GS1 DataMatrix Instructions
Jordan Food & Drug Administration
(JFDA)

GS1 Jordan
31 January 2016

GS1
Jordan

The Global Language of Business

JFDA New Bar Code Requirements for Pharmaceutical Products on Secondary Packaging

Introduction

Further to the circulation on JFDA Website Date:26/4/2013 about the Guidelines of Identification and Bar coding of Medicinal Products for Human Use.

JFDA has previously announced the adoption of the 2D bar-code (GS1 DataMatrix) to be implemented on all pharmaceutical Products in 2017, 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.

Objectives

 JFDA aims to improve 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. The GS1 System of Standards is the most widely used trade item identification system worldwide

This will help the Jordan Healthcare sector to develop their investment strategy in concert with new global healthcare developments building 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 :

I. **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.

   For more details on the Structure of GTIN, please refer to the document of "Identification and Bar coding of Medicinal Products for Human Use" .

Requirements

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.

The GS1 Application Identifier identifying the Batch/Lot Number is "10".

Application Identifier (AI)	Batch/Lot Number
1 0	X1---------- variable length ---------------X20

For example on Batch/Lot Number, please refer to the document of Identification and Bar coding of Medicinal Products for Human Use .

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.

The GS1 Application Identifier identifying the expiry date is "17".

Application Identifier (AI)	Expiry Date		
	Year	Month	Day
17	N1 N2	N3 N4	N5 N6

For example on Expiry Date, please refer to the document of Identification and Bar coding of Medicinal Products for Human Use .

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.

The GS1 Application Identifier identifying the serial number is "21".

Application Identifier (AI)	Serial Number
21	X1 ------variable length --------X20

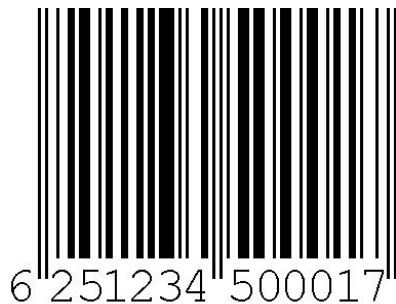**The guidelines of SN implementation will be published by JFDA in the near future to clarify the requirements.**

Requirements

II. 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.

GTIN: (01)06251234500017

6 251234 500017

(Figure A) Linear Barcodes

(Figure B) GS1 DataMatrix

Implementation Timeline

A migration period for The implementation of GS1 Data Matrix as follows:

- **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.

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 as in example (1) are:

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** (up to 20 characters).

Example 1 :

GTIN: (01) 06251234560011
Expiry: (17)010115
Batch/Lot: (10) ABC234

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 stage (1).

The guidelines of implementation will be published in the near future. Serial Number should be printed as it is shown in example (2):

d) The Application Identifier **AI(21)** and **Serial** (up to 20 characters).

Example 2 :

GTIN: (01)06251234500024
Expiry: (17)010115
Batch/Lot: (10) abc2345
Serial No.: (21)ABC205001

Note: Specific rules for use of "separators" to terminate variable length AI's such as AI(10) can be found in the GS1 General Specifications.

Printed Information

- 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.

- *For more details on HRI, please refer to the GS1 General Specifications for rules and recommendations in regard to Human Readable Interpretation.*

Recommendations

1) Jordan Food & Drug Association advise all pharmaceutical companies and their agents to comply with the due dates for the implementation of the bar-coding new specifications. For more information and guidance about this subject you can refer to the guidelines of "*Identification and Barcoding of Medicinal Products for Human Use*" published on JFDA website: **www.jfda.gov.jo**

2) Contact the GS1 Jordan (Jordan Numbering Association) for more information about acquiring GTIN and implementation of GS1 DataMatrix barcode.

3) Prepare your production lines for printing and verifying the new barcodes.

4) Plan to be logistically ready for drug serialization.

Recommendations

5) Stakeholders who must scan should invest in <u>Camera-based Bar Code Scanners</u> when introducing bar code scanners or when replacing existing laser bar code scanners. Please refer to GS1 HC position paper on website: www.gs1jo.org.jo

6) Stakeholder databases need to be constructed in such a way that they accept 14-digit Global Trade Item Numbers (GTINs). Please Refer to GS1 HC position paper on website: www.gs1jo.org.jo

7) Updates to IT infrastructure systems: to ensure that dynamic, variable attribute data (lot/batch, expiry, serial number, etc.) is available for encoding in a "real time" packaging environment as well as ensuring that the underlying systems can support the additional data where this is not already implemented.

8) *GS1 General Specification* is available on GS1 Jordan's website: www.gs1jo.org.jo

Contact Information

JFDA

T 00962 6 5632000

F 00962 6 4602557

E info@jfda.jo

www.jfda.jo

GS1 Jordan

T 00962 6 5620038
F 00962 6 5620035
E info@gs1jo.org.jo

www.gs1jo.org.jo