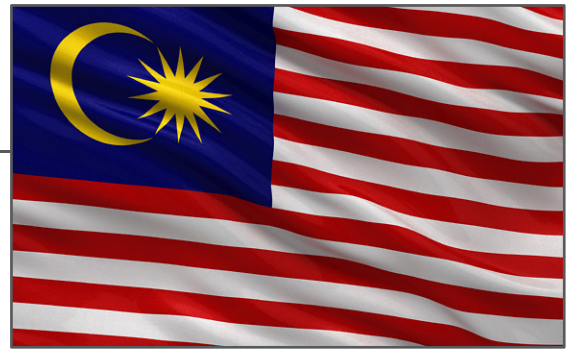


Malaysia



(Based only on a PowerPoint presentation delivered by Mr. Mohd Azuwan, MoH at the Malaysia National Regulatory Conference, October 3, 2018. *Not for compliance.*)

Regulatory Update

August 2020

Regulatory Agency	Malaysia Ministry of Health
Regulation Name or System Name	Pharmaceutical Track and Trace System
Compliance Dates	<p>Because nothing is official yet, no dates have been announced. However, during the presentation, Mr. Azuwan indicated the proposed milestones of:</p> <ul style="list-style-type: none"> • Phased implementation: Start in 2020 with scheduled poison products and rest will be implemented in phases. • Full implementation by 2023. <p>The system will be modeled after Turkey's system.</p>
Applies to	"Scheduled Poisons (A)" "All registered products (A, X, T, N)" Implemented in phases. "Primary Packaging" indicated as "Future implementation", implying that it will not be covered by the initial regulation when it is published.

Saleable Unit Packaging

Proposed Barcode Symbology	"GS1 2D DataMatrix"
Proposed Barcode Contents	<ul style="list-style-type: none"> • GTIN • Expiry date • Lot/Batch number • Serial Number
Serial Number Randomization	Not specified
Serial Number Reuse	Not specified
Human Readable Expiry Date Format	Not specified
Barcode Data Encoding	GS1 Standard
Barcode notes	•
Free Samples must be marked?	Not specified
Stickering after manufacturing allowed?	Not specified

Tertiary Packaging

Barcode Symbology	GS1-128 (apparently)
Barcode Contents	Appears to be the same as units
Notes	

Aggregation Data Capture

Parent-Child Mapping 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?	No
Send Aggregation Data to Government Repository?	Yes
Send Aggregation Data to Third-Party Repository?	No
Send Aggregation Data to Trading Partner?	No
Data Format?	EPCIS

Authentication

Who Offers Data Repository for Authentication?	Government
Manufacturers Must Register Shipments in Repository?	Yes
Downstream Trading Partners Must Authenticate on Receipt?	Dispensers authenticate at the time of dispense
Downstream Trading Partners Must Authenticate on Shipment?	Not clear

Government Reporting

Master Data Upload	Yes
Manufacturer Activity Reported?	Yes
Downstream Trading Partner Activity Reported?	Yes

Challenges

Information based on nothing more than a pre-regulation PowerPoint presentation. All parameters are subject to change when the draft and/or final regulations are eventually published (if that ever happens). Appears to be more of a wish than an actual requirement until more official information is published.

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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 or visit us online [here](#).