UPDATE ON IMPLEMENTATION OF BARCODE REGULATIONS IN LIGHT OF DRAP NOTIFICATION DATED 27.06.2025

Dated, 22-07-2025
PPMA Office, Karachi

Cepal & Co.

Title Slides

History and Regulations of Barcode on Therapeutic Goods	03
Framework & Scope of SRO 470/2017	04
The SCP Direction & Compliance in H.R.C. 2858 of 2006	06
Comparison & Amendments in SRO 470/2017	07
Industry Agreement on Phase wise Implementation	09
Draft Amendments dated 27.06.2025	11
Technical Issues Faced by Industry	14
International Practices	15
Recommendations & Way Forward	16
Merits & Demerits of Barcode Implementation	17
Current Guidance & Status for Barcode Labeling	18
References	19

Presentation Outline

Cepal & Co.

HISTORY & BACKGROUND OF S.R.O. 470 (1)/2017

Implementation of Barcode Regulations

01 The first draft of amendments in the Drugs (Labeling and Packing) Rules, 1986 for implementation of 2D barcode printing was published in 2015.

02 DRAP with the approval of the Federal Government under section 7 of DRAP Act, 2012 and section 43 of the Drugs Act, 1976, notified amendments in the Drugs (Labeling and Packing) Rules, 1986 vide S.R.O. 470 (I)/2017 (14th June, 2017) incorporating rules for implementation of 2D barcode printing on pharmaceutical product packaging.

03 As per Rule (9) of SRO 470, these rules shall:

- 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 order; and
- come into force for the batch manufactured or imported after six months of the publication of this notification in the official gazette.

MANDATE OF S.R.O. 470 (1)/2017

Mandatory labeling requirements

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

- GTIN Number
- Expiry Date
- Batch or Lot number
- Product Identification Including MRP (AI 240)
- Serial Number

02 Mandatory Product Information to be maintained at Company Database and communicated to DRAP for DRAP Database

- GTIN Number
- Expiry Date
- Batch or Lot number
- Product Identification
- Registration Number
- Strength, pack size and Dosage form

Cepal & Co.

PHASE WISE IMPLEMENTATION OF S.R.O. 470 (1)/2017

Barcode & Serialization on Packaging

Thirdly

For complete track & trace system of each product and package serial number was to be captured in all packaging components after three years of commencement of rules dated **14.06.2020**

Secondly

Serialization and barcoding on primary and serial shipping container (SSCC) on tertiary packaging was to be adopted after two years of commencement of these rules dated **14.06.2019**

Firstly

It was to be implemented only on secondary packaging after six months of notification dated **14.12.2017**

DIRECTIONS BY HONORABLE SUPREME COURT OF PAKISTAN

SC Order dated 03.08.2018 in the case H.R.C. 2858 of 2006

01 **Involvement of Pharma Industry**

Direction to Drug Regulatory Authority of Pakistan (DRAP) to take the pharmaceutical industry on board for deliberation and finalization on the issue of Barcode printing on drug product packaging.

02 **Timeline for implementation**

Direction to DRAP to decide upon issues such as barcode printing on primary/ secondary/ tertiary packaging, the timeline for implementation and any technical issues related to it, in shortest possible time and submit a summary to the Supreme Court.

CONSULTATION WITH INDUSTRY

Relaxation in Barcode Rules and Timeline for Implementation

In compliance with the SC order dated 03.08.2018, PPMA, Pharma Bureau and PCDA held two subsequent meetings with DRAP on 31.08.2018 and 27.09.2018 respectively, and following amendments issued by DRAP for further objections & suggestions by all stakeholders:

01 Requirement of 2D barcode and serialization may be omitted from primary packaging except for in cases where primary packing is directly sold and is not packed in secondary packaging.

02 Requirement of embedding Application Identifier AI-240 in the 2D Data Matrix may be omitted.

03 The timeline was agreed on phase-wise implementation of 2D Data Matrix Barcode printing on pharmaceutical product packaging.

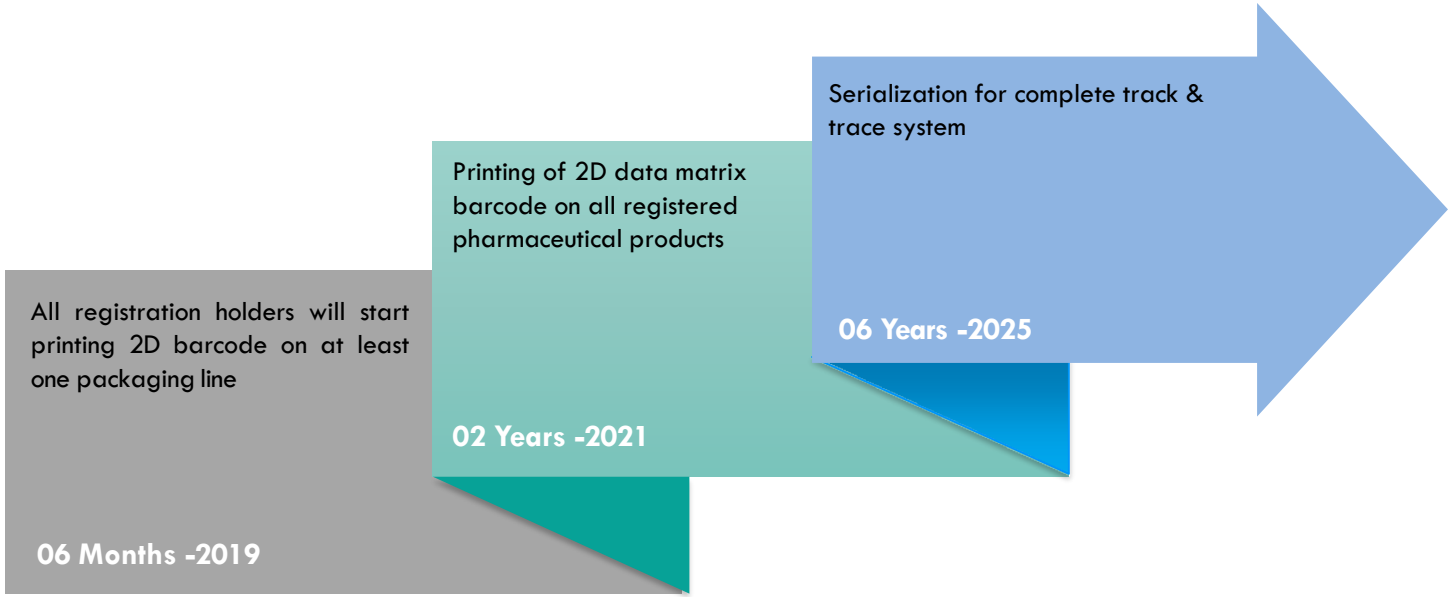
DRAFT AMENDMENTS S.R.O. 470 (1)/2019

Post DRAP-Industry Consultation

S. No	Barcode Requirement	Timeline As Per SRO 470 (1)/2017	Time Line As per 2019 Draft Amendments
i.	• GTIN for all registered drugs	• After 6 months of publication of this notification	• 6 months for secondary packaging • Not required for primary packaging
ii.	• 2D Data Matrix Barcode printing on all registered products by manufacturers/ importers	• On secondary packaging after 6 months of publication of this notification • On primary and tertiary packaging, after 2 years of publication of this notification	• On secondary packaging after two years of publication of this draft notification • Not required for primary packaging • The identification information AI 240 omitted
iii.	• Serialization for complete track and trace system only	• On primary, secondary, and tertiary packaging shall be mandatory after 2 years	• On secondary and tertiary packaging shall be mandatory after 6 years publication of this draft notification • Not required for primary packaging

AGREED PHASE-WISE IMPLEMENTATION

As per Draft Amendments 2019



Cepal & Co.

STATUS OF BARCODE REGULATIONS

Before the Amendment Notification dated 27.06.2025

01 The recommendations were submitted in Honorable Supreme Court in compliance of order dated 03.08.2018, & forwarded to the Federal Government for necessary approval and amendments in the Drugs (Labeling & Packaging) Rules 1986, but the matter remained pending.

02 As the amendments had not been affected as yet, the recommended 2 year clock for implementation of barcode has not started.

03 There is no legal operational value of SRO 470/2017 as its been overruled by the Supreme Court order.

04 2D Data matrix Barcode shall only be implemented when new barcode regulations or industry agreed amendments notified by Federal Govt & DRAP

DRAFT NOTIFICATION NO. F.13-1/2025-LA. DATED 27.06.2025

Salient Features of the Proposed Amendments in Barcode Regulations

01 **Rule 2 – Removal of Definitions**

Amended to remove bar code definitions of GTN, 2D Matrix, Serialization, etc. as they are now a part of Schedule-II under Rule 3A

02 **Rule 3A- Addition of Schedule-II & Revision of Form A**

Barcode regulations incorporated as Schedule-II containing revised Form A.

03 **Rule 3A- Addition of Sub-rule (4)**

The Authority may issue guidelines for effective implementation of Barcode label requirements.

04 **Rule 15- Addition of Provision of Power**

The Authority is prescribed power to omit, add or amend Schedules & Forms after approval of Policy Board.
The Authority may, on the recommendation of the Registration Board, amend Forms so as to omit, add or amend an entry.

05 **Amendments in Form A**

Part A (4) Product Identification Information (AI240) removed
Part B (4) Product Identification Information (AI240) is replaced with Serial Number (AI21)
Part C (mentioned in SRO 470) is removed

DRAFT NOTIFICATION NO. F.13-1/2025-LA. DATED 27.06.2025

Salient Features of the Proposed Amendments in Barcode Regulations

06

Schedule –II Amendments – Identification, Tracking & Tracing

Printing of machine-readable Barcode as per the GS1 general specification on the label of all drugs manufactured or imported for domestic market or for export purpose in the following manner, namely:-

(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.

Homogenous package: a package containing multiple units of the same (only one) product packaging type. Shipper Carton/Tertiary packaging of homogeneous package contains barcodes with GTIN, Exp., B. No. encoded.

Heterogeneous package: a package containing multiple units of different (more than one) product packaging type. Shipper Carton/Tertiary packaging of heterogeneous package contains only one barcode encoding SSCC on the label.

TECHNICAL ISSUES IN IMPLEMENTATION OF BARCODE & SERIALIZATION

Operational Challenges

Barcode Encoding & Printing

Smudged labels, incorrect label placement, or using the wrong type of barcode, compatibility with temperature/ humidity can affect readability

System Integration

with older, non-digital manufacturing and supply chain systems, enterprise resource planning (ERP), inventory management & other relevant databases

Cost

Investment in barcode scanners, software, and training of individuals, challenges for high volume of production

Scanning Equipment

Inadequate/ malfunctioning scanners, low battery life, poor connectivity, or compatibility problems with existing systems can affect the efficiency of scanning.

Data Accuracy

Track-and-trace systems, real-time data capture and processing

Security

Protection from unauthorized access to database, confidential drug information may be misused

INTERNATIONAL BARCODE IMPLEMENTATION STATUS

	USA	UK	EU	CANADA	JAPAN	CHINA	INDIA
REGULATIONS	FD&C ACT, 21 CFR (201 & 207) 2006, & Drug Supply Chain Security Act (DSCSA), 2013	MHRA Guidance, 2023 under Windsor Framework	Falsified Medicines Directive (FMD), EU Directive 2011/62/EU), Delegated Directives EU	Labeling of Pharma Drugs for Human Use 2015 under FDA & FDR	PMDA e-Labeling Insert Requirement, 2022, PMDA Act Proposal underway for future traceability updates	NMPA announcement for Drug Information Traceability System (Circular No. 2020/111)	CDSCO barcode regulations, G.S.R. 823(E) dated November 17, 2022
APPLICATION	OTC, Rx drugs, medical devices, biologicals	Not mandatory	Most Rx and some OTC medications	Rx drugs for human use	Pharmaceutical and biological products	Pharmaceuticals	Pharmaceuticals (mandatory for 300 brands listed in notification)
SUPPLY CHAIN LEVELS	Manufacturers, Repackers, & pvt. label distributors	MAHs (not compulsory)	Manufacturer for implementation, Wholesaler & retailer for scan/ verify	Manufacturer	Manufacturer	MAH, manufacturers, distributors	Manufacturers
BARCODE/ SERIALIZATION REQUIREMENT	2D matrix for packages & 12-digit linear or 2D matrix for homogenous cases	2D barcode and serial number of any format	unique 2D barcode (like a QR code) outer packaging of medicines	2D barcode, GTI, Exp, Lot No. on primary & secondary packaging (Sr. No. is optional)	GTIN, GS1 Data Matrix for medical devices, GS1-128 for tertiary, aggregation is optional	14-digit CNDC, 1D bar code, GS1-2D Data Matrix or RFID tag	2D Data Matrix, GTIN Unique Sr. No., GS1-128
TRANSITION TIMELINE	Initiated in 2006, 5 yrs from 2022 (proposal for all stakeholders for full package-level tracking)	New UK domestic framework begins	Mandatory since Feb 2021	31st Dec 2025	Mandatory since 2022	From 2022 onwards, new compliance framework issued by NMPA for manufacturer to self issue traceability codes	Mandatory on and after 01.08.2023, 2025 for rest of the products

RECOMMENDATIONS FOR WAY FORWARD

Compliance after Amendments in Labelling Rules 2025

DRAP	Phase-1	Phase-2	Phase-3	Phase-4
• After formal issuance of SRO, DRAP to issue Guidelines & establish Integrated database • Industry to set all equipment & establish ERP system	• Companies to implement 2D Barcode on all essential drugs with serial number	• Companies to implement 2D Barcode with serial number on all registered pharmaceutical drugs.	• DRAP to establish database or DRAP APP for verification in real time. • A GS1-128 linear barcode of 1D on the tertiary packaging.	• DRAP to establish aggregation system • Distributors to scan & process barcodes into ERP systems. • Pharmacies Integrate barcode data into inventory systems
Dec 2025	June 2026	Jan 2027	Dec 2030	Dec 2032

Cepal & Co.

DEMERITS OF IMPLEMENTATION OF BARCODE/ SERIALIZATION

AS PER 2025 AMENDMENTS

01 **Contradictory to Existing Labeling Rules**
Companies may face challenge of barcode verification in exporting countries, and contradictory with said rule 12.

02 **Limited Patient Access**
Patients may not be able to decipher 2D barcodes due to limited access to androids and internet.

03 **Machine/ Scanner Software Compatibility**
Software installed by manufacturers are not compatible with the latest versions of software used in scanners/ or at DRAP.

04 **Limited Data Storage Capacity**
Serialization is a tedious task as it requires management of data records of all the serialized batches of all the products manufactured.

05 **Mother-child Packaging Issues**
No check on sanctity of primary (child) packaging (blisters/ampoules) packed in Secondary (mother) packaging (Outer carton)

06 **Regulatory Standardization in Current Export Markets**
Different countries have varying regulations for barcodes, leading to compliance challenges for global pharma companies.

07 **Counter-productive Exercise**
Incapable to resolve counterfeit drugs issue, as 2D barcodes/ GTIN can be easily copied by malafide manufactures/ sellers.

08 **Compatibility with evolving technology**
Companies may face additional cost and wastage of resources in event of new technology against existing requirements.

09 **Non-operational & Inadequate DRAP Barcode Database**
Redundant exercise as DRAP's database is non-operational, & incapable of tracking/tracing the barcodes.

10 **Controlled Storage Conditions**
Controlled temperature/ humidity of the packs throughout the supply chain is required to maintain barcode quality/ readability

Cepal & Co.

CURRENT GUIDANCE & STATUS FOR BARCODE LABELING

What the industry should follow today?

- Current draft Amendments 2025 in the Drug (Labeling & Packaging) Rules 1986 are *not in line with* the Order dated 03.08.2018 passed by the Honorable Supreme Court of Pakistan in HRC 2858 of 2018

- The existing Drug (Labeling & Packaging) Rules 1986 as amended before 2015 *are still in place*.

- Those companies who are following Drug (Labeling & Packaging) Rules 1986 *without 2D data matrix barcode* are in compliance with the existing labeling requirements.

- Also, those companies who are currently printing 2D data matrix *with stand alone serial number* are compliant with new proposed draft amendments 2025 issued by DRAP.

REFERENCES

- *Drugs (Labeling & Packaging) Rules, 1986*
- *Amendments in Drug (Labeling & Packaging) Rules, 1986 vide SRO 470 (1)/2017*
- *Draft Amendments in Drug (Labeling & Packaging) Rules, 1986 vide SRO 962 (1)/2019*
- *Draft Amendments in Drug (Labeling & Packaging) Rules, 1986 vide Notification No. F.13-1/2025-LA. DATED 27.06.2025*
- *Supreme Court of Pakistan Order dated 03.08.2018 in the case H.R.C. 2858 of 2006*
- *US FD&C ACT, 21 CFR (201 & 207) 2006*
- *USFDA Drug Supply Chain Security Act (DSCSA), 2013*
- *USFDA Guidance for Industry, Bar Code Label Requirements Questions and Answers, August 2011*
- *MHRA Guidance under Windsor Framework, 2023*
- *EU Falsified Medicines Directive (FMD) Directive 2011/62/EU*
- *EU Delegated Directive 2016/161/ EU*
- *Health Canada Labeling of Pharma Drugs for Human Use, 2015 under Food & Drugs Act & Food & Drug Regulations*
- *Health Canada, Draft Guidance Document Electronic media in prescription drug labelling, 2021/03/12*
- *PMDA-Japan e-Labeling Insert Requirement, 2022*
- *Implementation of barcode labeling on prescription drugs, 2006, MHLW, Pharmaceuticals & Food Safety Bureau, Safety Measures Division*
- *NMPA- China Announcement for Drug Information Traceability System (Circular No. 2020/111)*
- *CDSCO-India Barcode Regulations, G.S.R. 823(E) dated November 17, 2022*

Cepal & Co.

Pakistan's First Pharmaceutical & Healthcare Corporate Law Firm

Contact: 0323-3030085 www.cepal.pk/