

A person wearing a white lab coat and a blue and red striped tie is using a handheld scanner to scan a brown medicine bottle with a gold cap. The scanner is held in their right hand, and the bottle is held in their left hand. The background is slightly blurred, showing what appears to be a pharmacy or laboratory setting.

PHARMACEUTICAL SERIALIZATION TRACK & TRACE

EASY GUIDE TO COUNTRY-
WISE MANDATES

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Introduction

Pharmaceutical companies have to contend with challenges stemming from supply chain security lapses (resulting in theft, diversion and product recalls), counterfeiting and stringent regulations. In addition to alarming safety concerns, these challenges also impair the health of the industry by adversely impacting profits, brand credibility and research initiatives.

With both industry and governments around the world realizing the significance of implementing product serialization, it becomes mandatory for all entities within the supply chain to comply with federal and/or state legislations pertaining to the locations in which they operate.

Typically, drug distribution systems consist of entities such as manufacturers, wholesale distributors and pharmacies before products reach the end consumer. Ensuring secure product track and trace capabilities across various touch points throughout the supply chain - through product serialization implementation - is crucial to address the challenges faced by the industry. Apart from providing visibility and full traceability within the supply chain, successful serialization programs will prove to be a key differentiator and a clear competitive advantage for pharmaceutical companies.

This guide, compiled by the Legal and Research team at the Infosys Life Sciences Center of Excellence provides a summary of the legal and regulatory framework proposed by countries including Argentina, Brazil, China, EU, France, India, South Korea, Turkey, and USA (Federal and California) to maintain supply chain integrity and ensure patient safety. This guide also provides information on mandates to be adhered to by various stakeholders, to ensure regulatory compliance.

We look forward to further discussing this research with you.



US Federal

Drug Quality and Security Act - H.R. 3204

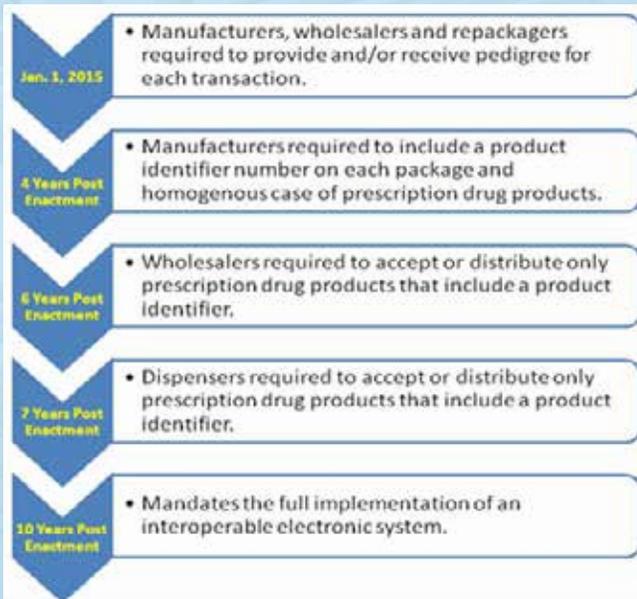
The Drug Quality and Security Act - H.R. 3204 was introduced on September 27, 2013. This bill was passed in the House on September 28, 2013 - also referred as Pharma track and trace bill - is approved by Senate as a US federal law effective Nov 27, 2013.

The Drug Quality and Security Act would address the following two important issues affecting the quality and security of America's drug supply:

1. Protect traditional pharmacies and clarify laws related to human drug compounding in response to the nationwide meningitis outbreak – one of the largest public health crises in recent times.
2. Strengthening of prescription drug supply chain in order to defend American families against counterfeit drugs and protect jobs.

The bill is supported by the National Community Pharmacists Association, U.S. Chamber of Commerce, UPS, PhRMA, GPhA, BIO, HDMA, HIDA, NACDS and many other organizations.

Below is the detailed mandate requirements and their respective timelines:



Title 1 - Compounding Quality Act

Title I of the Drug Quality and Security Act, which is based on Rep. Morgan Griffith's (R-VA) H.R. 3089 and the Energy and Commerce Committee's investigation of the meningitis outbreak (including four committee hearings), would clarify FDA's authority over the compounding of human drugs while requiring the agency to engage and coordinate with states to ensure the safety of compounded drugs.

This bill would enable the following:

1. Preserve and protect the practice of traditional pharmacy compounding occurring in community pharmacies.
2. Eliminate the unconstitutional provisions of Section 503A of the Federal Food, Drug, and Cosmetic Act (FFDCA) that created uncertainty regarding the laws governing compounding and require FDA to engage in two-way communication with state regulators – a major deficiency in FDA's response to the meningitis outbreak.
3. Permit entities engaged in the compounding of sterile drugs to register as "outsourcing facilities."

Title 2 - Drug Supply Chain Security Act

Title II of the Drug Quality and Security Act, which is based on Rep. Bob Latta's (R-OH) H.R. 1919, would create a uniform national standard for drug supply chain security to protect Americans against counterfeit drugs while eliminating needless government red tape. The bill also would help prevent increases in drug prices, avoid additional drug shortages and eliminate hundreds of millions of dollars' worth of duplicative government regulations on American drug manufacturers, wholesale distributors, pharmacies, repackagers and third-party logistic providers. The bill would:

This bill would enable the following:

1. Create a new framework for securing our prescription drug supply chain. The bill also would establish a 10-year transition to a unit level tracking system for enhanced security.
2. Eliminate the patchwork of red tape, like California's pedigree law, on drug manufacturers, wholesale distributors, pharmacies, repackagers, and third-party logistic providers (3PLs). These changes would help alleviate drug shortages and reduce government-imposed costs on prescription drugs.
3. Create floor and ceiling licensure standards for wholesale distributors and 3PLs while preserving state authority for licensure issuance and fee collection.



California

California's E-Pedigree Law Preempted

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. Included within this law are provisions that preempt California's e-pedigree requirements. These provisions are in addition to those in the California Business and Professions Code that also preempt California's provisions should federal legislation in this area be enacted.

The California Board of Pharmacy made it official late this afternoon, February 10th, 2014. As required by Section 4034.1 of the California Business and Professions Code (CB&PC), the Board posted a public notice late yesterday indicating that sections 4034, 4163, 4163.1, 4163.2, 4163.4, and 4163.5 of the CB&PC became inoperative due to the enactment of the Federal Drug Quality and Security Act (DQSA) on November 27, 2013 (see "It's Official, President Obama Signs H.R. 3204, DQSA, Into Law"). These specific sections of the CB&PC comprise what has been referred to in the industry as "the California Pedigree Law".

The public notice was mandated by California law within 90 days of federal preemption.

Compliance Mandate

- The pedigree shall be created and maintained in an interoperable electronic system, ensuring compatibility throughout all stages of distribution.
- A pedigree shall include all of the following information:
 - The source of the dangerous drug, including the name, the federal manufacturer's registration number or a state license number as determined by the board, and principal address of the source.
 - The trade or generic name of the drug, the quantity of the dangerous drug, its dosage form and strength, the date of the transaction, the sales invoice number, the container size, the number of containers, the expiration dates, and the lot numbers.
 - The business name, address, and the federal manufacturer's registration number or a state license number as determined by the board, of each owner of the dangerous drug, and the dangerous drug shipping information, including the name and address of each person certifying delivery or receipt of the dangerous drug.
 - A certification under penalty of perjury from a responsible party of the source of the dangerous drug that the information contained in the pedigree is true and accurate.
- A single pedigree shall include every change of ownership of a given dangerous drug from its initial manufacture through to its final transaction to a pharmacy or other person for furnishing, administering, or dispensing the drug, regardless of repackaging or assignment of another National Drug Code (NDC) Directory number.
- A pedigree shall track each dangerous drug at the smallest package or immediate container distributed by the manufacturer, received and distributed by the wholesaler, and received by the pharmacy or another person furnishing, administering, or dispensing the dangerous drug.
- Any return of a dangerous drug to a wholesaler or manufacturer shall be documented on the same pedigree as the transaction that resulted in the receipt of the drug by the party returning it.
- If a manufacturer, wholesaler, or pharmacy has reasonable cause to believe that a dangerous drug in, or having been in, its possession is counterfeit or the subject of a fraudulent transaction, the manufacturer, wholesaler, or pharmacy shall notify the board within 72 hours of obtaining that knowledge.



Argentina

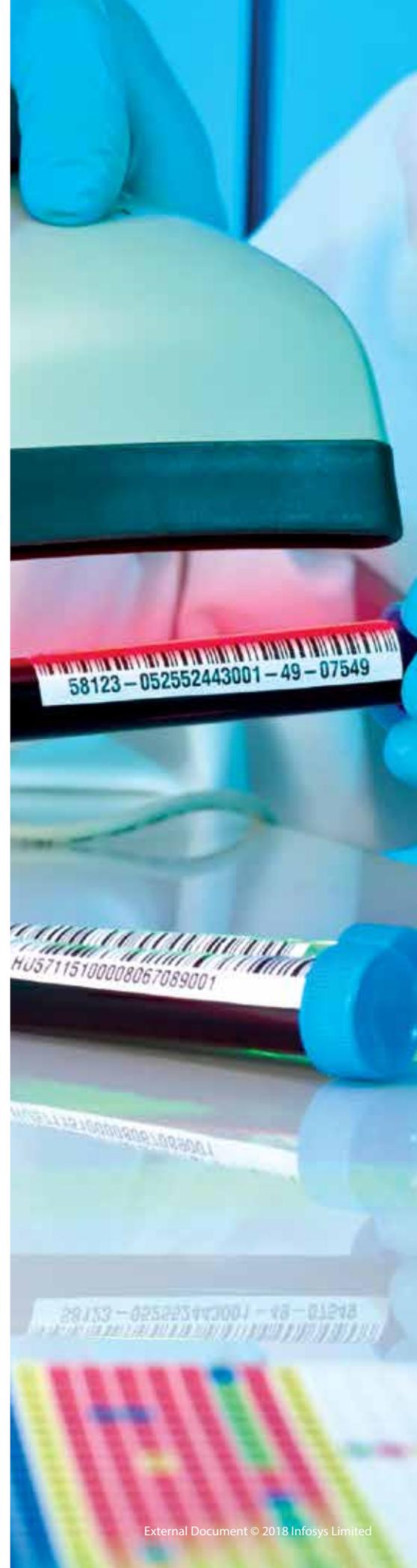
Summary of the Law

- The National Food, Drug and Technology Administration (ANMAT), through the Regulation 3683, has chosen GS1 Standards to distinctively identify drugs through the supply chain. Under the regulation, each unit has to be given a unique identifier that includes a batch number and expiration date, allowing the product to be monitored in the supply chain.
- A distinctive feature of the legislation is the inclusion of new categories of drugs over a period of time. On March 28, 2012, ANMAT added new drug classes to the traceability scheme, including antibiotics, insulin, clotting factors and a broad range of cardiovascular drugs and central nervous system treatments including antidepressants, antipsychotics and drugs for epilepsy and Parkinson's disease. Again, in 2013, the government added more than 200 additional drugs to the traceability system.
- The government plans to implement the serialization program on a phased approach with more drugs and agents being added to the system.
- The Argentine authority tasked with combating illegal narcotics, SEDRONAR, launched a national chemical precursors traceability system on 1 January 2013. The system will enable operators to digitally record precursor transactions nationwide via a computer network, while allowing regulators real-time monitoring of precursor movements, and the gathering and collection of such data for analysis.



Compliance Mandate

- Pharmaceutical companies must place a support or storing device with capacity to store a univocal code supervised and audited by ANMAT on the package of each of unit of a medicinal product for sale to the public. All information must be given in Spanish.
- Suppliers should place a code on their packaging complying with GS1 Standards.
- Each package-unit to be given a unique identifier that includes a batch number and expiration date, allowing the product to be monitored en route from the manufacturer to distributors, logistics operators, pharmacies, healthcare facilities, and patients.
- Each agent involved in the supply chain must record “logistic movements” of drugs and transmit that information, on a real-time basis, to a Database managed by ANMAT.



Brazil

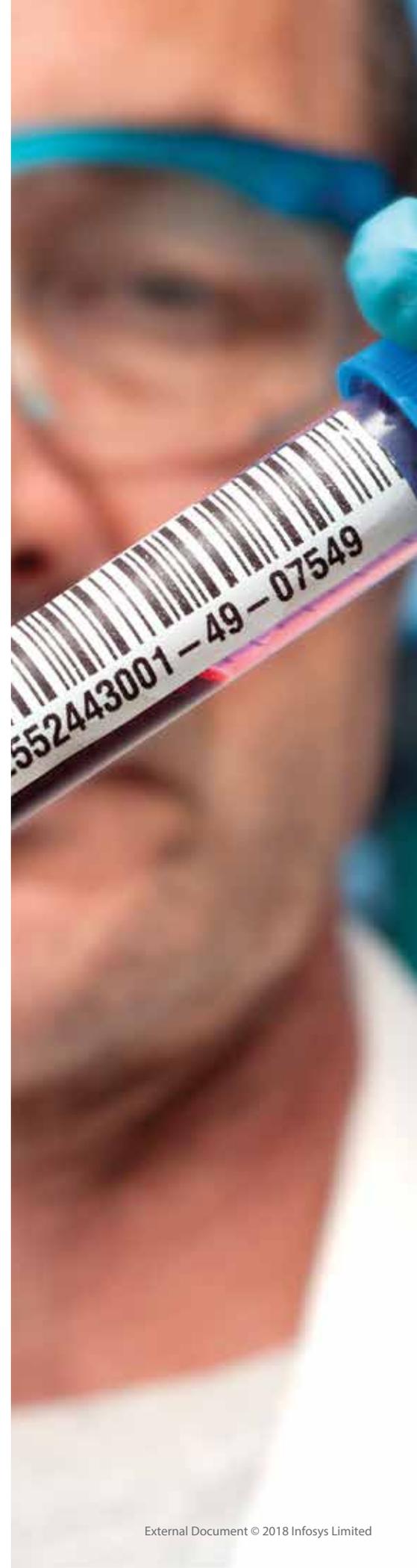
Summary of the law

- The Brazilian Federal Law 11.903 of 2009 and the subsequent regulations of the National Agency for Sanitary Surveillance in Brazil (ANVISA) mandate that a 2D data matrix code be put on all secondary packaging.
- The 2D data matrix should be with a human readable text including a Identificador Único de Medicamentos (IUM), Registration number, Batch and Validity.
- Each stakeholder in the supply chain is responsible for capturing, tracking, recording and transmitting of data to ANVISA.
- The National System of Drug Control proposal published in April 2013 by ANVISA mandate a 180-day implementation timeline for manufacturers and 1 year for the rest of the supply chain participants, to start upon publication of the final regulation.



Compliance Mandate

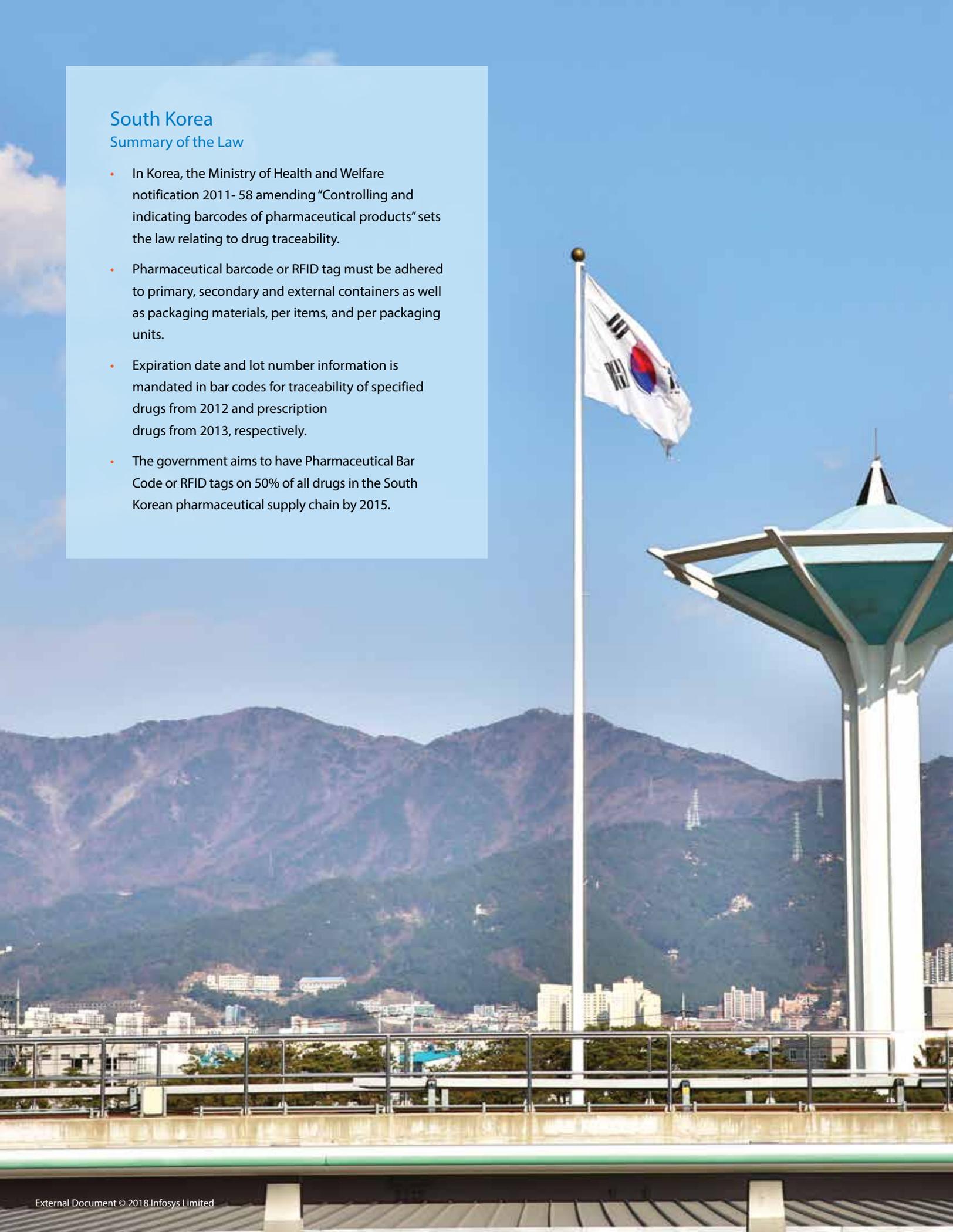
- The packaging of medicines must contain a traceable label. The packaging of medicines must be completely sealed with an un reusable security stamp, not recoverable after any attempt at tampering.
- Companies holding product registrations will be responsible for generating and placing a unique drug identifier (IUM) on secondary medicine packs, based on its 13-digit ANVISA registration number, plus a serial number, expiration date and lot number.
- Distributors are required to control their distribution chain and attach a stamp on the medicine packaging, evidencing the authenticity of the product.
- The secondary packaging should incorporate an identifiable feature for tracking and security. 2D data matrix code and associated text to be put on all secondary packaging.
- At identified points along the supply chain different stakeholders will be required to supply data to ANVISA.



South Korea

Summary of the Law

- In Korea, the Ministry of Health and Welfare notification 2011- 58 amending “Controlling and indicating barcodes of pharmaceutical products” sets the law relating to drug traceability.
- Pharmaceutical barcode or RFID tag must be adhered to primary, secondary and external containers as well as packaging materials, per items, and per packaging units.
- Expiration date and lot number information is mandated in bar codes for traceability of specified drugs from 2012 and prescription drugs from 2013, respectively.
- The government aims to have Pharmaceutical Bar Code or RFID tags on 50% of all drugs in the South Korean pharmaceutical supply chain by 2015.



Compliance Mandate

- Manufacturer must adhere or indicate barcode or RFID tag to distributed pharmaceuticals that are domestically manufactured or imported (excluding high pressure gas for medical use, drug substances manufactured just for other manufacturing process, herbal medicines, product for clinical trials). However, pharmaceutical barcode or RFID tag can be omitted for empty capsules.
- Pharmaceutical barcode or RFID tag must be adhered to primary, secondary and external containers as well as packaging materials, per items, and per packaging units.
- Pharmaceutical barcodes and RFID tags must be cared so not to be damaged or wiped out in distribution step.
- Types of barcode and component system:
 - In case of indicating barcode according to the article 4 paragraph 1, international standard barcode, GTIN-13 or GS1-128 code (one of the GS1 system) must be used.
 - Ethical drugs according to the article 2 paragraph 10 of the pharmaceutical affairs law (excluding radio pharmaceuticals, orphan drug, cell therapy product), or designated drugs according to its ordinance appendix 5, paragraph 2, B, international standard barcode, GS1-128 code must be used. However, in case that GS1-128 code is used to external containers and packaging materials, GTIN-13 can be used to primary containers and packaging.
- In case of indicating RFID tag according to the article 4 paragraph 1, SGTIN-96 or SGTIN-198 should be used (one of the GS1 system). However, in case that RFID tag is used, GTIN-13 can be used to one of primary or external containers or packaging materials.
- In case that Pharmaceutical RFID tag should be used, manufacturers should notify the minister of health and welfare the expiry date of shelf life, lot number that matches each serial number before sales.



India

Summary of the Law

- In India, the Directorate General of Foreign Trade (DGFT) made unique numbers and barcodes mandatory on tertiary, secondary and primary packaging for all pharmaceuticals exported from the country.
- The law also requires incorporation of 2D barcodes (GS1 data matrix) on medicines at the strip/bottle/vial level, as well as encoding GTIN and Unique Serial Numbers by July 1, 2014.
- As per earlier notification of the ministry, the exporters were to implement barcode on primary level packaging with effect from July 1, 2013. The deadline might be extended to 2015 in light of opposition from the industry.



Compliance Mandate

- Exporters of pharmaceutical products will adopt a trace and track system and incorporate its features for exported medicines using barcode technology as per GS 1 global standards as detailed below:
- Primary Level packaging requirement:
 - Incorporation of 2D (GS1 Data matrix) barcodes on medicines at strip/vial/bottle, etc. encoding unique product identification code (GTIN) and Unique Serial Number of the Primary pack.
- Secondary Level packaging requirement :
 - Incorporation of barcodes (1D or 2 D) encoding unique product identification code (GTIN), Batch Number, Expiry Date and Unique Serial Number of the Secondary pack.
- Tertiary Level packaging requirement:
 - Incorporation of barcodes (1 D) encoding unique product identification code (GTIN), Batch Number, Expiry Date and Unique Serial Number of the Tertiary pack (shipper/carton).
- Under the track and trace system, manufacturers would be required to maintain serialized record of exported pharmaceutical products for a minimum period of six months after the expiry date of the product.





China

Summary of the Law

- On April 9, 2008 China's State Food and Drug Administration (CFDA) made serialization mandatory on individual saleable pharmaceutical product units for 275 therapeutic classes by December 2011.
- From May 1, 2013, China's Ministry of Health has released the essential drug list (EDL) of products requiring serialization. This new list has expanded the EDL from 307 to 502 products.
- The China National Drug Code (NDC) plus serial number is required to be printed on primary and secondary packages up to the pallet with hierarchy information for the products listed on the EDL.
- China Drug Identification, Authentication and Tracking System, a division of China Product Identification, Authentication and Tracking System (PIATS), provides an online portal for drug manufacturers and other enterprises that involve drug supply chain activities to register their products and obtain serial numbers.
- Chinese law has extended serialization and compliance reporting to all pharmaceuticals by 2015.

Compliance Mandate

- The serial numbers need to be acquired from the CFDA; the same to be applied at the case and unit package level and the various commissioning and inventory movement transactions across the supply chain need to be reported.
- The serial number for the pharmaceutical drugs would be 20 numeric digits including manufacture code, serial number, check digits (6 digit codes that has one-to-one mapping with China's own NDC, 9 digit serial number and 4 checking/ encryption digits).
- 2012 National Essential Drug Lists (NEDL) drug products that are domestically packaged (i.e. w/in China) need to be serialized and reported upon to the China Food and Drug Administration (CFDA).
- 2012 NEDL drug products that are packaged outside of China and imported into the country will need to be serialized and reported upon to the CFDA.
- If the size of the minimum package is too small or the bottles are specially shaped and under other special circumstances where drug electronic supervision codes with unified logo cannot be printed/pasted the code may be printed on the larger package of the minimum one. If there are any such variances the manufacturers should apply to the provincial food and drug administration for its examination and approval. Thereafter they should be confirmed in the system applicable.
- There is an obligation to implement a quality control system with an electronic drug monitoring system, bar codes to ensure pharmaceutical traceability, use of standardized documentation and information technology, and ensuring that responsible persons are properly qualified.
- Drug makers importing drugs into China must designate a local pharmaceutical company, wholesaler, subsidiary or other office as their electronic monitoring agent in the country, according to the SFDA. Overseas drug makers must appoint a Chinese agent to handle all monitoring activities, including uploading product barcodes and facilitating drug recalls. Additionally, the local agent will be responsible for reporting vigilance findings to the SFDA. The requirements take effect Dec. 31 2013.
- All imported varieties of bid-winning essential drugs should be entered into the network and coded according to the requirements of documents of SFDA [2010] 194 and 237. For varieties that are sub-packaged in China the sub packaging manufacturers must print/ paste the drug electronic supervision code with a unified logo in the smallest sales package before March 31, 2011.
- If the imported varieties of bid-winning essential drugs that are packaged in the original producing areas belong to circumstances prescribed in the preceding paragraph, their offices or authorized agents in China shall apply to the provincial food and drug administration for its examination and approval. Thereafter they should be confirmed in the system applicable. If the imported varieties of bid-winning essential drugs that are packaged in the original producing areas belong to circumstances prescribed in the preceding paragraph, their offices or authorized agents in China shall

apply to the provincial food and drug administration for its examination and approval. Thereafter they should be confirmed in the system applicable.



EU

Summary of the Law

- The recently formulated Directive 2011/62/EU on falsified medicines foresees national enforcement of drug serialization activities by 2016 across the EU.
- Each member state must transpose the directive before January 2, 2013 by outlining laws, regulations and administrative provisions necessary to comply with the Directive.
- This Directive doesn't specifically address how serialization should practically look like and this is left up to each country. Nevertheless, European Commission published a Concept paper for public consultation proposing certain types of serialization including: linear barcodes, 2D barcodes, and radio-frequency identification (RFID).
- The barcodes will need to be printed or attached to every single pack of medicines subject to prescription and other medicines at risk of being falsified. The barcodes will be checked into a database repository system by the manufacturer and checked out when dispensed by a pharmacy.
- Once all parts of the directive come into force from 2016 onwards, manufacturers failing to comply with any aspect of the above will no longer be allowed to market their products in Europe.

Compliance Mandate

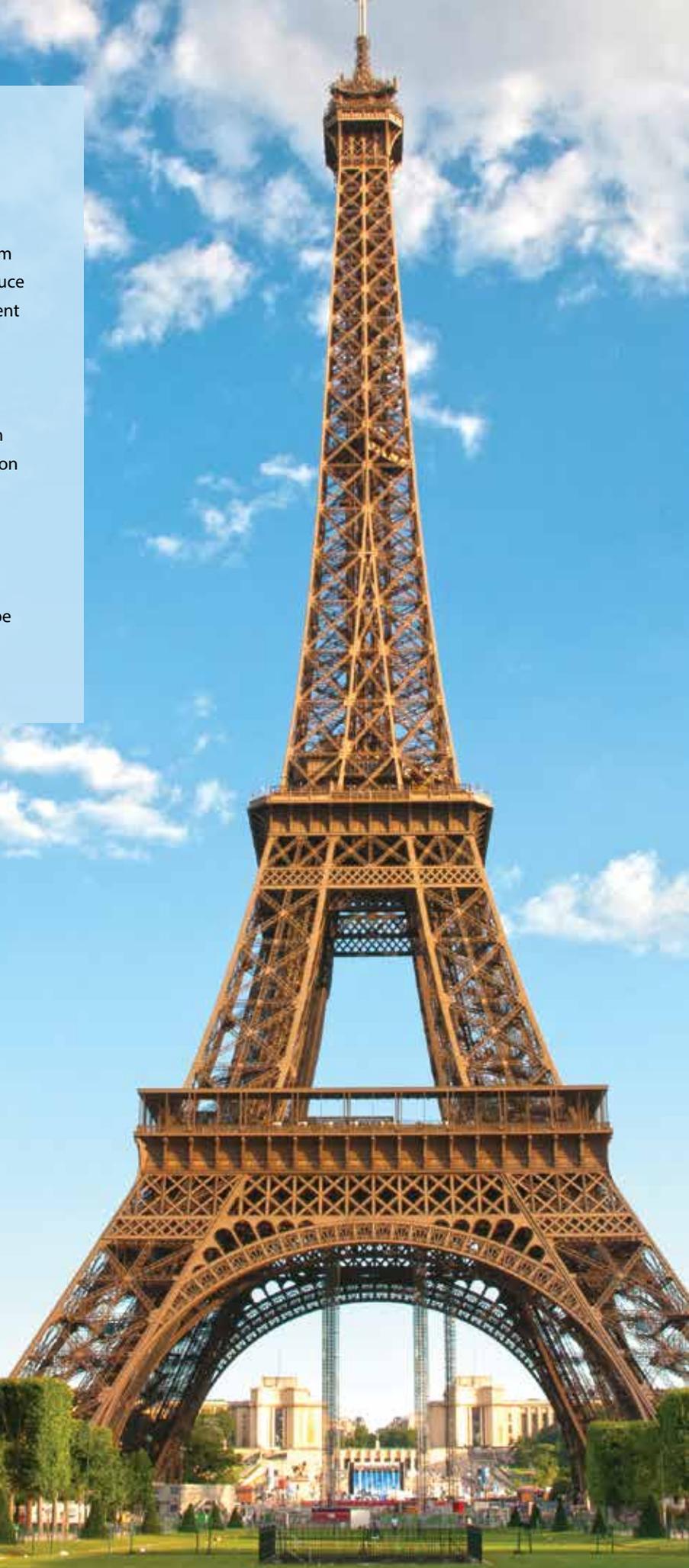
- Manufacturer to choose the appropriate technical solution for the serialisation number and its carrier.
- In order to allow identification of a pack of medicinal products, a serialisation number would have to contain, as a minimum, a manufacturer product code and the pack number.
- The serialisation number allows for inclusion of a range of other product related information such as (a) Batch number (b) expiry date (c) National reimbursement number.
- Various ways to carry the serialisation number on the outer packaging could be: (a) Linear barcode (b) 2D-Barcode (c) Radio-frequency identification (RFID).
- Manufacturers of active substances to comply with good manufacturing practice ('GMP') for active substances.



France

Summary of the Law

- France has also been in the forefront on the serialization activities. The objective of the program is to improve the efficiency of batch recalls, to reduce errors, to combat counterfeiting and reimbursement fraud and to increase the transparency of the distribution chain.
- The French CIP13 coding legislation requires all prescribed pharmaceutical products distributed in France to include a specified data matrix barcode on the outer packaging from January 1, 2011.
- The regulations framed by the French Agency of Sanitary Safety and Health Products (AFSSAPS) require that a 2D matrix barcode containing the new CIP 13 code, batch number, and expiry date be printed on each item of sale.



Compliance Mandate

- All prescribed pharmaceutical products distributed in France to include a specified data matrix barcode on the outer packaging.
- The requirement is to incorporate a fixed CIP13 number (effectively an SKU number or pseudo-GTIN) plus batch number and expiration date, into an ECC200 datamatrix code.
- Code is batch-specific not pack-specific, and only changes when the batch number or expiry date changes.
- Manufacturers, distributors, pharmacies and hospitals will be required to trace products by an electronic receipt notice.



Turkey

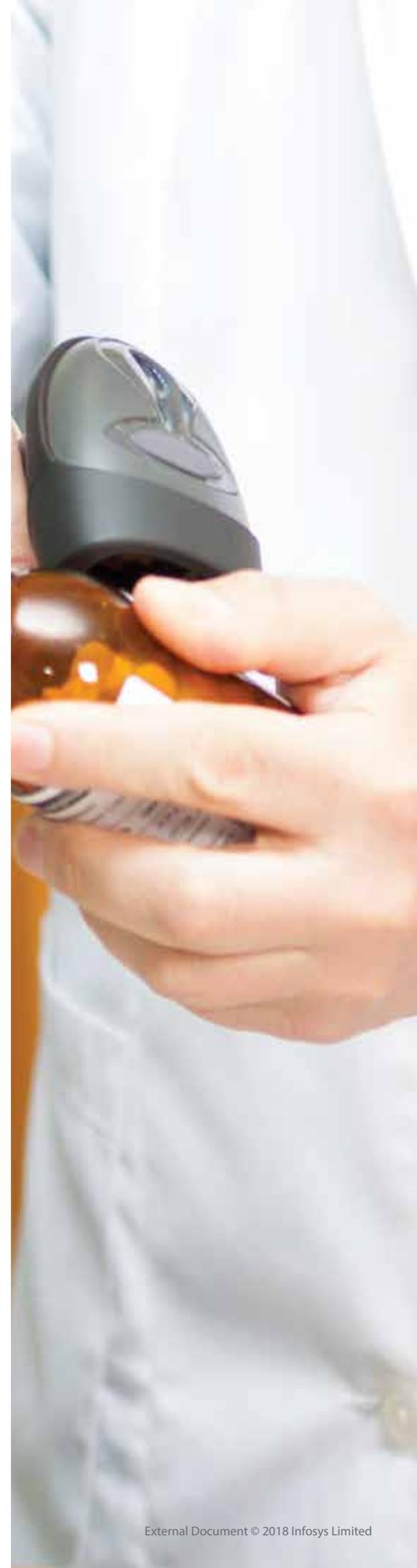
Summary of the Law

- Turkey's objective in launching the serialization program was to reduce instances of pharmaceutical reimbursement fraud. As of July 1, 2010, all pharmacists in Turkey's serialization scheme (ITS) were officially unable to gain reimbursement for medicines not carrying the 2D data matrix barcode.
- The Turkish Ministry of Health (MOH) requires serializing and tracking using 2D data matrix technology for all unit-level items that are reimbursed by MOH, including promotional samples, hospital packaged products, prescription drugs, and non-prescription drugs.
- Turkey's requirements have evolved in recent years to require that more data be recorded at more points along the supply chain.
- Another bright feature of the serialization framework in Turkey is the use of a centralized government database for managing all pharmaceutical serial numbers. All parties in the supply chain must report their receipt and sell data to the database or risk their product being restricted from distribution.



Compliance Mandate

- All the transactions of the drug units from their production to consumption are recorded by the system through notifications. After the transactions, stakeholders to transfer the final status and ownership information of the drug units to ITS.
 - The following identifiers will be used in the identification of Medicinal Products for Human Use: GTIN-Global Trade Item Number, Serial Number, Expiration Date, Batch/Lot Number and Group separator (FNC1).
 - The GTIN (Barcode Number) in EAN-13 Barcode Symbology might be printed on the product package as the primary identifier.
 - Data Matrix: All identifying information indicated in Article 4 of the Guidance on implementation of Identification and barcoding of medicinal products or human use will be included as secondary identifier in Data Matrix symbology on the package of the Medicinal Product for Human Use.
 - The data matrix, as a Datamatrix barcode in ECC200 standards, may be printed in either the square or the rectangle form, as indicated in the mentioned standard. This printing form shall be determined by then manufacturer/importer.
- Composition of Barcodes:
The company owning the product shall be responsible for the smooth reading by the automatic data collectors (barcode readers) for the composition of the barcodes to be placed on Medical Products for Human Use. When designating the quality principles of the barcodes and data matrices to be composed, the following standards shall be taken as basis in relation with barcode verification:
 - For Linear Barcodes (EAN-13, GS1-128): TS EN ISO/IEC 15416 Information Technology – Automatic identification and data capture techniques – Barcode printing quality trial property; Linear symbols.
 - For Dimensional Barcodes (Data Matrices): TS EN ISO 15415 Information technology – Automatic identification and data capture techniques – Barcode printing quality trial property specification – Two-dimensional symbols.



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- Notification-The Notifying of Products to ITS which have Newly Obtained a License-Notification Feb 27, 2012
- Notification-About the PTS Notifications of Manufacturer Companies and Pharmaceutical Wholesalers-Feb 28, 2012
- Notification- To the Attention of all the Companies which have the Authority to Export Pharmaceuticals and/or Companies which make Distributions for Pharmaceutical Exportation Purposes-December 30, 2011
- 05.01.2012 | About the Sharing of Error Codes
- Notification-About Phase 2 Processes of Pharmaceutical Wholesalers-December 23, 2011
- ITS News and Notifications
- Track and Trace Working Principles
- ITS News-Sep 17, 2012
- ITS Announcement-December 22, 2011

The various updates on the tracking requirements are being reflected in the ITS website under the following links:

- ITS Announcements
- ITS News
- ITS on Press
- ITS Events

EU

- Directive 2011/62/EU on falsified medicines
- Concept paper submitted for public consultation

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For more information, contact askus@infosys.com



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