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

NOTIFICATION

Islamabad, the 27th June, 2025.

No. F.13-1/2025-LA.– The following draft of further amendment in the Drugs (Labelling and Packing) Rules, 1986, which is proposed to be made by the Drug Regulatory Authority of Pakistan, with the approval of the Federal Government, 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) of section 7 thereof and section 43 of the Drugs Act, 1976 (XXXI of 1976), is hereby published for the information of all persons likely to be affected thereby and, as required by sub-section (3) of section 43 of the said Act (XXXI of 1976), notice is hereby given that objections or suggestions thereon, if any, may, for consideration of the Authority, be sent within seven days of the publication of this Notification.

Any objections or suggestions which may be received from any person in respect of the said draft before expiry of the aforesaid period shall be taken into consideration by the Authority.

DRAFT AMENDMENTS

In the aforesaid Rules,

(1) in rule 2,—

(A) clauses (h) to (w) shall be omitted;

(B) the existing rule shall be re-numbered as sub-rule (1) and thereafter the following new sub-rule (2) shall be inserted, namely:

"(2) The words and expressions used but not defined herein shall have the same meanings as assigned to them in the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012) and the Drugs Act, 1976 (XXXI of 1976).";

(2) in rule 3A,—

(A) sub-rule (1) shall be substituted with the following, namely:-

"(1) Notwithstanding anything contained in rule 3, a machine readable Barcode shall be printed on the label of all drugs manufactured or imported for domestic market or for export purpose, at different packaging level to identify, tracking and tracing, to eliminate spurious and counterfeit products, in the manner specified in Schedule-II."

(B) sub-rule (2) to (9) and (11) shall be omitted;

(C) sub-rule (10) shall be re-numbered as sub-rule (2);

(D) sub-rule (12) shall be re-numbered as sub-rule (3) and in the said sub-rule, after the words "or in this rule", the words "or Schedule-II" shall be inserted;

(E) after sub-rule (3), the following new sub-rule (4) shall be inserted, namely:-

"(4) The Authority may issue guidelines for effective implementation of Barcode label requirements."

(3) after rule 14, the following new rule 15 shall be inserted, namely:-

"**15. Power to amend Schedules and Forms.—** (1) The Authority may, with the approval of the Policy Board, amend Schedules so as to omit any entry therefrom, add any entry thereto or amend any entry therein.

(2) The Authority may, on the recommendation of the Registration Board, amend Forms so as to omit any entry therefrom, add any entry thereto or amend any entry therein."

(4) the existing Schedule shall be re-numbered as "Schedule-1" and thereafter the following new "Schedule-II" shall be added, namely:-

"SCHEDULE-II

[See rule 3A]

(1) for the purposes of this Schedule, unless there is anything repugnant in the subject or context,—

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

(b) "GS1" means an international organization dedicated to design and implementation of global standards and solutions;

(c) "GS1 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;

(d) "GS1 Data-Matrix" means a data matrix, two dimensional Barcode, which may be printed as a square 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 system;

(e) "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;

(f) "Healthcare Primary Packaging" means the first level 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;

(g) "1D (one dimensional) barcode" means a symbol that encodes data into a machine readable pattern of adjacent, varying width, parallel, rectangular dark bars and pale spaces or light bars with dark spaces;

(h) "Legible Information Human Readable Interpretation" 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 user characters, such as letters and numbers, which can be read by the persons and are encoded in GS1 data carriers confined to GS1 standard structure and format. The human readable interpretation is a one-to-one illustration of the encoded data;

(i) "Logistic unit" means an item of any composition established for transport and storage that needs to be managed through the supply chain;

(j) "Secondary Packaging" means a packaging containing one or more primary packs;

(k) "Serial Number" means randomized alphanumeric numbers that may range from twelve to twenty characters;

(l) "Serial Shipping Container Code" or "SSCC" means a unique number to identify a logistic unit used with a data carrier for automatic identification and data capture in electronic commerce;

(m) "Serialization" means the process of printing serial numbers on the label or package;

(n) "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;

(o) "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.);

(p) "Tertiary Packaging" means a packaging containing one or more secondary packs; and

(q) "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.

(2) a machine readable Barcode as per the GS1 general specification shall be printed on the label of all drugs manufactured or imported for domestic market or for export purpose, at different packaging level 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 in addition to batch or lot, expiry date and serial number on the secondary packaging;

(b) for homogenous products, a GS1-128 linear barcode of 1D barcode type encoding a unique global product identification code in the format of GTIN, expiry date, batch or lot, SSCC on the tertiary packaging; and

(c) for heterogonous products, a GS1-128 linear barcode of 1D barcode type encoding SSCC on the tertiary packaging.

Provided that the Authority, with the approval of Policy Board, may adopt any new standard for track and trace system, in addition to GS1 standard, if such standard is globally recognized.

(3) Where the imported drugs, at the time of import, do not conform to paragraph (2), 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 Drug (Import and Export) Rules, 1976, with the prior approval of the Registration Board to print the GS1 data matrix, before the drug is placed in to the market.

(4) The GS1 Data-Matrix, 2D barcode must carry the data information as prescribed in Form-A appended to this Schedule.

(5) Serialization, using random numbers, in the GS1 Data-Matrix as in Form-A on the Secondary Packaging.

(6) SSCC on Tertiary Pack logistic unit shall not be mandatory until six years after the commencement of these rules:

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

Provided further that in case of imported drug, the Data-Matrix barcoding will be printed on secondary package only or on primary package where primary package is directly sold and not packed in the secondary package.

(7) For complete track and trace of each product and shipment, the serial number shall also be captured in to GS1 Data Matrix on all the Secondary packing and Tertiary packing; in addition to information required in Form-A.

(8) 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.

(9) The machine readable barcode must appear on the drug's label in conformance with these rules 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.

(10) This Schedule shall be applicable to the allopathic drugs including biological, 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 radio-pharmaceuticals till further order.

(11) All the manufacturers or importers shall submit the information for each product along with the company information as prescribed in Form A appended to these rules, to the DRAP database."

(5) "Form-A" shall be substituted with the following, namely:-

"Form-A

A. Mandatory Product Information to be embedded in the 2D Data-Matrix

Sr.	**Parameter**	**Application Identifier**	**Explanation**	**Example**
(1)	(2)	(3)	(4)	(5)
1	Global Trade Identification Number (GTIN) (14 characters)	AI (01)	Follow the GSI Healthcare GTIN Allocation rules. This is allocated by GSI	(01)8965767400 2017
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	Serial Number	AI (21)	Alpha Numeric upto 20 element string – This is for items to be individually tracked (as and when applicable)	(21)AB 1238C92D56

B. Mandatory Product Information to be maintained at Company database and Communicated to DRAP Database

Sr.	Parameter	Application Identifier	Explanation	Example
(1)	(2)	(3)	(4)	(5)
1	Global Trade Identification Number (GTIN) (14 characters)	AI (01)	Follow the GSI Healthcare GTIN Allocation rules. This is allocated by GSI	(01)8965767400 2017
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	Serial Number	AI (21)	Alpha Numeric upto 20 element string – This is for items to be individually tracked (as and when applicable)	(21)AB 1238C92D56
5	Registration Number	N/A	National Healthcare Registration Number provided by DRAP	
6	Complete description of pack size	AI (37)	Description of Trade Item contained in a logistic unit	PVDA-Alu,blisterof10's x3
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	500mg
9	Complete description of Dosage form	N/A	Description of Complete dosage form of the product	Tablets

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