription Drug Information
- Transaction and Source Information
- Ownership Information
- Certification

Exemptions are,

- ▶ Radiologic drugs
- ▶ Drugs labeled "for veterinary use only"



- ▶ Compressed medical gases
- ▶ Solutions:IV solutions for replenishment
- ▶ IV solutions used to maintain equilibrium of water and minerals (dialysis)
- ▶ Solutions for irrigation or reconstitution
- ▶ Surgical kits containing a device and medical supplies, sealed by the Mfg.
- ▶ Kits containing a drug/device, biologic/device, drug/biologic/device that are physically or chemically or combined as produced as single entity
- ▶ Kits containing two or more products packaged together in a single package comprised of a drug and device or biologic and device
- ▶ Drugs received by a state or local government agency from a federal govt. agency⁹

Europe's Track and Trace Regulations Overview

In 2011, the European Commission published Directive 2011/62/EC, the so called Falsified Medicines Directive (or FMD). One goal was the fight against counterfeit medicines through serialization and verification. With the publication of the Delegated Act on safety features, those who manufacture, sell, or dispense medications in the European Union have until February 2019 to comply with new track and trace regulations outlined in the Falsified Medicines Directive (FMD).¹⁰

FMD compliance creates some unique challenges. The main requirements presented in the FMD involve serialization, compliance reporting, and verification. Medications in Europe are generally packaged and sold at the "unit of use" level, so the volume of product that needs to be serialized and the magnitude of transactions will be two to five times what companies will see in the U.S. where the saleable unit is in larger bulk quantities. Overall, the universe of data to be produced, managed, and reported on will be massive, with the added complexity that each EU Member State is provided flexibility to apply their own unique requirements. Manufacturers serving the EU are preparing to meet serialization requirements by 2018.¹¹

The FMD requires secondary-level (saleable unit) serialization only, with a GS1 standard serial number issued by the manufacturer. Product identifiers may include a GTIN or country-specific product code, and additional country-specific data elements may be required.

The manufacturer or marketing authorization holder has several types of reporting or notifications to make to the European hub. The two primary ones are for product master data and serialized product pack data. First, master data about the product including product codes, form, dosage, target market(s) for distribution and other data must be reported to the European hub. Serialized

product pack data must also be reported, including product codes, lot, expiry data and serial numbers. If manufacturers have subsequent status updates about the product, those must be uploaded to the hub as well. Additionally, if manufacturers have downstream companies that act as agents on their behalf, they must publish a list of those companies within the master data submitted to the hub.

As the drug product moves through the supply chain prior to dispensation, EU FMD provides for verification of the product identifier. The regulations specify that dispensers verify product identity, but also that wholesalers and parallel importers do so in certain circumstances.

For dispensers, the law dictates that they verify product at some point prior to dispensation. Scanning the product's barcode and verifying the information with a national system will validate serialization information and access any product updates from the manufacturer, including whether the product has been flagged as stolen or potentially counterfeit.

Wholesalers have their own unique set of risk-based verification requirements. If a wholesaler purchases product from another wholesaler, they must verify the product by interrogating its safety features, including scanning of the barcode to verify the product identifier, prior to resale of the product. Returned products that could re-enter the supply chain also have to be checked in a similar way to ensure the integrity of the product.

The FMD is an overarching guideline for manufacturing and distributing product in the EU, providing general harmonized standards across the EU while supporting the unique needs of individual Member States. Flexibility is afforded to each one of the Member States to apply their own unique requirements in areas such as product codes, national reimbursement numbers, etc. In addition, some drug products may be classified as prescription pharmaceuticals in one Member State and not in another. In 2014 the technical characteristics of these key ideas were defined, the unique identifier (UI), delivering the possibility of verification of the authenticity of single folding boxes. The unique identifier contains information on the:

- Manufacturer product code
- Serial Number
- National reimbursement number, if present
- Batch Number
- Expiry Date

The 2D barcode (data matrix) has been set as carrier of this unique identifier. An end-to-end verification system is guaranteed by risk-based verifications by wholesale distributors. Medicines will be systematically verified before being dispensed to patients. With the end-to-end



scanning process of the data matrix, the authenticity of each packaging is automatically verified via a protected centralized database. If identical numbers are found or if a number cannot be found in the database, an alarm will be triggered immediately. The repository containing the unique identifiers will be set up and managed by the stakeholders. National competent authorities will be able to access and supervise the database.

As this new requirement will become active in 2018, it is time to start defining strategies for both technical implementation and change control strategy.¹²

The French CIP (Club Inter Pharmaceutique) 13 coding legislation requires all prescribed pharmaceutical products distributed in France to include a specified data matrix barcode containing the new CIP13 code, batch No. and expiry date be printed on the outer packaging. The manufacturer should choose the appropriate technical solution for the serialization number and its carrier such as linear barcode, 2D barcode, and RFID etc.¹³

Japan's Track and Trace Regulation Overview

Efforts are being made along the entire value chain to maintain integrity and safety in the drug manufacture and distribution process. Additionally, the following measures have been taken to make the Japanese pharmaceutical supply chain safe, stable and secure.

SMS

Manufacturers assign a specific code to drug packages, and once a customer buys that drug, they send a message to a mobile authentication service that identifies it as counterfeit or legitimate. This is particularly useful for checking that no parallel trade exists in the distribution chain.

Barcoding

Barcodes are used extensively to identify specific products by conveying information such as the medication name, dose and route of administration. Depending on the arrangement of the strings, lines and spaces on the barcode, they are of three types, namely linear, two-dimensional matrix, and composite. In 2008, the Japanese government mandated that all medical products must be encoded with a Japan Article Number (JAN), which is a Global Trade Item Number (GTIN), assigned specifically for the Japanese market. A GTIN is 14 digits in length and signals the barcode format, packaging level, company prefix and an item reference number. After the issuance of the MHLW Guidelines for Barcode Marking, the rate of barcode marking on medical devices has been steadily increasing and now exceeds 80%.¹⁴

Table 1: Overview of track & Trace Regulations in Regulated Countries

Country	Act/rule	Requirements	Implementation
US FEDERAL	DRUG QUALITY AND SECURITY ACT (TRACK & TRACE BILL) DRUG SUPPLY CHAIN SECURITY ACT 2013 LAW 2013	-Framework for securing the prescription drug supply chain -Licensure standards for wholesale and distributors and Third party Logistics providers.	10 Year Plan- November 27 2013- November 27 2023
CALIFORNIA	E- PEDIGREE LAW Nov.27 2013	Pedigree (creation of Electronic transaction history of a drug) -Source -Generic name, strength, expiry, lot no, date of transaction etc -Certification	2015-2017
EUROPEAN UNION	FALSIFIED MEDICINE DIRECTIVE (FMD) Directive 2011/62/EU EUROPEAN MEDICINE VERIFICATION SYSTEM (EMVS)	Serialization - linear, 2D barcode, Radio Frequency Identification (RFID) -barcodes printed /attached to every single pack barcodes will be checked into a database repository system by mfr. 2D data matrix barcode on the outer packaging	2016-2019
FRANCE	FRENCH CIP13 CODING LEGISLATION	-CIP13 code, Batch no. & expiry printed on each item. -Code is batch specific	
JAPAN	ENCODING OF PHARMACEUTICALS WITH JAPAN ARTICLE NUMBER	Barcodes Serialization	2008-2021

Present Scenario in India

Sample survey data of CDSCO from 1996-2016 shows that there is same level of spurious drugs in India. At present tracking and tracing is implemented only for exported drugs. Government of India instituted a task force for studying T&T systems, which submitted its report to the Ministry of Health & Family Welfare, Government of India in March 2012.

Table 2: Sample survey Report of CDSCO

NO.	YEAR	SUBSTANDARD (%)	SPURIOUS (%)
1	1996	10.64	0.30
2	2008	6.42	0.16
3	2009	4.75	0.046
4	2016	3.16	0.023

On 10th January 2011, Directorate General of Foreign Trade (DGFT) issued guidelines for the Implementation of a track and trace system incorporating barcode technology as per GS1 standards for all drugs and pharmaceutical products exported from India. All export pharmaceutical consignments should be marked and coded at various packaging levels using GS1 barcode standards. DGFT issued this mandate as a step towards implementing a traceability system to address counterfeit and ineffective product recall challenges, which affects the entire healthcare supply chain, from manufacturers all the way to patients, wholesalers, distributors, exporters and healthcare providers.

Importance of Tracking and Tracing Technology in Reverse logistics

Reverse logistics for Pharma industry is a combination of product returns of expiring or overstocked product, and recalls initiated by manufacturers themselves or by regulatory authority for product defects.¹⁶

Reverse logistics became complicated, with unpredictable lots of prescription and OTC products from countless retail and institutional pharmacies, chain stores, and hospitals sent back through various intermediary partners in the reverse supply chain. Third-party logistic providers (3PLs) can mitigate potential risks and liabilities by providing the data and records necessary to comply with regulatory agencies.¹⁷

Many pharmaceutical companies are making investments in security measures, data systems and business processes to improve efficiencies in managing recalls. These include, among other things, bar coding or RFID tracking on returns packages and increased use of online resources to manage recall data.¹⁸

Another major benefit of utilizing 3PLs is their ability to collect critical data points from products received. This allows pharmaceutical companies to better understand where their returns are coming from, the condition in which they arrive, and whether or not return instructions were followed. 3PLs have access to every piece of

information about a returned package, so they can help companies understand where they face the greatest risks, from ineffective return policies to over-reimbursement.¹⁹

While a large component of handling a drug recall is the physical processing and disposition of the product, even more important is tracking and information exchange of the recall data. Extensive government regulations and reporting requirements, along with an increased focus on pedigree, have increased the need for good tracking, visibility and control measurements which are all critical components for any reverse logistics process.

Recalls of controlled substances are among the most challenging of recalls to manage. As with any other aspect of handling controlled substances, there are major differences in the reporting and handling when compared with noncontrolled products. Both types of recalls, however, require notification, product retrieval and form completion.²⁰

There are specific regulations governing the return of a controlled substance, for recall or other reason. Schedule II drugs require a DEA Form 222 (electronic or paper) be sent from the receiving DEA registrant to the returning entity in advance of the controlled substances being shipped. The DEA encourages registrants to implement procedures that may reduce or eliminate the potential for diversion.²¹

In an effort to reduce non-value-added activities, redundant handling and associated costs in reverse logistics, many major 3PL service providers have developed so-called “one-step” or “one-touch” programs, by which they function as the single intermediary between manufacturer and downstream trading partners. In the traditional scenario, upstream manufacturer and the downstream trading partners would each engage their own 3PL partners to handle routine returns. Using the newer approach, a single intermediary handles the entire return from initiation to final product destruction, acting as a partner to the drug maker, pharmacies or other retail partners.

These one-step programs offer many benefits, a number of which are linked to fewer touch points, sustainability, cost improvements and collaboration. It helps to decrease redundancies in processing and minimizes opportunities for theft or diversion by reducing the number of times product is picked up and handled. Choosing a ‘one-touch’ provider gives the data quickly, allowing making confident business decisions rapidly. It also minimizes the processing cost for the manufacturer by “touching” the product only once.

Over the next five to 10 years, it is anticipated that most, drugs will be serialized to the individual bottle or package. By reporting back the serial number, a manufacturer has the ability to review the actual purchase order where the drug was originally procured. Implementation of 2D Datamatrix serialization and EPCIS (Electronic Product Code Information Service) product tracking and history,



will provide full visibility to chain of custody. Some reverse logistic providers offer technology tools that provide online access to returns status down to product code level, authorization tracking, easy discrepancy reconciliation, shipping information and proof of destructions.²²

Reverse logistics planning and execution is also improving through wider adoption of standard electronic communications. Technology advances for product tracking, data management and improved communications between industry trading partners is helping drive reverse logistics to the next level. A case in point is the use of electronic data interchange (EDI) standards—EDI 180 and EDI 812—which has reportedly expanded from forward to reverse logistics in recent years.

Healthcare Distribution Management Association (HDMA) and others have been supportive of efforts to develop standard practices for serializing pharma packages with barcodes or other unique identifiers; many studies of the subject point to substantial savings in managing returns, recalls, and credit reconciliation when individual products can be tracked up and down the supply chain.²³

Utilization of electronic methods allows for the reduction/elimination of human input error and also speeds up the reconciliation and crediting process. The ability to fully automate and standardize electronic communications related to returns can lead to improvements in time efficiency, accuracy, and flexibility. Communicating with standardized electronic communications, such as EDI 180 and 812, is expected to help streamline the reverse logistics process, and lower the cycle time from notification and authorization to shipment and credit reconciliation of a return.

CONCLUSION

Drug counterfeiting is an important problem addressed by several countries. This requires multiple measures to protect the supply chain. The implementation of anti-counterfeit technologies is an important strategy taken up by several drug manufacturers and regulatory authorities. The track and trace system and serialization are given importance and are widely used among all anti-counterfeit technologies in different countries. This is even more important when managing a product recall or withdrawals, where time and accuracy of reporting is most important. Recalls, returns, drug take-backs will be greatly facilitated by track & trace and serialization. In India tracking and tracing is implemented only for exported drugs. It is very essential to include provisions in Drugs & Cosmetics Act for incorporating security measures in packaging of pharmaceuticals.

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