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

Islamabad, the 9<sup>th</sup> June, 2026.

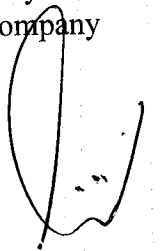
**S.R.O. 963(I)/2026.** – In exercise of the power conferred by section 23 of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012) read with clauses (a) and (t) of section 7 thereof and section 43 of the Drugs Act, 1976 (XXXI of 1976), the Drug Regulatory Authority of Pakistan, with the approval of the Federal Government, is pleased to direct that the following further amendments shall be made in the Drugs (Labeling and Packing) Rules, 1986, which, as required by sub-section (3) of the said section 43, were previously published *vide* Notification No. F.13-1/2025-LA, dated the 27th June, 2025, namely:-

In the aforesaid Rules,

(1) for rule 2, the following shall be substituted, namely:-

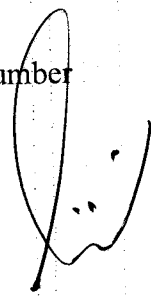
**“2. Definitions.**– (1) In these rules, unless there is anything repugnant in the subject or context,–

- (a) **“1D (one dimensional) barcode”** means a symbol that encodes data into a machine-readable pattern of adjacent, varying-width, parallel rectangular dark bars and light spaces;
- (b) **“Global Trade Item Number (GTIN)”** means a unique key for identifying trade items, comprising fourteen (14) characters that include the GS1 Company Prefix, Item Reference and Check Digit;
- (c) **“GS1”** means an international organization dedicated to the design and implementation of global standards and solutions;
- (d) **“GS1 Data-Matrix”** means a two-dimensional barcode that 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 systems;
- (e) **“GS1 Company Prefix”** means the 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;

- (f) **“human-readable information”** means descriptive content written under or near the identifier to demonstrate the information encoded in the barcode or Data-Matrix to the user. It consists of characters, such as letters and numbers, that can be read by persons and are encoded in GS1 data carriers, following the GS1 standard structure and format. The human-readable information illustrates the encoded data; at a minimum, the data identifiers specified in Schedule-II must be encoded;
- (g) **“international non-proprietary name”** means the name of a drug as recommended by the World Health Organization or such other name as may be notified by the Authority in the official Gazette;
- (h) **“logistic unit”** means an item of any composition, established for transport and storage, that needs to be managed through the supply chain;
- (i) **“pharmacopoeial name”** means the name of a drug as mentioned in the pharmacopoeia;
- (j) **“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 itself or on a label affixed to the packaging. For non-sterile products, the first level of packaging may be the packaging in direct contact with the product. For sterile products, the first level of packaging may consist of any combination of the sterile packaging system and may include a single item or a group of items intended for a single therapy, such as a kit. For packaging configurations that include a retail consumer trade item, primary packaging refers to a packaging level below the retail consumer trade item;
- (k) **“registered medical practitioner”** means a medical practitioner registered or provisionally registered under the Pakistan Medical and Dental Council Act, 2022 (IV of 2023);
- (l) **“Schedule”** means a schedule to these rules;
- (m) **“secondary packaging”** means packaging that contains one or more primary packs;
- (n) **“serial number”** means randomized, unique hexadecimal number that may range from twelve to twenty characters;



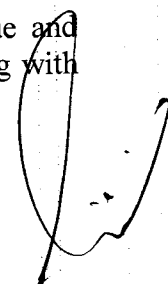
- (o) **“serial shipping container code (SSCC)”** means a unique number used to identify a logistic unit, applied with a data carrier for automatic identification and data capture in electronic commerce;
- (p) **“serialization”** means the process of printing randomized, unique hexadecimal serial numbers on the label or package;
- (q) **“symbol”** means a combination of characters and features required by a particular symbology, including the Quiet Zone, Start and Stop characters, data characters, and other auxiliary patterns, which together form a complete scannable entity; it represents an instance of a symbology and a data structure;
- (r) **“symbology”** means a defined method of representing numeric, alphabetic, or alphanumeric characters in a barcode; it refers to a specific type of barcode (e.g. GS1 Data-Matrix, GS1-128);
- (s) **“tertiary packaging”** means packaging that contains one or more secondary packs; and
- (t) **“trade item”** means any item or product for which there is a need to retrieve pre-defined information and that may be priced, 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, and other relevant details. It can be used for pharmaceutical products.

(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) for rule 3A, the following shall be substituted, namely:—

**“3A. Application of barcode label requirements for product track and trace system.—** (1) Notwithstanding anything contained in rule 3, four months after the issuance of this Notification, a machine-readable barcode as per the GS1 general specification shall be printed on the label of all drugs manufactured or imported for the domestic market or for export purposes, at different packaging levels, to enable identification, tracking and tracing, and to eliminate spurious and counterfeit products, in the following manner, namely:—

- (a) barcode on the secondary packaging shall encode a unique and global product identification code in the GTIN format, along with



the batch or lot number and expiry date, as specified in Schedule-II; and

- (b) serialization on the secondary packaging shall be carried out using random numbers in the GS1 Data-Matrix, as specified in Schedule-II.

Provided that the Policy Board may extend the timeline for printing of barcode or serialization on the secondary packaging.

(2) Where imported drugs, at the time of import, do not conform to sub-rule (1), the person importing the drug shall arrange, with the prior approval of the Registration Board, for printing the GS1 Data-Matrix at a local facility licensed to manufacture or sell drugs in accordance with clause (i) of rule 3 of the Drugs (Import and Export) Rules, 1976, before the drug is placed on the market.

(3) SSCC on tertiary pack (logistic unit) shall become mandatory six years after the issuance of this Notification, in the following manner:

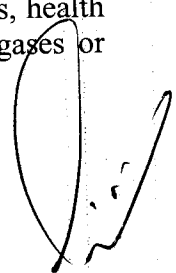
- (a) for homogenous products, a GS1-128 linear barcode (1D barcode type) encoding a unique global product identification code in the GTIN format, along with the expiry date, batch or lot number, and SSCC on the tertiary packaging; and
- (i) for heterogenous products, a GS1-128 linear barcode (1D barcode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

(4) Where the primary packaging is not further packed in any secondary package and the drug is offered for sale directly in its primary packaging, barcode labeling on the primary packaging shall be mandatory.

(5) The barcode shall be printed in a legible manner and surrounded by a sufficient blank space (Quiet Zone) to ensure correct scanning, and it shall remain intact under normal conditions of use.

(6) The machine-readable barcode must appear on the label of each drug in conformance with this rule, and the human-readable information shall be equivalent to the requirements prescribed in rule 3.

(7) This rule shall apply to 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.



(8) All manufacturers and importers shall submit product information, along with company details, as specified in Schedule-III, to the Authority's database.

(9) The Registration Board may, in exceptional circumstances and for reasons to be recorded, exempt any drug or class of drugs from the application of this rule.

(10) The Authority, with the approval of the Policy Board, may adopt any new standard for the track-and-trace system, in addition to the GS1 standard, provided that such standard is globally recognized.

(11) The Authority may issue guidelines for the effective implementation of barcode labelling and serialization requirements.

(12) Any provision inconsistent with the terms of this rule is repealed and shall be modified accordingly.”;

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

“**15. Fees.**— The fee for the track-and-trace system shall be as notified by the Authority under the Drug Regulatory Authority of Pakistan (Fee and Levy) Rules, 2022.”; and

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

#### “Schedule-II

[See rules 2(f) and 3A(1)]

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

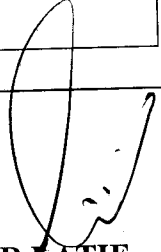
| Sr. | Parameter                                                 | Application Identifier | Explanation                                                                                            | Example            |
|-----|-----------------------------------------------------------|------------------------|--------------------------------------------------------------------------------------------------------|--------------------|
| (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)89657674002017 |
| 2   | Expiry Date                                               | AI (17)                | Format will be YYMMDD                                                                                  | (17)201230         |
| 3   | Batch Number or Lot Number                                | AI (10)                | Alphanumeric up to 20 elements string long                                                             | (10)ABCD1234       |
| 4   | Serial Number                                             | AI (21)                | Hexadecimal unique number from 12 to 20 elements string – This is for items to be individually tracked | (21)AB1238C92D56   |

**Schedule-III**  
[See rule 3A(8)]

**Mandatory Product Information to be maintained by Company  
and submitted to Authority's Database**

| Sr. | Parameter                                                 | GS1<br>Application<br>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 GS1                              | (01)89657674002017           |
| 2   | Expiry date                                               | AI (17)                          | Format will be YYMMDD                                                                                  | (17)201230                   |
| 3   | Batch number or lot number                                | AI (10)                          | Alphanumeric up to 20 elements string long                                                             | (10)ABCD1234                 |
| 4   | Serial number                                             | AI (21)                          | Hexadecimal unique number from 12 to 20 elements string – This is for items to be individually tracked | (21)AB1238C92D56             |
| 5   | Registration number                                       | N/A                              | Registration number provided by the Authority                                                          |                              |
| 6   | Complete description of pack size                         | N/A                              | Description of Trade Item contained in a logistic unit                                                 | PVDA-Alu, blister of 10's x3 |
| 7   | Price                                                     | N/A                              | Price per unit of measure                                                                              | 00.00                        |
| 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"                     |

[No. F.13-1/2025-LA]

  
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