

Saudi Arabia – Saudi Drug Code Barcoding Requirements



Regulatory Update August 2020

Regulatory Agency	Saudi Food and Drug Authority
Regulation Name or System Name	Saudi Drug Code Barcoding Requirements
Compliance Dates	<p>March 21, 2015: All drug unit of sale packages must contain a GS1 Datamatrix barcode affixed by the manufacturer;</p> <p>March 12, 2017: All the GS1 Datamatrix barcode affixed by the manufacturer must include a GS1 serial number.</p> <p>As of January 7, 2019 each local pharmaceutical factory and warehouse:</p> <ul style="list-style-type: none"> • must be identified with a GLN and the related data must be registered/updated at the Drug Establishment National Registry (DENR) and Establishment Licensing System (ELS) by entering the GLN at the specified field. • Register in the Drug Track & Trace System (DTTS) • Begin reporting all transactions of drug packages <p>August 20, 2020: Aggregation data must be provided by local manufacturers, the foreign manufacturer or the "local agent". This deadline has been postponed at least 3 times since December 2019.</p>
Applies to	Domestic and foreign drug manufacturers of human and veterinary drugs including prescription and over-the-counter drugs

Secondary Packaging

Barcode Symbology	GS1 DataMatrix
Barcode Contents	<ul style="list-style-type: none"> • A GTIN; • The expiration date of the drug; • Batch/log number; • Unique Serial Number
Serial Number Randomization	No
Serial Number Reuse	Not specified

Human Readable Expiry Date Format	Month Year
Barcode Data Encoding	GS1 standard
Product Code notes	<ul style="list-style-type: none"> SFDA technical documents define a 10 character "Saudi Drug Code", but it appears they do not expect it to be encoded in the barcode. <i>"The GS1 Data Matrix barcode must be printed on one side of the secondary packaging—preferably on a flat surface. To facilitate the reading process, it should be placed on the same side where possible."</i>
Free Samples must be marked?	No
Sticker after manufacturing allowed?	Yes, by implication

Homogeneous Cases

Barcode Symbology	GS1 DataMatrix or GS1-128
Barcode Contents	GTIN+serial number

Logistics Units

Logistics Units Must be Serialized?	Yes, SSCC
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Data Capture

Unit-to-Case Aggregation Capture?	Yes
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Data Exchange

Send Unit Data to Government Repository?	Yes
Send Unit Data to Third-Party Repository?	No
Send Unit Data to Trading Partner?	Yes, but not fully defined yet
Send Aggregation Data to Government Repository?	Yes
Send Aggregation Data to Third-Party Repository?	No
Send Aggregation Data to Trading Partner?	Probably

Authentication

Who Offers Data Repository for Authentication?	Saudi FDA
Manufacturers Must Register Shipments in Repository?	Yes
Downstream Trading Partners Must Authenticate on Receipt?	Apparently
Downstream Trading Partners Must Authenticate on Shipment?	Not sure

Government Reporting

Manufacturer Activity Reported?	Yes
Downstream Trading Partner Activity Reported?	Probably

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Regulatory Questions?

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