The Global Language of Business

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GS1 DataMatrix instructions on secondary packaging in Jordan

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المؤسسة العامة للغذاء والدواء

مـديــريــة الـــــــدواء

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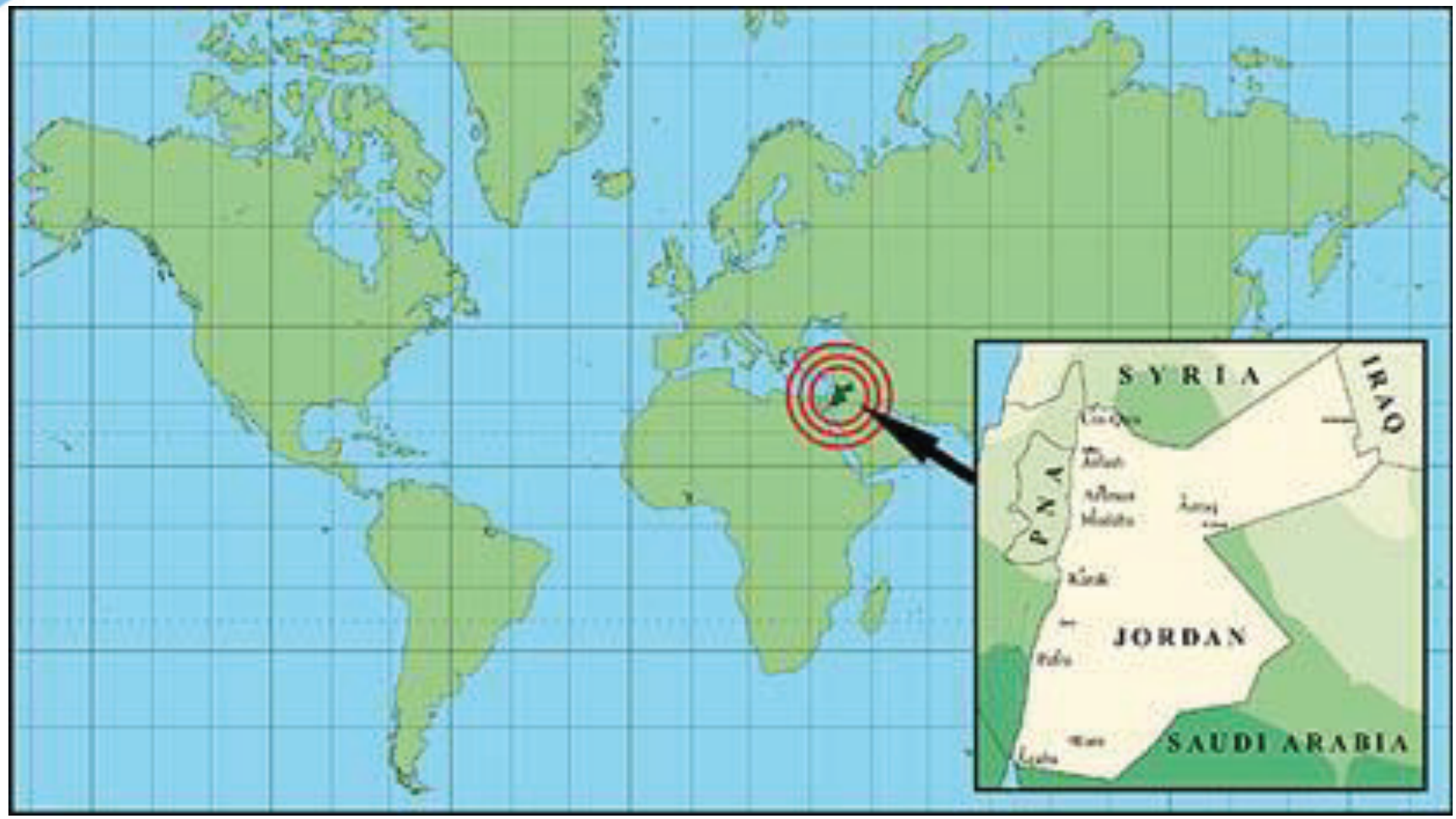
بسم الله الرحمن الرحيم

Jordan Food and Drug Administration

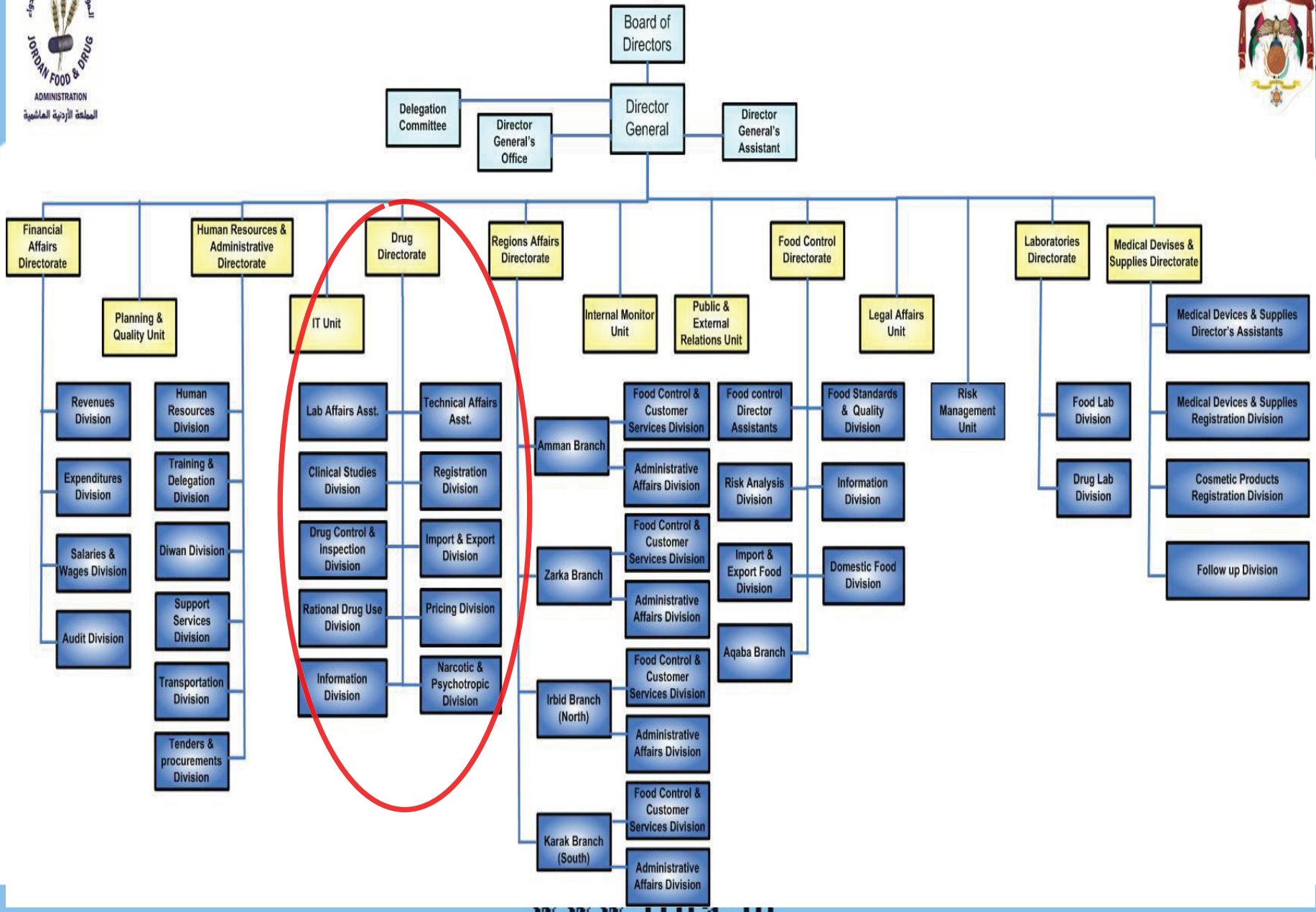
GS1 DataMatrix Instructions on Secondary Packaging

المؤسسة العامة للغذاء والدواء
JORDAN FOOD & DRUG ADMINISTRATION
المملكة الأردنية الهاشمية




JFDA was established in April, 2003
According to the Provisional law #31 for year 2003 .

Organizational Structure
Jordan Food & Drug Administration



Drug Directorate's Departments

- Registration.
- Inspection.
- Import & export.
- Pricing.
- Rational Drug use.
- Information.
- Narcotics.
- Clinical studies.

Products Regulated by Drug Directorate

- Medicinal Products/Drugs:

Ordinary =Chemical (Originators/NCEs, Generics)

Biological Products (Originators/Reference, Biosimilars)

Herbal medicines/ medicines containing vitamins

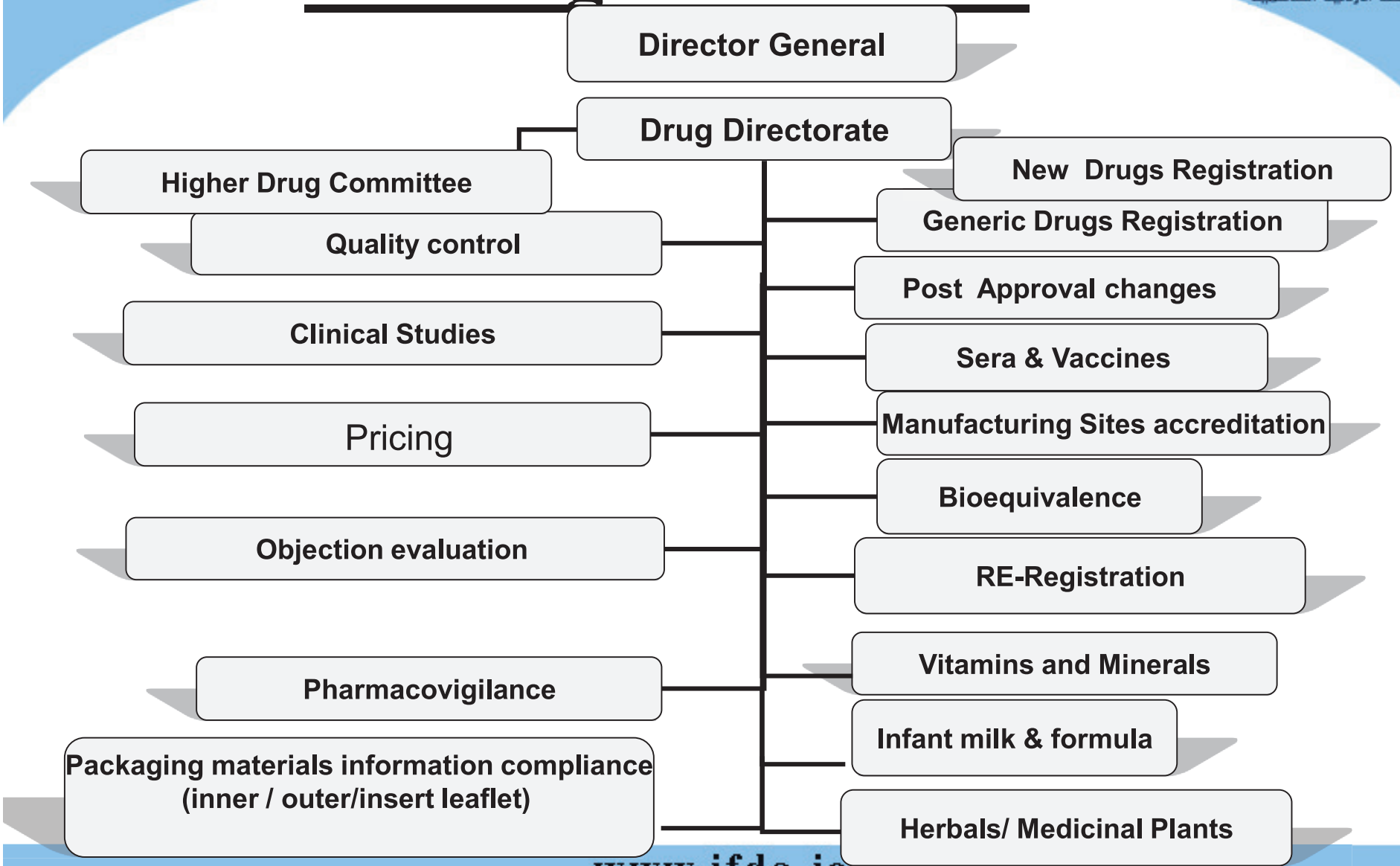
- Herbal & Natural Products.
- Products Containing Vitamins & Minerals.
- Infant milk & special formulas.
- Radiopharmaceuticals & Radioactive Materials.
- Any product used to treat, cure or protect human.
- Medical Devices & Disinfectants.*

* transferred to Medical equipment & supplies directorate Cosmetics.*

Scope of activities

- Marketing Authorizations /product registration.
- Laboratory analysis of samples
- Post-marketing surveillance
- Monitoring and inspections
- Clinical trials monitoring
- Price regulation
- Raising public awareness

Working Committees



Legal Basis:

- Public Health **Law**.
- Drug & Pharmacy **Law** / + it's amendment /2003)
- JFDA Law 2008
- Clinical Studies **Law**.
- Drug testing **By Law**/2006.

- Drugs registration & re-registration **criteria** /2004, & amendments.

- Manufacturing sites accreditation **criteria** /2013.
-API **criteria** /2007
- Pharmacovigilance **criteria**/2010
- Bioequivalence **criteria**/2010.
- Post approval Changes/2010.
- Guidelines for Stability requirements, Alternative Manufacturing sites
& transfer of MAH.
- Biosimilars criteria 2015.
- Guidelines for other products (herbals, vitamins, medical devices, infant milk &

GS1 DataMatrix Instructions on Secondary Packaging

Article 50 from drug and pharmacy law

(It is not permissible for any warehouse to sell any medication or products without barcode , and printed or labeled by pricing patches which approved by the (Pharmacists association) and with the specified price by JFDA, according to the instructions issued by the general Director in coordination with the JPA.

JFDA and Drug Barcoding

- As we are the responsible authority for the healthcare field who have to make the drug supply chain in Jordan safer, more efficient and accurate we believed that a standardized system from the manufacture to the patient is a must, therefore and since the GS1 system is one of the most widely used identification system we argue all the manufactures in Jordan and the exporting one to adopt the GS1 supply standers .

JFDA adopted the following instructions for the purpose of improving Jordan healthcare supply chain efficiency, inventory management , combat counterfeiting as well as cost savings by means of capture technology, electronic storage and transmission of data.

All stakeholders need to work to commonly agreed standards if the benefits are to be realized fully.

This will also help Jordan Healthcare sector to develop their investment strategy to be complied with global healthcare new developments and to build the infrastructure that is adequate with new modern technologies this will lead to improve Patient safety and reduce costs.

MOH & JFDA are working to build their Databases in order to enable drug verification and control stock management as well as to control and manage prices of pharmaceutical products.

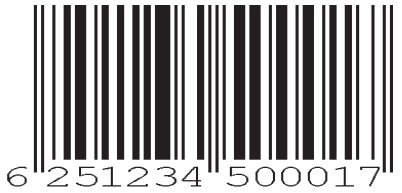
procedure

- Circulation on JFDA Website about the "**Guidelines of Identification and Bar coding of Medicinal Products for human Use.**"

- So we use GTIN -13 in a linear barcode.

GTIN -13:

Data structure and format of GTIN-13



GS1 Company Prefix							>	< Item Reference					Check Digit
N1	N2	N3	N4	N5	N6	N7		N8	N9	N10	N11	N12	N13

Information workshop was held in collaboration with GS1 Jordan draft instructions coded medications and barcode application on medicines, in which pharmaceutical association were invited and the Association of pharmaceutical importers and domestic pharmaceutical producers association to introduce the importance of application.

Announcement of the adoption of the 2D bar-code (GS1 DataMatrix) to be implemented on all pharmaceutical Products in 2017, as JFDA wants to share with the pharmaceutical companies and drug agents the time plan regarding developing the drug bar code and the required information inside it.

- A migration period is allowed Starting from 01/06/2017 till 30/6/2018. During this period of time it will be allowed to print a 1D/Linear barcode and/or a GS1 Data Matrix on medicinal products on the Secondary Package, however after this period only the GS1 Data Matrix will be allowed.

Steps

Our first step of the implementation of GS1 DataMatrix was specifying several requirements in a published circulation at our website after the discussion with the stakeholders in order to develop building of an infrastructure with new modern technologies leading to improve Patient safety and reduce costs.

Requirements

The following are the new requirements that must be applied by Pharmaceutical companies on the Secondary Packaging of all Medicinal products :

1.Identification of Products

a) **GTIN-(Global Trade Item Number):** This is a number composed of at most 14 digits used to uniquely identify products on a global scale.

b) Batch/Lot Number: This is a number used to differentiate one batch/lot from others during production. The Batch/Lot Number is of variable length and may contain up to 20 alphanumeric characters.

Requirements

c) Expiration Date: It refers to the final date on which the product may be used, it is the date that determines the limit of consumption or use of a product. It is numeric data composed of 6 characters. The format of the data shall be **YYMMDD**. YY will indicate the Year information in two digits, MM shall indicate the Month information in two digits whereas DD will indicate the day information in two digits.

Requirements

d) Serial Number (SN): This is a number used in identifying each unit of a product when combined with a GTIN, a serial number uniquely identifies an individual item. The serial number is of variable length and may contain up to 20 alphanumeric characters.

JFDA Requirements

2. Bar Coding of Products

All of the Medicinal Products for Human Use' marking must be upgraded from linear barcodes (Figure A) to GS1 DataMatrix Barcode (Figure B) on the secondary package.

(Figure A) Linear Barcodes

(Figure B) GS1 DataMatrix

Implementation Timeline

The implementation of GS1 DataMatrix will be on two main stages as follows:

1- Starting from 01/07/2018: GS1 DataMatrix symbology shall be printed on all of the medicinal products on the Secondary Package, the required information are as follows:

a) The Application Identifier **AI (01)** with **GTIN**.
b) The Application identifier **AI (17)** and **6-digit Expiry date**.
c) The Application identifier **AI (10)** and the **Batch Number**

Implementation Timeline

2- Starting from year 2020, each medicinal pack coding must include a **unique serial number** encoded within the GS1 DataMatrix and it must be printed with the other data as indicated in (1).

Using the Application Identifier **AI (21)** and **Serial**

The guidelines of implementation will be published in the near future.

It is recommended to print the ***Human Readable Interpretation (HRI)*** of the encoded data that is in the 2D bar code in a clear and readable way. Format rules are found in the GS1 General Specifications.

It is sufficient to print the item identification number ***(GTIN)*** number only by the 2D bar-code if the ***Expiry date, Batch/Lot*** Number are found elsewhere on the package.

Comments from Manufacturers

- Having 2 barcodes on a pack can be confusing to those who are scanning. Further, 2 barcodes on the same panel and in close proximity can lead to scanning errors and challenges.

- Does the meaning of "all drugs" extend to samples, name patient, government tenders

- Human readable expiry date format is a challenge for many manufactures. Date format can vary between packaging sites of a manufacture as well as between packaging lines. Standardizing on a single date format can be a challenge requiring some packaging line printers to be reconfigured.

Comments from Manufacturers

- It is requested that JFDA provide flexibility to the human readable date format such as (but not limited to)
  - YYYY MM ex/ 2015 01
  - MM YYYY ex / 01 2015
  - YYYY MM DD ex/ 2015 01 31
  - YY MMM DD ex 15 JAN 31
  - YYYY MMM ex/ 2015 JAN

For products that are imported under the exporting countries labeling (e.g. US or EU) the date format has already been established and implemented. Changing the date format specific to the Jordanian market is a challenge

Comments from Manufacturers

- Can “DD” in the date format be set to “00” in the event a specific day is not included in the expiry date format?

- GS1 Gen spec specifies that the order in which the data elements are to be presented should be determined by the manufacture but always beginning with the GTIN. Clarification as to the order of the data elements which allows manufacture discretion is requested.

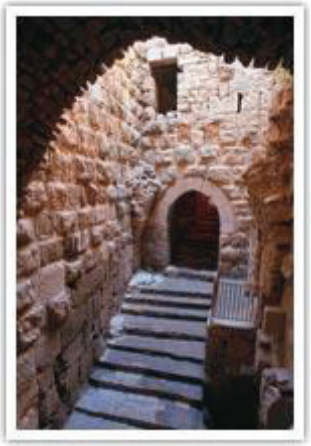
- Printing of the abbreviation and the application identifier is redundant and takes of valuable space. The requirement should be for either an abbreviation OR the application identifier and not both. The decision for which to use should be left to the manufacturer.

Conclusion

- JFDA is working with GS1 Jordan to increase awareness by organizing workshops for HC Stakeholders to urge to comply with these instructions.

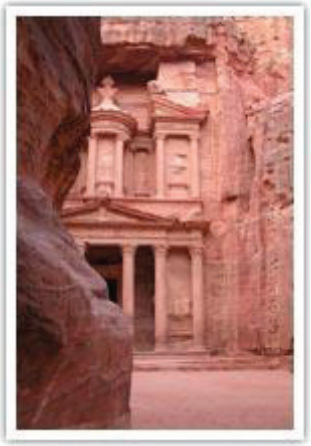
- JFDA will provide all support and reply on any queries they have on the implementation of GS1 DataMatrix.

- JFDA will benefit from other countries experience and implementation in the field of traceability.



Ajloun Castle.

The Mosaic at St. Georges Church in Madaba



The Treasury at Petra

The Temple of Artemis at Jerash

The Roman Theatre in Amman.

Thank You

The Fort at Aqaba

Qusair Amra.

Shobak Castle

Ruins at Umm Qays

Karak Castle.