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## PART II

Statutory Notifications (S.R.O.)

GOVERNMENT OF PAKISTAN  
Ministry of National Health Services, Regulations and Coordination  
Drug Regulatory Authority of Pakistan

### NOTIFICATION

*Islamabad, the 27th August, 2019*

**S.R.O. 962(I)/2019.**— 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 Federal Government, be sent within fourteen days of the publication of this Notification in the official Gazette.

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 Federal Government.

### DRAFT AMENDMENT

In the aforesaid Rules.—

- (1) in rule 2.—
  - (a) in clause (p),—
    - (i) after the words “Legible information” the words “human readable interpretation” shall be inserted; and
    - (ii) after the word “users”, the following shall be inserted, namely.—

“characters, such as letters and numbers, which can be read by the persons and are encoded in GSI data carriers confined to GSI standard structure and format. The human readable interpretation is a one-to-one illustration of the encoded data”;

(b) for clause (t), the following shall be substituted, namely.-

“(t) “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;”;

(c) after clause (t), the following new clause shall be inserted, namely.-

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

(2) in rule 3A,-

(a) in sub-rule (1),-

(i) after the word “export”, the words “as per requirement of the importing country” shall be inserted;

(ii) clause (a) shall be omitted;

(iii) in clause (b), after the expression “GTIN”, the words “in addition to batch or lot and expiry” shall be inserted; and

(iv) in clause (c), the expression “a one dimensional ID barcode”, the expression “a GS1-128 linear barcode of ID barcode type or a GS1 Data-Matrix of a 2D barcode type” shall be substituted;

(b) in sub-rule (4),-

(i) the words "Primary Packing and" shall be omitted; and

(ii) in the proviso, for the word "two", the word “six” shall be substituted;

(c) in sub-rule (5),-

(i) the words, "Barcode labeling on the Primary Packing and" shall be omitted;

(ii) for the expression “SSCC on Tertiary Packing”, the expression “SSCC on the Tertiary Pack logistic unit” shall be substituted; and

(iii) for the word "two", the word "six" shall be substituted;