

# 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

# SFDA

- **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.

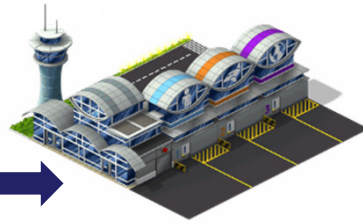


# Track and Trace system benefits

- 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



Manufacturer



Ports



Wholesale



Hospitals

**Each pharmaceutical unit  
will be tracked**



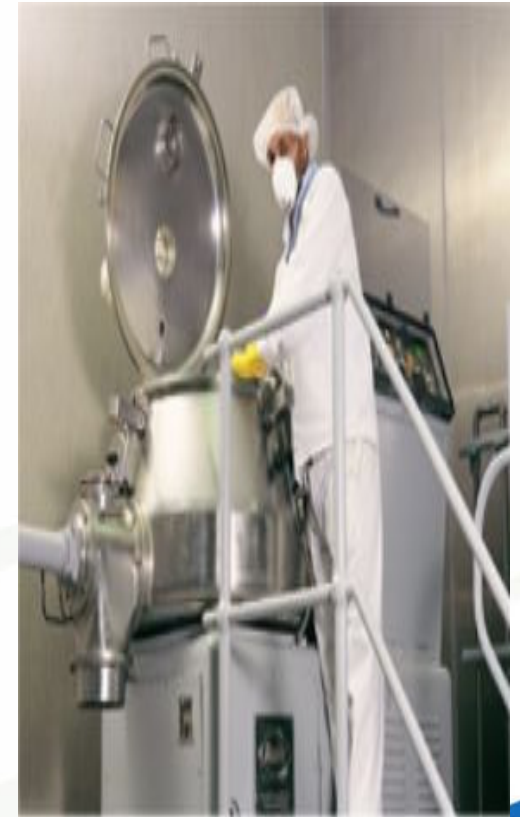
Pharmacies



Patient

# 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

**IBRCS**  
Importing, Batch-Release and Clearance System

**Main**

- الرئيسية
- About IBRCS
- FAQs
- Guidance to IBRCS
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**IMPORTING, BATCH-RELEASE & CLEARANCE SYSTEM**

**Importing, Batch-Release & Clearance System (IBRCS)**

**Importing, Batch-Release & Clearance System (IBRCS)**  
Importing, Batch-Release & Clearance System (IBRCS) is an electronic system that issues importing and clearance permissions of pharmaceutical shipments at points of entry. Moreover, IBRCS is used to notify the SFDA about any batch released to the market by the local manufacturers.

**Security and Confidentiality of Data**  
All data submitted online will be protected and encrypted via the IBRCS security infrastructure.

Kingdom of Saudi Arabia  
Saudi Food & Drug Authority

SFDA Intranet

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# 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 enter 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



GTIN: 6280000000000  
EXPIRY: YYMMDD  
BATCH/LOT: ABCD1234  
SN: 12015484

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.

المملكة العربية السعودية  
الهيئة العامة للغذاء والدواء

الدواء

رواية الهيئة > الأخبار > هيئة الغذاء والدواء ومركز الترميم بمجلس الغرف بوقعا مذكرة تفاهم لتنظيم تداول الأدوية تجاريا

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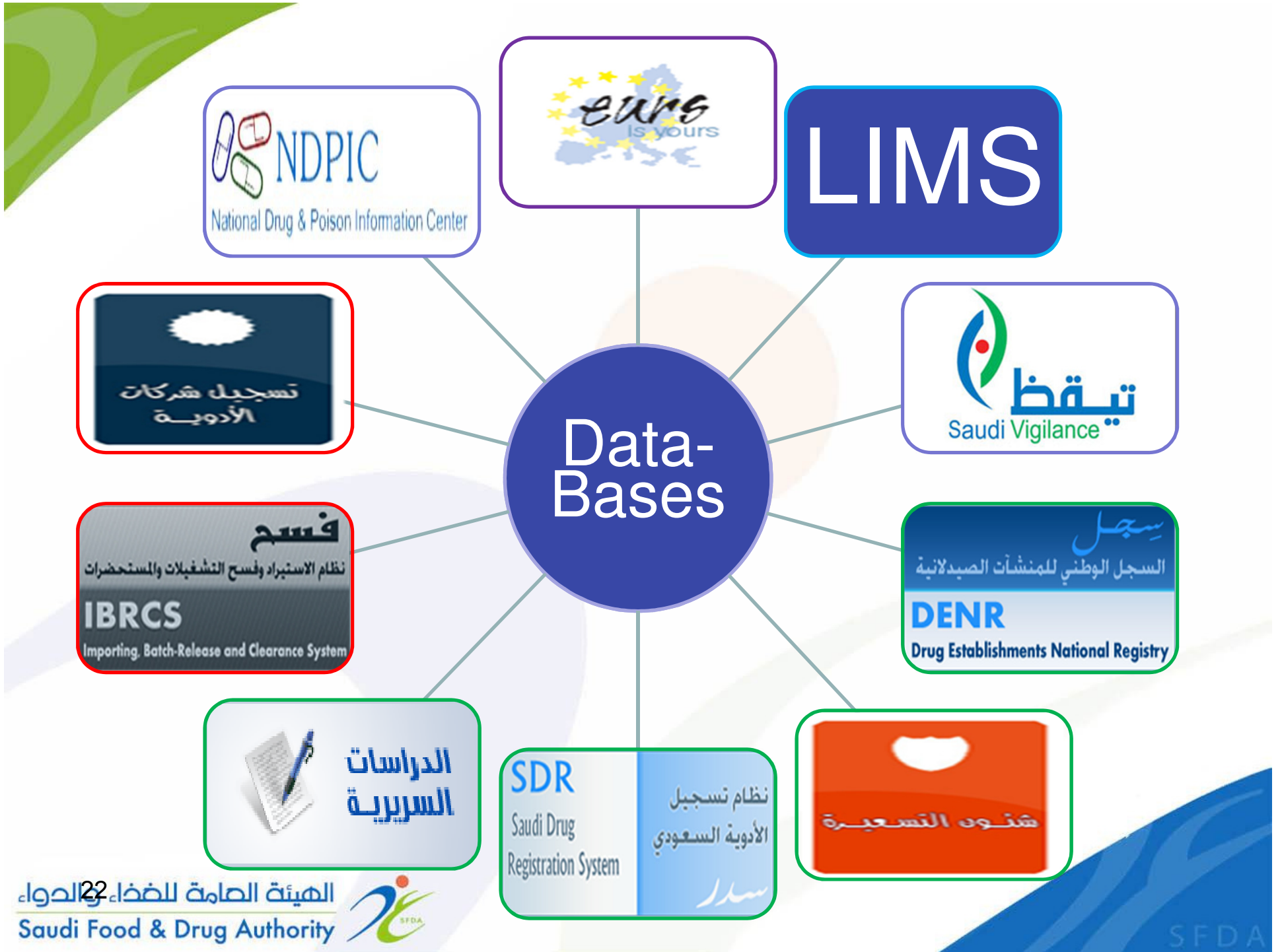
21/11/2013



وقعت الهيئة العامة للغذاء والدواء ومجلس الغرف السعودية ممثلا في قطاع الدواء أمس بالهيئة ومركز الترميم السعودي التابع لمجلس الغرف السعودية مذكرة تفاهم للتعاون بين الطرفين من أجل تنظيم الأدوية وتداولها تجاريا داخل المملكة، وذلك من خلال دعم تطبيق نظام GS1 الدولي للترميز (الباركود) على الأدوية المصنعة محليا والمستوردة من الخارج وذلك تحت رعاية معالي الرئيس التنفيذي للهيئة العامة للغذاء والدواء د. محمد بن عبد الرحمن المشعل، و وقع الاتفاقية عن الهيئة العامة للغذاء والدواء الدكتور صالح بن عبد الله باوزير نائب الرئيس التنفيذي لقطاع الدواء بالهيئة، فيما وقعها عن مجلس الغرف السعودية المهندس خالد بن محمد العتيبي الأمين العام للمجلس .

# 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 deal with e-CTD files.
- After a drug registered, the company contact GS1 to issue GTIN which will be stored in Drug Sector central database.





# www.SFDA.gov.sa

Saudi Food and Drug Authority - Windows Internet Explorer provided by SFDA

http://www.sfda.gov.sa/En/Drug

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ELECTRONIC SERVICES OF DRUG SECTOR

Drug News

**Combining insulin with metformin or an insulin secretagogue in non-obese patients with type 2 diabetes**  
Objectives To study the effect of insulin treatment in combination with metformin or an insulin secretagogue, repaglinide, on glycaemic regulation in non-obese patients with type 2 diabetes..more

**Sodium Bicarbonate Treatment Regimens for the Prevention of Contrast-Induced Nephropathy**  
Background: Intravenous sodium bicarbonate has been proposed to reduce the risk for contrast-induced nephropathy (CIN). Purpose: To determine the effect of sodium bicarbonate on the risk for CIN..more

**Using rituximab and incidence of progressive multifocal leukoencephalopathy PMI**

Drug and Poison Information Center

National Pharmacovigilance Center

Circulars

Poll

Have you been affected with allergy caused by food?

Yes  
 No

Poll Results

Previous Polls

Specialists and Consultants Registration

Quick Links

Workshop: "Pricing of Pharmaceutical Products"

A nighttime aerial photograph of a city, featuring a prominent skyscraper illuminated in blue. The city lights are visible in the background, and the skyscraper's top is lit with a blue glow. The text "THANK YOU" is overlaid in large, bold, blue letters across the center of the image.

**THANK YOU**