

# South Africa



(based on the concept paper published for comment on September 15, 2017.

**Not for compliance.**

Official regulations were expected in late September 2018. Nothing new has been published as of the date of this update.)

## Regulatory Update

August 2020

<b>Regulatory Agency</b>	National Department of Health (NDoH)																		
<b>Regulation Name or System Name</b>	NATIONAL DEPARTMENT OF HEALTH PHASED IMPLEMENTATION OF GTIN -14 DATAMATRIX BARCODES																		
<b>Compliance Dates</b>	<p><b>Appears to be on hold. No change since 2017.</b></p> <p>Extracts from the draft concept paper:            “In accordance with global best practice, NDoH is considering implementing a product identification, labeling and data exchange requirement, including GTIN-14 Datamatrix barcode requirements in the special conditions of contract applicable to contracts for pharmaceuticals.”            “...”            “It is envisioned that the implementation of the GTIN-14 barcode structure will be phased in according to international suggested best practice implementation timeframes as follows:</p> <p><b>“TERTIARY PACKAGING – TRADE ITEM (PALLET OR CASE).</b> The minimum GS1 identification key and AI to be included in a GS1 128 Linear Barcode or GS1 Datamatrix, with the applicable HRI printed adjacent:</p> <table border="0"> <thead> <tr> <th><b>Application Identifier</b></th> <th><b>Implementation Date</b></th> </tr> </thead> <tbody> <tr> <td>(01) GTIN</td> <td>Not later than Dec 30, 2018</td> </tr> <tr> <td>(10) BATCH/LOT</td> <td>Not later than Dec 30, 2018</td> </tr> <tr> <td>(17) EXPIRATION DATE</td> <td>Not later than Dec 30, 2018</td> </tr> <tr> <td>(21) SERIAL NUMBER</td> <td>Not later than Jun 30, 2022</td> </tr> </tbody> </table> <p><b>“SECONDARY PACKAGING – MULTI-PACK AND/OR SINGLE PACK CARTON.</b> The minimum GS1 Identification Key and AI to be included in a GS1 Datamatrix, with the applicable HRI printed adjacent:</p> <table border="0"> <tbody> <tr> <td>(01) GTIN</td> <td>Not later than Jun 30, 2020</td> </tr> <tr> <td>(10) BATCH/LOT</td> <td>Not later than Jun 30, 2020</td> </tr> <tr> <td>(17) EXPIRATION DATE</td> <td>Not later than Jun 30, 2020</td> </tr> <tr> <td>(21) SERIAL NUMBER</td> <td>Not later than Jun 30, 2022”</td> </tr> </tbody> </table>	<b>Application Identifier</b>	<b>Implementation Date</b>	(01) GTIN	Not later than Dec 30, 2018	(10) BATCH/LOT	Not later than Dec 30, 2018	(17) EXPIRATION DATE	Not later than Dec 30, 2018	(21) SERIAL NUMBER	Not later than Jun 30, 2022	(01) GTIN	Not later than Jun 30, 2020	(10) BATCH/LOT	Not later than Jun 30, 2020	(17) EXPIRATION DATE	Not later than Jun 30, 2020	(21) SERIAL NUMBER	Not later than Jun 30, 2022”
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<b>Applies to</b>	Probably manufacturers and importers
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## Pharmaceutical Packaging

<b>Barcode Symbology</b>	2D Datamatrix following GS1 standards
<b>Barcode Contents</b>	(01) GTIN (10) Batch/lot (17) Expiration date (21) Serial number (proposed later requirement)
<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>	Not specified

## Case Packaging

<b>Barcode Symbology</b>	GS1 128 or GS1 Datamatrix
<b>Barcode Contents</b>	(01) GTIN (10) Batch/lot (17) Expiration date (21) Serial number (proposed later requirement)

## Aggregation Data Capture

<b>Parent-Child Mapping Aggregation Capture?</b>	Not specified
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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>	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>	Not specified
<b>Manufacturer Activity Reported?</b>	Not specified
<b>Downstream Trading Partner Activity Reported?</b>	Not specified

## Challenges

- Information based on a request for comment on a draft concept paper rather than an official regulation.
- No information after 2017 so it appears to be dormant.

## Disclaimer

This information is being provided 'As Is' with no claims of suitability for a particular purpose. It represents just one possible interpretation of information available in the public domain or through membership organizations, and that interpretation is subject to change. This information does not constitute legal advice. Users must refer to the source material for the complete requirements and form their own interpretation before making business decisions.

## 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](#).