TO BE PUBLISHED IN PART-III OF THE GAZETTE OF PAKISTAN

Government of Pakistan
Ministry of National Health Services, Regulations and Coordination,
Drug Regulatory Authority of Pakistan
****

Islamabad, the 02nd May , 2017

NOTIFICATION

S.R.O. 307 (I)/2017.- The following draft of certain further amendments in the Drugs (Labelling and Packing) Rules, 1986, which are proposed to be made in exercise of the powers conferred by section 23 of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012), read with clause (a) and clause (t) of section 7 thereof and section 43 of the Drugs Act, 1976 (XXXI of 1976), is hereby published, as required by sub-section (3) thereof, for the information of all persons likely to be affected thereby and notice is hereby given that the draft will be taken into consideration after fifteen days of its publication in the official Gazette.

Any objection or suggestion which may be received from any person in respect of the said draft, before the expiry of the said period, will be considered by the Drug Regulatory Authority of Pakistan.

DRAFT AMENDMENTS

In the aforesaid Rules,-

(a) in rule 2, after clause (d), the word "and" shall be omitted and after clause (e), the following new clauses shall be added, namely:-

"(f)"Ministry" means Ministry of National Health Services, Regulations and Coordination;

(g)"DRAP" means Drug Regulatory Authority of Pakistan;

(h)"Symbology" means a defined method of representing numeric or alphabetic characters or alpha numeric characters in a Barcode: a type of Barcode, (e.g. GS1 Data-Matrix, GS1-128, etc.);

(i) “Barcode” means a symbol that encodes data into a machine readable pattern of adjacent, varying width, parallel, rectangular dark bars and pale spaces and barcoding shall be construed accordingly;

(j) “Symbol” means a combination of symbol characters and features required by a particular Symbology, including Quiet Zone, Star and Stop characters, data characters, and other auxiliary patterns, which together form a complete scannable entity; an instance of Symbology and a data structure;

(k) “GS1” means an international organization dedicated to design and implementation of global standards and solutions and is represented in Pakistan by GS1 Pakistan;

(l) “GS1 Company Prefix” means part of the GS1 System Identification number consisting of a GS1 Prefix and a company number, both of which are allocated by GS1 Member Organizations, including GSI Pakistan;

(m) “GTIN” Global Trade Item Number means a uniquely identifying trade items key comprising of 14 characters that includes GS1, Company Prefix and Item Reference and Check Digit;

(n)“Trade Item” means any item, product or service upon which there is a need to retrieve pre-defined information and that may be priced or ordered or invoiced at any point in the supply chain. This identification key may be combined with other information encoded within data carriers such as GS1 Data-Matrix to uniquely identify a healthcare product along with a serial number, lot or batch number, expiry date, product shipment information, etc. and can be used for pharmaceutical products and medical devices;

(o)“GS1 Data-Matrix” means a data matrix, one dimensional or two dimensional Barcode, which may be printed as a square or rectangular symbol made up of individual dots or square modules arranged within a perimeter finder pattern. GS1 Data-Matrix symbols are read by two dimensional imaging scanners or vision systems;

(p)“Legible Information” means descriptive content information written under or near the identifier for the purpose of demonstrating the content relating to the Barcode or data matrix to the users;

(q)“Healthcare Primary Packaging” means the first level of packaging for the product marked with an Automatic Identification and Data Capture (AIDC) data carrier either on the packaging or on a label affixed to the packaging. For non-sterile packaging, the first level of packaging can be the packaging in direct contact with the product. For sterile packaging, the first level of packaging can be any combination of the sterile packaging system and may consist of a single item or group of items for a single therapy such as a kit. For packaging configurations that include a retail consumer trade item. Primary Packaging is a packaging level below the retail consumer trade item;

(r)“Secondary Packaging” means the packaging containing one or more primary packs;

(s)“Tertiary Packaging” means a shipper containing one or more secondary packs;

(t) Serial Shipping Container Code (SSC) means a unique identifying logistic unit. A logistic unit is an item of any composition established for transport and or storage that needs to be managed through the supply chain. In the supply chain to easily identify logistic shipping units consisting of multiple products enabling quick and easy identification, tracking of deliveries and receipt of goods. This identification key is used with a data carrier for automatic identification and data capture and in electronic commerce;

(u)“GLN” Global Location Number means a number to identify physical location or legal entities. The key comprises a GS1 Company Prefix, Location Reference and Check Digit;

(v)"Serial Number" means randomized alphanumeric numbers that may range from twelve to twenty characters. It may be a completely randomized number or partly randomized and partly showing numbers in series;

(w) "Serialization" means the process of printing Serial Number on the label or package;

(b) After rule 3, the following new rule 3A shall be inserted, namely:-

"3A. Application of Barcode label requirements for product track and trace system.- (1) Notwithstanding anything contained in rule 3, a machine readable Barcode as per the GS1 general specification shall be printed on the label of all drugs manufactured for domestic market or export or imported, at different packaging levels to facilitate identification, tracking and tracing of these products in the following manner, namely:-

(a) a GS1 Data-Matrix of a 2D barcode type encoding a unique and global product identification code in the format of a GTIN on the primary packaging;

(b) a GS1 Data-Matrix of a 2D barcode type encoding a unique and global product identification code in the format of a GTIN on the secondary packaging; and

(c) a one dimensional 1D barcode encoding a unique global product identification code in the format of GTIN, along with batch number, manufacturing date and expiry date, etc. i.e. SSC on the tertiary packaging.

(2) Where the imported drugs, at the time of import, do not conform to the provision of sub-rule (1), the person importing the drug shall make an arrangement at a local facility licensed to manufacture drugs or sell drugs in terms of clause (i) of rule 3 of the Drugs (Import and Export) Rules, 1976, with the prior approval of the Registration Board to print the GS1 application, before the drug is placed in to the Pakistani market.

(3) The GS1 2D Data-Matrix Barcode must carry the data information as prescribed

in Form A appended to these rules.

(4) Serialization, using random numbers, for complete trace and track system, in the GS1 Data-Matrix as in Form A on the Primary Packing and Secondary Packing:

Provided that it shall be optional and not mandatory until two years after the commencement of these rules.

(5) Barcode labeling on the Primary Packing and SSC on Tertiary Packing shall not be mandatory until two years after the commencement of these rules.

Provided that where the primary packing is not further packed in any secondary package and the drug is offered for sale in a primary packing directly, Barcode labeling on the primary packing shall be mandatory.

(6) For complete track and trace of each product and shipment, the serial-number shall also be captured into GS1 Data-Matrix on all primary packing, secondary packing and tertiary packing; in addition to information required in Form A, after three years of commencement of these rules.

(7) Barcode shall be printed in a legible manner and shall be surrounded by sufficient blank space, quiet zone, so that the Barcode can be scanned correctly; and remain intact under normal conditions of use.

(8) The machine or camera or human readable barcode must appear on the drug's label in conformance with rules under the Drugs (Labelling and Packing) Rules, 1986 and shall be in addition to and not equivalent to a manufacturing batch or lot number or replacement for any of its requirements already prescribed in rule 3.

(9) This rule shall,-

(a) be applicable to the allopathic drugs including biologicals, for human and veterinary use only and shall not apply to alternate medicines, health and OTC non-drug products, nutraceuticals, medical devices, medical gases or radiopharmaceuticals till further orders; and

(b) come into force for the batches manufactured after six months of the publication of this notification in the official gazette.

(10) Any regulation or provision inconsistent with the terms of this rule is repealed and shall be modified accordingly.

(11) All the manufacturers or importers shall submit the 2D Barcode (GTIN) information for each product along with the company information as prescribed in Form A appended to these rules, initially manually or electronically via email from official id and later online directly to the online DRAP database.

(12) The Registration Board for the purpose of giving effect to this rule may allow relaxation of any of the condition in rule 3 or in this rule to resolve any practical difficulty for a particular product or class of products:

Provided that safe administration of drug is not compromised.

Form A [see rule 3A]

A. Mandatory Product Information to be embedded in the 2D Data-Matrix				
Sr #	**Parameter**	**Application Identifier**	**Explanation**	**Example**
1	Global Trade Identification Number (GTIN) (14 characters)	AI (01)	Follow the GS1 Healthcare GTIN Allocation rules. This is allocated by GS1 Pakistan	(01)89657674002017
2	Expiry Date	AI (17)	Format will be YYMMDD	(17)201230
3	Batch or Lot Number	AI (10)	Alphanumeric upto 20 element string long	(10)ABCD1234
4	Product Identification Information	AI (240)	Alpha Numeric upto 30 element string. Product name with strength, dosage form, pack size and price must be embedded in 2D Data-Matrix in said format without space e.g, abcd250cap30sRs100, abcdinj1sRs75, abcd250syp60Rs37	(240)abcd250syp60Rs37
5	Serial Number or Serialization or both	AI (21)	Alpha Numeric upto 20 element string - This is for items to be individually tracked, Currently this is not mandatory requirement by DRAP	(21)00101

B. Mandatory Product Information to be maintained at Company Database and communicated to DRAP for DRAP Database				
Sr #	**Parameter**	**Application Identifier**	**Explanation**	**Example**
1	GTIN	AI (01)	Follow the GS1 Healthcare GTIN Allocation rules. This is allocated by GS1 Pakistan	(01)8965767400201 7
2	Expiry Date	AI (17)	Format will be YYMMDD	(17)201230
3	Batch Number or Lot Number	AI (10)	Alphanumeric upto 20 element string long	(10)ABCD1234
4	Product Identification Information	AI (240)	Alpha Numeric upto 30 element string. Product name with strength, dosage form, pack size and price must be embedded in 2D Data-Matrix in said format without space e.g, abcd250cap30sRs100, abcdinj1sRs75, abcd250syp60Rs37	(240)abcd250syp60 mlRs37
5	Registration number	N/A	National Healthcare Registration Number provided by DRAP	
6	Complete description of pack size	AI (37)	Number of Trade Item contained in a logistic unit	PVDA-Alu,blister of10'sx3
7	Price	AI (8005)	Price per unit of measure	(8005)75
8	Complete description of Strength	N/A	Description of Complete strength of the product	500 mg
9	Complete description of Dosage from	N/A	Description of Complete dosage form of the product	Tablets

C. Mandatory Company Information to be maintained at Company Database and communicated to DRAP				
Sr #	**Parameter**	**Application Identifier**	**Explanation**	**Example**
1	Name of Company	N/A	This information is part of the GTIN allocation	ABC Pharma
2	Manufacturing or import License of the company	N/A	License Number provided by DRAP	1111
3	Address of its manufacturing site(s) of the licensed premises	N/A	This information is part of the GTIN Allocation	9-C, ABC, Karachi
4	Global Location Number	N/A	All Pharma companies must acquire a GLN from GS1 in order to uniquely identify every physical location. It will be gradually	8961234567890

			introduced into DRAP system/database	
5	Address of the registered office of the company if different from the manufacturing site.	N/A	Only one address is listed in the GS1 registration which shall be preferably business address of Manufacturer or importer	7-C, ABC, Karachi

[F. No.1-2/2015-CEO-DRAP (pt)].

(Dr. Ghazanfer Ali Khan)
Deputy Director (Legal Affairs)
Drug Regulatory Authority of Pakistan.

The Manager,
Printing Corporation of Pakistan,
Islamabad.