

Pakistan Track and Trace System for Pharmaceuticals for the Domestic market, Imported or Exported



Regulatory Update August 2020

Regulatory Agency	Drug Regulatory Authority of Pakistan (DRAP), Ministry of National Health Services, Regulations & Coordination, and Ministry of Commerce and Industry
Regulation Name or System Name	DRAP Track and Trace Regulation for import, export and domestic manufacture
Compliance Dates	<p>Following a supreme court ruling dated April 26, 2018, the Court ruled, in part:</p> <p><i>"[...] We also direct that all the pharmaceutical companies, within a period of three months, shall implement and enforce a bar code not only on the box but also on the wrappers affixed upon the containers/bottles of the pharmaceutical products [...]"</i></p> <p>Some in the industry believe that "the wrappers" refers to drugs that have a primary package but no secondary package (a bottle of drugs), and "the box" refers to any secondary packaging.</p> <p>On August 27, 2019 DRAP published a statutory notification S.R.O. 962(I)/2019 stating that it had amended the regulations with the following deadlines and changes:</p> <ul style="list-style-type: none"> – All manufacturers and importers will print 2D barcode in 6 years (August 27, 2025) – 2D barcode printing on primary package will be omitted – AI 240 data element in the 2D barcode will also be omitted
Applies to	Drugs imported, exported or manufactured domestically, including allopathic drugs including biologicals, for human and veterinary use only. Alternate medicines, health and OTC non-drug products, nutraceuticals, medical devices medical gases and radio-pharmaceuticals are exempt at this time

Secondary Packaging

(a carton containing one or more primary packs)

Proposed Barcode Symbology	2D Datamatrix following GS1 standards
Proposed Barcode Contents	<ul style="list-style-type: none"> • GTIN-14 (AI=01), • Expiry Date (AI=17), • Batch/Lot Number (AI=10)
Serial Number Randomization	N/A
Serial Number Reuse	N/A
Human Readable Expiry Date Format	“YYMMDD”
Barcode Data Encoding	GS1 standard
Barcode notes	
Free Samples must be marked?	Not specified
Stickering after manufacturing allowed?	Yes, on import of non-conforming drugs, with prior approval of the Registration Board

Tertiary Packaging

(a shipper containing one or more secondary packs)

Barcode Symbology	Unspecified linear barcode
Barcode Contents	Logistics containers must contain an SSCC

Aggregation Data Capture

Parent-Child Mapping Aggregation Capture?	No
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Data Exchange

Send Unit Data to Government Repository?	Yes, via email until their online portal is set up
Send Unit Data to Third-Party Repository?	No
Send Unit Data to Trading Partner?	No
Send Aggregation Data to Government Repository?	No
Send Aggregation Data to Third-Party Repository?	No
Send Aggregation Data to Trading Partner?	No

Authentication

Who Offers Data Repository for Authentication?	n/a
Manufacturers Must Register Shipments in Repository?	No
Downstream Trading Partners Must Authenticate on Receipt?	No
Downstream Trading Partners Must Authenticate on Shipment?	No

Government Reporting

Manufacturer Activity Reported?	Only manufactured, imported and exported drugs.
Downstream Trading Partner Activity Reported?	No

Challenges

The regulation claims to include exported drugs but the specific requirements and exemptions are not explained.

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Global brands across industries rely on us to keep their products authentic, safe and connected—from manufacturing to the consumer's hands. Together we are revolutionizing brand protection!

Regulatory Questions?

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