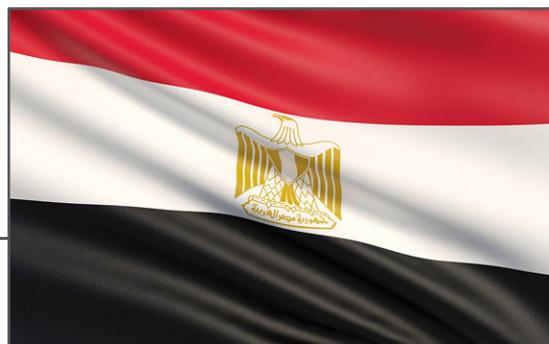


# Egypt Drug Tracking System



## Regulatory Update

August 2020

<b>Regulatory Agency</b>	Ministry of Health & Population
<b>Regulation Name or System Name</b>	Egyptian Pharmaceutical Track & Trace System (EPTTS)
<b>Compliance Dates</b>	<p>It appears that the dates below may not be accurate. In January 2020 the MoH&amp;P apparently said that they would establish a work group within 3 months' time to "...define the timeline and technical guidance for implementation...". The following dates predate that statement.</p> <p><b>Manufacturers, importers, warehouses and distributors:</b></p> <p>September 1, 2017:</p> <ul style="list-style-type: none"> <li>Registering a Global Trade Item Number (GTIN) for each product of plants and importers</li> <li>Registering a Global Location Number (GLN) for each work location correlated to production or sending products inside Egypt or abroad</li> </ul> <p>February 1, 2018:</p> <ul style="list-style-type: none"> <li>E-connection to the system that the Ministry of Health will establish to apply the tracking project. Testing was to begin in Q4 2017.</li> </ul> <p>March 1, 2018:</p> <ul style="list-style-type: none"> <li>Fitting the devices &amp; systems required to read and print the barcode determined in the project</li> </ul> <p>June 1, 2019:</p> <ul style="list-style-type: none"> <li>Each company (manufacturing or toll-manufacturing) shall print a two-dimensional barcode (Data Matrix) by the specifications mentioned in Article 3 of Ministerial Decision no. 29/2016 (see below)</li> <li>Linking the shipping pack to the packs included in it using the SSCC</li> <li>Upload data to the MoH track and trace system</li> </ul> <p>By January 1, 2019:</p> <ul style="list-style-type: none"> <li>Each company must do the above with a single product.</li> </ul> <p><b>Pharmacies:</b></p> <p>December 1, 2017:</p> <ul style="list-style-type: none"> <li>Obtaining a GLN for each pharmacy from GS1 &amp; notifying the Ministry of Health</li> </ul> <p>February 1, 2018:</p> <ul style="list-style-type: none"> <li>E-connection to the system that the Ministry of Health will establish to apply the tracking project</li> </ul> <p>March 1, 2018:</p>

	<ul style="list-style-type: none"> <li>Fitting the devices &amp; systems required to read and print the barcode determined in the project</li> </ul> <p>June 1, 2019:</p> <ul style="list-style-type: none"> <li>Start activating and reading the data of the pharmaceuticals produced, imported on which the data matrix is printed</li> </ul> <p>December 1, 2019:</p> <ul style="list-style-type: none"> <li>Pilot started. Once it is complete, the guidelines and timeline will be updated</li> </ul> <p>In September, 2019 the Egypt MoH published <a href="#">version 2 of their Implementation Guide</a>.</p> <p>Starting in April 2020 the Egypt MoH conducted a survey of drug manufacturers, called "Track &amp; Trace Status Update" to assess their readiness.</p>
<b>Applies to</b>	Manufacturers (plants), importers, warehouses, distributors and pharmacies

## Pharmaceutical Secondary Packaging

<b>Barcode Symbology</b>	2D Datamatrix following GS1 standards
<b>Barcode Contents</b>	The pharmaceutical's GTIN, The pharmaceutical's expiry date, The batch number, The serial number of each pack
<b>Serial Number Randomization</b>	Not specified
<b>Serial Number Reuse</b>	Not specified
<b>Human Readable Expiry Date Format</b>	Not specified
<b>Barcode Data Encoding</b>	GS1 Standard
<b>Product Code notes</b>	
<b>Free Samples must be marked?</b>	Not specified
<b>Stickering after manufacturing allowed?</b>	Under consideration. Labels known as "Pandora" are viewed by the local industry as a low-cost alternative.

## Case & Pallet Packaging

<b>Barcode Symbology</b>	GS1 128 or DataMatrix
<b>Barcode Contents</b>	GS1 SSCC

## Aggregation Data Capture

<b>Parent-Child Mapping Aggregation Capture?</b>	Yes, but no details on what to do with it
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## Data Exchange

<b>Data Format</b>	GS1 EPCIS required
<b>Send Unit Data to Government Repository?</b>	Yes, in EPCIS events once their online portal is set up
<b>Send Unit Data to Third-Party Repository?</b>	No
<b>Send Unit Data to Trading Partner?</b>	No
<b>Send Aggregation Data to Government Repository?</b>	Yes, in EPCIS Aggregation events once their online portal is set up
<b>Send Aggregation Data to Third-Party Repository?</b>	No
<b>Send Aggregation Data to Trading Partner?</b>	No

## Authentication

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

## Government Reporting

<b>Master Data Upload</b>	Yes, to government subcontractor (GS1 Egypt)
<b>Manufacturer Activity Reported?</b>	Eventually
<b>Downstream Trading Partner Activity Reported?</b>	Not clear

## Challenges

- Master data upload must include photos

## Disclaimer

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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](#).