South African Health Products
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GUIDELINE ON TRACEABILITY OF HEALTH PRODUCTS

The purpose of the document is to guide the implementation of global standards for product identification, data capture, and data sharing. It represents the South African Health Products Regulatory Authority's (SAHPRA)'s current thinking on the safety, quality and efficacy of medicines. The implementation of unique product identification will enable efficient data capturing, enhance end-to-end supply chain efficiencies, and improve patient safety.

Document History

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Contents

Glossary

Term	Meaning
Aggregation	Defines the relationship between the unique identifiers for parent and child packaging hierarchies, where each packaging level will carry a unique identifier encoded in a data carrier uniquely identified, allowing the receiver of the product to scan one code and understand exactly what is in the whole shipment—every case, bundle, or individual carton.
Automatic identification and data capture (AIDC)	A technology used to automatically capture data. AIDC technologies include barcodes, smart cards, biometrics, and radio frequency identification devices.
Barcodes	A symbol that encodes data into a machine-readable pattern of adjacent, varying-width, parallel, rectangular dark bars and pale spaces.
Batch number/lot number	The batch or lot number associates an item with information that the manufacturer considers relevant for the traceability of the trade item. The data may refer to the trade item itself or to items contained in it.
Data capture	The process of collecting data about products. This includes data to be encoded into a data carrier to be affixed to an instance of a product package, as well as data read from existing data.
Data carrier	It is a standardised, machine-readable format for encoding and storing data about products, locations, and other entities within a supply chain.
Data exchange	The sharing/ movement of structured data from one party to one or more other parties.
Data Matrix	A standalone, 2D matrix symbology that is made up of square modules arranged within a perimeter finder pattern. GS1 Data Matrix symbols are read by 2D imaging scanners or vision systems.
Expiry date	The date up to which a medicine will retain the strength and other properties stated on the label which strength and other properties can change after the lapse of time, and after which date the medicine shall not be sold to the public or used.
Falsified	Products that deliberately/ fraudulently misrepresent their identity, composition, or source(WHO).
Function 1 Symbol Character (FNC1)	When used as the first character, Function 1 Symbol Character (FNC1) indicates that the barcode follows the GS1 standard, allowing the scanner to properly decode it. It is also used as a separator between specific. Application Identifiers that do not have a fixed character count (e.g., AI (10) Batch/Lot, AI (21) Serial Number).
Global data standards/ "family" of standards	A set of standards specifically defined as working together coherently to facilitate a specific purpose, i.e., secure commerce within a supply chain.
Global Trade Item Number (GTIN)	The GS1 identification key is used to identify trade items. The key comprises a GS1 Company Prefix, an item reference, and a check digit.
Global/ globally unique product	A product code that cannot be assigned to more than one product throughout the world because it is defined by elements that are controlled via a global assignment agency and the manufacturer.
GS1	A neutral, not-for-profit, global organisation that develops and maintains the most widely used supply chain data standards in the world.

GS1 Application Identifier (AI)	The field of two or more digits at the beginning of an element string that uniquely defines its format and meaning.
GS1 Member Organisation	A member of GS1 who is responsible for administering the GS1 system in its country (or assigned area). This task includes, but is not restricted to, ensuring user companies make correct use of the GS1 system; have access to education, training, promotion, and implementation support; and have an opportunity to play an active role in the Global Standards Management Process.
GS1-128 linear barcode	A barcode symbology using bars and spaces in one dimension that leverages a subset of Code 128, which uses the function that allows the encoding of element strings.
Health care primary packaging	The first level of packaging for the product is marked with an AIDC data carrier either on the packaging or on a label affixed to the packaging. For non-sterile packaging, the first level of packaging can be in direct contact with the product. For sterile packaging, the first level of packaging can be any combination of the sterile packaging system and may consist of a single item or group of items for a single therapy, such as a kit. For packaging configurations that include a retail consumer trade item, primary packaging is a packaging level below the retail consumer trade item.
Health care secondary packaging	A level of packaging marked with an AIDC carrier that may contain one or more primary packages or a group of primary packages containing a single item.
Health establishment	The whole or part of a public or private institution, facility, building, or place, whether for profit or not, that is operated or designed to provide inpatient or outpatient treatment, diagnostic or therapeutic interventions, nursing, rehabilitative, palliative, convalescent, preventative, or other health services.
Human Readable Interpretation (HRI)	Characters, such as letters and numbers, that can be read by people and are encoded in GS1 AIDC data carriers confined to a GS1 standard structure and format. The HRI is a one-to-one illustration of the data encoded in a data carrier. However, start, stop, shift, and function characters, as well as the symbol check character, are not shown in the HRI.
Interoperability	The ability to exchange product traceability information accurately, efficiently, and consistently among trading partners in a supply chain and/ or authorised regulators.
Item	Any item (product or service) upon which there is a need to retrieve pre-defined information and that may be priced, ordered, or invoiced at any point in any supply chain.
Logistic unit	An item of any composition established for transport and/ or storage of pharmaceuticals that needs to be managed through the supply chain. It is identified with an SSCC.
Manufacturer	A person manufacturing a medicine, including a manufacturing pharmacy (compounding).
Package	Any article that may be used for filling, inserting, wrapping, or packing regulated products and includes the immediate container and other wrapping materials.
Packaging levels	The hierarchy of product packaging. Each level includes a specific way of protecting and identifying the product during different types of handling. Recognised levels include “primary”, “secondary”, and “tertiary”.
Pharmaceutical	Any substance or mixture of substances: a) used in the diagnosis, treatment, mitigation, or prevention of human disease, disorder, abnormal physical or mental state, or the symptoms thereof b) used

	in restoring, correcting, or beneficial modification of organic or mental functions in humans c) articles other than food, intended to affect the structure or any function of the body of humans Includes articles intended for use as a component of any articles specified in clause a), b), or c)
Primary pack	The product packaging that touches the dose, i.e., a blister pack and/or a vial. If no secondary pack exists, then the primary pack is usually the lowest saleable pack.
Secondary pack	The layer of packaging surrounding the primary package. It may be used for presentation and branding or for additional mechanical protection that the primary package might not be able to provide. May contain one or more primary packages.
Serial number	A code, numeric or alphanumeric, assigned to an individual instance of an entity for its lifetime. Example: microscope model AC-2 with serial number 1234568 and microscope model AC-2 with serial number 1234569. A unique individual item may be identified with the combined Global Trade Item Number (GTIN) and serial number.
Serial Shipping Container Code (SSCC)	The GS1 identification key is used to identify logistic units. The key comprises an extension digit, GS1 Company Prefix, serial reference, and check digit.
Serialisation	The processes and results of defining, assigning, and affixing unique serial numbers to product packaging at any level. A unique number that identifies a single instance of a product.
Tertiary homogeneous pack	A tertiary pack that consists entirely of the same trade item with the same batch number and expiry date.
Tertiary mixed pack	A tertiary pack that contains either more than one unique trade item or entirely the same trade item with different batch numbers or expiry dates.
Tertiary packaging	The highest level of packaging that may include a pallet that contains (one or usually) several cases or a case that contains (one or usually) several items in its primary or secondary packaging.
Tertiary partial pack	A homogeneous pack of products that is not to be considered a trade item because it is less than full.
Trace	The ability to know where a product has been within a supply chain before its current location.
Traceability	The capability to trace something. In some cases, it is interpreted as the ability to verify the history.
Track	The ability to know where a product is right now.
Track and trace	A type of traceability model that attempts to track and trace products through a supply chain.
Trade item	A product or a homogeneous grouping of a product that is identified so that it may be treated as a “quantity one” unit for registration, listing, marketing, sales, shipment, billing, and other value chain and supply chain applications. Not all homogeneous groupings are trade items. Trade items are products and services for which there is a need to retrieve predefined information and that may be priced, ordered, or invoiced at any point in the supply chain.

Trading partner	Supply chain stakeholders that engage in the purchase, sale, and donation of products between each other.
Unique identifier	A numeric or alphanumeric string captured in a machine-readable data carrier and human-readable form on the label of the pharmaceutical package that is associated with a single product or product group. In this instance, the unique identifier refers to the combination of GTIN with Expiry Date, Batch/ Lot, and serial number.

Abbreviation	Meaning
AI	GS1 Application Identifier
AIDC	Automatic Identification and Data Capture
EAN	EAN International, now called GS1
FNC1	Function 1 Symbol Character
GDSN	Global Data Synchronisation Network
GLN	Global Location Number
GTIN	Global Trade Item Number
HRI	Human Readable Interpretation
IDMP	Identification of Medicinal Products
NDoH	National Department of Health
SAHPRA	South African Health Products Regulatory Authority
SSCC	Serial Shipping Container Code

1. INTRODUCTION

Patient safety and the security of the supply of medicines are of paramount importance within the health sector. To this end, modern mechanisms must be explored and implemented to satisfy these requirements within the South African Health Products Regulatory Authority (SAHPRA). There is thus a need to be able to track and trace health products (orthodox medicines, biological products, complementary medicines, and veterinary medicines) through the supply chain and provide documented assurance that the product being dispensed or consumed by the patient is indeed a genuine product.

Unique product identification provides an opportunity to differentiate a product's identification in a machine-readable form. Such information is rapidly becoming a prerequisite when linked with the product's batch number, unique serial number, and expiry date for traceability of pharmaceutical products from production to delivery to the point of care.

1.1 Purpose

The aim is to implement the unique product identification and medicine monitoring system for all medicines used in South Africa by adopting the ISO/IEC 15416:2016 and ISO/IEC 15415:2011, which specifies the methodology for the measurement of specific attributes of bar code/ GS1 Data Matrix symbols together with GS1 standards for product identification, data capture, and data exchange.

The implementation of unique product identification and barcodes aims to improve transparency and increase efficiency across the supply chain of medical products for the public and private health sector, including manufacturers, wholesalers, distributors, health care providers, insurers, and patients. It will also ensure standardisation, thereby increasing the competitiveness of local manufacturers at the international level. The implementation will be phased, starting with batch-level identification and moving towards unit/ product-level serialization.

The requirements seek to harmonise with the global health market to:

- enable end-to-end supply chain data visibility,
- identify and implement supply chain efficiencies,
- ensure supply chain security, and
- improve patient safety.

1.2 Scope

This guideline details the scope and approach for the implementation of product identification for all health products regulated by SAHPRA. This guideline further aims to map out the requirements for product identification, data capturing, and sharing.

It applies to all health products in the South African market except for:

- Whole blood and blood components,
- Homeopathic medicines and allied substances,
- Extemporaneous preparations,
- Medicines imported for personal use only are subject to authorisation by the Authority,
- Unregistered medicines imported by special authorisation from the Authority,
- Donated medicines imported for emergency cases are subject to authorisation by the Authority.
- Products manufactured and labelled before their unique identification compliance effective dates,
- Food and related supplements,
- Investigational drugs,
- Any other product the Authority may determine.

The following areas are out of the scope of this document:

- Requirements for implementation of data capturing at downstream health establishments,
- Master data systems to enable data capture and sharing, and
- Requirements for interoperability of systems at all levels.

2. LEGAL PROVISION

This document is informed by the following legislative and policy provisions:

2.1 Medicines and Related Substances Act 1965 (Act No 101 of 1965)

- **Section 18 of the Act - Labels and advertisements, states that**

- *(1) No person shall sell any medicine or Scheduled substance unless the immediate container or the package in which that medicine or a Scheduled substance is sold bears a label stating the prescribed particulars.*
- *(3) The label referred to in subsection (1) shall be approved by the Authority.*
- *(4) The Authority may authorize a deviation from the prescribed format and contents of any lab.*
- *(5) The Minister may prescribe additional requirements for the labelling of medicines, medi cal devices, or IVDs.*

- **Section 19(2) of the Act states that:**

  - *(2) The Authority may by notice in writing require any person who manufactures or sells medicines, medical devices or IVDs or administers or prescribes any medicine, medical device or IVD or on whose direction any medicine or medical device is administered to furnish it, within a period stipulated in such notice, with any information which such person has in his or her possession or which such person is in a position to obtain regarding such medicine, medical device or IVD.*

2.2 General regulations relating to medicines, 25 August 2017 (Government Gazette 41064, Vol 626)

- **Section 10(1)(p) states that:**

  - *"a GS1 barcode suitable for the identification and tracking of medication: Provided that where such barcode appears on the outer label, it may be excluded on the immediate container label".*

2.3 Regulations relating to a transparent pricing system for medicines and scheduled substances, Regulation 21(2)

The Director-General may publish or otherwise communicate, or require manufacturers, importers, wholesalers, distributors, pharmacists or persons licensed in terms of section 22C(l)(a) of the Act to publish or otherwise communicate in such manner and format as he or she may by notice in the Gazette determine, information in relation to a particular medicine or Scheduled substance or class or category of medicines or Scheduled substances or the sale of a medicine or Scheduled substance for the purpose of informing the public on the following matters –

(a) the availability of a medicine or Scheduled substance;

(b) the pricing system contemplated in section 22G of the Act;

(c) the supply chain for a medicine or Scheduled substance;

(d) the fees charged by wholesalers, distributors, retailers, and other persons selling medicines or Scheduled substances;

(e) the country from which a medicine or Scheduled substance is sourced.

3. REQUIREMENTS FOR THE IMPLEMENTATION OF PRODUCT IDENTIFICATION, CAPTURE AND DATA SHARING

3.1 General Requirements

3.1.1 All health products that are manufactured and/ or distributed in South Africa shall be identified with a GS1 unique identifier. Except those products defined under Section 1.2.

3.1.2 The manufacturer shall maintain records about each of such unique identifiers up to five (5) years after the expiry of a trade item to which the unique identifier is affixed or imprinted and provide those records to SAHPRA upon request.

3.1.3 Labelling with the unique identifier of a trade item shall be applied to the product before the product enters the South African supply chain.

3.1.4 When a new trade item is created by co-packing of two or more physical items (e.g., creating a kit, overpacking), the authorised and approved re-packager shall link the original unique identifier and assign a new unique identifier.

3.1.5 The unique identification data carrier for all secondary and higher packaging levels in scope shall remain on or attached to the pharmaceutical product throughout the life cycle.

3.1.6 The GS1 General Specifications shall be used to construct a unique identifier in the data carrier, which allows the identification and accurate decoding of each data element of which the unique identifier is composed.

3.1.6.1 The unique identifier of the primary package, where necessary, shall be encoded in a GS1 Data Matrix.

3.1.6.2 The unique identifier of the secondary package shall be encoded in a GS1 Data Matrix.

3.1.6.3 The unique identifier of the tertiary package(s) shall be encoded in a GS1 Data Matrix, and/ or GS1-128 linear barcode. The unique identifier of the logistics unit shall be encoded as stated in the GS1 General Specifications.

3.1.6.4 It is not allowed to use multiple two-dimensional barcodes on a single packaging of an allopathic drug product to identify and verify its authenticity.

3.2 Composition of the Unique Identifier

a) The unique identifier shall be constructed according to the globally accepted GS1 General Specifications.

b) The unique identifier shall be a sequence of numeric or alphanumeric characters that are unique to a given primary packaged trade item, secondary packaged trade item, tertiary packaged trade item, or logistic unit.

c) The unique identifier of the primary, secondary, and tertiary packages for pharmaceutical products published by the Authority shall contain the following information:

i. GTIN (Global Trade Item Number)

ii. Batch/ lot number

iii. Expiry date

iv. Manufacturing/ Production date

v. Serial number

vi. Logistic units shall be identified with a Serial Shipping Container Code (SSCC).

d) Notwithstanding Section 3.2(c), the brand owner/ HCR shall notify the Authority of any other information it intends to add to the data carrier.

e) When the logistic unit is an orderable trade item, the logistic unit shall be identified with an SSCC and a GTIN.

f) The relationship between the unique identifiers of different packaging levels shall be captured in the manufacturer's electronic internal systems.

3.3 Data Carriers (Available Product identification keys)

There are multiple product identification keys issued by GS1 to identify products at different levels of packaging:

A) **GS1-128 barcode** – is a linear barcode symbology using bars and spaces in one dimension that leverages a subset of Code 128 that is used exclusively for GS1 system data structures. A linear barcode must be concatenated (i.e., represent all elements of the data string in a single barcode.

Concatenated linear barcode:

B) **The European Article Number (EAN) barcode** – identifies the package at an item level. The GS1 EAN-13 is used at the point of sale to identify the item, consisting of the GS1 prefix, the manufacturer's code, the product code, and the checksum digit, which is part of the artwork of the product. The medicine registration holder must use EAN 13 Barcode Symbology, to be printed in primary print to the item level i.e., secondary packaging. The barcode symbology must be surrounded by sufficient blank space to be scanned correctly, appear in both a human-readable format and as a machine-readable data carrier that conforms to the GS1 global standards.

C) **(01) The GS1 Global Trade Item Number (GTIN)**– is a globally unique product identifier key used worldwide for trade items. (N2+N14)

GS1 AI (01) indicates that the data field contains a GTIN. Batches of unique GTINs are issued to the brand owner by GS1 and are then assigned by the applicant to a unique health product.

Once a brand owner has allocated a GTIN to a trade item, it provides a common language for all its entities and trading partners worldwide to identify the trade item and easily communicate information about the product. The GTIN is also used to identify types of products at any packaging level (e.g., consumer unit, inner pack, case, pallet).

The GTIN may be comprised of 8, 12, 13, or 14 digits. The format of the GTIN-14 is as follows:

GS1 Application Identifier	Global Trade Item Number (GTIN)													
	GS1-8 Prefix or GS1 Company Prefix →							← Item Reference						Check digit
0 1	N_1	N_2	N_3	N_4	N_5	N_6	N_7	N_8	N_9	N_{10}	N_{11}	N_{12}	N_{13}	N_{14}

D) **(00) The serial shipment container code (SSCC)** is the GS1 identification key used to identify logistics units. The key comprises an extension digit, GS1 Company Prefix, serial reference, and check digit. The GS1 Application Identifier (AI) (00) indicates that the data field contains an SSCC. (N2+N18)

The SSCC format is as follows:

GS1 Application Identifier	Serial Shipping Container Code (SSCC)																
	Extension digit	GS1 Company Prefix →									← Serial Reference						Extension digit
0 0	N_1	N_2	N_3	N_4	N_5	N_6	N_7	N_8	N_9	N_{10}	N_{11}	N_{12}	N_{13}	N_{14}	N_{15}	N_{16}	N_{17}	N_{18}

E) **(21) Serial number** - the GS1 AI (21) indicates that the data field contains a serial number. When combined with a GTIN, a serial number uniquely identifies an individual item. The manufacturer determines the serial number. (N2+X..20).

The serial number field is alphanumeric. The character sequence resulting from the combination of the GTIN and the serial number must be unique forever, and it can never be reused.

The format of the serial number is as follows:

GS1 Application Identifier	Serial Number
2 1	X_1 → variable length → X_{20}

F) **(17) Expiry Date** – the GS1 AI (17) indicates that the data field contains an expiry date. (N2+N6)

The structure of the expiry date should be as follows:

Year: the tens and units of the year (e.g., 2003 = 03), which is mandatory

Month: the number of the month (e.g., January = 01), which is mandatory

Day: the number of the day of the relevant month (e.g., second day = 02). Expiry date to be encoded in the format YYMMDD, and a valid date (including the day) should be used.:

GS1 Application Identifier	Expiration Date					
	Year		Month		Day	
1 7	N_1	N_2	N_3	N_4	N_5	N_6

G) **(10) Batch/ Lot** – the GS1 AI (10) indicates that the data field contains a batch or lot number. The batch or lot number field is alphanumeric. (N2+X..20)

The format of the batch or lot number is as follows:

GS1 Application Identifier	Batch or Lot Number
1 0	X_1 → variable length → X_{20}

3.4 SAHPRA requirements for each packaging level

All tertiary and secondary packages are required to be labelled in accordance with the specified barcode requirement, with relevant GS1 Identifiers encoded and printed in their human-readable form.

Barcodes play a key role in supply chains, enabling parties like retailers, manufacturers, transport providers, and hospitals to automatically identify and track products as they move through the supply chain

All barcode symbols should meet print-quality "Grade C" (1.5 or above). As part of the regular manufacturing or production process, barcode symbol print quality and data content must be verified and graded in accordance with the appropriate sections within the GS1 General Specifications.

3.4.1 Primary Pack

The primary packaging, also known as retail packaging, is the first level of packaging for the product marked with an AIDC data carrier either on the packaging or on a label affixed to the packaging. For non-sterile packaging, the first level of packaging can be the packaging in direct contact with the product. For sterile packaging, the first level of packaging can be any combination of the sterile packaging system, which may

consist of a single item or group of items for a single therapy, such as a kit. For packaging configurations that include a retail consumer trade item, primary packaging is a packaging level below the retail consumer trade item. Primary packaging will include simple materials such as blisters, bottles, plastics, and paper. The blister must be marked with a GS1 Data Matrix barcode, either directly on the packaging or on a non-removable label affixed to the packaging.

Identification and labelling of trade items at this level is a preferred characteristic unless the supplier is providing items in "carton-less packaging" (i.e., without a secondary packaging level, in which case it is mandatory).

Marking trade items at this level is also recommended where the secondary package will likely be opened or removed before being dispensed to one or several patients (e.g., a display carton is opened, and individual or split blister packs are distributed to patients).

Example of a GS1 Data Matrix for a trade item on Primary Packaging:

(01) 10857674002017
(17) 251231
(10) NYFUL01
(21) 192A837H7

AI	Description	Required by
01	GTIN (*all health products)*	No later than 2 years for imported health products and 4 years for domestically manufactured health products from the date of publication of the guideline
17	Expiry Date (*all health products)*	No later than 2 years for imported health products and 4 years for domestically manufactured health products from the date of publication of the guideline
10	Batch/ Lot (*all health products)*	No later than 2 years for imported health products and 4 years for domestically manufactured health products from the date of publication of the guideline
21	Serial Number (*all health products)*	No later than 2 years for imported health products and 4 years for domestically manufactured health products from the date of publication of the guideline

FNC1 Symbol Character	AI	GTIN	AI	Expiry Date	AI	Batch/ Lot Number	FNC Separator	AI	Serial Number
FNC1	01	10857674002017	17	251231	10	NYFUL01	<GS>	21	21192A837H7

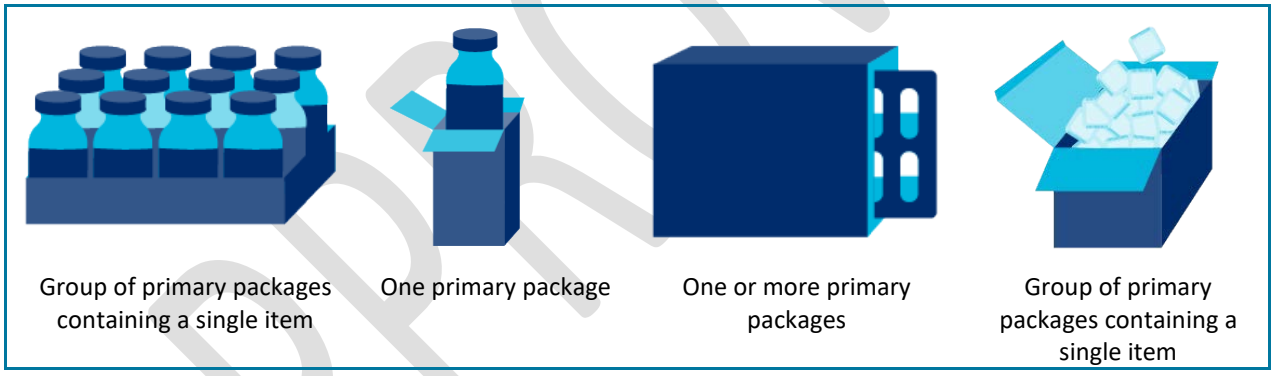
Read via AIDC technology, this example will take on the following format:

]d2011085767400201717251231l0NYFUL01<GS>21192A837H7

3.4.2 Secondary Pack

Secondary packaging is a level of packaging that may contain one or more primary packages, or a group of primary packages containing a single item. The secondary pack is always a trade item. This packaging level is marked with a GS1 Data Matrix, either on the packaging itself or on a label affixed to the packaging.

Primary and secondary packaging often get confused or overlapped with one another. The packs are similar as both including manufacturer branding on the packaging materials. However, while primary packaging is the most immediate form of protection to contain products, secondary packaging is the next layer of retail boxing. Secondary packaging provides the second layer of retail packaging, which also protects against possible damage. For example, if the product is tablets, the primary packaging for the product is the blister pack, and the secondary packaging is the boxed pack of tablets (2 x 8 tablets). The packaging must be marked with a GS1 Data Matrix barcode, either directly on the packaging or on a non-removable label affixed to the packaging.



In-scope medical products can have more than one level of secondary packaging, such as an inner pack (bundles) and intermediate packs (inner case). Identification and marking of inner and intermediate secondary packaging levels is required. Examples of inner or intermediary secondary packaging include, but are not limited to:

AI	Description	Required by
01	GTIN (*all health products)*	No later than 2 years for imported health products and 4 years for domestically manufactured health products from the date of publication of the guideline
17	Expiry Date (*all health products)*	No later than 2 years for imported health products and 4 years for domestically manufactured health products from the date of publication of the guideline
10	Batch/Lot (*all health products)*	No later than 2 years for imported health products and 4 years for domestically manufactured health products from the date of publication of the guideline
21	Serial Number (*all health products)*	No later than 2 years for imported health products and 4 years for domestically manufactured health products from the date of publication of the guideline

Example of a GS1 Data Matrix for a trade item on Secondary Packaging:

(01) 10857674002017
(17) 251231
(10) NYFUL01
(21) 192A837H7

FNC1 Symbol Character	AI	GTIN	AI	Expiry Date	AI	Batch/ Lot Number	FNC Separator	AI	Serial Number
FNC1	01	10857674002017	17	251231	10	NYFUL01	<GS>	21	21192A837H7

Read via AIDC technology, this example will take on the following format:

]d2011085767400201717251231 10NYFUL01<GS>21192A837H7

3.4.2.1 Tertiary Pack

Tertiary packaging refers to upper levels of the packaging hierarchy. A tertiary pack may be:

- A pallet that contains one or several cases
- A case that contains one or several items in the items' primary or secondary packaging

Tertiary packaging may be used as either a logistic unit or as a trade item. Tertiary packages can be homogenous (i.e., consisting entirely of the same trade item, batch or lot, and expiry date), partial (i.e., consisting of a homogenous pack of items that is not to be considered a trade item because it is less than full), or mixed (i.e., either more than one unique trade item or entirely the same trade item with different batch numbers or expiry dates).

For label placement, please refer to Section 8: Label placement" of GS1's logistics label guidelines to fine-

tune the recommendation - https://www.gs1.org/standards/gs1-logistic-label-guideline/1-3.

Tertiary packaging includes more extensive protective materials such as corrugated boxes. A standard shipping unit that contains “eaches” (packaged either individually or grouped as an inner pack). All the items in a case must have the same GTIN. Example: a case containing eight shrink-wrap packs, each containing seven packs of tablets.

3.4.3 Tertiary Pack – Logistics Unit

This packaging is assembled in warehouses where products are securely wrapped and organised on different layers of wooden/plastic pallets to safely store large quantities of stock while shipping merchandise to different distributors and dispensing sites. Example: 8 Shippers on a pallet.

The logistic unit is identified using the SSCC. This packaging level is marked with a GS1 Data Matrix or a GS1-128 linear barcode, either on the packaging itself or on a label affixed to the packaging.

A GS1 Data Matrix may be included in addition to the GS1-128 symbol. When used, the GS1 2D symbol SHALL include all element strings included in the GS1-128 symbol(s), and MAY include additional element strings. If a logistics unit does not have at least one surface area greater than an A6 or 4” x 6” logistic label, a GS1 Data Matrix may be used by itself on a logistic label, though a GS1-128 containing a SSCC is still recommended. If a logistic label is used with only a GS1 Data Matrix, care must be taken to ensure trading partners are able to scan this barcode.

AI	Description	Required by
00	SSCC	No later than 5 years from the date of publication of the guidelines

A Serial Shipping Container Code may be reused after a period of one year, as noted within the GS1 General Specifications.

An example of this in practice:

Encoded in the data carrier, this example will take on the following format:

FNC1 Symbol Character	AI	GTIN	AI	Expiry Date	AI	Batch/ Lot Number	FNC Separator	AI	Serial Number

FNC1	01	10857674002017	17	251231	10	NYFUL01	<GS>	21	21192A837H7

Read via AIDC technology, this example will take on the following format:

]C1000061414112345678 90

3.4.3.1 Tertiary Pack – Trade Item

Trade items are products and services for which there is a need to retrieve predefined information and that may be priced, ordered, or invoiced at any point in the supply chain.

The tertiary package trade item will typically be a case or carton but may also be a shrink-wrapped tray or another configuration.

The GS1 Data Matrix barcode must contain the following (and printed adjacent to it in Human Readable format):

AI	Description	Required by
01	GTIN/ (*all health products)*	No later than 2 years for imported health products and 4 years for domestically manufactured health products from the date of publication of the guideline
17	Expiry Date (*all health products)*	No later than 2 years for imported health products and 4 years for domestically manufactured health products from the date of publication of the guideline
10	Batch/ Lot (*all health products)*	No later than 2 years for imported health products and 4 years for domestically manufactured health products from the date of publication of the guideline
21	Serial Number (*all health products)*	No later than 2 years for imported health products and 4 years for domestically manufactured health products from the date of publication of the guideline

An example of this in practice:

(01) 10857674002017
(17) 251231
(10) NYFUL01
(21) 192A837H7

(01)10857674002017(17)251231(10)NYFUL01(21)192A837H7

Encoded in the data carrier, these examples will take in the following format:

	AI	GTIN	AI	Expiry Date	AI	Batch/ Lot Number	FNC Separator	AI	Serial Number
FNC1	01	10857674002017	17	251231	10	NYFUL01	<GS>	21	21192A837H7

Read via AIDC technology, this example will take on the following format:

]d201108576740020171725123110NYFUL01<GS>21192A837H7

The character sequence resulting from the combination of the product identifier and the serial number shall be unique to a given pack of a medicine.

SAHPRA shall not stipulate the order in which data is encoded into the data carrier.

However, for the most efficient encoding, it is recommended to have fixed-length data elements precede variable-length elements. In this instance where a tertiary pack trade item is also considered a logistics unit, the SSCC can be applied in lieu of the serialised GTIN.

Stakeholders shall notify the Authority if they need to add information other than the four data elements described above in the unique identifier.

3.4.4 Multi-pack

Intermediate package of multiples of the same trade item or a predefined assortment of trade items (representing a single GTIN). The inner pack is NOT traditionally sold to consumers (e.g., seven packs of tablets for shipping/ receiving only).

3.5 Data Capture

All packages are required to be labelled in accordance with the specified barcode requirement, encoded with relevant GS1 application identifiers, and printed in their human-readable form. The data carrier must be a two-dimensional barcode. The GS1 Data Matrix symbology must be unique per product, which can be scanned at fixed points along the supply chain, encoded with the GTIN and other data elements such as the batch number, expiry date, and serial number.

The benefits of implementing a GTIN-14 GS1 Data Matrix barcoding system for identification purposes allow for the following across the medicine supply chain:

- **Automatic Identification and 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 barcode or radio frequency identification (RFID) tags). Scanning allows the data exchange to be linked to the physical flow of trade items through the supply chain.

- **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 globally unique product identifier.

- **Data accuracy**: Use of the product ID scanning across the supply chain assists in improving inventory management accuracy, order replenishment and the management of expiry dates.

- **Multi-sectoral**: GTINs are unique across all business sectors, and an assigned GTIN can be used anywhere in the world.

- **Source Numbering:** The GTIN is enumerated by the market authorisation holder of the product using their GS1 Company prefix. Once assigned, all trading partners and internal users can use GTIN.

3.6 Requirements for Medicines and Location Master Date Data Sharing

This section guides manufacturers, holders of certificate of registration, and/ or other supply chain stakeholders on the collection and submission of product and GS1-based trade item master data to SAHPRA to be displayed on the Health Product Registration database - including GTINs and relevant Global Location Numbers (GLNs) for Health products that are procured/ manufactured and/ or distributed in the South African market.

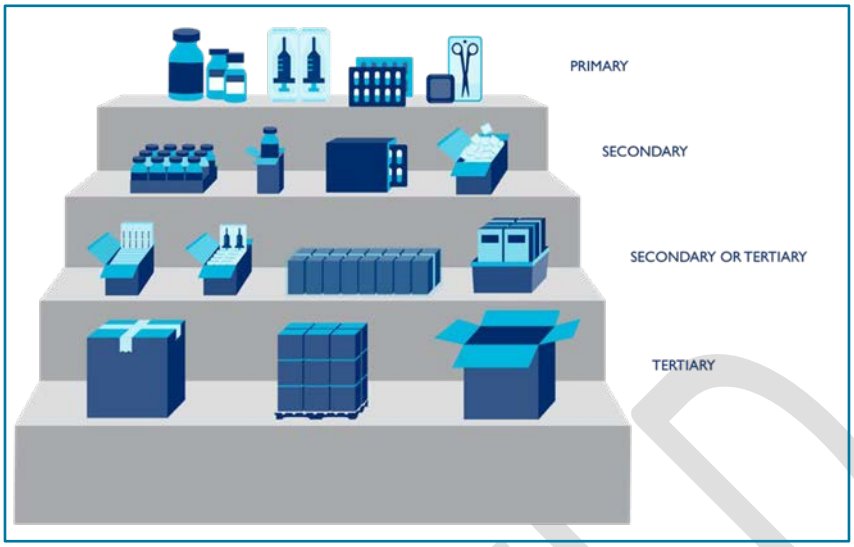
3.6.1 Steps for Sharing Product and Location Master Data with SAHPRA

To synchronise data with SAHPRA, the applicants are advised to undertake the following actions:

- Assign a GLN for each of the relevant locations or legal entities, including local Applicant **and** manufacturing site(s). GLN (Global Location Number) for the specific production or service site (health product manufacturing site).

- Assign a GTIN to each level of the trade item packaging hierarchy (e.g., each inner, case, pallet).

An example of a trade item packaging hierarchy in the healthcare context is:



Gather the product and location attribute data on each trade item packaging hierarchy level. **Note** that these attributes are based on the GS1 Global Data Synchronisation Network (GDSN) standard.

Ensure that the IDMP Health Product Master data is provided to SAHPRA during the new product registration process or any amendment submissions where IDMP health product data attributes are affected. This will be done via the SAHPRA portal.

Further data integration and information sharing requirements will be captured as updates to this guideline under Section 3.6.

4. The use of Human Readable Interpretation (HRI) PHASED IMPLEMENTATION

The implementation will be phased, starting with batch-level identification, and in time, will move to unit-level identification. It is envisioned that the implementation will be phased according to the following timeframes:

- Batch-level identification:
  - *GTIN-14, expiry date, and batch number for primary, secondary, and homogenous tertiary packaging – xxx*
  - *SSCC for mixed or logistics unit tertiary packaging – xxx*
- Unit-level identification:
  - *Serialised GTIN – xxx*
  - *Serialised SCCC*

Additionally, the implementation will be phased and staggered according to medicine categories.

An Implementation Roadmap will be published in support of the Guideline.

5. REFERENCES

The following related documents are referenced:

5.1 **GS1 General Specification** - This resource is the primary document that details the foundational GS1 standards that define how identification keys, data attributes, and barcodes must be used in business applications. https://www.gs1.org/standards/barcodes-epcrfid-id-keys/gs1-general-specifications

5.2 **10 Steps to Barcode your product** - This resource provides a step-by-step instruction for implementing AIDC on your products. https://www.gs1.org/standards/barcodes/10-steps-to-barcode-your-product/english

5.3 **GTIN Healthcare Allocation Rules** - This resource provides the rules for assigning GTINs to trade items in the health sector. https://www.gs1.org/standards/gs1-healthcare-gtin-allocation-rules-standard/current-standard

5.4 **Global Health Standards Technical Implementation Guideline for Global Medical Products** - This resource was developed by a set of international procurement agents in the global health community to support suppliers in meeting their AIDC requirements. It includes several technical references and a Frequently Asked Questions section that may be useful to Applicants in their implementation. http://ghsupplychain.org/global-standards-technical-implementation-guideline-global-health-commodities-v21

6. VALIDITY

This guideline is valid for a period of five (5) years from the effective date. It will be reviewed within this timeframe or as and when required.