



PHARMACY AND POISONS BOARD

**STANDARDS FOR AUTHENTICATION AND TRACEABILITY OF HEALTH
PRODUCTS AND TECHNOLOGIES**

September 2025

CEO/EIU/STD/001	STANDARDS FOR AUTHENTICATION AND TRACEABILITY OF HEALTH PRODUCTS AND TECHNOLOGIES	REVISION NO: 0	Effective Date: --/--/---- Review Date: --/--/----
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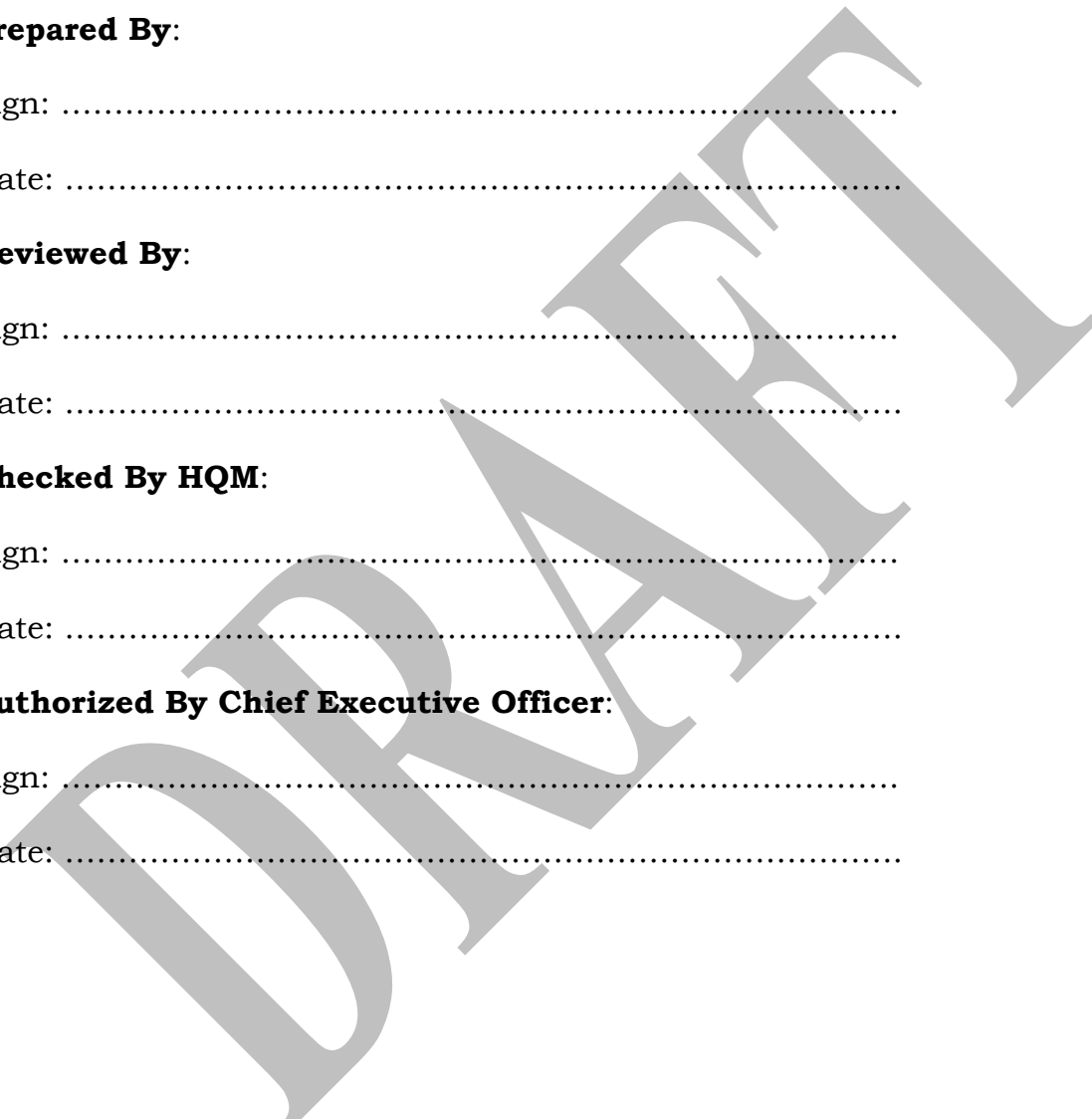
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Acronyms and Abbreviations

A&T – Authentication and Traceability
AU – Africa Union
EPC – Electronic Product Code
EPCIS – Electronic Product Code Information Services
ERP – Enterprise Resource Planning
EU – European Union
FDA – Food and Drug Authority
FNC – Functional Code
GS1 – Global Standards International
GTIN – Global Trade Item Number
HCP – Health Care Provider
HIPAA – Health Insurance Portability and Accountability Act
HPT – Health Products and Technologies
ISO – International Organisation for Standardisation
KRA – Kenya Revenue Authority
ODPC - Office of the Data Protection Commissioner
PIN – Personal Identification Number
PPB – Pharmacy and Poisons Board
PRIMS – Pharmaceutical Regulatory Information Management System
RFID – Radio Frequency Identification Device
SSCC – Serial Shipping Container Code
VAT – Value-Added Tax
WHO – World Health Organization
WMS – Warehouse Management System

Glossary of Terms

1. Aggregation

The documented parent/child relationships between uniquely identified items and the uniquely identified outer container that they are contained within for the purposes of improving the efficiency of serialization business processes involving data exchange and/or regulatory requirements.

2. Authentication

The act of determining the authenticity of a product or a system user.

3. Authenticity

The quality of a product and labelling, establishing that they are unquestionably genuine.

4. Automatic identification and data capture

The processes used to automate the assignment, marking and capturing (reading) of product identification, through the use of carrier technologies such as barcodes and radio frequency identification tags.

5. Barcodes

A symbol that follows a data carrier standard that allows it to encode a finite amount of data, which may be read repeatedly and reliably to extract the data it contains. There are generally two types of barcodes used in commercial supply chains around the world: linear and two-dimensional.

6. Batch number/lot number

An identifier assigned to a homogeneous quantity of a product that has identical manufacturing and packaging characteristics, including raw materials, manufacturing processes and timing. The batch or lot number associates an item with production 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.

7. Data capture

The process of collecting data about product instances. 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 carriers on one or more product instances at any level of packaging.

8. Data carrier

One of several technologies used to encode and present product identification data on a product package. There are many specific types of data carriers but those used in medical product supply chains generally fall into these categories: linear barcodes, two-dimensional barcodes and radio frequency identification tags.

9. Data exchange/information exchange

The sharing/movement of structured data from one party to one or more other parties. To be successful, all parties must agree in advance on the structure and the data transmission protocol. This is normally the subject of global standards.

10. Data ownership

The recognition of the party that retains ownership rights to a given set of data.

11. Data standard

A published standard that describes the characteristics of a set of data for a particular purpose.

12. Decommissioning

1. The act of documenting the disassociation of a unique identifier from a specific instance of an object class, typically when the object no longer exists or reaches the absolute end of its life cycle (i.e. after destruction or consumption of a product).
2. A type of “visibility event” defined in the GS1 EPCIS standard that documents the decommissioning as defined in 1 above.

13. Expiry date

The latest date that the manufacturer of a product is confident a given instance of the product will meet the published/regulated application.

14. Falsified

Products that deliberately/fraudulently misrepresent their identity, composition or source.

15. Global data standards/“family” of standards

A set of standards specifically defined to work together coherently to facilitate a specific purpose, i.e. secure commerce within a supply chain.

16. Globally unique

Adjective describing something with a characteristic that it is unique throughout the world.

17. Global/globally unique product identifier

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.

18. Governance

The process of developing and enforcing technical rules intended to enable secure product supply chains.

19. Grandfathering exception

An exception to a traceability regulation granted explicitly by that regulation applies to products already in the supply chain on the day the new regulation comes into effect because they were packaged prior to that date and therefore cannot be expected to comply. These products are said to be “grandfathered”.

20. Inference

The process of determining the unique identifiers on objects contained inside of outer containers like cases, totes, and pallets, using aggregation data rather than opening the containers themselves. The unique identifiers found are said to be “inferred” from the aggregation data because their accuracy depends on the accuracy of the aggregation data and the integrity of the outer container, since the actual objects and their identifiers are not visible.

21. Interoperability

The ability to exchange product traceability information accurately, efficiently, and consistently among trading partners in a supply chain and/or authorized regulators.

22. Legal supply chain

The supply chain paths and participants that are recognized and authorized by the government(s) of jurisdiction. Also sometimes referred to as the “legitimate supply chain”.

23. Marketing authorization holder

The legal entity that has been authorized to place specified medical products on a regulated market by the national regulatory authority.

24. Packaging levels

The hierarchy of product packaging. Each level includes a specific way of protecting and identifying the product during different types of handling. Recognized levels include “primary”, “secondary” and “tertiary”.

25. Pack

The packaged product that moves through a supply chain and is sold/administered/dispensed to the end patient and that is typically the subject of serialization requirements.

26. Pharmaceutical product

Any material or product intended for human or veterinary use presented in its finished dosage form or as a starting material for use in such a dosage form, that is subject to control by pharmaceutical legislation in the exporting state and/or the importing state.

27. Point of dispense verification

A recognized traceability architectural model that aims to limit the points in a supply chain where a drug must be verified to the point where it is dispensed or administered to a patient. Also referred to as a “book-end approach” because it usually requires manufacturers at one end of the supply chain to apply a unique identifier to drug packages, and dispensers at the other end of the supply chain to perform the verification step. The European Union Falsified Medicines Directive (Directive 2011/62/EU) as defined by the Commission Delegated Regulation (EU) 2016/161 is an example of a system that implements point of dispense verification.

28. Primary pack

The product packaging that touches the dose, i.e. a blister pack, a vial. If no secondary pack exists, then the primary pack is usually the lowest saleable pack.

29. Product

Usually a drug, biologic, vaccine or other health-related consumable that is regulated and moves through a supply chain from manufacturer to consumer.

30. Product code

A numeric or alphanumeric sequence of characters that is registered as an identifier for a class of objects (e.g. a trade item).

31. Product identifier

A numeric or alphanumeric sequence of characters that is registered as an identifier for a class of objects (e.g. a trade item) or an instance of an object (e.g. a logistic unit).

32. Product master data

Data that describe various characteristics of a specific product to differentiate it from all others.

33. Real-time

A qualifier of an event or process that occurs so fast in response to a trigger that it appears to happen immediately or even simultaneously. “Near real-time” describes an event or process that occurs rapidly in response to a trigger but not fast enough to be considered “real-time”.

34. Secondary pack

A package that contains one or more primary packages. A secondary pack in most, but not all, markets is the lowest saleable pack in the supply chain, when it exists. Sometimes referred to as the “finished pack”, “finished product” or “sales pack”.

35. Serial number

1. A unique numeric or alphanumeric code that, when associated with a product code, identifies a single instance of a product.
2. (Colloquial) A unique number that identifies a single instance of a product.

36. Serialization

The processes and results of defining, assigning and affixing unique serial numbers to product packaging at any level.

37. Stakeholder funding model

A method of funding the construction and management of the technology infrastructure necessary for a national traceability system that relies on the companies that are regulated (the “supply chain stakeholders”) to pay for all or part of it.

38. Substandard

Also called “out of specification”, these are authorized products that fail to meet either their quality standards or specifications, or both.

39. Supply chain

Two or more companies that buy and/or sell products, starting with the manufacturer and ending with the entity that supplies or administers the products to the end patient.

40. Supply chain stakeholders

Companies, including nongovernmental organizations and aid agencies, that participate in the supply chain of medical products, including, but not limited to, manufacturers, third-party logistics providers, importers, distributors, wholesale distributors, logistics companies, pharmacies, hospitals, clinics, etc.

41. Tertiary pack

A third level of packaging or higher, usually including logistic units like shippers, cases, totes and pallets.

42. Trace

The ability to know where a product has been within a supply chain prior to its current location.

43. Traceability

The capability to trace something. In some cases, it is interpreted as the ability to verify the history, location, or application of an item by means of documented recorded identification.

44. Traceability data/traceability information

Data that document where a product, or products, has/have been within a supply chain.

45. Traceability model

A well-defined approach to capturing, sharing and storing traceability data.

46. Traceability system

A systematic implementation of a traceability model.

47. Track

The ability to know where a product is right now.

48. Track and trace

1. A type of traceability model that attempts to track and trace products through a supply chain.
2. (Colloquial) A term used to refer to any and all traceability models.

49. 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 the purpose of registration, listing, marketing, sales, shipment, billing and other value chain and supply chain applications. Not all homogeneous groupings are trade items.

50. Trading partner

Supply chain stakeholders that engage in the purchase, sale and donation of products between each other.

51. Transactional data

Data that describe one or more transactions, whether financial or supply chain (product change of ownership), or both.

52. Transactional interoperability

A transaction in one system is extended automatically to another system.

53. Unique identifier

A unique serial number in combination with a product code. A unique identifier identifies a single instance of a product.

54. Unique number

A numeric or alphanumeric sequence of characters that identifies a single instance of a product such that no other instance has the same sequence associated with it.

55. Unregistered/unlicensed

Medical products that have not undergone evaluation and/or approval by the national regulatory authority for the market in which they are

marketed/distributed or used, subject to permitted conditions under national or regional regulation and legislation.

56. Verification

The process of determining that the unique identifier on a product is valid.

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Acknowledgments

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Preface

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Chapter 1: Introduction to Authentication and Traceability (A&T) Standards for Medical Products

1.1 Background

The healthcare landscape is constantly evolving, demanding robust systems to ensure patient safety and product integrity. In this ever-changing environment, **Authentication and Traceability (A&T)** for medical products has become paramount. A&T safeguards patients from falsified or substandard **Health products and Technology (HPT)**, protects public health, and fosters trust within the healthcare supply chain.

Due to the expansion and worldwide integration of commerce, medical products are today produced and supplied through intricate supply chains. On their way to the patient, products go via a number of different entities. They are frequently manufactured in one nation and sent across borders to be promoted or sold in other countries. The ability of national regulatory bodies to oversee the supply chain grows more fragmented, and distribution expands geographically. As a result, there is less effective supply chain oversight, which increases the possibility that substandard or falsified HPT would infiltrate the legitimate supply chain and pose risk to unsuspecting public. This may result in a decline in public trust, which in turn may cause hesitation, poor adherence, and underutilization of health interventions. Patient safety must thus be prioritised when addressing these vulnerabilities and bolstering the supply chain's efficiency and integrity.

In order to improve the near real-time monitoring of the supply chain integrity and the location data of HPT along the supply chain, there is need to embrace traceability technologies, as outlined in this document.

1.2 Scope

The standard document addresses the authentication of HPTs as finished goods in the supply chain, from the point of manufacture to reception by the registered pharmacist or pharmaceutical technologist.

This refers to the supply chain and its authorised stakeholders, who are duly registered, licenced, or authorised, starting from manufacturers of finished products (lot/batch release) and ending at the point of administration (e.g., hospitals or clinics) or medicine dispensing outlets such as pharmacies (public or private). Patient verification is incorporated, allowing patients to confirm the HPTs they have been given by using traceability features.

The purpose of this standard is to provide stakeholders with guidance on regulatory measures, specifically pertaining to the data management and governance of traceability systems. This standard does not seek to analyse existing technology or data standards or suggest which ones are better. Instead, it emphasises the advantages and situations that affect the

application of the standards selected by Pharmacy and Poisons Board (PPB) as well as the significance of system-wide standardisation.

The standard document addresses the integrity and efficiency of the supply chain with regard to the usage of traceability systems. The standard makes reference to the International Organisation for Standardisation (ISO) identification of HPTs.

This standard applies to all stakeholders involved in the supply chain of regulated medicines, including:

1. Manufacturers
2. Importers
3. Distributors
4. Wholesalers
5. Retailers (pharmacies)
6. Healthcare providers
7. Dispensing personnel
8. Logistics providers
9. A&T providers

The standard covers all medicinal, cosmetic, and personal care products consumed, injected, or applied to the human body. The list below provides further details on products that are in A&T's scope.

A) Therapeutics and Medical Devices

- Oral medications (pills, capsules, syrups, drops, dissolvable, sprays, inhalants)
- Non-oral medications (transdermal, submucosal, subcutaneous, intramuscular, intravenous, intraspinal)
- Topical medications (ointments, drops, patches)
- Suppositories (vaginal, rectal)
- Herbal products (ayurvedic, homeopathic)
- Medical Devices and Invitro Diagnostics

B) Non-therapeutics

- Cosmetic products with medical claims

1.3 Objective of the Standard

The objective of this standard is to bring together the available knowledge around existing traceability systems to guide stakeholders in their efforts to ensure the authentication and traceability of HPTs is done successfully.

1.4 Rationale for A&T Standards for HPTs

The implementation of A&T standards for HPTs is driven by a critical need to ensure patient safety, product integrity, and a secure supply chain. The following summarises the main arguments in favour of the necessity of A&T standards:

1. Countering the Threat of Falsification:

- The rise of falsified HPTs poses a significant threat to public health. These falsified HPT may contain ineffective or even harmful ingredients, leading to adverse patient outcomes and fatalities.
- A&T standards make it more difficult for unscrupulous business entities to infiltrate the supply chain by establishing robust verification mechanisms for product authenticity. This deters falsification and protects patients from unknowingly receiving falsified HPTs.

2. Enhancing Patient Safety:

- A&T safeguards patients by ensuring they receive genuine and authorized medical products. This reduces the risk of adverse reactions, treatment failures, and other complications associated with counterfeit or substandard products.

3. Building Trust in HPTs Supply Chain:

- Concerns about falsified products and medication errors can erode public trust in the HPTs supply chain. A&T standards demonstrate a commitment to patient safety and product integrity, fostering trust among patients and healthcare providers alike.

4. Facilitating Targeted Recalls:

- In the event of product defects or safety concerns, A&T systems enable efficient and targeted recalls by accurately identifying compromised products within the supply chain. A&T minimizes potential harm to patients and streamlines the recall process.

5. Promoting Supply Chain Efficiency:

- A&T systems provide real-time visibility of product movement throughout the supply chain.

6. Strengthening Regulatory Oversight:

- Robust A&T standards will empower the Pharmacy and Poisons Board to effectively monitor the medical supply chain and enforce compliance with regulations.

7. Increased Market Competitiveness:

- Manufacturers implementing A&T systems demonstrate a commitment to product quality and patient safety. This can give them a competitive edge in the market by inspiring greater confidence among healthcare providers and patients.

In conclusion, A&T standards are not simply a regulatory requirement but a vital tool for safeguarding public health, promoting patient safety, and fostering a secure and efficient HPT supply chain. By deterring falsification and facilitating **targeted recalls**, A&T standards play a critical role in ensuring trust within the healthcare system.

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Chapter 2: Features of the PPB A&T System

A&T systems for HPTs are designed to ensure patient safety and product integrity throughout the supply chain. Here's a breakdown of their key features:

2.1 Unique Identification

The following four essential components must be identified in a standard manner in order to successfully trace items across a supply chain: (a) products; (b) stakeholders; (c) locations; and (d) A&T service providers.

- a. Products (Pharmaceuticals and Medical Devices) – Annex I
- b. Stakeholders – Annex II
- c. Locations – Annex III
- d. A&T Service Providers – Annex IV

2.2 Standards

All serialized units of medicines (individual packages) must be assigned a unique identifier (Global Trade Item Number + Serial Number) compliant with GS1 standards - GS1-128 with Application Identifier 01 and a unique 20-digit serial number. Standards available Annex V.

GTIN stands for Global Trade Item Number. It's a unique identifier used to track products throughout the supply chain.

- a. Identification of a trade item (GTIN): AI (01)

The GS1 Application Identifier (01) indicates that the GS1 Application Identifier data field contains a GTIN. The GTIN is used to identify trade items. The GTIN for trade items may be a GTIN-8, GTIN-12, GTIN-13 or a GTIN-14. The PPB standard is GTIN-14 which is used for HPTs. The check digit is explained in section Figure 2. Its verification, which must be carried out in the application software, ensures that the number is correctly composed.

	GS1 Application Identifier	Global Trade Item Number (GTIN)													
		GS1-8 Prefix or GS1 Company Prefix							Item reference					Check digit	
(GTIN-8)	0 1	0	0	0	0	0	0	N ₁	N ₂	N ₃	N ₄	N ₅	N ₆		N ₇
(GTIN-12)	0 1	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
(GTIN-13)	0 1	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
(GTIN-14)	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

Figure 1: GTIN Format of the element string

Digit positions																		
GTIN-8											N ₁	N ₂	N ₃	N ₄	N ₅	N ₆	N ₇	N ₈
GTIN-12							N ₁	N ₂	N ₃	N ₄	N ₅	N ₆	N ₇	N ₈	N ₉	N ₁₀	N ₁₁	N ₁₂
GTIN-13						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
GTIN-14					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
17 digits		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
18 digits	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
Multiply value of each position by																		
	x3	X1	x3	x1	x3	x1	x3	x1	x3	x1	x3	x1	x3	x1	x3	x1	x3	
Accumulated results = sum																		
Subtract sum from nearest equal or higher multiple of ten = check digit →																		

Figure 2: Check digit algorithm

- b. Application Indifiers starting with digit 1
 - i. Batch or lot number: AI (10)

A batch or lot number is contained in the GS1 Application Identifier data field, according to the GS1 Application Identifier (10). The item's batch or lot number links it to details the manufacturer deems important for the trade item's traceability, which is what the element string is applied to. The information could be about the trade item itself or its contents. The number could be an internal production code, a machine number, a shift number, a manufacturing lot number, or a time. The brand owner and the manufacturer are in charge of making sure that batch/lot numbers for a GTIN are unique when the same product is made in multiple locations. Reusable batch/lot numbers with a GTIN are subject to industry-specific restrictions that must be taken into account.

GS1 Application Identifier	Batch or lot number
1 0	X ₁ —————> variable length —————> X ₂₀

Figure 3: Batch or lot number: AI (10)

- ii. Expiration date: AI (17)

An expiration date is present in the GS1 Application Identifier data fields, according to the GS1 Application Identifier (17). The date on which a product or coupon's maximum amount of usage or consumption is determined is called its expiration date. Its interpretation depends on the context of the trade item (for example, if the date is for food, it could mean a direct health risk from using

the product after that date; if it is for pharmaceuticals, it could mean an indirect health risk from the product becoming ineffective after that date). "Use by date" or "maximum durability date" are common terms used to describe it.

GS1 Application Identifier	Expiration date		
	Year	Month	Day
1 7	N ₁ N ₂	N ₃ N ₄	N ₅ N ₆

Figure 4: Expiration date: AI (17)

- c. Application Indifiers starting with digit 2
 - i. Serial number: AI (21)

A serial number is present in the GS1 Application Identifier data field, according to the GS1 Application Identifier (21). An entity is given a serial number for the duration of its existence. A serial number helps to uniquely identify a single object when it is paired with a GTIN. All characters found in Annex VI may be entered in the alphanumeric serial number field. Ensuring that a GTIN's serial numbers are unique is the responsibility of both the manufacturer and the owner of the brand. Serial numbers may not be reused.

GS1 Application Identifier	Serial number
2 1	X ₁ ————— variable length —————> X ₂₀

Figure 5: Serial number: AI (21)

The final encoding is summarized in

Table 1: Product encoding

Application Identifier (AI)	Referred Data	Character Requirements
01	Global Trade Item Number (GTIN)	AI + 14 numeric digits
10	Batch or Lot Number	AI + 20 alphanumeric characters
17	Expiration Date	AI + 6 numeric digits (yymmdd)
21	Serial Number	AI + 20 alphanumeric characters

Example:

Product has a GTIN **09521207311504**, the expiry is on **31st December 2027**, the serial number is **PC123454321Y1** and batch/lot number is **PC12365**.

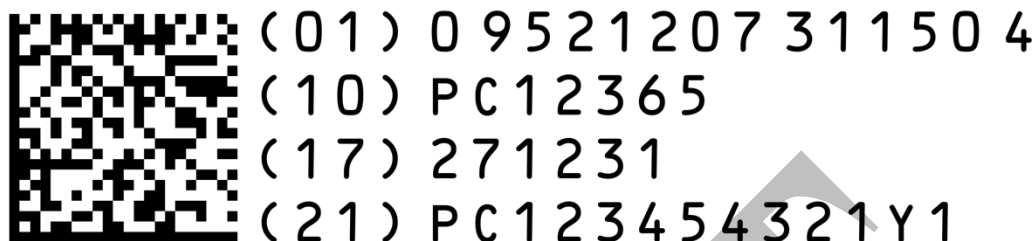


Figure 6: Sample 2D Data Matrix. Source <https://www.gs1.org/standards/barcodes/2d>

The use of Functional Code (FNC) as shown in Table 2. Because the serial number might have up to 20 characters in it, using the functional code means putting it after the serial number. The barcode scanner won't be able to determine the end of the serial number if it doesn't finish with the FNC code if the serial numbers are shorter than 20 characters. The preceding is also relevant. The function code must come at the end of both the serial number and the batch number since they both contain it.

jd2 **01** 09521207311504 **21** PC123454321Y1 **<GS>** **17** 271231 **10** PC12365

Table 2: Use of Functional Codes in barcodes.

j d2	01	09521207311504	21	PC123454321Y1	<GS>	17	271231	10	PC12365
FNC Opening Character	AI	GTIN	AI	Serial Number	FNC separator	AI	Expiration Date	AI	Batch Number

2.3 Unit-Level Serialization

Unit-level serialization is a prerequisite for unit-level tracing. The unique identifier described in 2.2 Standards, must be placed on each sellable unit of a class of HPT item in order to implement unit-level serialisation. In the supply chain, the level of packaging that is typically given (sold or donated) to a pharmacy or hospital is known as the saleable unit.

The following unique identifier application rules must be followed on the different types of saleable packs:

- a. Blister pack and sachet unique identifier application rules
 - i. All blister packs and sachets sold directly as such to consumers: unique identifier must be printed directly on the blister pack or sachet

- ii. Blister pack or sachet placed singly inside a carton and sold directly as a carton to consumers: unique identifier must be printed directly on the carton only

In the first instance, the unique identifier should be printed to the back surface at any location without covering the drug name and dose form.

b. Bottle and vial unique identifier application rules

- i. All bottle or vial products sold directly as such to consumers: unique identifier must be printed directly on bottle or vial
- ii. Bottle or vial placed singly inside a carton and sold directly as a carton to consumers: unique identifier must be printed at any place on the carton
- iii. Multiple bottles or vials are placed inside a carton, but bottles are sold individually to consumers: a unique identifier must be printed on each individual inserted bottle

3. Ampoule unique identifier application rules

- i. Multiple ampoules (injectables) placed in tray or carton and transferred as such: unique identifier must be printed directly on tray or carton only

4. Carton unique identifier application rules

- i. Carton containing single blister, sachet, or bottle (monocarton): unique identifier must be printed directly on carton only
- ii. Carton with two or more blisters, sachets or bottles, but where carton only is directly sold as such to consumers — i.e., no internal item is sold or donated separately: unique identifier must be printed directly on carton only
- iii. Carton with two or more blisters, sachets or bottles, but where internal items can be removed and sold separately: each internal item must be have a unique identifier seperately

The fundamental and overriding rule is that all saleable (customer-facing) packages must have a unique identifier to comply.

The secondary level packaging as shown in Figure 8, which contains the primary packaging level (the packaging that comes into contact with the dose itself), as shown in Figure 7, is typically where the unique identifier is placed. In the event that there isn't a secondary packaging level, the primary packaging would bear the unique identity.



Figure 7: Primary packaging



Figure 8: Secondary packaging

Tertiary units will be used for Post-Marketing Surveillance safety checks. For a portion of the trip to the destination, logistic units may be combined or nested into other logistic units. Parcel bundles, for instance, could be

assembled onto pallets. The contained logistic units may then be tracked and traced using the Serial Shipping Container Code (SSCC) of the higher logistic unit.

Tertiary units, Figure 9, shall receive SSCC. Upon importation of the tertiary units, the SSCC shall be considered for inspection and verification before PPB releases the products.

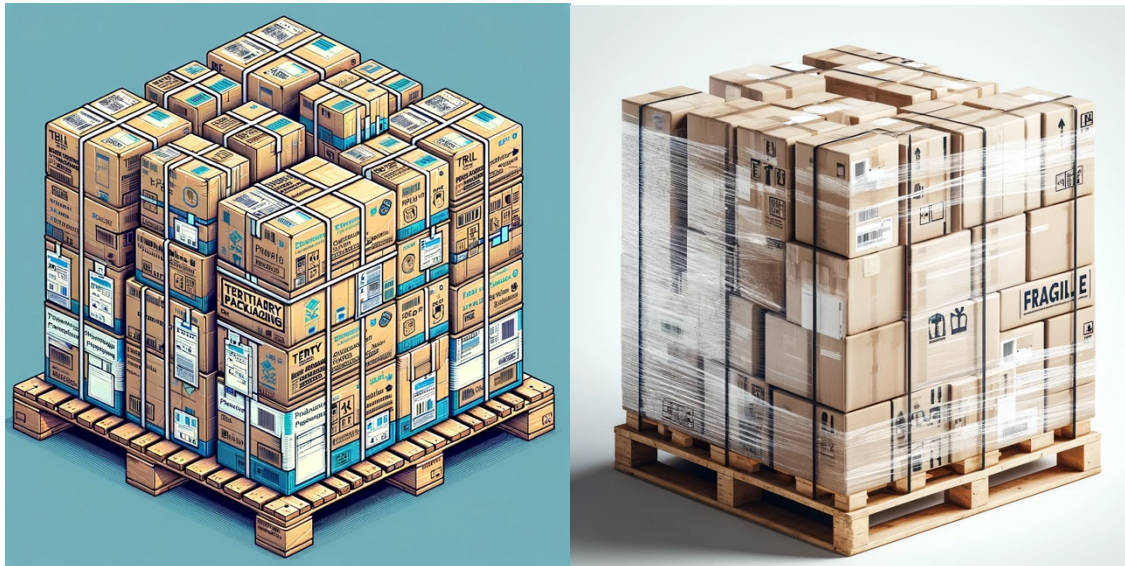


Figure 9: Tertiary Packaging

The following guidelines are applicable when working with nested or aggregated logistic units to guarantee accurate identification of the higher logistic unit:

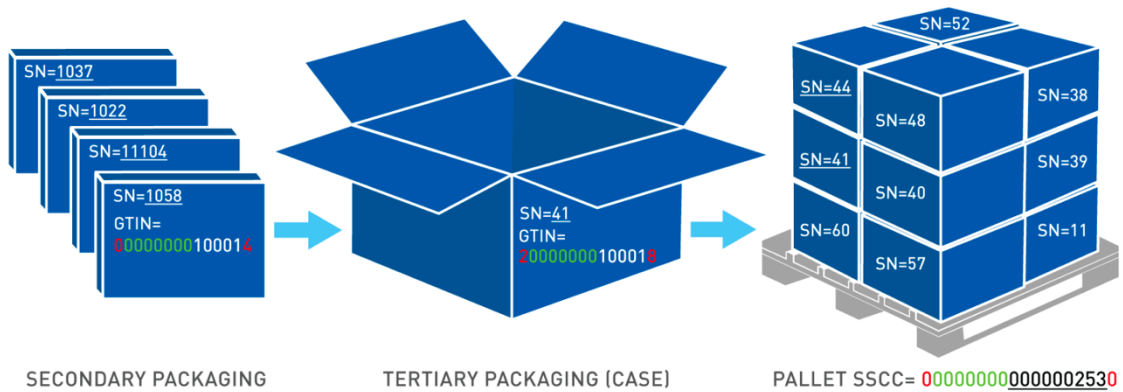
- (1) The only barcode that should be legible is the higher logistic unit's. The lowest-level logistic units' barcodes ought to be hidden.
- (2) The filter value used for the higher logistic unit when utilising EPC/RFID tags SHALL vary from the filter value used for the lower logistic units.

Table 3: SSCC application table.

Data Printed	Barcode Requirements	Application
Expiry date, Shipment number, SSCC, ***GTIN+SN	1-128GS (linear barcode or datamatrix GS1 (DataMatrix) is encoded with the following information: SSCC or GTIN + SN. In addition to the DataMatrix (1GS), it is	This will apply to tertiary units used for safety checks. The hierarchy can go as high as necessary and as long as the rules for nested or aggregated logistic units are adhered to.

	<p>encrypted with the following information: GTIN, Expiry, dateBatch number 1-128GS (linear barcode or datamatrix GS1 (DataMatrix) is encoded with the following information: SSCC or GTIN + SN.</p> <p>In addition to the DataMatrix (1GS), it is encrypted with the following information: GTIN, Expiry, dateBatch number</p>	
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Aggregation of serialized secondary packages into a serialized tertiary package (case) and then onto a serialized pallet. Aggregation data are shown in the table below.



AGGREGATION DATA	Carton SGTINs (with AIs)	Case SGTINs (with AIs)	Pallet SSCC (with AI)
	01 0000000100014 21 1037 01 0000000100014 21 1022 01 0000000100014 21 1104 01 0000000100014 21 1058 01 0000000100014 21 235 01 0000000100014 21 236 01 0000000100014 21 237 01 0000000100014 21 238 01 0000000100014 21 239	01 2000000100018 21 41 01 2000000100018 21 44	00 00000000000002530

Note: Drawing shows GS1 standards in use. Adapted from drawing by Dirk Rodgers.

Figure 10: Aggregation of Serialized secondary packages. Adopted from the WHO policy paper on Traceability of Medical Products (2021)

2.4 Verification

Verification is a process that enables patients, regulators, and/or law enforcement authorities to confirm the legitimacy and authorization of items that are either in the supply chain or, if permitted by law, in the hands of patients.

PPB has chosen to use the centralised model. In the centralised model, all traceability data are kept in a single database or repository. Verification of the identifiers can be carried out by government agencies (national and county), supply chain participants, medical professionals, and/or patients corresponding with the central repository.

All A&T data, including unique identifiers (GTIN, serial numbers, SSCC), product information (name, batch number, expiry date), and transaction data (manufacturing, distribution, dispensing) are stored in a centralized, secure database managed by the PPB either directly or with the help of A&T service providers.

PPB has also chosen a full A&T approach – i.e, all products are verified individually at the serial level. Every change of ownership in the supply chain requires the completion of traceability documentation or verification and authentication as part of the whole A&T methodology. Early detection of the introduction of falsified or substandard HPT items into the supply chain is intended to enable prompt detection and withdrawal of those products. The A&T methodology shall require:

1. Supply Chain:

Verification and authentication shall be done at every location through out the entire supply chain i.e. manufacturer, importer, distributor/wholesaler.

2. Dispensing:

The healthcare professional (HCP) scans the unique identifier, 2D datamatrix, on the medicine package (primary or secondary) at the point of dispensing. This identifier can be a GTIN for the product or an SSCC for a bundled package.

3. Data Transmission:

The scanner transmits the captured identifier securely to the central A&T database via the internet or a dedicated network.

4. Verification Check:

The central database verifies the received identifier against its records. The verification process will involve checking:

- **Serial Number Validity:** serialized products (individual packages), the system checks if the serial number is genuine and not tampered with (has not been utilised and changed).
- **Product Information:** The system retrieves information about the product (name, manufacturer, batch number, expiry date) linked to the identifier.
- **Dispensing Eligibility:** The system checks if the dispensed medicine is within the patient's prescription or authorized for the specific healthcare provider to dispense.
- **Supply Chain Integrity:** The system will check if the item has been verified using the SSCC at the distribution levels (import/manufacturer, distributor, retail)

5. Verification Response:

The central database transmits a real-time response back to the scanner or HCP's device, indicating:

- **Valid:** The medicine is genuine and can be dispensed to the patient.
- **Invalid:** The medicine is suspected to be falsified. The HCP should not dispense it and report the incident to the PPB post-marketing surveillance.
- **Verification Pending:** Further investigation is needed. The HCP may need to hold off on dispensing until a confirmed response from PPB post-marketing surveillance.

6. Documentation:

The A&T system documents the verification result (valid/invalid/pending) in the patient's medical record and any relevant A&T system logs.

Who Can Verify?

- **PPB:** The PPB can access the central database for various purposes, including:
 - Monitoring the overall effectiveness of the A&T system.
 - Investigating suspected falsified or substandard product incidents.
 - Conducting targeted audits of specific parts of the supply chain.
- **Supply Chain Members:** Authorized distributors, wholesalers, and pharmacies might have access to the central database to verify the authenticity of products they receive or dispense.

- **Healthcare Providers (HCPs):** As described above, HCPs can verify medicines at the point of dispensing to ensure patient safety.
- **Patients:** Patients can verify their dispensed medicines using a mobile app linked to the central database.

2.5 Detection Response including reporting

The PPB A&T is for the purposes of HPTs safety. All issues should be reported back to the following departments:

1. Trade – for all import and export related issues
2. Post Marketing Surveillance – for all safety-related issues, including falsified and substandard products
3. Pharmacovigilance – for all adverse events
4. Practice and Licensing – for practitioner and premises-related issues.
5. All tests for quality will be handled by the quality control directorate.

2.6 System Access

A&T will be controlled from the Government domain names, that is, .go.ke. The system to be used is PRIMS, which is accessible from prims.pharmacyboardkenya.org or prims.ppb.go.ke. Only entities granted access to PRIMS will be authorized to participate in A&T.

All codes should be verifiable by any device or smart app that is a professional barcode reader app approved by PPB that can decode GS1 application identifiers (AI) for GS1 barcodes like GS1-128, EAN-128, UCC-128, DataMatrix, and QR Code and validate on PRIMS.

Chapter 3: Authentication and Traceability Pathway: From Batch to Serialized Level

This pathway outlines a phased approach for Kenya to implement an Authentication and Traceability (A&T) system for health products and technologies (HPTs), starting with batch-level tracking and progressing to serialized, unit-level traceability.

Guiding Principles:

- **Gradual Implementation:** Allowing stakeholders time to adapt and build capacity.
- **Scalability:** Designing the system to accommodate increasing data volume and complexity.
- **Stakeholder Engagement:** Ensuring collaboration and buy-in from all participants.
- **Focus on High-Risk Products First:** Prioritizing the implementation for medicines most susceptible to counterfeiting or posing significant public health risks.

Phase 1: Foundational Batch-Level Traceability

Goal: Establish a basic system to track HPTs at the batch level, enabling identification of affected batches during recalls and providing a basic level of supply chain visibility.

Requirements:

- **Product Identification:** Implement standardized product identification using Global Trade Item Numbers (GTINs) at the product level.
- **Batch Number Recording:** Mandate the recording of batch numbers at key points in the supply chain (manufacturing, importation, distribution).
- **Basic Data Exchange:** Establish simple mechanisms for exchanging batch information between stakeholders (e.g., paper-based documentation, basic electronic spreadsheets).
- **Centralized Batch Repository (Optional):** Explore the feasibility of a basic central repository where batch information can be voluntarily submitted.

What is to be Achieved and Delivered:

- **Basic Recall Capability:** Ability to identify and trace specific batches of HPTs in case of quality issues or recalls.
- **Initial Supply Chain Visibility:** Understanding the movement of HPTs at the batch level.
- **Stakeholder Awareness:** Introduction of basic traceability concepts and data recording practices.

Stakeholder Roles:

- **Manufacturers:** Assign GTINs to products, record batch numbers during manufacturing, and include batch information on dispatch documents.
- **Importers:** Record batch numbers upon receiving imported HPTs and include this information on onward distribution documents.
- **Distributors:** Record batch numbers when receiving and dispatching HPTs.
- **Retailers (Pharmacies):** Record batch numbers upon receiving HPTs and maintain records linking dispensed products to batch numbers (manually or through basic pharmacy systems).
- **PPB:** Develop guidelines for batch number recording and reporting, conduct awareness campaigns, and potentially establish a basic central repository.

Phase 2: Enhanced Batch-Level Traceability with Electronic Data Exchange

Goal: Improve the efficiency and accuracy of batch-level tracking through the introduction of electronic data exchange and a more robust central repository.

Requirements:

- **Mandatory Electronic Data Exchange:** Implement standardized electronic formats (e.g., basic EDI) for exchanging batch information between stakeholders.
- **Centralized Batch Repository:** Establish a mandatory central repository managed by the PPB for storing batch information and transaction data.
- **Standardized Location Codes:** Introduce standardized location codes (e.g., GS1 Global Location Numbers - GLNs) to identify supply chain actors.
- **Basic Reporting Capabilities:** Implement basic reporting functionalities within the central repository for stakeholders and the PPB.

What is to be Achieved and Delivered:

- **Improved Recall Efficiency:** Faster and more accurate identification of affected batches.
- **Enhanced Supply Chain Visibility:** Better understanding of product flow and potential bottlenecks at the batch level.
- **Reduced Errors:** Minimization of manual data entry errors through electronic exchange.
- **Foundation for Future Serialization:** Building the infrastructure and data exchange mechanisms necessary for serialized tracking.

Stakeholder Roles:

- **Manufacturers:** Implement systems for electronic recording and transmission of batch information, including GTINs and location data.
- **Importers:** Implement systems for electronic recording and transmission of batch information and location data.
- **Distributors:** Implement systems for electronic recording and transmission of batch information and location data.
- **Retailers (Pharmacies):** Implement basic pharmacy systems capable of capturing and transmitting batch information and dispensing data electronically.
- **Regulatory Authority (PPB):** Manage the central repository, develop and enforce data exchange standards, provide training and support, and generate reports for monitoring and analysis.

Phase 3: Pilot Serialization for High-Risk Products

Goal: Introduce unit-level serialization and tracking for a selected category of high-risk HPTs to test and refine the serialized A&T system.

Requirements:

- **Mandatory Serialization for Pilot Products:** Require manufacturers of selected high-risk products to assign a unique serial number to each saleable unit, along with the GTIN and batch number.
- **GS1 DataMatrix Barcodes:** Mandate the use of GS1 DataMatrix barcodes to encode the GTIN, serial number, batch number, and expiry date on the primary packaging of pilot products.
- **Enhanced Electronic Data Exchange:** Upgrade data exchange systems to handle serialized data.
- **Serialized Central Repository:** Enhance the central repository to store and manage serialized data.
- **Verification System Pilot:** Implement a pilot verification system allowing authorized stakeholders (e.g., pharmacies, regulators) to verify the authenticity of serialized products by scanning the DataMatrix barcode against the central repository.

What is to be Achieved and Delivered:

- **Unit-Level Traceability for Pilot Products:** Ability to track the movement of individual units of high-risk HPTs.
- **Enhanced Authentication Capabilities:** Verification of the authenticity of individual product units.
- **Identification of Counterfeit Products:** Ability to detect and flag potentially counterfeit products in the supply chain.
- **Learning and Refinement:** Gaining practical experience with serialized A&T to inform the full-scale implementation.

Stakeholder Roles:

- **Manufacturers (Pilot Products):** Implement serialization processes, print GS1 DataMatrix barcodes on packaging, and transmit serialized data electronically.
- **Importers (Pilot Products):** Capture and transmit serialized data upon receiving imported products.
- **Distributors (Pilot Products):** Implement systems for handling and tracking serialized products, including scanning and transmitting data.
- **Retailers (Pharmacies):** Utilize scanners to capture and transmit serialized data during dispensing and verify product authenticity against the central repository.
- **Regulatory Authority (PPB):** Manage the enhanced central repository and pilot verification system, provide specialized training, monitor the pilot implementation, and refine the system based on learnings.

Phase 4: Full-Scale Serialized Authentication and Traceability

Goal: Implement mandatory unit-level serialization and tracking for all regulated HPTs across the entire supply chain.

Requirements:

- **Mandatory Serialization for All Regulated HPTs:** Extend the serialization requirements to all regulated medicines and potentially other high-risk medical devices.
- **Robust Verification System:** Fully implement and scale the national verification system, accessible to all authorized stakeholders.
- **Integration with Healthcare Systems:** Explore integration of the A&T system with pharmacy dispensing systems and potentially patient health records (with appropriate privacy safeguards).
- **Public Awareness Campaign:** Launch a national campaign to educate healthcare professionals and the public about the benefits of serialized A&T and how to use verification tools (if applicable).

What is to be Achieved and Delivered:

- **Complete Unit-Level Traceability:** End-to-end tracking of individual units of all regulated HPTs.
- **Strong Authentication Capabilities:** Widespread verification of product authenticity at all levels of the supply chain, including dispensing to patients.
- **Significant Reduction in Counterfeit Medicines:** Deterrence and detection of counterfeit products, leading to a safer pharmaceutical market.
- **Improved Patient Safety:** Enhanced ability to conduct targeted recalls and ensure patients receive genuine medications.

Stakeholder Roles:

- **Manufacturers (All Products):** Implement and maintain robust serialization processes for all regulated HPTs.
- **Importers (All Products):** Ensure imported products comply with serialization requirements and transmit serialized data.
- **Distributors (All Products):** Manage and track serialized products throughout their operations.
- **Retailers (Pharmacies):** Routinely verify the authenticity of dispensed medicines using the national verification system.
- **Healthcare Professionals:** Understand and utilize the A&T system to ensure the medicines they administer are genuine.
- **Regulatory Authority (PPB):** Oversee and manage the national A&T system, enforce compliance, provide ongoing support and training, analyze data for trends and risks, and continuously improve the system.

Ongoing Activities:

- **Continuous Monitoring and Evaluation:** Regularly assess the effectiveness of the A&T system and identify areas for improvement.
- **Capacity Building:** Ongoing training and support for all stakeholders.
- **Technological Updates:** Adapting the system to new technologies and evolving threats.
- **International Collaboration:** Sharing best practices and collaborating with other countries on cross-border A&T efforts.

This phased pathway provides a structured approach for Kenya to build a comprehensive Authentication and Traceability system for its health products and technologies. By starting with basic batch-level tracking and gradually progressing to unit-level serialization, Kenya can build the necessary infrastructure, expertise, and stakeholder buy-in to create a safer and more secure healthcare supply chain.

ANNEXURES

Annex I – Products (Pharmaceutical and Medical Devices)

Pharmaceuticals:

- Application/national code number – A unique system generated number that identifies a specific product at the point of new application by the Pharmacy and Poisons Board
- Brand/proprietary name – Item name used by the enterprise that manufactures this item
- INN – Generic name of pharmaceutical from WHO INN System
- Strength –The amount of the active ingredient usually measured in metric weight e.g., micrograms, grams, milligrams, etc.
- Dosage form – a specific physical form in which a medicine is produced or administered, e.g., tablets, capsule
- Route of administration – The method of administering a product
- Pack size – The number of dosage units or items contained in a single primary package or product
- Primary packaging image – A picture/image of the packaging that is in direct contact with the product dosage form, with the label clearly visible, e.g., blister pack for tablets, vial for injections, tube for creams
- Secondary packaging image - A picture/image of the packaging that is used to group and protect multiple units of primary packaging, e.g., a carton, a box, shrink wrapping
- Shelf life – The period (in months) guaranteed by the manufacturer before the expiration date of the product based on production
- Storage temperature – Refers to the specific temperature conditions at which the product is to be stored to maintain its stability and efficacy
- Registration status – The current legal status of the product in respect to the approval for sale or distribution, e.g., registered, recalled, withdrawn, rejected, etc.
- Registration number – A unique identifier issued for a product upon successful registration by the Pharmacy and Poisons Board
- Retention number - A unique identifier issued for a product upon successful renewal of a license and is based on the application number issued by the Pharmacy and Poisons Board
- Market Authorization Holder (MAH) name – An entity that has the legal and regulatory responsibility to distribute, sell and commercialize a medical product in Kenya
- Local Technical Representative (LTR) – The company or other legal entity appointed by the manufacturer, who is licensed to distribute, sell and commercialize a medical product
- Manufacturer name – The company (name and postal address) or legal entity who produces a medicine

- Manufacturing site – The physical address associated with the production site for a medicine
- Country of origin (logistics)
- ATC code (Anatomical Therapeutic Chemical classification) - A unique code assigned to a medicine according to the organ and system it works on
- Other international and classification codes e.g., GS1, UNODC
- Therapeutic classification – Categorization based on characteristics of a medicine, e.g., analgesic, cardiovascular, etc.
- Medicine scheduling – categorization of a medicine based on their potential for harm, abuse or misuse as well as their therapeutic value, e.g., OTC, POM, Controlled Medicines, Pharmacy-Only
- KEML status - Inclusion in the current Kenya Essential Medicines List (Yes/No)

Medical Devices

Any instrument, apparatus, implement, machine, appliance, implant, reagent for in-vitro use, software, material, or other similar, or related article, intended by the manufacturer to be used alone, or in combination for human beings, for one or more of the specific medical purpose (s)

- Application code - A unique system generated number that identifies a specific product at the point of new application by the Pharmacy and Poisons Board
- Registration code – A unique identifier issued for a product upon successful registration by the Pharmacy and Poisons Board
- Retention code - A unique identifier issued for a product upon successful renewal of a license and is based on the application number issued by the Pharmacy and Poisons Board
- Item/product/ name – Generic/common name of a medical device e.g., Bag Valve Mask (BVM)
- Trade name – device proprietary name, e.g., Ambubag
- Device family – grouping of medical devices with the same intended use, same packaging system, same sterilization system e.g., surgical set
- Device group - product grouping e.g., single, family, system, group, dental grouping term (DGT)
- Device sub-set/subgroup – subclassification
- Device classes (risk-based categories)
 - Class A – low risk, e.g., cotton wool, bandages
 - Class B – low to moderate, e.g., orthodontic materials, dental prostheses
 - Class C – moderate to high, e.g., urethral stent, catheter containing sealed radio-isotopes
 - Class D – high risk, e.g., pacemaker, implantable defibrillators
- GMDN name – The Global Medical Device Nomenclature (GMDN) is an internationally agreed descriptor for the naming, classification and categorization of medical device products

- GMDN code - The Global Medical Device Nomenclature (GMDN) is an internationally agreed code for medical device products
- Unique Device Identification (UDI) – A series of alpha-numeric characters that are assigned by the PPB to a medical device. This will be the national unique code (descriptive, logical and meaningful)
- Device accessories – A list of articles which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device
- Product size/configurations – The various forms or designs of a product
- Pack size - The number of dosage units or items contained in a single primary package or product
- Primary packaging image – A picture/image of the packaging that is in direct contact with the product
- Secondary packaging image - A picture/image of the packaging that is used to group and protect multiple units of primary packaging, e.g., a carton, a box, shrink wrapping
- Storage conditions - Refers to the specific environmental conditions accompanying the products, e.g., humidity, temperature, light exposure, under which a product should be stored to maintain its stability and efficacy
- Instructions for Use (IFU) – to health care professional, user, owner
- Shelf life - The period guaranteed by the manufacturer before the expiration date of the product based on production
- Market Authorization Holder (MAH) – An entity that has the legal and regulatory responsibility to distribute, sell and commercialize a medical device in Kenya
- Manufacturer – The company or legal entity who produces a medical device
- Manufacturing site – The address associated with the production site for a medical device
- Country of origin – Country from which the device originated from
- Quality and standards e.g., CE, KEBS, ISO 13485, etc.
- Make/model – Proprietary name as given by the manufacturer
- Serial number – Unique number given to an equipment by the manufacturer
- Lifespan or service life – The period an equipment is usable before it becomes obsolete

Additional information for diagnostics

Consumables

- Articles/instruments e.g., pipettes, slides, slide holders
- Reagents – a substance used to carryout a laboratory test
- Buffers – A solution that resists pH change upon the addition of an acid or base
- Diluents – A liquid used for diluting a concentrated solution

- Chemicals – A distinct compound or substance especially one that has been artificially prepared or purified
- Preservatives – A chemical used to prevent growth of micro-organisms
- Disinfectants – A chemical liquid that destroyed micro-organisms on surfaces
- Specificity – Ability of a test to identify a true negative (does not have a disease)
- Sensitivity – Ability of a test to pick out a true positive (has disease as positive) from a large sample
- Test category – Categorization of laboratory test systems and assays based on disease
 - General tests – Used for routine care, detection of multiple conditions, or detection of a set of symptoms that suggest the presence or risk of certain diseases, e.g., liver function test, full hemogram, etc.
 - Disease specific tests – Used for detecting specific diseases or target infections, e.g., HIV, TB, Diabetes, etc.
- Test disciplines – the classifications of laboratories and diagnostics concerned with specialists available, e.g., hematology, microbiology, etc.

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Annex II – Stakeholders

a. Stakeholders

Stakeholders comprise of all parties involved in the supply chain of regulated medicines, including:

- Manufacturers
- Importers
- Distributors
- Wholesalers
- Retailers (pharmacies)
- Healthcare providers
- Dispensing personnel
- Logistics providers

They can be broadly described as:

- Carrier / Third Party Logistics Provider (3PL): The party responsible for the delivery or shipping of the traceable item.
- Processor / Manufacturer / Primary Producer / Compounder: Typically receives inputs and transforms those inputs. Examples include the pharmaceutical or medical device manufacturer, or a kit manufacturer that consolidates product from a number of suppliers, or a pharmacist (compounder) who processes APIs into a finished product, or a party that reprocesses (cleans and sterilises) surgical instruments. A supply chain may be comprised of more than one processor/manufacturer/primary producer/compounder.
- Point of administration, Use or Service Operator / Provider: Has the final relationship with the patient. For example, a pharmacist, physician, nurse or healthcare provider.
- Patient: Final consumer of the HPT.
- Warehouse / Distribution Centre: Responsible for the handling (may transform the traceable item) and storage of the traceable item.
- Authorities: The party legally mandated to protect the public interest and for the purposes of this standard, the Pharmacy and Poisons Board (PPB).

Annex III – Locations

In the context of A&T for HPTs, locations don't refer to physical places, but rather the data points within the system that track the movement of a product throughout the supply chain.

Here's how location data functions in A&T systems:

Unique Identifier: Each HPT has a unique identifier (barcode, RFID tag).

Scanning and Recording: At various stages of the supply chain (manufacturing, distribution, dispensing), the unique identifier is scanned, and the location data is captured.

Data Storage: This location data, along with other product information (batch number, expiry date), is stored in a central repository.

Therefore, the "locations" in A&T systems are not physical addresses but rather timestamps linked to the unique identifier, indicating where a product was at a specific point in time. This allows for:

Real-time Tracking: Some A&T systems offer real-time visibility, allowing authorized users to see the current location of a product.

Traceability: By analyzing past location data, you can track the complete journey of a product from manufacturing to dispensing.

Identifying Issues: Location data can help identify potential problems in the supply chain, such as delays or deviations from the expected route.

Here's an example:

A box of medication is scanned at the manufacturing facility (location 1).

The medication is shipped to a distribution center (location 2).

Upon arrival at the pharmacy, the medication is scanned again (location 3).

The A&T system records these location points for each unique identifier, allowing for comprehensive tracking and traceability of the medication throughout the supply chain.

Annex IV – A&T Service Providers

A&T system service providers are companies that offer a variety of services related to implementing and managing A&T systems for HPTs. These service providers play a crucial role in ensuring the smooth functioning and effectiveness of A&T within the healthcare supply chain.

Specifications for Authentication and Traceability (A&T) System Service Provider

1. System Expertise and Experience:

Proven experience in implementing and managing A&T systems for HPTs.

Familiarity with various A&T software and hardware solutions, including those compatible with different serialization standards (e.g., GS1 standards).

Understanding of integration capabilities with existing enterprise systems (ERP, WMS) used in the healthcare supply chain.

2. Data Management Capabilities:

Secure and scalable data storage solutions compliant with relevant data privacy regulations (e.g., HIPAA).

Expertise in data cleansing, validation, and management to ensure data accuracy and integrity within the A&T system.

Ability to provide data access controls and user management functionalities.

3. Implementation and Integration Services:

Proven track record of successfully implementing A&T systems for organizations of varying sizes and complexities.

Experience integrating A&T systems with existing business systems and workflows within the healthcare supply chain.

Project management expertise to ensure smooth implementation within budget and timeframe.

4. Training and Support:

Comprehensive training programs for all stakeholders involved in the A&T system, including manufacturers, distributors, dispensers, and healthcare providers.

Ongoing technical support to address user queries and troubleshoot any issues with the A&T system.

User manuals, documentation, and online resources readily available for training and reference purposes.

5. System Maintenance and Upgrades:

Proactive maintenance plans to ensure the system functions optimally and remains secure.

Ability to implement system upgrades and updates to keep pace with evolving technologies and regulations.

Clear communication regarding upcoming upgrades and their potential impact on users.

6. Track and Trace Functionality:

Real-time track and trace capabilities for monitoring the movement of medical products throughout the supply chain.

Ability to track key data points such as location, temperature, and other critical information for specific products.

User-friendly interface for accessing track and trace data and generating reports.

7. Security and Compliance:

Robust security protocols to safeguard the A&T system from unauthorized access, data breaches, and cyberattacks.

Compliance with relevant national and international regulations governing A&T for HPTs (e.g., FDA regulations, EU Falsified Medicines Directive).

Regular security audits and risk assessments to identify and mitigate potential vulnerabilities.

8. Reporting and Analytics:

Ability to generate comprehensive reports on A&T data, including product movement, verification history, and potential discrepancies.

Data analytics tools to identify trends, optimize supply chain efficiency, and generate reports required by regulatory bodies.

User-friendly dashboards for visualizing A&T data and key performance indicators.

9. Statutory Requirements:

Kenya Revenue Authority (KRA) tax compliance certificate.

KRA value-added taxation (VAT) registration.

KRA Personal Identification Number (PIN) for the company.

Company Registration by the Registrar of Companies.

Office of the Data Protection Commissioner

10. Additional Considerations:

Experience integrating A&T systems with anti-counterfeiting technologies.

Scalability to accommodate future growth and changing business needs.

Competitive pricing structure and transparent service costs.

Excellent customer service and responsiveness to inquiries.

Proven track record of successful client relationships within the healthcare industry.

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Annex V – References for A&T Standards

There are several key standards that govern A&T for HPTs. These standards establish a framework for ensuring a secure and efficient system, ultimately protecting patient safety. Here's an overview of some prominent standards:

Global Standards Organization (GS1):

Provides global standards for identification and barcoding.

GS1 standards, like GS1 DataMatrix and EPC (Electronic Product Code), are widely used for serializing medical products in A&T systems. - GTIN Management Standard, Version 1.1, Sep 2023

International Organization for Standardization (ISO):

Develops technical standards for various industries, including healthcare.

ISO standards relevant to A&T include ISO 23023 (track and trace for medical devices) and ISO 17971 (risk management for medical devices).

World Health Organization (WHO):

Provides global guidance on medicines and medical devices, including A&T.

The WHO Falsified Medical Products Programme offers resources and recommendations for implementing A&T systems.

Policy paper on traceability of medical products. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO.

Regional Regulations:

In addition to these global standards, individual countries or regions may have specific regulations governing A&T for medical products. Some prominent examples include:

European Union (EU) Falsified Medicines Directive (FMD): Requires mandatory serialization and verification of all prescription medicines within the EU. - DIRECTIVE 2011/62/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products

United States Drug Supply Chain Security Act (DSCSA): Establishes a phased approach for implementing serialization and track and trace of prescription drugs in the U.S. - Drug Quality and Security Act. 21 USC 301 - Public Law 113-54.

Standardization plays a crucial role in A&T because it ensures:

Interoperability: Different stakeholders within the supply chain can use A&T systems from various vendors as long as they adhere to the same standards. This facilitates seamless data exchange and product tracking across the entire network.

Data Consistency: Standardized data formats ensure that information captured by different systems is compatible and can be easily integrated within the overall A&T infrastructure.

Global Harmonization: By following common standards, countries can more effectively collaborate on combating counterfeit medical products and ensure the integrity of the global medical supply chain.

DRAFT

Annex VI - GS1 AI encodable character set 82

Graphic symbol	Name	Coded representation	Graphic symbol	Name	Coded representation
!	Exclamation mark	2/1	M	Capital letter M	4/13
"	Quotation mark	2/2	N	Capital letter N	4/14
%	Percent sign	2/5	O	Capital letter O	4/15
&	Ampersand	2/6	P	Capital letter P	5/0
'	Apostrophe	2/7	Q	Capital letter Q	5/1
(Left parenthesis	2/8	R	Capital letter R	5/2
)	Right parenthesis	2/9	S	Capital letter S	5/3
*	Asterisk	2/10	T	Capital letter T	5/4
+	Plus sign	2/11	U	Capital letter U	5/5
,	Comma	2/12	V	Capital letter V	5/6
-	Hyphen/Minus	2/13	W	Capital letter W	5/7
.	Full stop	2/14	X	Capital letter X	5/8
/	Solidus	2/15	Y	Capital letter Y	5/9
0	Digit zero	3/0	Z	Capital letter Z	5/10
1	Digit one	3/1	_	Low line	5/15
2	Digit two	3/2	a	Small letter a	6/1
3	Digit three	3/3	b	Small letter b	6/2
4	Digit four	3/4	c	Small letter c	6/3
5	Digit five	3/5	d	Small letter d	6/4
6	Digit six	3/6	e	Small letter e	6/5
7	Digit seven	3/7	f	Small letter f	6/6
8	Digit eight	3/8	g	Small letter g	6/7
9	Digit nine	3/9	h	Small letter h	6/8
:	Colon	3/10	i	Small letter i	6/9
;	Semicolon	3/11	j	Small letter j	6/10
<	Less-than sign	3/12	k	Small letter k	6/11
=	Equals sign	3/13	l	Small letter l	6/12
>	Greater-than sign	3/14	m	Small letter m	6/13
?	Question mark	3/15	n	Small letter n	6/14
A	Capital letter A	4/1	o	Small letter o	6/15
B	Capital letter B	4/2	p	Small letter p	7/0
C	Capital letter C	4/3	q	Small letter q	7/1
D	Capital letter D	4/4	r	Small letter r	7/2
E	Capital letter E	4/5	s	Small letter s	7/3
F	Capital letter F	4/6	t	Small letter t	7/4
G	Capital letter G	4/7	u	Small letter u	7/5
H	Capital letter H	4/8	v	Small letter v	7/6
I	Capital letter I	4/9	w	Small letter w	7/7
J	Capital letter J	4/10	x	Small letter x	7/8
K	Capital letter K	4/11	y	Small letter y	7/9
L	Capital letter L	4/12	z	Small letter z	7/10