Saudi Food and Drug Authority: Experience to Ensure Drug Supply Chain Integrity

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outlines

- Drug Sector Core Functions
- Track and Trace system
- Drug Supply Chain
- Implementation process
- The use of barcode in Drug Sector electronic system
The SFDA was established in 2004. The Authority objective is to ensure safety of food and drug for man and animal, and safety of biological and chemical substance as well as electronic products. A Board of Directors chaired by HRH the Crown Prince.
Drug Sector Vision

To be the leading regional Drug Regulatory Authority for pharmaceuticals and cosmetic products, with professional excellence and services that contribute to the protection and advancement of public health in the Kingdom of Saudi Arabia
SFDA Mission

Protecting public health by ensuring safety, quality, efficacy and accessibility of human and veterinary drugs and biological products, and safety of cosmetics, through administration of a national regulatory system which is consistent with international best practice. Through our mission, we also provide accurate and scientific-based information to the public and healthcare professionals.
Saudi Pharmaceutical Market

- The market is expected to reach 4 billion $ USD 2014 with CAGR of 5.7%.
- Local manufacturers supply between 17-20%.
- 70% of the imports is from Europe, USA (13.1%), Middle East & North Africa (12.3%) – others 4.6%.
SFDA Core Functions

- Products Evaluation and Licensing.
- Licensing Pharmaceutical Establishments
- Pharmacovigilance & Products Quality Monitoring.
- Inspection, Surveillance & Enforcement
- Clinical Trials Approval
- Cosmetic Products Monitoring
- Communication & Awareness
What is Track and Trace system

- It is a system that will be used to track and trace all units belonging to each pharmaceutical product marketing in Saudi Arabia.
Track and Trace system benefits

- Prevent the sale of counterfeit drugs
- Prevent the sale of smuggled drugs
- Prevent illegal sale of drugs
- Prevent barcode scams
- Support rational use of medicines, supply data to control market
Each pharmaceutical unit will be tracked
Supply Chain-1 Manufacturers

- GMP
- Batch number and Expiration date
- Bar-coding
- Tamper Proof.
- Serialization.
Supply Chain-2
Ports

- Priority release
- Shipment inspection
- Temperature Logger reading.
- Product Art work inspection.
- Shipment recording in IPRICS
Clearance System

- **Import and Batch Release Clearance System (IBRCS)**: this system is used at the ports to issue clearance for imported products.
- Pharmaceutical companies used IBRCS to issue Imported permit to import drugs to Saudi Arabia.
- They can use IBRCS to inform SFDA about new shipment so SFDA can be prepared and their shipment will not be late at the port.
Clearance System

- When the drug shipment arrived to Saudi ports the pharmaceutical companies used IBRCS to issue clearance permit.
- IBRCS will use GTIN to identify and track products entering the Saudi Arabia market.
Supply Chain 3
Wholesalers

- Good Storage and Distribution Practices.
- Track and Trace
- Sales restricted to Licensed institutions
- Recall effectiveness.
- Quarantine and Destruction of Expired products.
Supply Chain-4
Pharmacies

- Good storage and inventory control
- Drug Bar-coding
- Track and trace
- Ensure product authenticity.
- Obsolescence reduction: Excellent management of nearly expired product
Implementation process

- A circular has been sent to pharmaceutical companies explain how to get GTIN and where to print Data matrix on their products.

- The Data matrix will be implemented in two phases. Phase one will contain GTIN, Exp. data, Batch number 3/2015

  Phase two, the Serialization number (SN) will be added. 3/2016
Cont....

- **General guidelines** has been published on SFDA web site.

- This document explain the purpose of the project, the impact of this project on manufactures and hospitals, the data matrix barcode information and how it should be printed on the product.
What Industry has to do?

For Barcodes:
1. Contact the GS1 Saudi Arabia office for more information about acquiring GTIN, GLN, and Data Matrix barcodes.
2. Prepare your production lines for printing and verifying the new barcodes.
3. Plan to be logistically ready for drug serialization.
FDA Sign an agreement with Saudi Coding Center to Apply GS1 Standards.
The use of barcode in Drug Sector electronic system

- **Saudi Drug Registration (SDR)**: is a system used to manage the process of drug registration. This system deals with e-CTD files.

- After a drug registered, the company contacts GS1 to issue GTIN which will be stored in Drug Sector central database.
Data-Bases

- National Drug & Poison Information Center (NDPIC)
- LIMS
- Saudi Vigilance
- Drug Establishments National Registry (DENR)
- Importing, Batch-Release and Clearance System (IBRCS)
- Saudi Drug Registration System (SDR)
- تقيس
- الدخال
- الدواء
- السعودية
- الهيئة العامة للغذاء والدواء (SFDA)
THANK YOU