

COMMUNICATION TO STAKEHOLDERS

Issue No.: HPA16-2025/26

29 September 2025

Traceability Guideline – Implementation Roadmap

DOCUMENT HISTORY

First Publication – Version 1	17 September 2025
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INTRODUCTION

Dear Applicants,

This roadmap outlines the phased implementation of unique product identification requirements for all health products in South Africa, transitioning from batch-level to unit-level serialisation across primary, secondary, and tertiary packaging levels.

Implementation Timeline Overview

Phase 1: Batch-Level Identification (2025-2029)

- **Focus:** GTIN-14, expiry date, and batch number implementation

Phase 2: Unit-Level Serialisation (2027-2031)

- **Focus:** Addition of unique serial numbers to create fully serialised products

Detailed Implementation Milestones

PRIMARY PACKAGING

First level packaging (blisters, bottles, direct product contact)

Milestone	Imported Products	Domestic Products	Requirements
Batch Level	1 October 2027	1 October 2029	GTIN (01) + Expiry Date (17) + Batch/Lot (10)
Unit Level	1 October 2029	1 October 2031	Above + Serial Number (21)
Data Carrier	GS1 Data Matrix required on packaging or non-removable label		

SECONDARY PACKAGING

Retail packaging containing one or more primary packages

Milestone	Imported Products	Domestic Products	Requirements
Batch Level	1 October 2027	1 October 2029	GTIN (01) + Expiry Date (17) + Batch/Lot (10)
Unit Level	1 October 2029	1 October 2031	Above + Serial Number (21)
Data Carrier	GS1 Data Matrix required on packaging or affixed label		

TERTIARY PACKAGING - TRADE ITEMS

Cases, cartons, shipping containers sold as trade items

Milestone	Imported Products	Domestic Products	Requirements
Batch Level	1 October 2027	1 October 2029	GTIN (01) + Expiry Date (17) + Batch/Lot (10)
Unit Level	1 October 2029	1 October 2031	Above + Serial Number (21)
Data Carrier	GS1 Data Matrix and/or GS1-128 linear barcode		

TERTIARY PACKAGING - LOGISTICS UNITS

Pallets, large shipping units for distribution

Milestone	All Products	Requirements
SSCC Implementation	1 October 2030	Serial Shipping Container Code (00)
Data Carrier	GS1 Data Matrix or GS1-128 linear barcode	

Key Implementation Requirements

Technical Standards

- All barcodes must meet print-quality "Grade C" (1.5 or above)
- GS1 General Specifications compliance mandatory
- ISO/IEC 15416:2016 and ISO/IEC 15415:2011 standards adoption

Data Elements Required

- **GTIN (01):** Global Trade Item Number
- **Expiry Date (17):** Format YYMMDD
- **Batch/Lot (10):** Alphanumeric, up to 20 characters
- **Serial Number (21):** Alphanumeric, up to 20 characters
- **SSCC (00):** For logistics units

Record Keeping

- Manufacturers must maintain unique identifier records for 5 years after product expiry
- Records must be available to SAHPRA upon request

Product Categories and Staggered Implementation

Implementation will be staggered based on imported vs locally manufactured product – as indicated in the guideline.

Excluded Products

- Whole blood and blood components
- Homeopathic medicines and allied substances
- Extemporaneous preparations
- Personal use imports (authorised)
- Emergency donations (authorised)
- Food and related supplements
- Investigational drugs

Compliance Checkpoints

A Declaration Letter will be required by all applicants, indicating the completion of the key activities. A template will be provided to applicants.

October 2026

- Industry readiness assessment
- GS1 membership verification
- System capability evaluation

April 2027

- Pre-implementation testing phase
- Data sharing protocols establishment
- Trading partner alignment

October 2027

- Phase 1 compliance for imported products
- Batch-level identification mandatory

October 2029

- Phase 1 compliance for domestic products
- Phase 2 initiation for imported products

October 2031

- Full serialization compliance for all products
- Complete traceability system operational

Data Sharing Requirements to note:

Further enhancements to the SAHPRA Portal will be undertaken to accommodate the data sharing requirements.

Master Data Submission

- Global Location Numbers (GLN) for all relevant locations
- GTIN assignment for each packaging level
- IDMP health product data via SAHPRA portal
- Integration with Health Product Registration database

Ongoing Compliance

- Real-time data capture at supply chain touchpoints
- Aggregation relationships between packaging levels
- Trading partner data exchange protocols

For any further information, please feel free to reach out to the Senior Manager and Unit Manager for Regulatory Compliance or the COO at SAHPRA.

Industry webinars will be scheduled to discuss the data sharing requirements once the ICT ecosystem scoping has been completed.

Regards,




Christelna Reynecke

Chief Operating Officer

SAHPRA

Date: 29 September 2025