DEPARTMENT OF HEALTH

NO. 988 **15 SEPTEMBER 2017**

HEADING

REQUEST FOR INFORMATION: NATIONAL DEPARTMENT OF HEALTH PHASED IMPLEMENTATION OF GTIN-14 DATAMATRIX BARCODES

EXECUTIVE SUMMARY

In accordance with global best practice, the National Department of Health intends to implement the GTIN-14 Datamatrix barcode requirements in the special requirements and conditions of contract for pharmaceutical products.

The Global Trade Item Number™ (GTIN™) Datamatrix barcode is used for the unique identification of trade items worldwide and leverages existing global standards. The requirement seeks to harmonise with the global health marketplace to:

- Enable end-to-end data visibility
- Identify and implement supply chain efficiencies
- Ensure supply chain security
- Improve patient safety

Interested persons are requested to submit comments and additional information in writing (in hard copy, on compact disc or by e-mail) on the request for information within six (6) weeks of publication of this notice to the following address:

> Private Bag X828, 242 Civitas Building, Cnr Thabo Sehume & Bloed Street, Pretoria or email Ms K Jamaloodien at: khadija.jamaloodien@health.gov.za, with *GTIN-14 Datamatrix Barcodes* in the subject line.

Document name	Request for Information: Phased implementation of GTIN-14 Datamatrix barcodes
Purpose	Request for comment and information on proposed inclusion of GTIN-14 Datamatrix barcodes for the special conditions of contract for pharmaceuticals

1. Introduction

Over the past four years, the National Department of Health (NDOH) has implemented a number of supply chain reforms aimed at improving the efficiency and agility of the distribution of medicines. These reforms have incorporated international best practice and global standards to promote efficiency, reliability, and effectiveness within the medicine supply chain.

In accordance with global best practice, NDOH is considering implementing a product identification, labelling, and data exchange requirement including GTIN-14 Datamatrix barcode requirements in the special conditions of contract applicable to contracts for pharmaceuticals. The Global Trade Item Number™ (GTIN™) Datamatrix barcode is used for the unique identification of trade items worldwide and leverages existing global standards. The requirement seeks to enable end-to-end data visibility, identify and implement supply chain efficiencies, ensure supply chain security and improve patient safety.

The phasing in of GTIN-14 Datamatrix barcodes aim to improve transparency and increase efficiencies across the entire supply chain of medical products for NDOH, provincial departments of health, manufacturers, wholesalers, distributors, providers, and patients. It will also ensure standardisation thereby increasing the competitiveness of local manufacturers on the international level. This document serves as a request for information and comment regarding implementation of GTIN-14 Datamatrix barcodes.

2. Background

Patient safety and the security of supply of medicines are of paramount importance within the health sector. To this end, it is important that mechanisms are explored and implemented to assist in satisfying these requirements. There is thus a need to be able to track and trace health products through the supply chain, and provide assurance that the product being used or consumed by the patient is indeed the genuine product.

According to Interpol International on a global level, there is a "*Significant increase in the manufacture, trade and distribution of counterfeit, stolen and illicit medicines and medical devices. Patients across the world put their health, even life, at risk by unknowingly consuming fake drugs or genuine drugs that have been doctored, badly stored or that have expired*".[1] Pharmaceutical crime involves the manufacture, trade and distribution of fake, stolen or illicit medicines and medical devices. It encompasses the counterfeiting and falsification of medical products, their packaging and associated documentation, as well as

[1] https://www.interpol.int/Crime-areas/Pharmaceutical-crime/Pharmaceutical-crime

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Pharmaceutical crime involves the manufacture, trade and distribution of fake, stolen or illicit medicines and medical devices. It encompasses the counterfeiting and falsification of medical products, their packaging and associated documentation, as well as theft, fraud, illicit diversion, smuggling, trafficking, the illegal trade of medical products and the money laundering associated with it. [2]

Unique identification provides an opportunity to differentiate, in a machine readable form, an item's identification. Such information is rapidly becoming a pre-requisite, when linked with the item's batch number (or unique serial number) and expiration date, for traceability of all healthcare products from production to delivery to the patient (point of care).

A trade item is any item (product or service) upon which there is a need to retrieve pre-defined information and that may be priced, or ordered, or invoiced at any point in any supply chain. This includes individual items as well as all their different configurations in different types of packaging. The Global Trade Item Number™ (GTIN™) is used for the unique identification of trade items worldwide. It is seen as an internationally accepted method of identifying products, serialising shipping containers and clearly communicating other important business transaction data such as purchase order numbers, expiration dates, lot numbers, etc. in a standard, machine readable (barcode) format. [3]

The data structure of a GTIN require up to 14- digit fields. All GTIN processing software should allow for 14 digits. GTINs uniquely identify items that are traded (Pharmaceuticals, Medical Devices, etc.) in the supply chain. Integrity of these numbers throughout the item's lifetime is a key to maintaining uniqueness for manufacturers, wholesalers, distributors, hospitals, regulatory bodies and other supply chain stakeholders. A change to one aspect, characteristic, variant or formulation of a trade item may require the allocation of a new GTIN.[4]

3. Current requirements

As per the proposed draft regulations intended to give effect to the Medicines and Related Substances Amendment Act, 2008 (Act No, 72 of 2008), and the Medicines and Related Substances Amendment Act, 2015 (Act No. 14 of 2015), in accordance with the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) gazetted on 27 January 2017, Labelling of medicines intended for human use, section 8(1)(p) states that "a barcode suitable for the identification and tracking of medication as determined by the Authority;"[5].

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[1] https://www.interpol.int/Crime-areas/Pharmaceutical-crime/Pharmaceutical-crime
[2] https://www.interpol.int/Crime-areas/Pharmaceutical-crime/Pharmaceutical-crime
[3] http://www.gs1.org/docs/gsmp/healthcare/GS1_Healthcare_GTIN_Allocation_Rules.pdf
[4] http://www.gs1.org/docs/gsmp/healthcare/GS1_Healthcare_GTIN_Allocation_Rules.pdf
[5] http://www.gov.za/documents/medicines-and-related-substances-act-regulations-general-comments-invited-27-jan-2017-0000

Current mandatory contracting requirements stipulated by the National Department of Health require all products supplied to include a barcode (number plus symbology). In terms of the special requirements and conditions of contract shipper, shelf and unit packs must be marked with the appropriate number and symbology. The European Article Number (EAN-13) barcode system is currently accepted as the standard.

Extract from current special conditions of contract

BARCODES

It is mandatory that all products supplied must include a barcode (number plus symbology). All shipper, shelf and unit packs must be marked with the appropriate number and symbology. The European Article Numbering Code 13 (EAN 13) has been accepted as standard.

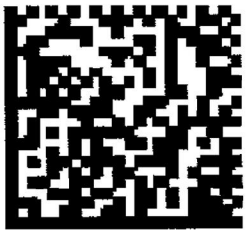
Suppliers are encouraged to include a 2D barcode or similar on their packaging that will include the following information:

a) Item name as contained in the contract circular and the Master Procurement Catalogue (MPC);
b) Registered product name (if applicable);
c) Dosage form and strength;
d) Pack size;
e) Batch number;
f) Expiry date.

4. Proposed new requirements and timelines

This requirement would mean that the current scenario of an EAN-13 (European Article Number) barcode which identifies the package at an item level will be replaced with a GTIN-14 (Global Trade Item Number) barcode as a means of identification. The GTIN-14 barcode will include batch/lot and expiry data, and eventually a unique serial number.

EAN-13 Barcode



(01) 07046261398572
(10) TEST5632
(17) 130331
(21) 19067811811

GTIN-14 Datamatrix Barcode

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:

TERTIARY PACKAGING – TRADE ITEM (PALLET OR CASE). 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:

Application Identifier	**Implementation Date**
(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

SECONDARY PACKAGING – MULTI-PACK AND/OR SINGLE-PACK CARTON. The minimum GS1 Identification Key and AI to be included in a GS1 Datamatrix, with the applicable HRI printed adjacent:

Application Identifier	**Implementation Date**
(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

5. Rationale

Using the GTIN simplifies supply chain management and provides accuracy, speed, and efficiency throughout the healthcare system. This allows for the following forward thinking initiatives that will align with the NHI implementation and roll-out.

The benefits of implementing a GTIN-14 Datamatrix barcoding system for identification purposes allows for the following across the supply chain of medicine and devices:

Automatic Data Capture: One of the key benefits of the GTIN is that it can be encoded in many automatic data capture (AIDC) technologies (such as a barcodes, datamatrix or radio frequency identification (RFID) tags). Scanning allows the information flow to be linked to the physical flow of trade items through the supply chain[6]

Data Integrity: The Check Digit ensures the integrity of data passing into the system.

Uniqueness: The GTIN identifies an item uniquely. The rules for assigning GTINs ensure that every variation and packaging level of an item (product or service) is allocated a single reference number that is globally unique.

Facilitates accuracy: Use of the GTIN improves scanning at clinic, warehouse, or hospital level. It is also essential for accurate stock control, order replenishment and management of expiry dates.
Multi-sectoral: GTINs are unique across all business sectors and an assigned GTIN and can be used anywhere in the world.

Security: Security of GTINs is provided through a combination of database lookup and the fixed length, numeric format that includes a standard Check Digit.

Source Numbering: The GTIN is enumerated by the brand owner of the product using their GS1 Company Prefix. Once assigned, all trading partners and internal users can use the GTIN. The same GTIN can be used to identify a series of identical items.

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https://www.gs1us.org/DesktopModules/Bring2mind/DMX/Download.aspx?command=core_download&entryid=174&language=en-US&PortalId=0&TabId=134

6. Concluding remarks

These guidelines serve as the barcoding requirements for the NDoH for the special requirements conditions of contract. All additional information and comment is welcomed by the NDoH.

For additional information pertaining to the requirements of GTIM-14 barcode datamatrix, please refer to the following:

- GS1 Healthcare Conferences
  - GS1 Healthcare Conference, 17-19 October 2017, Chicago, U.S
  - GS1 Healthcare Conference, 10-12 April 2018, Bogotá, Colombia
- GS1 South Africa
  - https://www.gs1za.org
- McKinsey Report
  - Strength in unity: the promise of global standards in healthcare
- GHSC-PSM Contract Requirements
  - *Announcement of Intention to Implement Global Standards for Product Identification and Labeling*
- GHSC-PSM Supplier Summit Presentation
  - *Implementation of Global Standards for Product Identification*
  - *You Say Data, I Say Data – Streamlined Data Exchange with PSM*
- Reproductive Health Global Traceability Advisory Group (RH GTAG)
  - *Identification Recommendations for Reproductive Health Pharmaceutical Products*
- Vaccine Presentation and Packaging Advisory Group (VPPAG)
  - *Generic Preferred Product Profile for Vaccines*