

# Bahrain



(based on Version 1.2 of Medicines Barcoding and Serialization Guideline, dated May 2019, and Health Resolution #41-2017, dated October 2019)

## Regulatory Update

August 2020

<b>Regulatory Agency</b>	Supreme Council for Health and the National Health Regulatory Authority (NHRA)	
<b>Regulation Name or System Name</b>	System for Tracking and Tracing Medicine Provision and Supply Chain inside the Kingdom of Bahrain	
<b>Compliance Dates</b>	<b>Action</b>	<b>Deadline</b>
	Allocating GTINs for medicines supplied in the Kingdom of Bahrain	November 2017 – April 2018
	Reporting of master data by manufacturers	November 2017 – April 2018
	“Soft” deadline to comply with the barcoding and serialization requirements <i>(Imports without DataMatrix barcodes were not blocked)</i>	December 31, 2019
	Aggregation data capture	September 1, 2021
<b>Applies to</b>	Manufacturers, distributors, importers, pharmacies and hospitals  Products that require a barcode: <ul style="list-style-type: none"> <li>Registered medicines with NHRA.</li> <li>Non-registered medicines, with valid temporary importation licenses from NHRA.”.</li> </ul>	

## Pharmaceutical Packaging

<b>Barcode Symbology</b>	GS1 Datamatrix
<b>Barcode Contents</b>	GTIN, AI(01) Expiration Date, AI(17) Serial number, AI(21) Batch number, AI(10)
<b>Serial Number Randomization</b>	Not specified
<b>Serial Number Reuse</b>	Not specified

<b>Human Readable Expiry Date Format</b>	Follow GS1 General Specification for HRI for healthcare items
<b>Barcode Data Encoding</b>	GS1 Standard
<b>Barcode notes</b>	
<b>Free Samples must be marked?</b>	No
<b>Stickering after manufacturing allowed?</b>	No unless exceptionally authorized by NHRA

## Case Packaging

<b>Barcode Symbology</b>	GS1 standard: presumably either a Datamatrix if a GTIN is used, or GS1-128 if an SSCC is used, but this is not exactly specified
<b>Barcode Contents</b>	Not specified except it must be serialized so aggregation is enabled
<b>Notes</b>	

## Aggregation Data Capture

<b>Parent-Child Mapping Aggregation Capture?</b>	Yes, by September 2021
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## Data Exchange

<b>Send Unit Data to Government Repository?</b>	Not specified
<b>Send Unit Data to Third-Party Repository?</b>	Not specified
<b>Send Unit Data to Trading Partner?</b>	Not specified
<b>Send Aggregation Data to Government Repository?</b>	Not specified
<b>Send Aggregation Data to Third-Party Repository?</b>	Not specified
<b>Send Aggregation Data to Trading Partner?</b>	Not specified

## Authentication

<b>Who Offers Data Repository for Authentication?</b>	Not specified
<b>Manufacturers Must Register Shipments in Repository?</b>	Yes
<b>Downstream Trading Partners Must Authenticate on Receipt?</b>	Not specified
<b>Downstream Trading Partners Must Authenticate on Shipment?</b>	Not clear

## Government Reporting

<b>Master Data Upload</b>	Yes, to the BrandSync website operated by GS1 UAE
<b>Manufacturer Activity Reported?</b>	Yes
<b>Downstream Trading Partner Activity Reported?</b>	Not clear

## Challenges

This appears to be only the beginning of what may become a more thorough regulation in the future.

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## About Systech

Systech provides digital product authentication and traceability solutions to combat counterfeiting, prevent diversion and meet regulatory compliance. Built on decades of experience as the leader in pharmaceutical serialization, our comprehensive brand protection suite delivers the real-time insight, actionable product data, digital connectivity and consumer engagement functionality needed to fight supply chain threats.

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?

Contact us at [info@systechone.com](mailto:info@systechone.com) or visit us online [here](#).