2ND FRANCOPHONE AFRICA GS1 HEALTHCARE SUMMIT (2023)

Day 1 Summary
July 20, 2023 |12:00 – 12:05 GMT

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Un sommaire du 1e jour

- Le Nigeria: Projets pilote. Identification unique pour les produits (GTIN - norme GS1). Engager les parties prenantes et commencer où vous êtes avec les ressources que vous avez
- Le Bénin: Projet e-pharmacie pour tracer les produits, l'importance du catalogue national des produits pharmaceutiques, l'importance d'interopérabilité entre les systèmes utilisé dans le domaine de santé au niveau national. C'est important d'assurer l'adhésion des parties prenantes à chaque étape
- Le Burundi: développement de la stratégie de traçabilité, engagements des parties prenantes des différents organismes locaux incluant la centrale d'achat, les représentants des programmes de santé publique, les industries pharmaceutiques, etc.
- Le Rwanda: publications des réglementations depuis l'an dernier: pour identifications unique de produits, définitions des éléments pour le catalogue national des produits, l'importance de la règlementation et de l'engagement des parties prenantes, et l'interopérabilité entre les systèmes.
- Le Togo: Première étape au côté de traçabilité en faisant une analyse des différents départements dans le domaine de la santé.
- Sophie Molle (GS1 GO): GS1 ne pas un offreur de solutions. Conseille pour engager au mieux la communauté des offreurs de solution locaux. Contacter GS1 pour un conseil.
- Ramy Guirguis (USAID): Introduction du l'objectif du sommet la transformation numérique de la chaine d'approvisionnement.

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2nd Francophone Africa GS1 Summit (2023): Agenda

DAY 2: Enabling digital health supply chain transformation

8:00 – 8:15 EDT **12:00 – 12:15** GMT	**Introduction to the Day/Summary of day before**	Virtual
8:15 – 8:30 EDT **12:15 – 12:30** GMT	**The Role of GS1 Standards in Digital Health Supply Chain Transformation** A brief introduction of how global GS1 standards can enable the digital supply chain transformation in country healthcare settings. ***Presenter:*** *Pete Alvarez (GS1 Global Office)*	Virtual
8:30 – 9:15 EDT **12:30 – 13:15** GMT	**Panel Discussion on Traceability Architecture Approaches - Part 1: Foundation - Zambia, Rwanda, Ethiopia** This session provides a high-level overview of the efforts done by countries that are starting their health product traceability journey focusing especially on the foundational efforts in defining their architecture. ***Facilitator:*** *Dah El Hadj Sidi (GHSC-TA Francophone TO)* ***Panelists:*** *Heran Gerba (Ethiopian FDA), Al Shiferaw (JSI), Jean Baptiste Byiringiro (Rwanda MOH), Matthews Mwale (Zambia MOH), Petros Lukonde (Zambia MOH)*	Virtual
9:15 – 9:30 EDT **13:15 – 13:30** GMT	**Q&A**	Virtual
9:30 – 10:15 EDT **13:30 – 14:15** GMT	**Panel Discussion on Traceability Architecture Approaches - Part 2: Traceability Systems - Türkiye, Argentina, India, South Africa** High level overview from countries that have set up pharmaceutical traceability and/or integrated global GS1 standards into supply chain digital transformation. ***Facilitator:*** *Nuran Idris (GS1 Global Office)* ***Panelists:*** *Cihan Korucu (GS1 Türkiye), Mario Abitbol (GS1 Argentina), Subrato Dey (GS1 India), Michele Francis Padayachee (GS1 South Africa)*	Virtual
10:15 – 10:30 EDT **14:15 – 14:30** GMT	**Q&A**	Virtual
10:30 – 10:45 EDT **14:30 – 14:45** GMT	**A Review of the WHO Digital Supply Chain Architecture Handbook** ***Presenters:*** *Swaroop Jayaprakash (WHO) & Carl Leitner (WHO)*	Virtual
10:30 – 10:45 EDT **14:30 – 14:45** GMT	**Closing Remarks: Next steps & recommendations** This session will provide a recap of resources available to support countries embarking on their traceability journey including providing key contact information for support. Furthermore, the countries will discuss what needs to happen to have more dialogue and what next steps each country wishes to take.	Virtual

8:00 – 8:15 HAE **12:00 – 12:15** GMT	**Introduction à la journée/Résumé de la veille**	Virtuel
8:15 – 8:30 HAE **12:15 – 12:30** GMT	**Le rôle des normes GS1 dans la transformation numérique de la chaîne d'approvisionnement en matière de santé** Une brève introduction sur la façon dont les normes mondiales GS1 peuvent permettre la transformation numérique de la chaîne d'approvisionnement dans les environnements de soins de santé des pays. ***Présentateur:*** *Pete Alvarez (Bureau mondial GS1)*	Virtuel
8:30 – 9:15 HAE **12:30 – 13:15** GMT	**Table ronde sur les approches de l'architecture de la traçabilité – Partie 1: La fondation - Zambie, du Rwanda, et de l'Éthiopie** Cette session offre une vue d'ensemble des efforts réalisés par les pays qui commencent leur parcours de traçabilité des produits de santé, en se concentrant particulièrement sur les efforts fondamentaux dans la définition de leur architecture. ***Animateur du panel:*** *Dah El Hadj Sidi (GHSC-TA Francophone TO)* ***Panélistes:*** *Heran Gerba (FDA éthiopienne), Al Shiferaw (JSI), Jean Baptiste Byiringiro (MS Rwanda MOH), Matthews Mwale (Zambia MOH), Petros Lukonde (Zambia MOH)*	Virtuel
9:15 – 9:30 HAE **13:15 – 13:30** GMT	**Q&R**	Virtuel
9:30 – 10:15 HAE **13:30 – 14:15** GMT	**Table ronde sur les approches de l'architecture de traçabilité - Partie 2 : Les systèmes de traçabilité - Turkiye, l'Argentine, l'Inde, et l'Afrique du Sud** Un aperçu des pays qui ont mis en place la traçabilité pharmaceutique et/ou intégré les normes mondiales GS1 dans la transformation numérique de la chaîne d'approvisionnement. ***Animateur du panel:*** *Nuran Idris (Bureau mondial GS1)* ***Panélistes:*** *Cihan Korucu (GS1 Türkiye), Mario Abitbol (GS1 Argentine), Subrato Dey (GS1 Inde), Michele Francis Padayachee (GS1 l'Afrique du Sud)*	Virtuel
10:15 – 10:30 HAE **14:15 – 14:30** GMT	**Q&R**	Virtuel
10:30 – 10:45 HAE **14:30 – 14:45** GMT	**Une revue du "WHO Digital Supply Chain Architecture Handbook"** ***Présentateurs:*** *Swaroop Jayaprakash (WHO) & Carl Leitner (WHO)*	Virtuel
10:30 – 10:45 HAE **14:30 – 14:45** GMT	**Conclusion: Prochaines étapes et recommandations** Cette session permettra de récapituler les ressources disponibles pour aider les pays qui s'engagent dans la traçabilité et de fournir des informations sur les personnes à contacter pour obtenir de l'aide, y compris les informations relatives aux contacts clés pour l'assistance. En outre, les pays discuteront de ce qu'il faut faire pour renforcer le dialogue et les prochaines étapes que chaque pays souhaite entreprendre.	Virtuel

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2ND FRANCOPHONE AFRICA GS1 HEALTHCARE SUMMIT (2023)

WHO SMART Guidelines and Digitized Product Catalogue
July 20, 2023 |12:05 – 12:20 GMT

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Carl Leitner

Technical Officer, WHO Digital Health and Innovation

Carl Leitner is the Technical Officer for Architecture and Informatics for WHO's Digital Health and Innovation team working on the SMART Guidelines approach. He was worked for over fifteen years in global digital health including the development and support to open-source digital health tools and standard development across a range of business domains in support of clinical health, public health and health system information needs.

Swaroop Jayaprakash

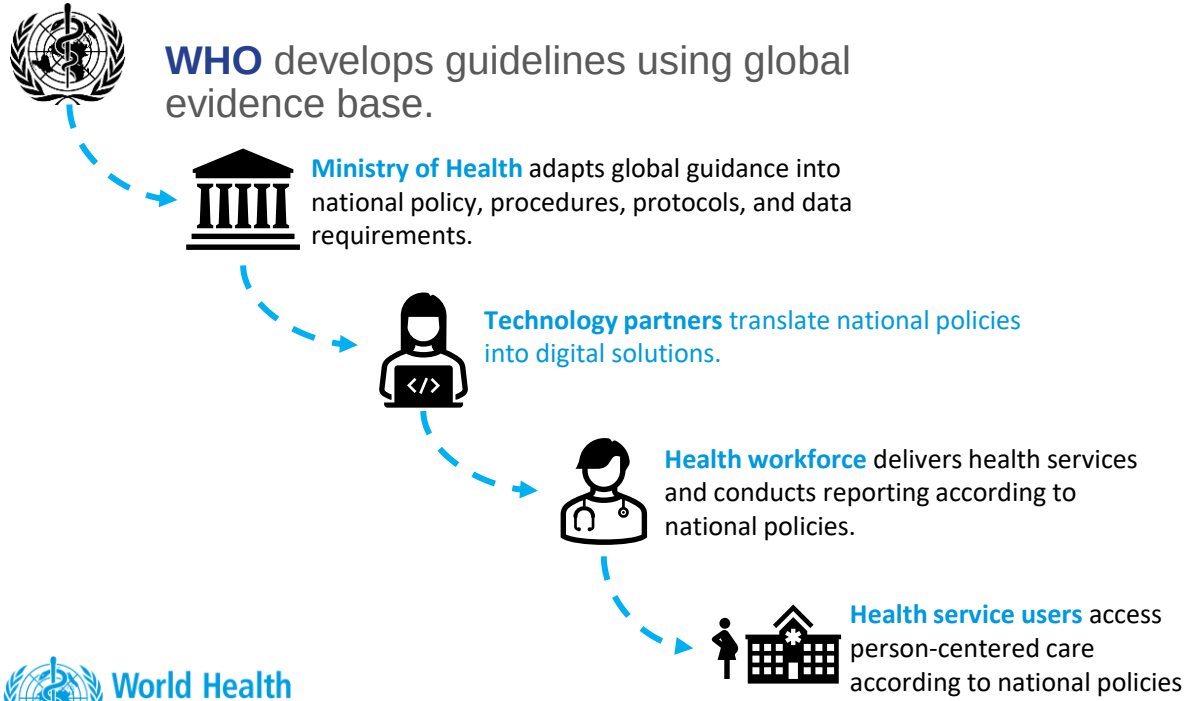
Digital Supply Chain Consultant, WHO

In his 22+ years of experience in IT he has designed & implemented large scale supply chain management systems for customers in retail, distribution, telecom & manufacturing. He helped design & implement ARTMIS application that facilitates procurement & distribution for USAID GHSC-PSM program. He developed the Supply Chain Information Systems Maturity Model (SCISMM) in collaboration with USAID, to help countries assess supply chain information system capabilities. He recently facilitated the development of digital supply chain strategy & architecture in Malawi & Rwanda.

Global Strategy Policy Actions

- Recommends defining “a national digital health architecture blueprint or road map, adopt **open-source health data standards** and aim for **reusable systems or assets** including interoperability of health information systems both at national and international levels in order to establish an innovative integration of **different digital technologies using shared services, ensuring data are of good and comparable quality**”
- “The global strategy promotes **syntactic and semantic interoperability** with WHO norms and standards as a cornerstone of health information to enable sharing of information in a connected world.”

Digital tools can help facilitate the adoption and integration process, but if done inappropriately, can lead to questionable results

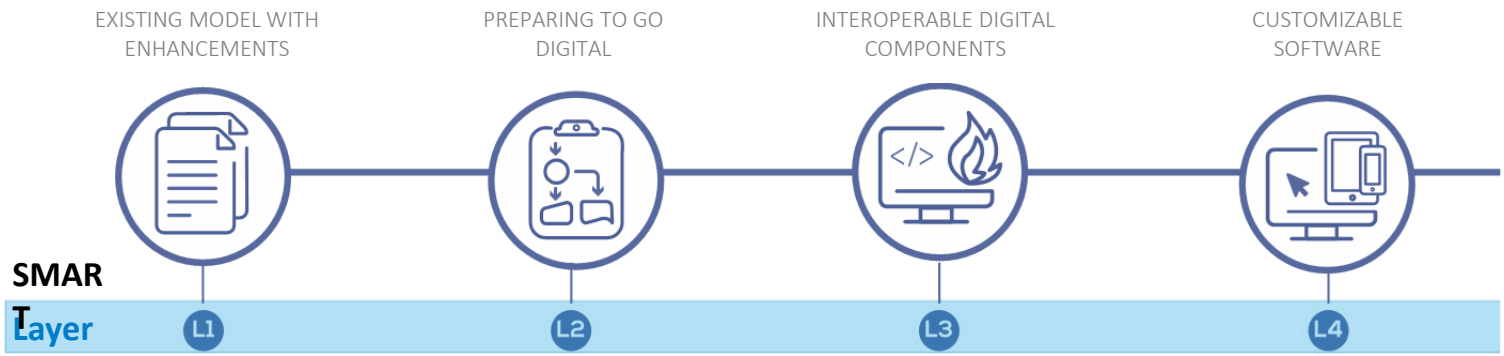


- **Difficult to operationalize** intentionally vague guideline content into digital systems with fidelity
- Infrequently digitized with **interoperability standards**, and **architectural good practice**, leading to siloed systems
- "**Black box**" digital systems become **difficult to maintain** sustainably in the long-term

World Health Organization

SMART Guidelines are health and data Content Digital Public Goods

Standards-based, **M**achine Readable, **A**daptive, **R**equirements-based, **T**estable



- Reinforce operational specificity in existing guidelines
- Digital curation of recommendations
- Panels include informatics and standards experts

- Digital Adaptation Kit (DAK) – requirements document
- Human-readable components
- Describes how a digital tool should function
- Data dictionaries mapped to ICD, LOINC

- FHIR Implementation Guide (IG) documentation
- Based on Clinical Practice Guidelines IG
- Consistent execution across systems - software as a function
- Decision support services and indicator calculations (CQL)

- Fully executable software tools
- Mechanism for real-time updates
- Interoperate with national systems

WHO SMART guidelines: optimising country-level use of guideline recommendations in the digital age - The Lancet Digital Health

Current status of SMART Guidelines development in WHO

Health Domain (L1)	Digital Adaptation Kits (L2)	Machine Readable (L3)			Executable Software (L4)	
		Data	Logic	Forms	Not on FHIR	FHIR-based
Antenatal Care (**ANC**) *+ Adolescent Sexual Reproductive Health (ASRH) overlay*	✓	✓	✓	✓	✓	In progress*
Family Planning (**FP**) *+ ASRH overlay*	✓	✓			MVP	
Sexually Transmitted Infections (**STI**) *+ ASRH overlay*	Will be published soon	✓				
HIV	Will be published soon	In progress				
Immunizations **(EIR)**	Will be published soon	Will be published soon				Being discussed
Child Health in Emergency Settings **(Em Care)**	Will be published soon	In progress				In progress
Digital Documentation of COVID-19 Certificates: **Vaccination Status**	✓	✓	✓	✓		✓
Digital Documentation of COVID-19 Certificates: **Test Results**	✓	✓	✓	✓		✓
Self Care – Sexual and Reproductive Health	In progress					
Tuberculosis **(TB)**	In progress					
Neglected Tropical Diseases **(NTD)**	Being discussed					
Nutrition	Being discussed					
Postnatal Care **(PNC)**	Being discussed					
Health financing	Being discussed					
Primary Health Care	Being discussed					
Emergency Care	Being discussed					
Cervical cancer	Being discussed					
Intrapartum care	Being discussed					

L1: Narrative | Existing model with enhancements

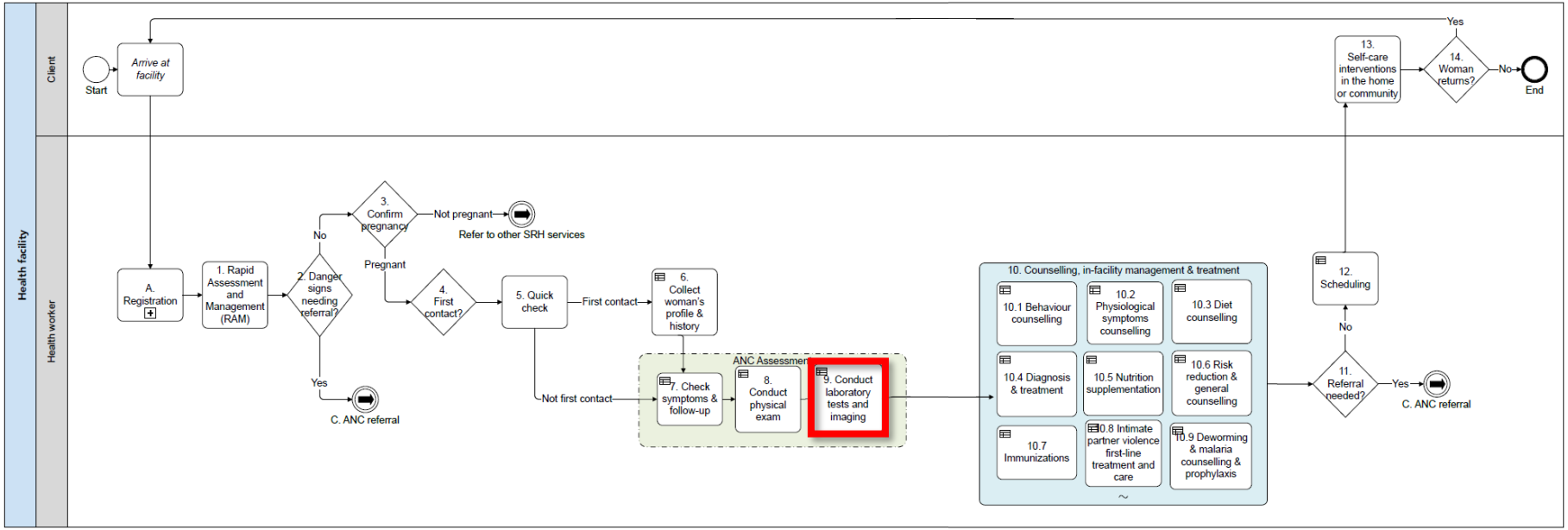
Current guideline format from the guideline document

Iron and folic acid supplements	**A.2.1:** Daily oral iron and folic acid supplementation with 30 mg to 60 mg of elemental iron[b] and 400 µg (0.4 mg) of folic acid[c] is recommended for pregnant women to prevent maternal anaemia, puerperal sepsis, low birth weight, and preterm birth.[d]	Recommended
	A.2.2: Intermittent oral iron and folic acid supplementation with 120 mg of elemental iron[e] and 2800 µg (2.8 mg) of folic acid once weekly is recommended for pregnant women to improve maternal and neonatal outcomes if daily iron is not acceptable due to side-effects, and in populations with an anaemia prevalence among pregnant women of less than 20%.[f]	Context-specific recommendation
Anaemia	**B.1.1:** Full blood count testing is the recommended method for diagnosing anaemia in pregnancy. In settings where full blood count testing is not available, on-site haemoglobin testing with a haemoglobinometer is recommended over the use of the haemoglobin colour scale as the method for diagnosing anaemia in pregnancy.	Context-specific recommendation

Source: https://www.who.int/reproductivehealth/publications/maternal_perinatal_health/anc-positive-pregnancy-experience/en/

L2: Operational | Preparing to go digital

ANC Consultation workflow



Source: Digital Adaptation Kit for Antenatal Care: Operational requirements for implementing WHO recommendations in digital systems

L2: Operational | Preparing to go digital

Indicator calculation for % of women who have received iron and folic acid supplements

Indicator code	Indicator name	Numerator		Denominator		Disaggregation	Reference
		Definition	Computation	Definition	Computation		
ANC.IND.2	**Percentage of pregnant women who received iron and folic acid (IFA) supplements for 90+ days**	Number of pregnant women who received the recommended number of IFA tablets during all previous contacts	COUNT of number of women who were prescribed IFA tablets at each ANC contact they have had	Total number of antenatal clients with a first contact	COUNT of all women whose records were closed (ANC close form) in the last reporting period due to any of the reasons below: » live birth » stillbirth » miscarriage » abortion » woman died » lost to follow-up » moved away	Age (10–14, 15–19, 20+) Education level (none, don't know, primary, secondary, higher)	WHO ANC monitoring framework *(43)*

- Indicators can be aggregated from individual level data rather than a separate reporting system
- Each 'variable' must be encoded to a standard terminology (ICD, ICHI, ICF, LOINC)
- Data dictionary, decision support logic, indicator tables, functional and non-functional requirements are in spreadsheet formats

Source: Digital Adaptation Kit for Antenatal Care: Operational requirements for implementing WHO recommendations in digital systems

L3: Machine-readable | Interoperable digital components

Same recommendations in standards-based software code format

ANC.DT.25 Anaemia, iron and folic acid supplementation:
When: *named-event:* ANC.B9. Conduct laboratory tests and imaging
Then:

Anaemia can be diagnosed if Hb level is less than 11 in first or third trimester or Hb level less than 10.5 in second trimester; OR there is no Hb test result recorded, but woman has pallor. If a woman is diagnosed with anaemia during pregnancy, conduct counselling for managing and treating anaemia. Her daily elemental iron should be increased to 120 mg until her haemoglobin (Hb) concentration rises to normal (Hb 110 g/L or higher). Thereafter, she can resume the standard daily antenatal iron dose to prevent recurrence of anaemia. The equivalent of 120 mg of elemental iron equals 600 mg of ferrous sulfate heptahydrate, 360 mg of ferrous fumarate or 1000 mg of ferrous gluconate. Please refer to iron sources listed below for additional guidance that can be provided.

If: *applicability:* ((((("Blood haemoglobin test result" < 110 g/L) AND ("Gestational age" ≤ 12 weeks)) OR (("Blood haemoglobin test result" < 110 g/L) AND ("Gestational age" ≥ 28 weeks))) OR (("Blood haemoglobin test result" < 105 g/L) AND (13 weeks ≤ "Gestational age" ≤ 27 weeks))) OR (("Blood haemoglobin test conducted" = FALSE) AND ("Pallor present" = TRUE)) *(Should Conduct REQUIRED anaemia counselling)*
Then:

Conduct REQUIRED anaemia counselling:
"Amount of iron prescribed" = 120 mg:
"Type of iron supplement dosage provided" = "Daily":
"Amount of daily dose of folic acid prescribed" = 0.4 mg:

If a woman is not diagnosed for anaemia, iron and folic acid supplementation is still recommended. Due to the population's high anaemia prevalence, a daily dose of 60 mg of elemental iron is preferred over a lower dose. A daily dose of 400 micrograms (0.4 mg) folic acid is also recommended. The equivalent of 60 mg of elemental iron is 300 mg of ferrous sulfate heptahydrate, 180 mg of ferrous fumarate or 500 mg of ferrous gluconate. Please refer to iron sources listed below for additional guidance that can be provided.
If: *applicability:* ((((("Blood haemoglobin test result" ≥ 110 g/L) AND ("Gestational age" ≤ 12 weeks) AND ("Population prevalence of anaemia" ≥ 40%)) OR (("Blood haemoglobin test result" ≥ 110 g/L) AND ("Gestational age" ≥ 28 weeks) AND ("Population prevalence of anaemia" ≥ 40%))) OR (("Blood haemoglobin test result" ≥ 105 g/L) AND (13 weeks ≤ "Gestational age" ≤ 27 weeks) AND ("Population prevalence of anaemia" ≥ 40%))) OR (("Blood haemoglobin test conducted" = FALSE) AND ("Pallor present" = FALSE) AND ("Population prevalence of anaemia" ≥ 40%)) *(Should \"Anaemia counselling conducted\" IS OPTIONAL)*
Then:

"Anaemia counselling conducted" IS OPTIONAL:
"Amount of iron prescribed" = 60 mg:
"Type of iron supplement dosage provided" = "Daily":
"Amount of daily dose of folic acid prescribed" = 0.4 mg:


```
        "id" : "1",
        "title" : "Conduct REQUIRED anaemia counselling",
        "description" : "Conduct REQUIRED anaemia counselling",
        "textEquivalent" : "Anaemia can be diagnosed if Hb level is less than 11 in first or third trim
ester or Hb level less than 10.5 in second trimester; OR there is no Hb test result recorded, but woman h
as pallor.\n\nIf a woman is diagnosed with anaemia during pregnancy, conduct counselling for managing and
treating anaemia. \n\nHer daily elemental iron should be increased to 120 mg until her haemoglobin (Hb) c
oncentration rises to normal (Hb 110 g/L or higher). Thereafter, she can resume the standard daily antena
tal iron dose to prevent recurrence of anaemia.\n\nThe equivalent of 120 mg of elemental iron equals 600
mg of ferrous sulfate heptahydrate, 360 mg of ferrous fumarate or 1000 mg of ferrous gluconate.\n\nPlease
refer to iron sources listed below for additional guidance that can be provided. ",
        "documentation" : [
          {
            "type" : "citation",
            "label" : "WHO ANC recommendations (2016): B1.1, A.2.1, A.2.2 (3)\nPregnancy, childbirth, p
ostpartum and newborn care guide (2015): C4 (1)"
          }
        ],
        "condition" : [
          {
            "kind" : "applicability",
            "expression" : {
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ge\" ≤ 12 weeks))\n  OR ((\"Blood haemoglobin test result\" < 110 g/L)\n  AND (\"Gestational age\" ≥ 28 w
eeks)))\n  OR ((\"Blood haemoglobin test result\" < 105 g/L)\n  AND (13 weeks ≤ \"Gestational age\" ≤ 27
weeks)))\n  OR ((\"Blood haemoglobin test conducted\" = FALSE)\n  AND (\"Pallor present\" = TRUE))",
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              "expression" : "Should Conduct REQUIRED anaemia counselling"
            }
          }
        ],
        "action" : [
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          },
          {
            "title" : "\"Amount of iron prescribed\" = 120 mg"
          },
          {
            "title" : "\"Type of iron supplement dosage provided\" = \"Daily\""
          },
          {
            "title" : "\"Amount of daily dose of folic acid prescribed\" = 0.4 mg"
```

Country Example: Malawi

Ministry of Health and Population – Malawi

Malawi Supply Chain Systems Architecture for Commodity Tracking and Tracing

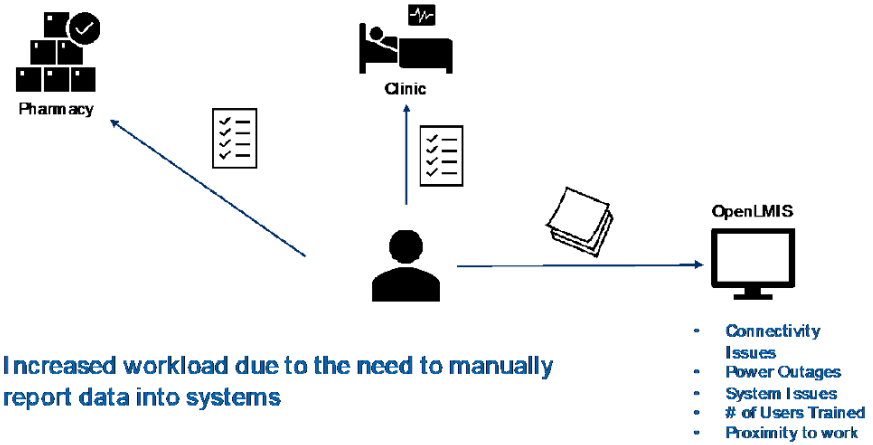


Figure 5. Operational Challenges at Downstream Facilities

- Stock-outs
- Need for emergency orders and stock transfers by facilities
- Overload of manual processes
- Manual data entry leading to errors
- Clarity on consumption versus issue, impacting forecasting and distribution
- Use of multiple overlapping systems

Country Example: Malawi

Ministry of Health and Population – Malawi

Malawi Supply Chain Systems Architecture for Commodity Tracking and Tracing

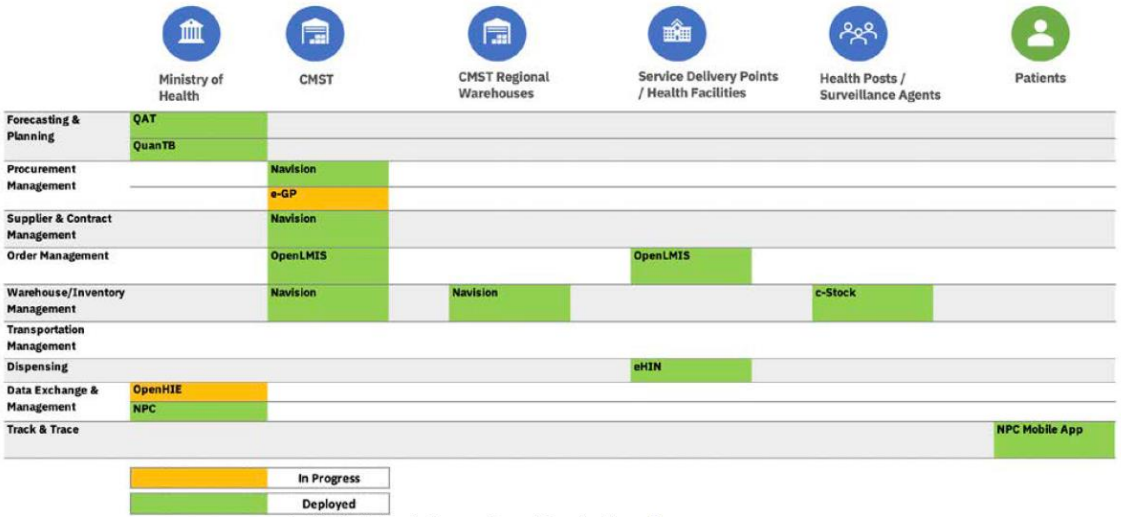


Table 1. Malawi's Existing Digital Supply Chain Footprint

Country Example: Malawi

Ministry of Health and Population – Malawi

Malawi Supply Chain Systems Architecture for Commodity Tracking and Tracing

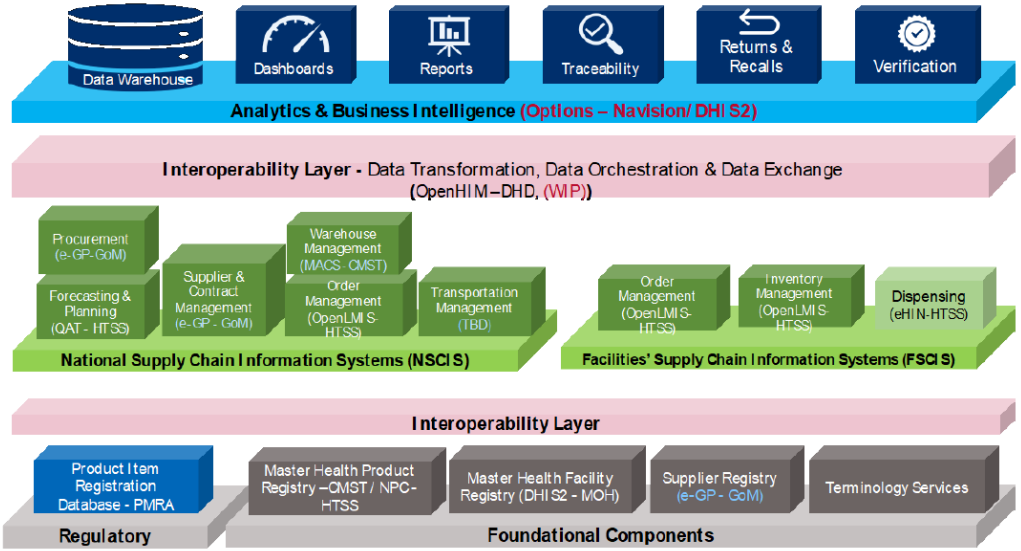
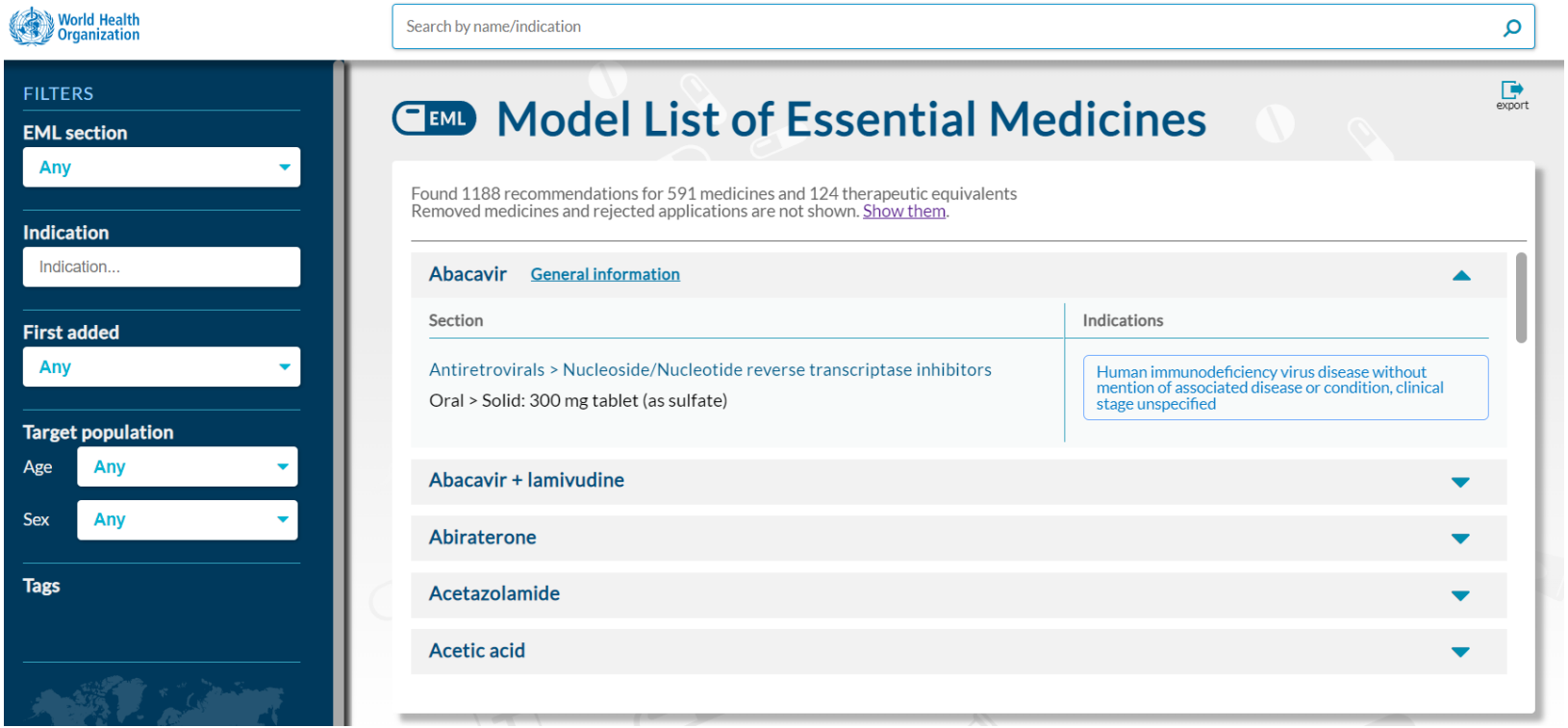


Figure 17. Malawi To-Be Supply Chain Logical Architecture

Product master data management: As noted in the as-is architecture section, NPC serves as the product master data management tool and has been operational in Malawi since mid 2021. To leverage the benefits of standardized data managed within NPC, NPC will be integrated with SC systems and HIS. The integration will be accomplished through the interoperability layer.



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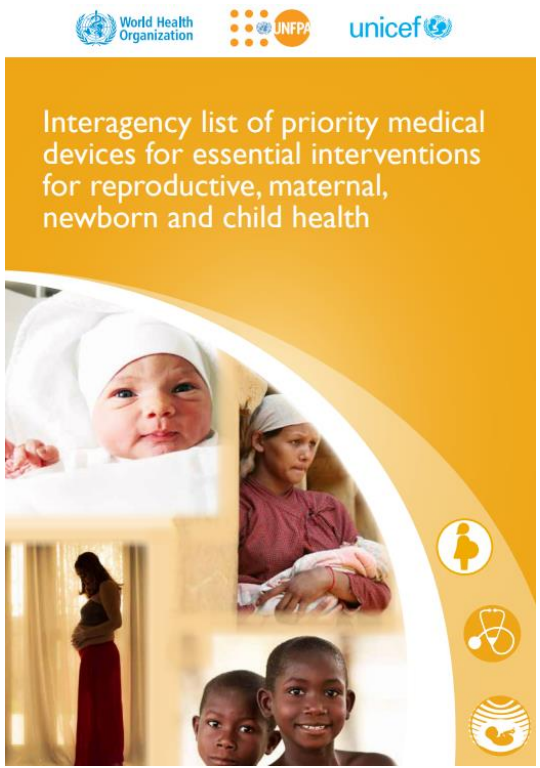

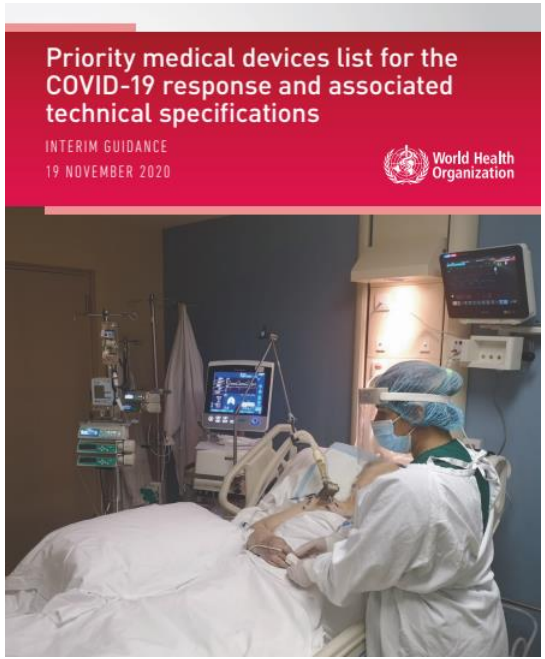

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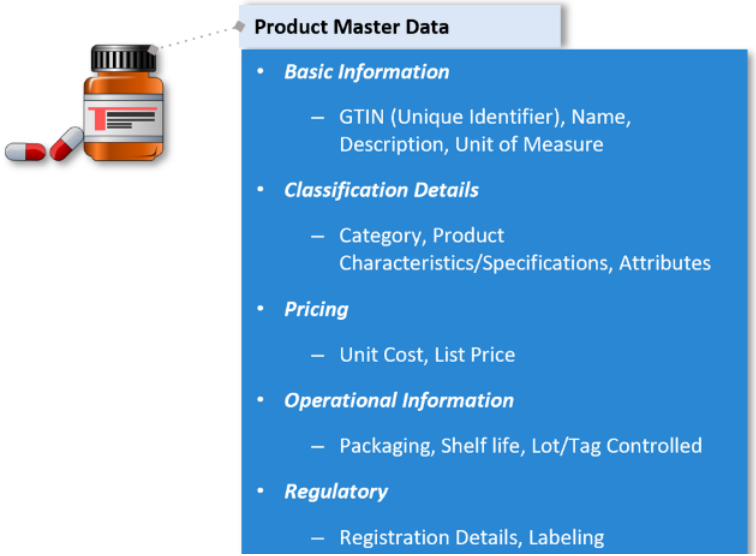
National Product Catalog

A key component on this is the use of online National Product Catalog (NPC). This tool facilitates the adoption of standardized product information, thus eliminating the need for manual interventions to keep all supply chain actors in synch, which represents a very common challenge for national healthcare supply chains in low- and middle-income countries.

Product Master Data



Category	Attributes (GS1 Nomenclature)	Definition
GENERAL ITEM INFORMATION	Item Id (gtin)	The Global Trade Item Number is the standard 14-digit representation of the number used to identify all trade items in GDSN
	Hierarchy level (tradeItemUnitDescriptorCode)	Describes the hierarchical level of the trade item. (each, case, pallet)
	Brand Name (brandName)	The recognizable name used by a brand owner to uniquely identify a line of trade item. This is recognizable by the consumer.
	Functional Name (functionalName)	Describes use of the product by the consumer. Should help clarify the product classification associated with the GTIN.
	Country Of Origin (placeOfProductActivity/countryOfOrigin/countryCode)	The country code (codes) in which the goods have been produced or manufactured, according to criteria established for the purposes of application of the value may or may not be presented on the trade item label.
PRODUCT DESCRIPTION INFORMATION	Product Description (tradeItemDescription)	An understandable and useable description of a trade item using brand and other descriptors.
	Manufacturer GLN (manufacturerOfTradeItem/gln)	The Global Location Number used to identify the organization that manufactures this trade item.
	Manufacturer Name (manufacturerOfTradeItem/partyName)	The name of the manufacturer of this trade item.
PHARMACEUTICAL INFORMATION	Dosage Form (dosageFormTypeCodeReference)	A dosage form is the physical form of a medication that identifies the form of the pharmaceutical item.
	Route of Administration Description (enumerationValueDescription)	The description for the method(s) of administering the product. In pharmacology and toxicology, a route of administration is the path by which a drug, fluid, or other substance is brought into contact with the
HIERARCHY	Child Item (gTIN (child) (nextLowerLevelTradeItemInformation)	Unique product identification number (GTIN) for a child item with a higher-level trade item (parent) in a product hierarchy. This item may repeat in the case of a combination pack (multiple GTINs in lower level).
	Total Quantity of Next Lower Level Trade Item (totalQuantityOfNextLowerLevelTradeItem)	This represents the Total quantity of next lower level trade items that this trade item contains.
SHELF LIFE	Shelf Life from Production (minimumTradeItemLifespanFromTimeOfProduction)	The period of days, guaranteed by the Manufacturer, before the expiration date of the product, based on the production.

VAN INTRODUCES GROUNDBREAKING PRODUCT CATALOG MANAGEMENT TOOL

15th January 2020

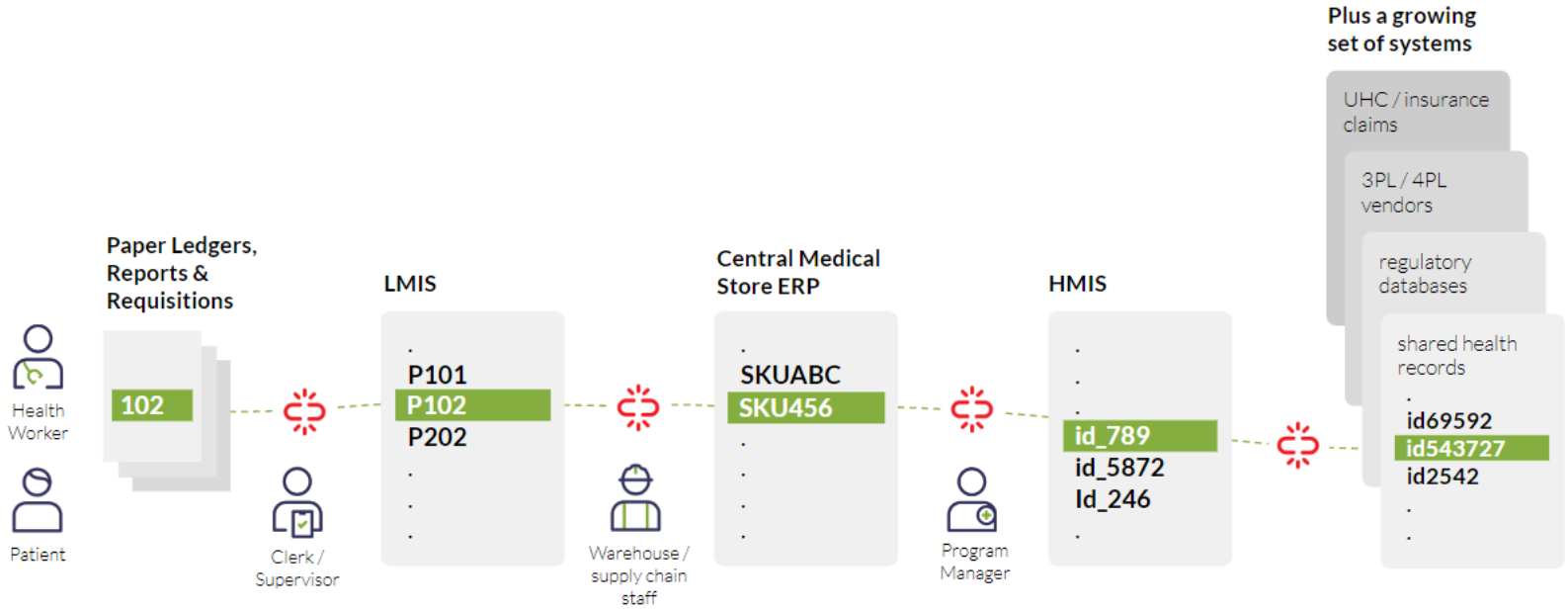
Global FP VAN members and other key health supply chain stakeholders came together in Washington, DC recently to learn more about the groundbreaking Product Catalog Management Tool (PCMT). Health systems around the globe face challenges with inconsistent product identifiers (the ID numbers and barcodes used to manage inventory and delivery of medicines). These inconsistencies undermine supply chain efficiency and visibility. ID numbers differ across hundreds of paper and digital systems, contributing to a heavy manual effort and low data quality. PCMT is a user-friendly tool for publishing and managing product catalogs; GFPVAN is the first PCMT user, managing its family planning product catalogue in the tool and using it as the definitive global source for product information for family planning products.

PCMT interoperates with many systems in LMIC countries using global standards such as GS1. GS1 – a business language designed to improve the efficiency, safety and visibility of supply chains. If GS1 were used by all organizations and countries, everyone would be referencing the same product identifiers, which helps increase efficiencies in supply chain management. If shared data standards are defined, these harmonized standards can make transactions efficient, speedy, and effective.

In National Health Systems

Each stakeholder has different needs for product information, across many systems and organizations.

There are no consistent product identifiers to connect the dots.



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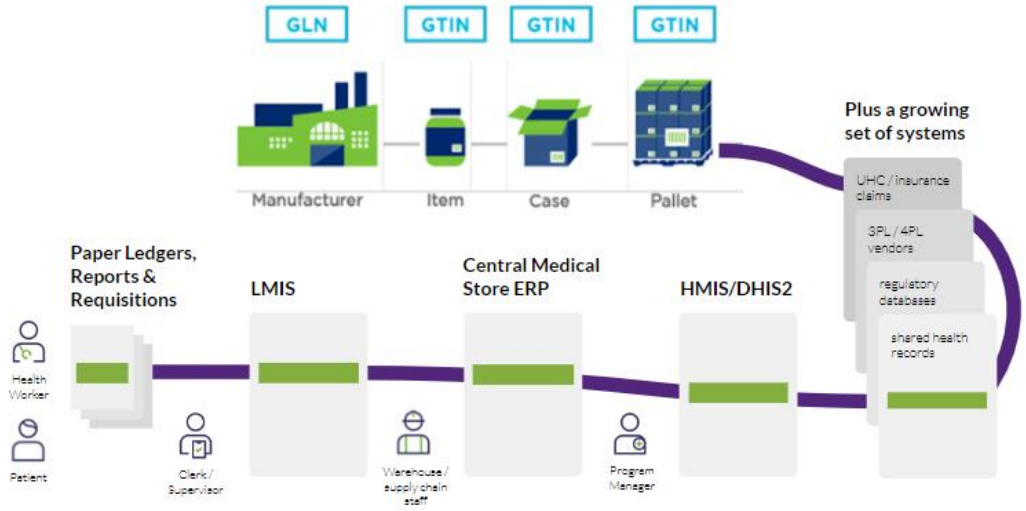
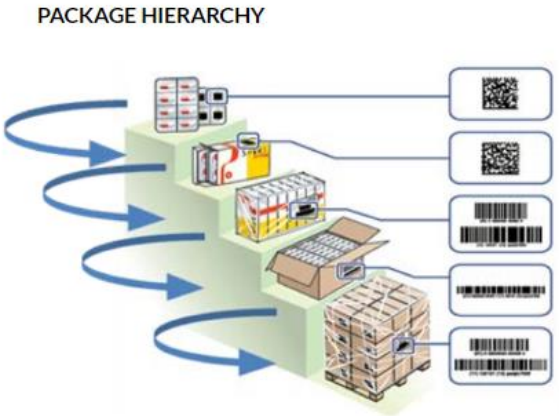
PCMT and GS1

PCMT supports using GS1 identifiers, sourcing manufacturer data through the GDSN, and mapping GTINs to local identifiers





Product Registry for WHO SMART Guidelines

- Feature development and hosting of PCMT to support country adaptation workflows for SMART Guidelines as core component of the planned SMART Guidelines Exchange Platform including multi-tenant support and synchronization with HL7 FHIR compliant terminology services

- Publication of product master data such as the Global Product Catalog (GPC) and the RHSC Family Planning Catalogue with the capacity to expand to other health areas

- Incorporation of key WHO product catalogues into the hosted PCMT environments

- Incorporating approaches to implementing standardized national product catalogues (NPC) in the digital supply chain architectural approaches handbook, being developed as part of WHO SMART guidelines

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2ND FRANCOPHONE AFRICA GS1 HEALTHCARE SUMMIT (2023)

Enabling Supply Chain Digital Health Transformation: How GS1 standards underpin digital transformations

July 20, 2023 | 12:20 – 12:35 GMT

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Pete Alvarez

Senior Director, Identification and Master Data Standards, Healthcare

Pete is part of the GS1 Global Office healthcare team and has been with GS1 since 1999. He is a subject matter expert on GS1 standards for Automatic Identification and Data Capture (AIDC), master data and data quality, the Global Data Synchronisation Standard (GDSN), product classification standards, and the GS1 Digital Link standard in the healthcare sector.

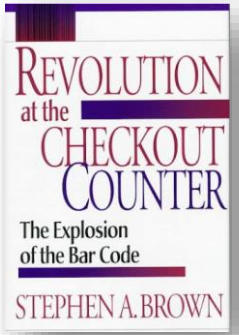
He is passionate about the work GS1 is doing to improve patient safety, medical outcomes and supply chain efficiency.

9:05a.m. EDT, 26 June 1973, Troy Ohio, US

The first U.P.C. barcode scanned at Marsh Supermarket started a revolution…

…a digital transformation that changed the world.

The birth of the Global Trade Item Number (GTIN).



How Amazon is changing healthcare: Amazon is setting up initiatives to transform pharmacy, the medical supply chain, health insurance, and care delivery. Amazon is leveraging its delivery power to carve into the medical supplies distribution space and using its massive employee base to test the telehealth waters.

Apple Healthcare: Apple is eager to build out its health division and live out CEO Tim Cook's goal of having health be Apple's 'greatest contribution to mankind.' Apple is striving to turn its consumer products into portable patient health hubs and valuable clinical research tools.

Google (Alphabet) Healthcare: Alphabet is focusing on its expertise in Artificial Intelligence and data storage to help drive the industry-wide push for predictive analytics, precision medicine, and interoperability. Alphabet hopes to enhance consumer health and clamp down on healthcare costs.

Microsoft Healthcare: Microsoft is facing off against Alphabet and Amazon in the race to control the healthcare cloud market. Microsoft is largely staying out of the consumer-facing realm with its health play—zeroing in on Azure, and enabling providers and payers to target specific pockets of populations for better health outcomes and helping to optimize data storage.

Source: https://www.insiderintelligence.com/insights/big-tech-in-healthcare-report/

WHO SMART Guidelines

Digital Health and Innovation

Digital technologies are now integral to daily life, and the world's population has never been more interconnected…

…Despite this, the potential of digital technologies and innovation to improve the health of populations remains largely untapped.

- Strategy and Governance
- Public Digital Health Technology
- Be He@lthy, Be Mobile
- WHO Innovation Hub
- Digital Channels
- Capacity building and collaboration
- WHO Digital Health Technical Advisory Group
- SMART Guidelines
- WHO Digital Clearinghouse

Source: https://www.who.int/teams/digital-health-and-innovation/smart-guidelines

About digital transformation

"What must stay the same, so that the rest can change?"

Dr. Bill Hardgrave, University of Memphis

Supply Chain Digital Health Transformation

- **Digitization** of the healthcare supply chain requires *interoperability* across all functions and systems from manufacturing to the point of care.
- **Interoperability** requires *harmonisation* of the basic components.
- **Harmonisation** of basic components requires identification of ***what*** and ***who***.

GTIN

GLN

The GS1 system of standards

Identify

GS1 Standards for Identification

Company & Location
- Global Location Number (GLN)

Product
- Global Trade Item Number (GTIN)
- Serialised Global Trade Item Number (SGTIN)

Logistics & Shipping
- Serial Shipping Container Code (SSCC)
- Global Shipment Identification Number (GSIN)
- Global Identification Number for Consignment (GINC)

Assets
- Global Individual Asset Identifier (GIAI)
- Global Returnable Asset Identifier (GRAI)

Services & More
- Global Service Relation Number (GSRN)
- Global Document Type Identifier (GDTI)
- Global Coupon Number (GCN)

Capture

GS1 Standards for Barcodes & EPC/RFID

GS1 Barcodes

EAN/UPC

GS1-128

ITF-14

GS1 DataBar

GS1 DataMatrix

GS1 QR Code

GS1 Composite Barcode

GS1 EPC/RFID

Electronic Product Code (EPC) RFID

EPC HF Gen 2

EPC UHF Gen 2

Share

GS1 Standards for Data Exchange

Master Data
- Global Data Synchronisation Network (GDSN)

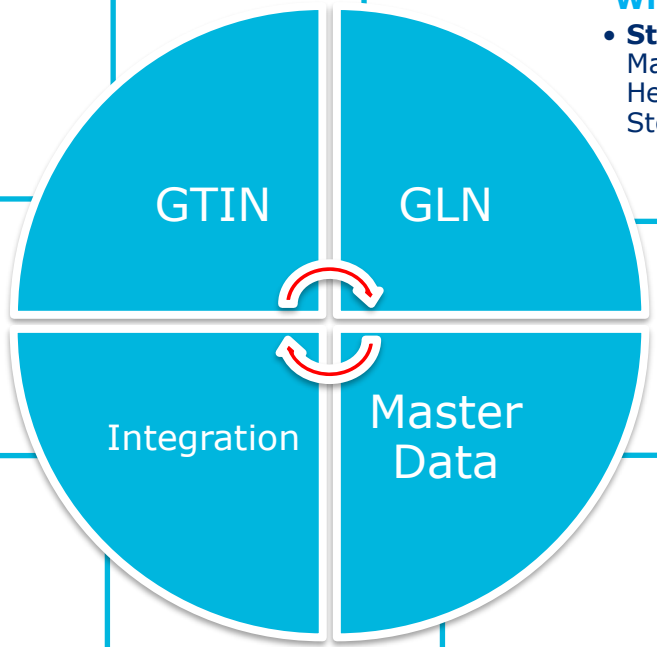
Transactional Data
- eCom (EDI): EANCOM, GS1 XML

Event Data
- EPC Information Services (EPCIS)

Foundational elements

WHAT
- **Product identification** including additional data elements as needed (e.g., Bath/Lot, Expiry and Serial Number)

WHO
- **Stakeholder identification** (i.e., Manufacturer, Distributor, Healthcare Provider, Country Store, etc.)



INTEROPERABILY
- GTIN + GLN + Master Data enable a digital transformation

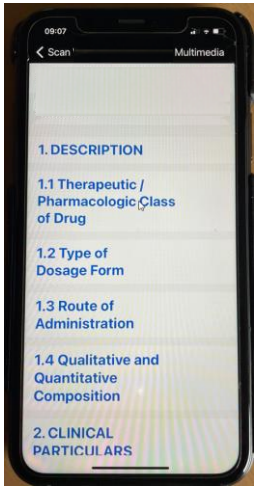
DESCRIBE & DEFINE
- Information about the WHAT and the WHO

(i.e., NPC, registry)


One more thing

From paper to digital

Migration from paper to digital



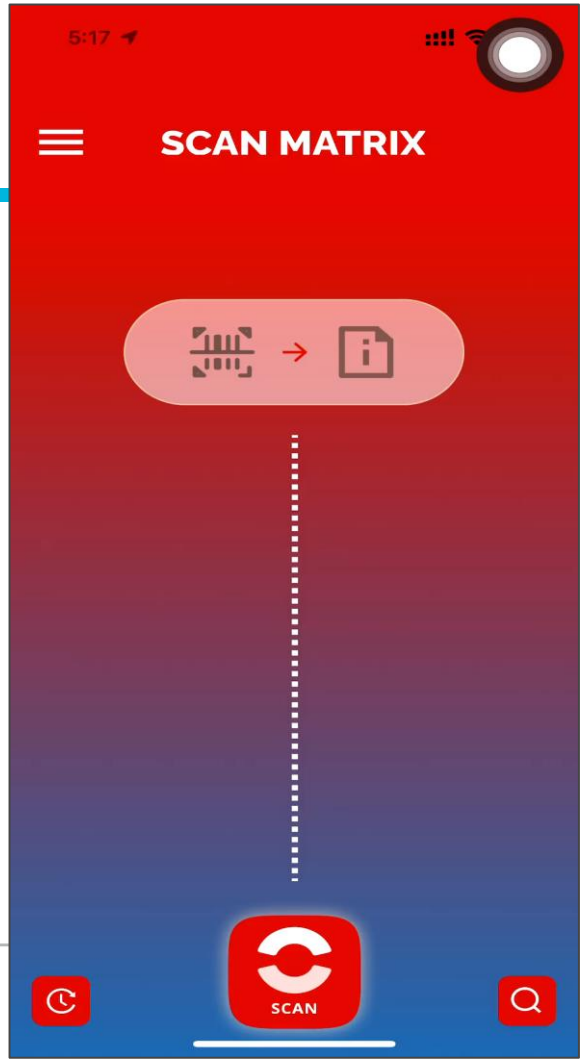
THEME 1 – ENVIRONMENTAL SUSTAINABILITY

Advisory Committee Leads: Hao Vo-Tran, Jeanie Misko
Theme Leads: Grace Wong, Debbie Rigby

Link

The GS1 Digital Link Standard

- Connecting the physical product to online information with the existing GS1 barcode on the product
- Scanning the barcode from actual product from **J&J in Singapore** and access the e-leaflet
- Test demonstration of a barcode from **Bayer** to showcase integration with GS1 resolver and access the e-leaflet from Bayer



Source: Diane Riccardi, J&J. Presented at the GS1 US Connect Conference, June 2023.

Thank you

Pete Alvarez
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2ND FRANCOPHONE AFRICA GS1 HEALTHCARE SUMMIT (2023)

Panel Discussion on Traceability Architecture Approaches

July 20, 2023 | 12:35 – 13:05 GMT

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Dr. Dah El Hadj Sidi

Technical Director, GHSC-TA Francophone Task Order

Dr. Dah El Hadj Sidi is a specialist in health commodity management with more than 20 years of experience in the management of essential drugs, pharmaceutical systems and policies, and logistics and supply chain management. Currently, Dr. El Hadj Sidi serves as a technical director at Chemonics' Global Health Division. As a previous senior procurement and supply chain management technical manager for the Grant Management Solutions project, he supported both the Global Fund Principal Recipients (PR) and the Countries Coordinating Mechanism (CCM) to ensure timely and appropriate execution of technical assistance in more than 61 countries. Over eight years, Dr. El Hadj Sidi has served as a technical adviser in Mauritania's Ministry of Health as well as a deputy general director of the country's Central Medical Stores (CAMEC). He holds a medical degree in pharmacy from the Faculty of Pharmacy of Monastir, Tunisia.

2ND FRANCOPHONE AFRICA GS1 HEALTHCARE SUMMIT (2023)

Panel Discussion on Traceability Architecture Approaches - Ethiopia

July 20, 2023 | 12:30 – 13:15 GMT

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Heran Gerba

Director General of the Ethiopian Food and Drug Authority

Since 2018, Ms. Heran Gerba is Director General of the Ethiopian Food and Drug Authority (EFDA), previously the Ethiopian Food, Medicine and Healthcare Administration and Control Authority (EFMHACA). Heran has worked for the Authority since 2003, taking up different roles, including Chief Pharmacist for the Quality Control Laboratory and Acting Head of the Physicochemical Division.

Before taking up the role as Director General, she was Deputy Director General for four years.

Ms. Heran Gerba has a Master's degree in Pharmaceutical Analysis & Quality Assurance from the Addis Ababa University School of Pharmacy.

Al Shiferaw

Technical Director for USAID Digital Health Activity

Al Shiferaw is the Deputy Chief of Party and Technical Director for USAID Digital Health Activity which is the primary digital health project funded by USAID to assist the Ethiopian government in its digital transformation of the health sector.
He also serves as the principal representative for JSI's technology teams, providing Ethiopia projects overall guidance for aspects of digital health and information technology including management assistance, technical support, and strategic advice.

Strategic Objectives

Strengthen regulatory system

Build the capacity of stakeholders

Strengthen knowledge, communication and collaboration

Create visibility in the pharmaceutical supply chain

Improve patient safety and efficiency in the pharma supply chain

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Traceability Approach

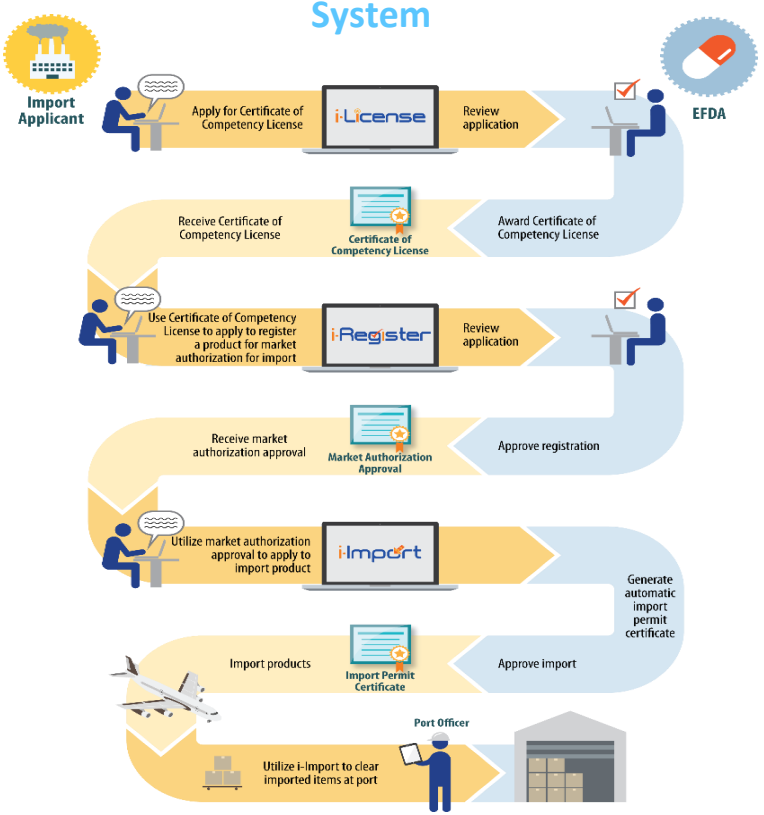
- **Communication**: Effective communication is crucial in pharmaceutical traceability approaches to socialize the importance of traceability and create stakeholder awareness.
- **Establishment of legal framework:** The establishment of clear guidelines and regulations is necessary to ensure proper implementation and adherence to pharmaceutical traceability practices.
- **Digitization**: The digitization of the different pieces of the supply chain and introducing standard barcode systems can enhance pharmaceutical traceability by providing real-time tracking and recording of product information.
- **Enforcement and follow-up:** Strict enforcement measures, including regular audits and inspections, should be implemented to ensure compliance with traceability requirements and to address any non-compliance issues promptly.

Digitization: Regulatory Products

- **Electronic Regulatory Information System (eRIS) at EFDA:**

- **i-License** – used to apply for a certificate of competency to register and import products.
- **i-Register** – used to manage the market authorization process where an applicant seeks to register a medical product.
- **i-Import** – used to manage the import process for medical products, once registered in Ethiopia.
- **i-Verify** - used by the public to verify authenticity of a product
- **i-Clearance** - used to request and review document verification and physical inspection prior to port clearance.

Electronic Regulatory Information System



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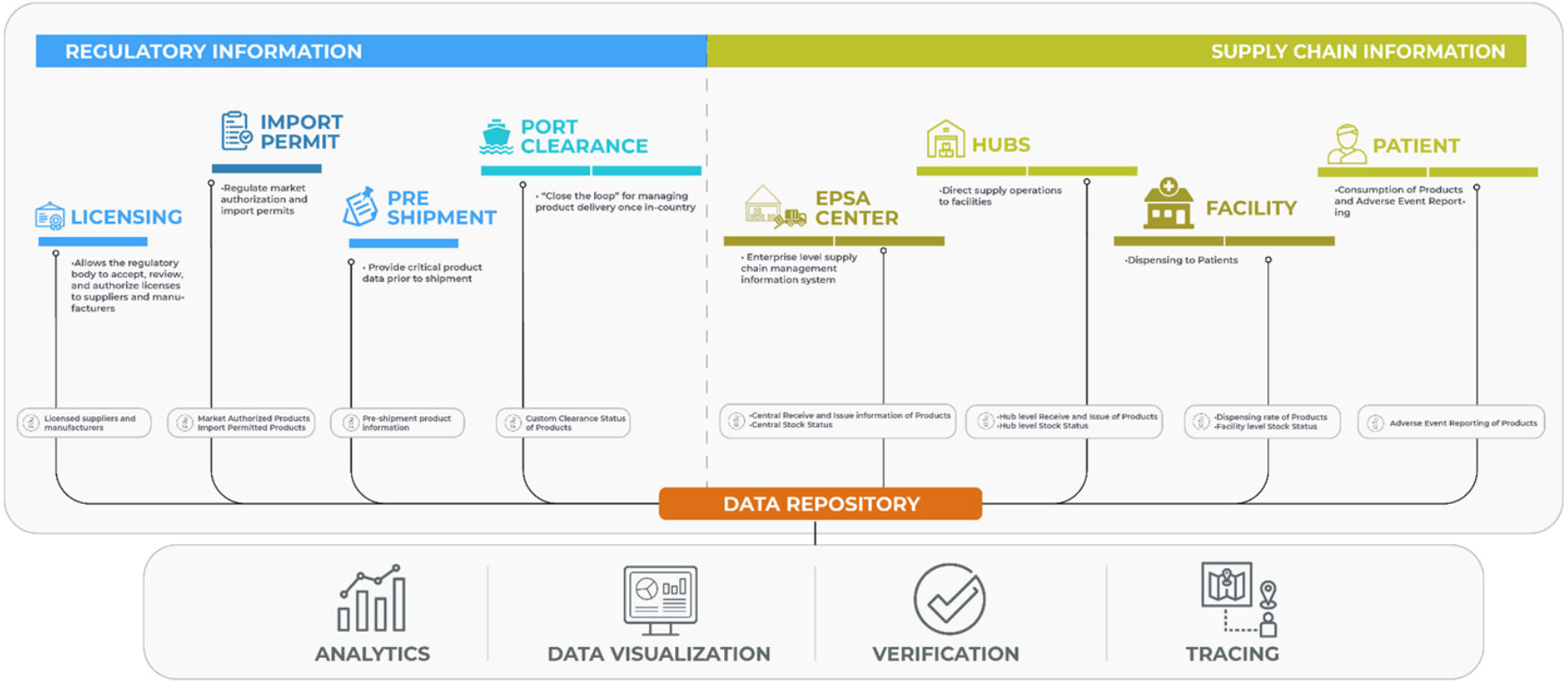
Digitization: Supply Chain Products

- **Vitas:** EPSS, Ethiopia's largest government owned importer, has a digitized warehouse management, real-time capturing of commodity movements across the warehouse network, as well as expiries, losses, and adjustments.

- **Dagu:** Health facilities have implemented an inventory management system designed to manage daily transactions.

- **mBrana:** an inventory management system designed to manage daily transactions at health facilities. This system facilitates the use of standard operating logistics procedures including issue and receipts, 'first to expire, first out', and batch/expiry tracking.

Digitization: Products Stack



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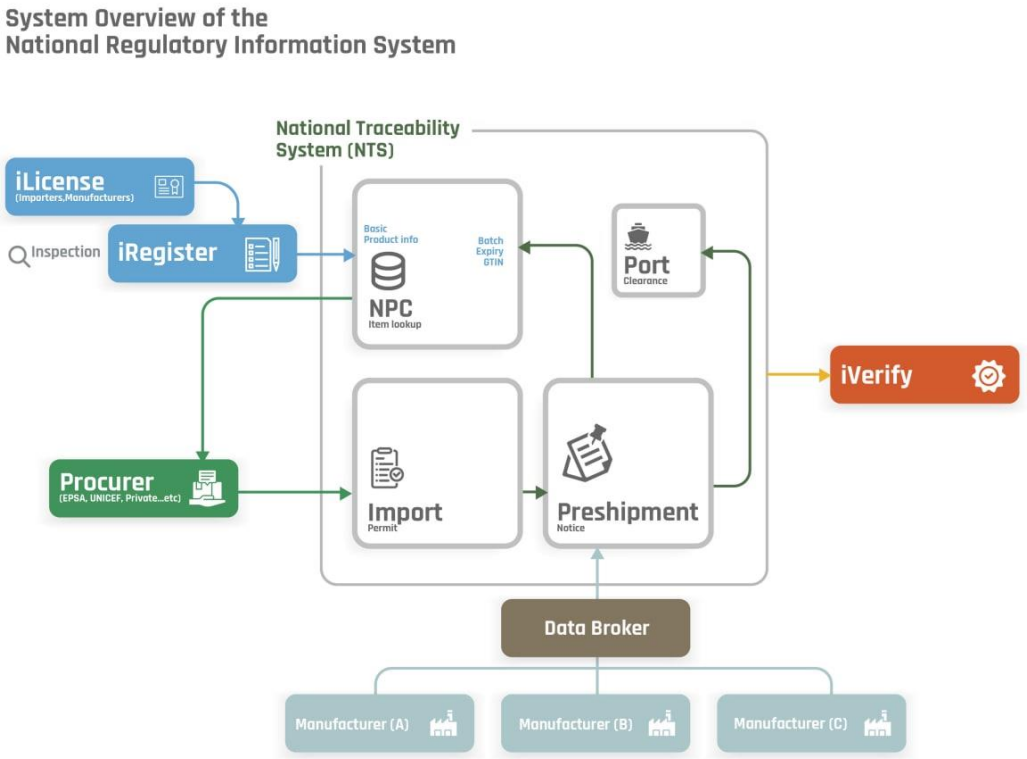
Digitization: Traceability Flow



Operations & Enforcement

- Detailed operational on-boarding strategy needs to be developed with the buy in of all stakeholders
- Anticipate a great deal of handholding, clarifications and assistance will be required as request will come from suppliers and manufacturers
- Practical deadlines most using a phased approached by various criteria. Lessons learned that a one site fits all approach will be problematic
- Issues surrounding product identification, attributes, package sizes and exceptions will be a challenge and decision will have to be made
- Last, the process will not work without strict enorment and leadership

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2ND FRANCOPHONE AFRICA GS1 HEALTHCARE SUMMIT (2023)

Panel Discussion on Traceability Architecture Approaches - Zambia

July 20, 2023

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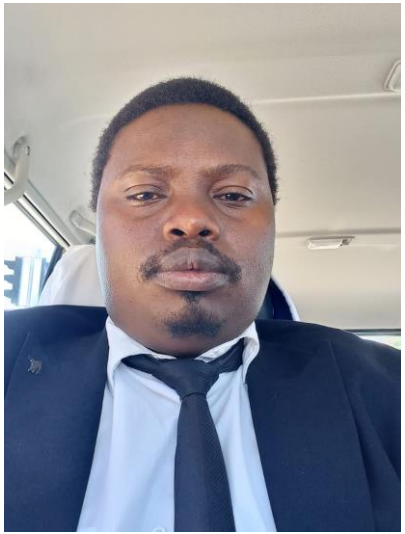


LUKONDE Petros

Pharmacist, Ministry of Health Zambia

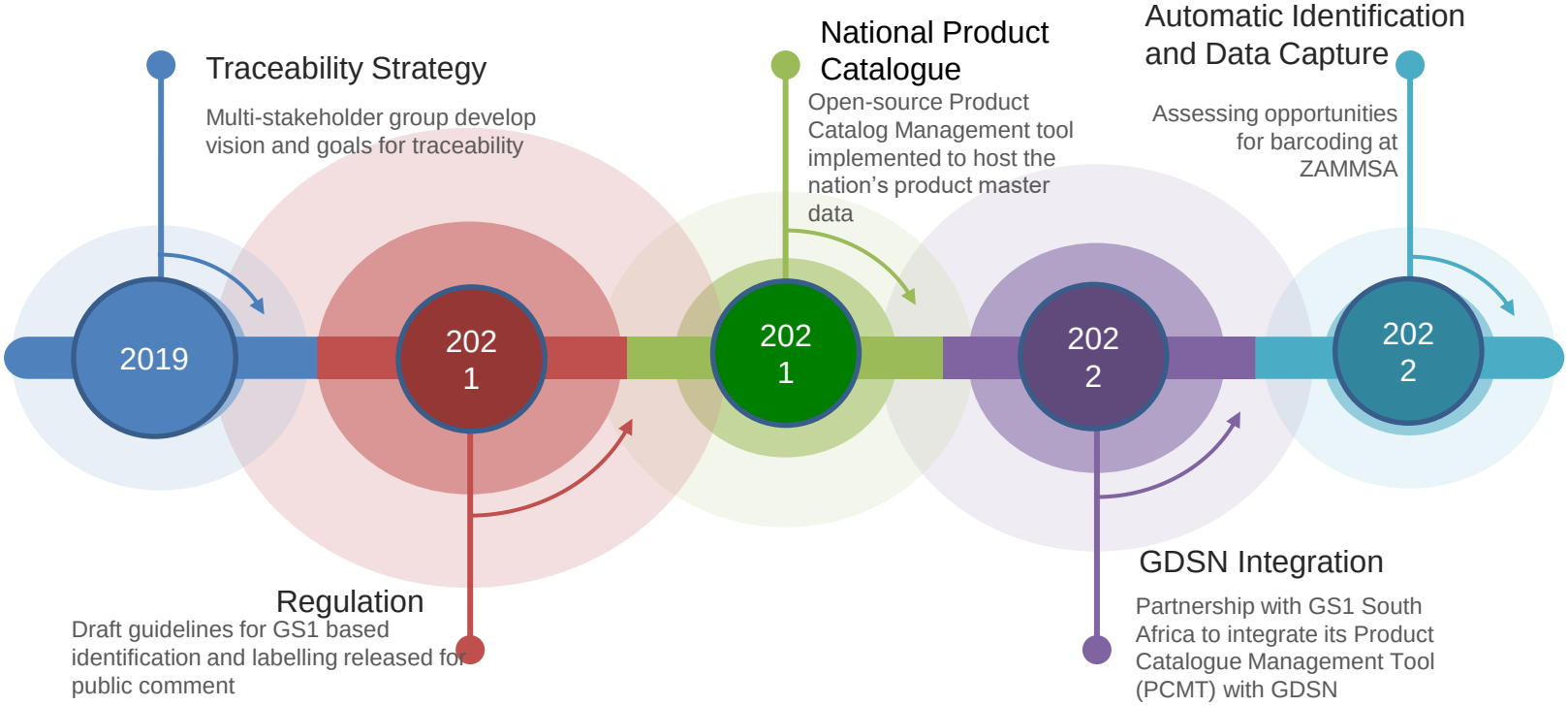
Mr. Lukonde is currently with MOH as a Pharmacist - Commodity Security at MOH for the past 8 years. His main role is to manage the security of medicine and medical supplies to ensure availability and accountability of medicines and medical supplies in the country and to safeguard medicines and medical supplies in the supply chain systems to ensure availability and accountability. He previously worked for the ministry of community development mother and child health headquarters as Logistician in charge of HIV/STI and VMMC for the ministry for a year. He also served at service delivery points at Lufwanyama District Medical Office Pharmacy in charge for 3 years and St Johns Medical Hospital for a year.

Zambia GSI Implementation

Presented by

Ministry of Health

Summary of Zambia Traceability Implementation



In 2019, Zambia National Pharmaceutical Traceability Strategy was developed

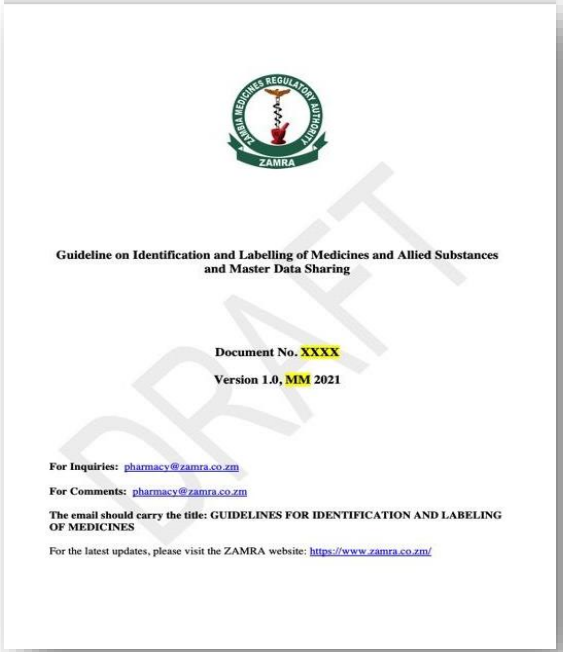
01 Objective 1: Establish a governance structure to lead the strategy, collaboration, outreach, and oversight of global standards and traceability implementation

02 Objective 2: Strengthen the regulatory environment to include legal frameworks that enable traceability of medicines and medical products throughout the supply chain

03 Objective 3: Evaluate, build, and sustain technology to support interoperability of public sector health systems to improve data visibility

04 Objective 4: Create efficiencies in the public health supply chain through standardized identification and automated data capture and reporting

Regulations



Guideline on Identification and Labelling of Medicines and Allied Substances and Master Data Sharing

Document No. XXXX

Version 1.0, MM 2021

For Inquiries: pharmacy@zamra.co.zm

For Comments: pharmacy@zamra.co.zm

The email should carry the title: GUIDELINES FOR IDENTIFICATION AND LABELING OF MEDICINES

For the latest updates, please visit the ZAMRA website: https://www.zamra.co.zm/

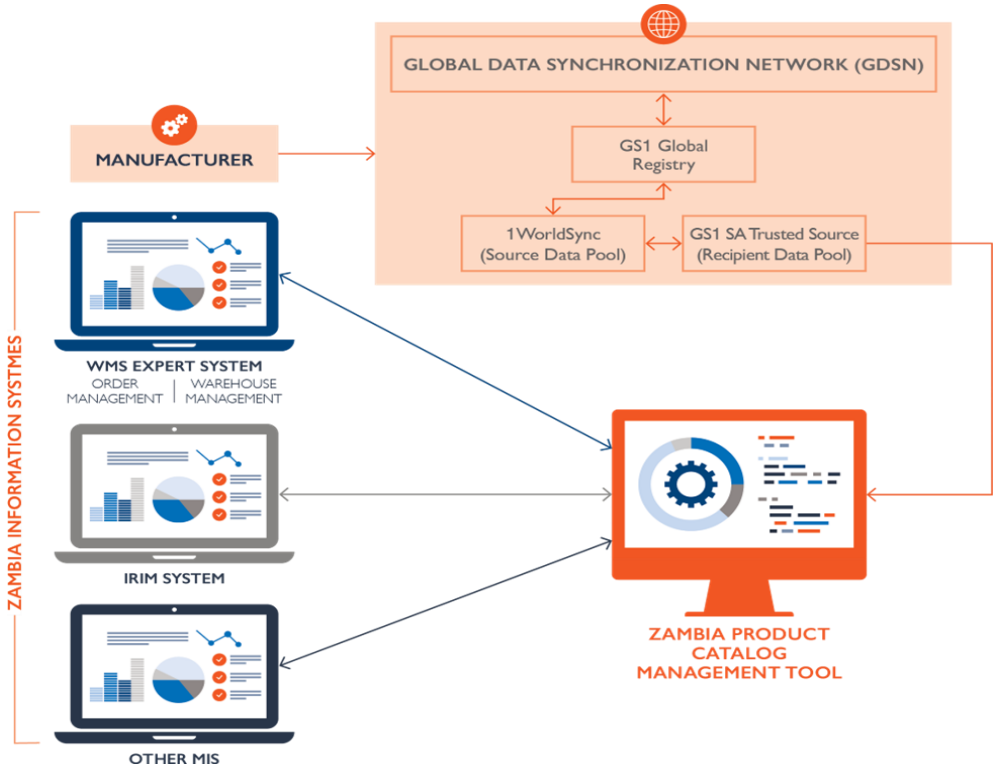
DRAFT

- Regulation 20 (j) of Statutory Instrument No. 79 of 2019 promulgated under the Medicines and Allied Substances Act No. 3 of 2013, gives ZAMRA the mandate to enforce a ‘suitable coding” system for all medicines and allied substances meant for the Zambian market as part of “Product Labelling and Packaging Requirements.”
- Guidelines developed by ZAMRA focused on the identify, capture and sharing components of GS1 Standards.
- Guidelines were approved and publication is underway.

National Product Catalogue - MOH

Launched in September 2021, an open-source Product Catalog Management Tool (PMCT) was selected by MOH to host the national product master data

- ✓ Ability to integrate with GDSN for product data sourced directly from manufacturer
- ✓ An open-source tool that can support relational data models and flexible enough to integrate with other national systems
- ✓ Ability to share product data with downstream systems



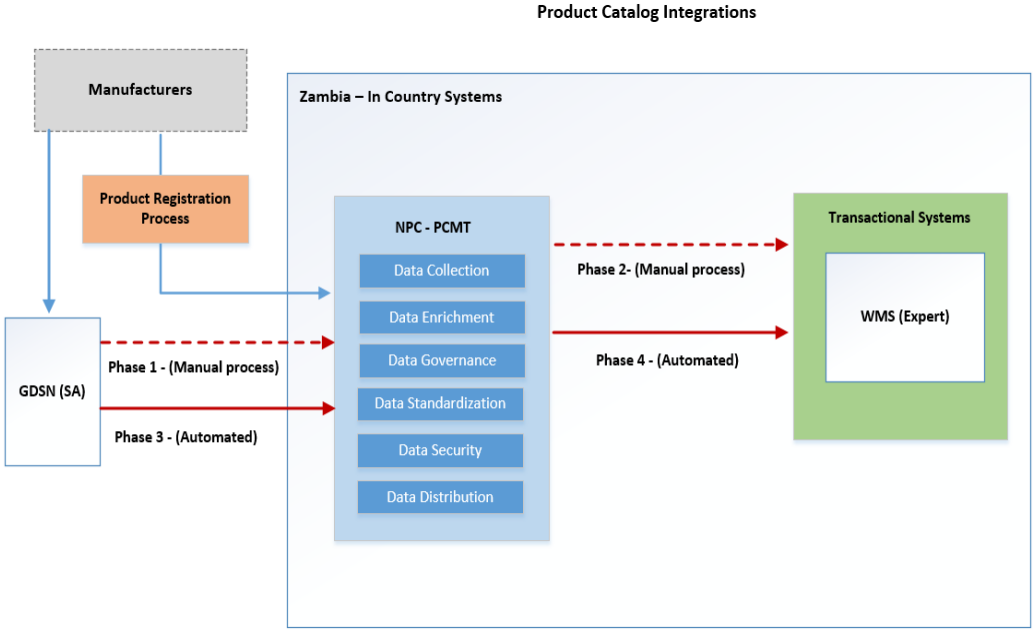
Zambia NPC Accomplishments

Data	• More than 4077 products (pharmaceuticals) harmonized • 551GTINs collected and paired with volumetric data GTINs mapped to national product identifiers (ZAMMSA SKU, MOH Classification and ZAMRA MAH Number) • Ongoing Data harmonization and cleaning processes
Technology	• NPC system implemented using Product Catalog Management Tool (PCMT) as an open-source tool • PCMT hosted by MOH ICT • NPC integration with GDSN South Africa and other system through HIE
Process & people	• Training conducted for data stewards from ZAMMSA and custodians from ZAMRA and MOH • Comprehensive SOPs developed for product master data management processes • Regulations issued to drive GTIN data collection directly from manufactures • Onboarded a catalog Manager

GDSN Pilot

2022, the MOH partnered with GS1 South Africa to integrate it's national product catalog tool with the global data synchronization network (GDSN) to source master data directly from suppliers starting with ARV and malarial products

- Demonstrate capability of PCMT to source data from a certified GDSN data pool
- Demonstrate capability of one ZAMMSA Expert System to integrate to data sourced from PCMT



Global Data Synchronization Network (GDSN) Accomplishments

Phase 1 (GDSN-SA to PCMT)

- ✓Global Location Number obtained through GS1 South Africa
- ✓Set-up a process to receive and upload GTIN data from suppliers
- ✓Architectures and data structures aligned with identified use cases (ZAMMSA)
- ✓13 suppliers onboarded to MOH GDSN instance following ZAMRA communication

Phase 2 (PCMT to Expert) manual

- ✓WMS Expert configured to support GS1 data structures
- ✓Defined attributes required in the extract with a focus on supporting automation at the warehouse
- ✓Established a process to export/extract item and trade item data

Efficiency Gains at the Central Warehouse - ZAMMSA

ZAMMSA is a key player in the National Supply Chain forming an interface between suppliers and beneficiary health facilities.

By virtue of its position, ZAMMSA aims to develop systems that are interoperable with other systems e.g., eLMIS. Data should therefore be consistent across platforms.

This requires synchronization of data with a source of truth for product information i.e., PCMT

ZAMMSA uses internal barcodes for bin and floor locations to facilitate put-aways, picking and loading - opportunity to include scanning of GS1 barcodes

ZAMMSA Transformation towards Barcoding

- WMS data not configured to support the concept of “each” ”case”, ”pallet)
- Manually enter product information - error prone
- Manually calculate self-life for FIFO principles
- Use of Cubiscan to measure volumetrics

- Master data from GDSN is shared with WMS through PCMT
- Configure WMS to support data hierarchies (Pallet, each, case)
- Automate integration of WMS with national product catalog

- Attributes such as volumetrics sourced directly from GDSN via PCMT
- GS1 Barcode is scanned, GTIN used to query master data against MSL SKU.
- GTIN data used to automatically complete the receiving documents

TRANSFORMATION

Lessons Learned

1

Leadership

Have key champions for traceability at the national leadership level

2

Governance

Establishment of the pharmaceutical traceability TWG and sub groups namely regulation, supply chain operations, traceability and master data management

3

Regulations

Development of the traceability guidelines

4

Results

Target low-hanging fruit e.g. barcoding.

✓Learn from other countries, **Architectures and data structures aligned with identified use cases (ZAMMSA)** that have implemented traceability e.g.; Ethiopia, Nigeria

Contact Details

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mbkasonde@gmail.com

QUESTIONS & ANSWER
QUESTIONS & RÉPONSES

2ND FRANCOPHONE AFRICA GS1 HEALTHCARE SUMMIT (2023)

Session 7: Panel Discussion on Traceability Architecture Approaches - Part 2: Traceability Systems - Türkiye, Argentina, India, South Africa

July 20, 13:20 GMT

USAID FROM THE AMERICAN PEOPLE

GS1

Nuran Idris

Manager Healthcare Africa, GS1 Global Office

Nuran joined GS1 global office in January 2020. Her primary role at GS1 Global office's Healthcare team is to support countries in Africa in establishing pharmaceutical traceability systems using GS1 standards.

Nuran's experiences have seen her engage multiple stakeholders from the grass root level up in local and international settings.

From the digital health angle, Nuran has managed systems deployment, sensitized and trained stakeholders; efforts which have supported digital supply chain transformation across multiple countries.

With the power of standards, Nuran strongly believes that even more efficiencies and mostly, improved care to patients can be achieved in developing countries.

Nuran is a Political Scientist and a global eHealth specialist by training.

2ND FRANCOPHONE AFRICA GS1 HEALTHCARE SUMMIT (2023)

Turkey's End to end traceability system

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Cihan Korucu

Assistant General Manager, GS1 Türkiye

For 14 years he has been working at the business development department of GS1 Türkiye. He is responsible from the account management with Ministry of Health, Ministry of Trade Customs and Ministry of Environment.

He is the leading support in Türkiye's Pharmaceutical Tracking System of Ministry of Health that was developed by using GS1 standards. And the catalyst persuading usage of GS1 systems in the Cosmetics Tracking System of Ministry of Health. He is also the project manager of the Alcoholic Beverages Project in GS1 in Europe since April'19, also part of the team for Cloud for Locations Project since June'19. He was appointed as COO of GS1 Türkiye in the beginning of year 2023.

Healthcare in Turkey

Agenda

- General Healthcare Numbers in Turkey
- History of GS1 Turkey in Healthcare
- Current Status in Turkey
- Plans for Future

General Healthcare Numbers in Turkey

General Healthcare Numbers in Turkey

MoH	University	Private	Total*
900	68	566	1534

MoH	University	Private	Total*
156.965	41.987	52.230	251.182

MoH	University	Private	Total*
23.939	6.866	16.895	47.700

* MoH Statistics 2022

General Healthcare Numbers in Turkey-2

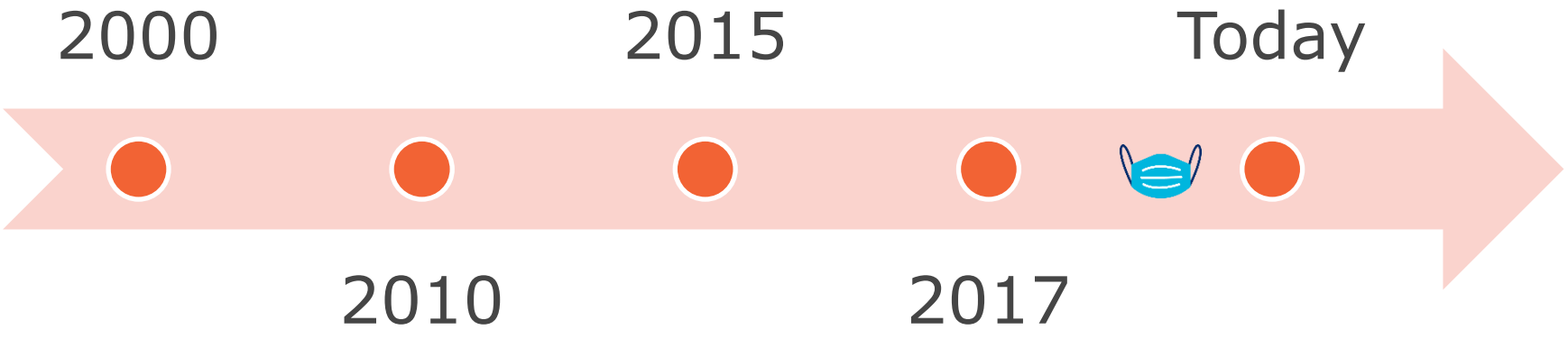
	MoH	University	Private	Total*
Specialist	46.603	15.025	26.499	88.127
GP	45.291	285	4.184	49.760
Assistant	12.264	21.108	-	33.372

26.177* pharmacies

* MoH Statistics 2022

History

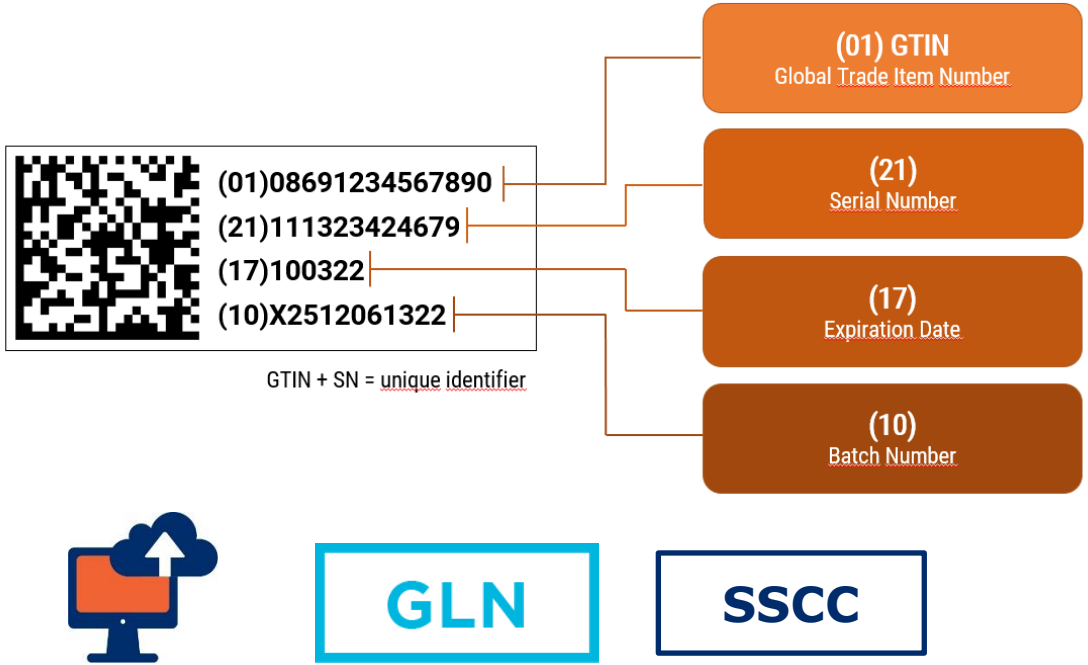
History of GS1 Turkey in Healthcare



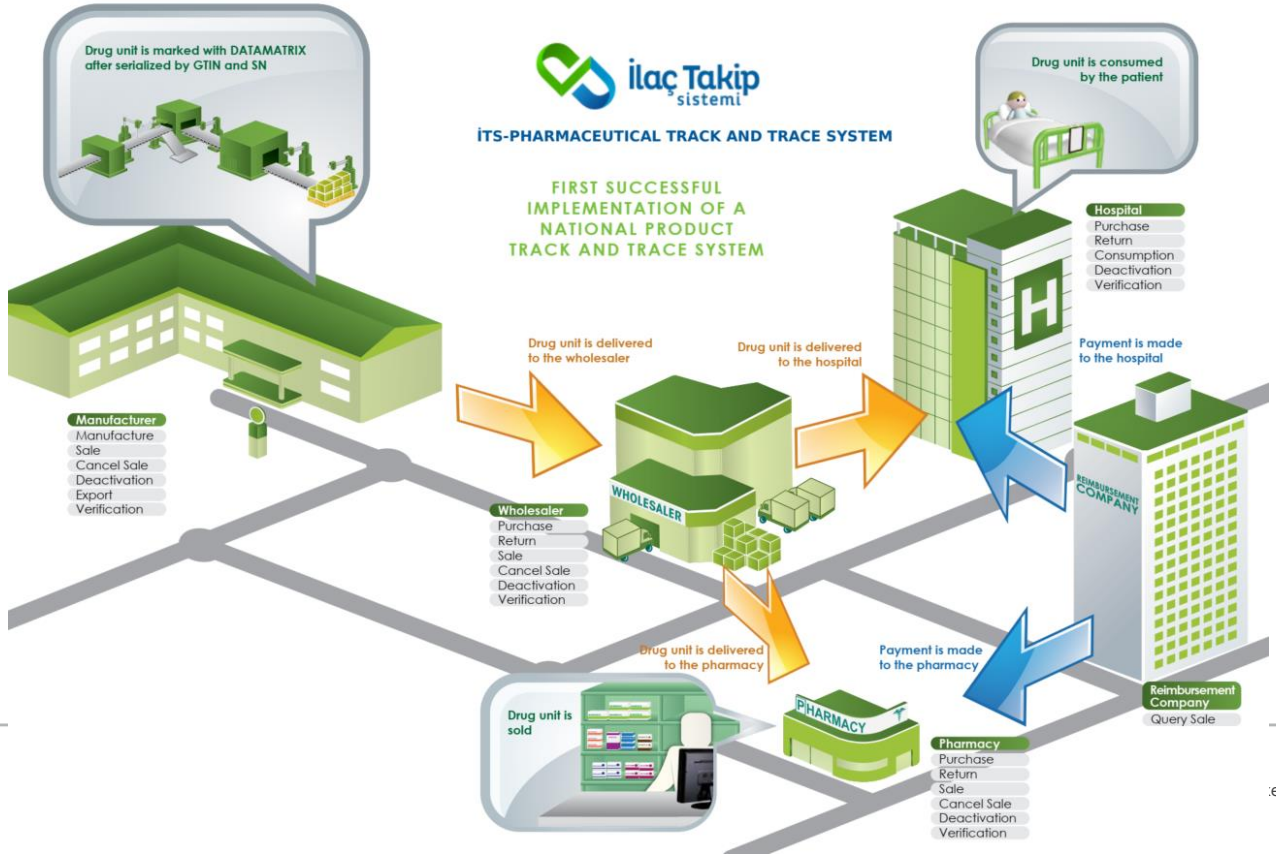
Current Status in Turkey

- ITS
- UTS
- Covid-19 Vaccination

Pharmaceutical Track and Trace System (İTS) and GS1 Standards



İTS Workflow

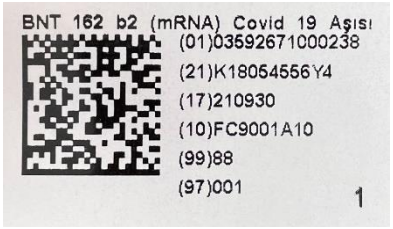


İTS with Numbers

TOTAL STAKEHOLDERS	≈ 42.705
MEDICINE TYPES	≈ 8.950
MEDICINE UNITS	≈ 18.272.358.106
MEDICINE UNITS SOLD BY PHARMACIES	≈ 12.730.093.485
MEDICINE UNITS RECALLED	≈ 16.829.923
MEDICINE UNITS IN PHARMACY STOCK	≈ 513.237.738
DAILY AVERAGE TRANSACTIONS	≈ 79.177.448 (2020 avg.)
TRANSACTIONS IN A SECOND	≈ 916.4
RESPONSE TIME	< 0.5 Second

Vaccines and GS1 Standards

- Sinovac
- BioNTech



- (01) GTIN
- (21) Serial Number
- (17) Expiry Date
- (10) Lot Number
- (99) HL7 Code
- (97) Dose Calculation

Future and next steps

Future and Next Steps

- Learning
- Helpdesk
- New API connections with MoH

Let’s be safe together

Thank you!

GS1 Türkiye

2ND FRANCOPHONE AFRICA GS1 HEALTHCARE SUMMIT (2023)

Argentine's National Traceability System

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Mario Abitbol

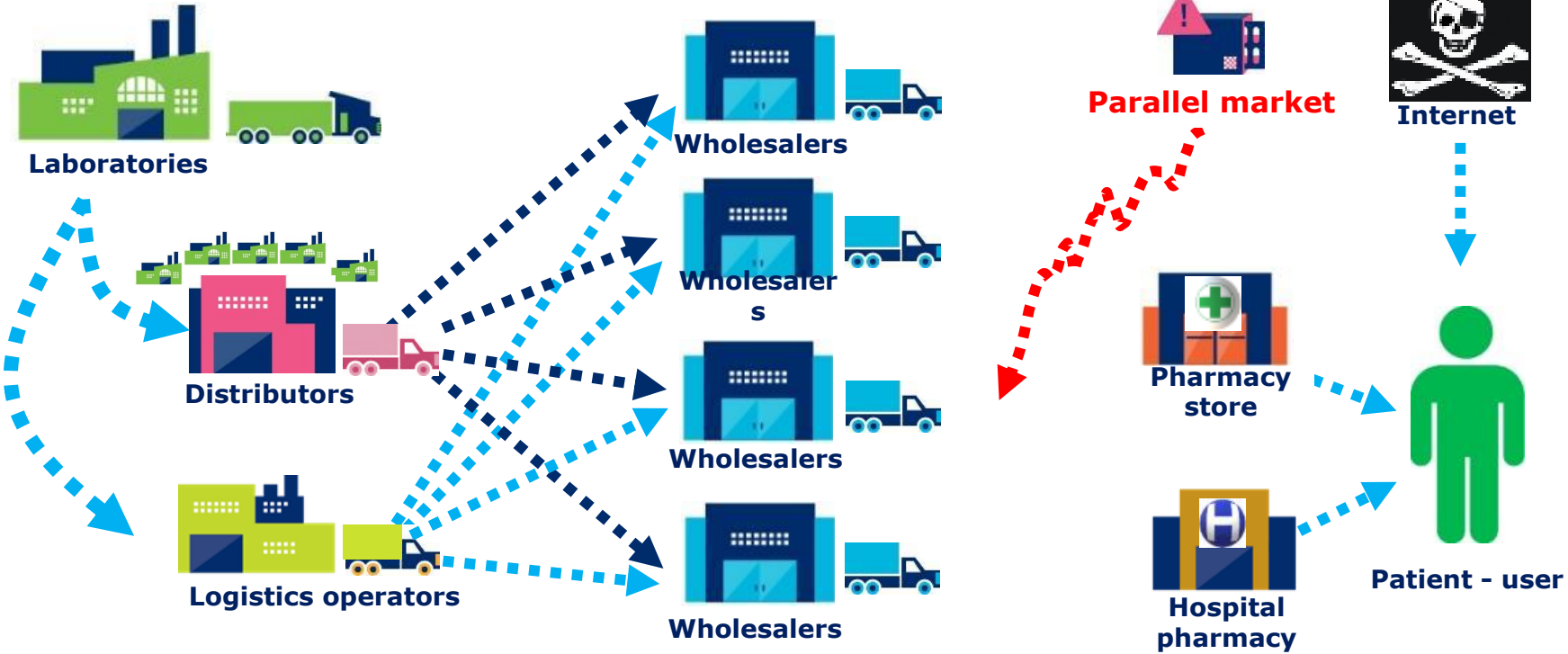
GS1 Healthcare Manager in Argentina

He is a traceability specialist in the healthcare sector. He is member of the "Quality of Certified Delivery" and "Standardization of Sanitary Supplies" in industry teams.

He also works as an advisor for the Healthcare Sector of several GS1 organizations in Latin America.

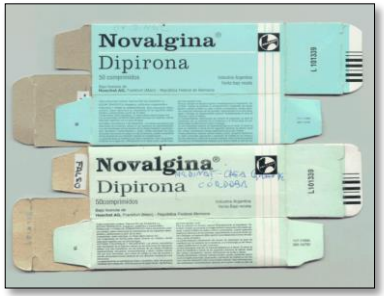
He has been working as a traceability instructor at public and private institutions.

Drug supply chain



Counterfeiting and fraud in Argentina

Counterfeiting and fraud in Argentina



SALUD : LAS INYECCIONES DE HIERRO PARA COMBATIR LA ANEMIA

Yectafer falso: sin responsables a más de un año del escándalo

La falsificación del medicamento les costó la vida a tres mujeres y afectó a más de treinta. Todavía no se sabe quiénes fueron los autores de la adulteración ni dónde se hizo. El caso está casi en foja cero.

Mafia de medicamentos: siete obras sociales estarían involucradas

Lo confirmó el superintendente de Salud, Ricardo Belayo, ya que se encontró vinculación entre esas entidades y la droguería 'San Javier' de Néstor Lorenzo. Se sumarían al caso de "La Bancaria".

Familias de los pacientes que murieron en La Bancaria piden que Zanola "vaya preso"

anmat

Argentine Ministry of Health
Provision 435/2011

Individuals or legal entities involved in the marketing, distribution and dispensing chain of medicinal specialties, included in the ANMAT Registry of Medicinal Specialties, must implement a traceability system that ensures their control and monitoring, from their production or import, until its acquisition by the user or patient.

Trazabilidad de Medicamentos

SISTEMA NACIONAL DE TRAZABILIDAD

Si ya es usuario: Ingresar al Sistema

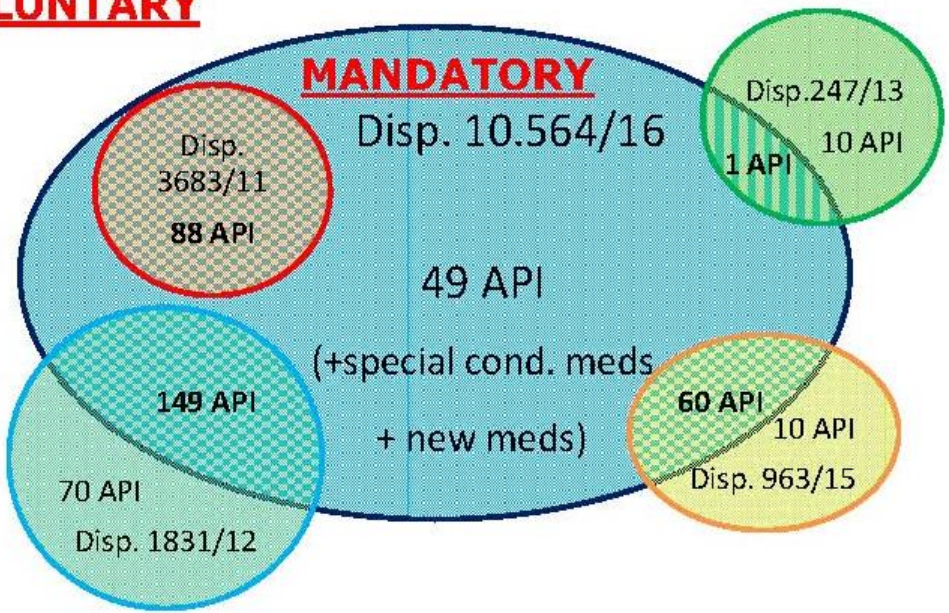
¿Aún no es usuario? Regístrese

Recuerde cumplimentar los pasos 01 y 02 antes de registrarse aquí.

- LABORATORIO
- DISTRIBUIDOR
- OPERADOR LOGÍSTICO
- DROGUERÍA
- FARMACIA
- ESTABLECIMIENTO ASISTENCIAL
- PERSONA

TOTAL:

- **347 API traced**
- **+15.000 GTIN involved.**



anmat

Fuente: ANMAT – Administración Nacional de Medicamentos, Alimentos y Tecnología Médica

Trazabilidad de Medicamentos

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- PERSONA

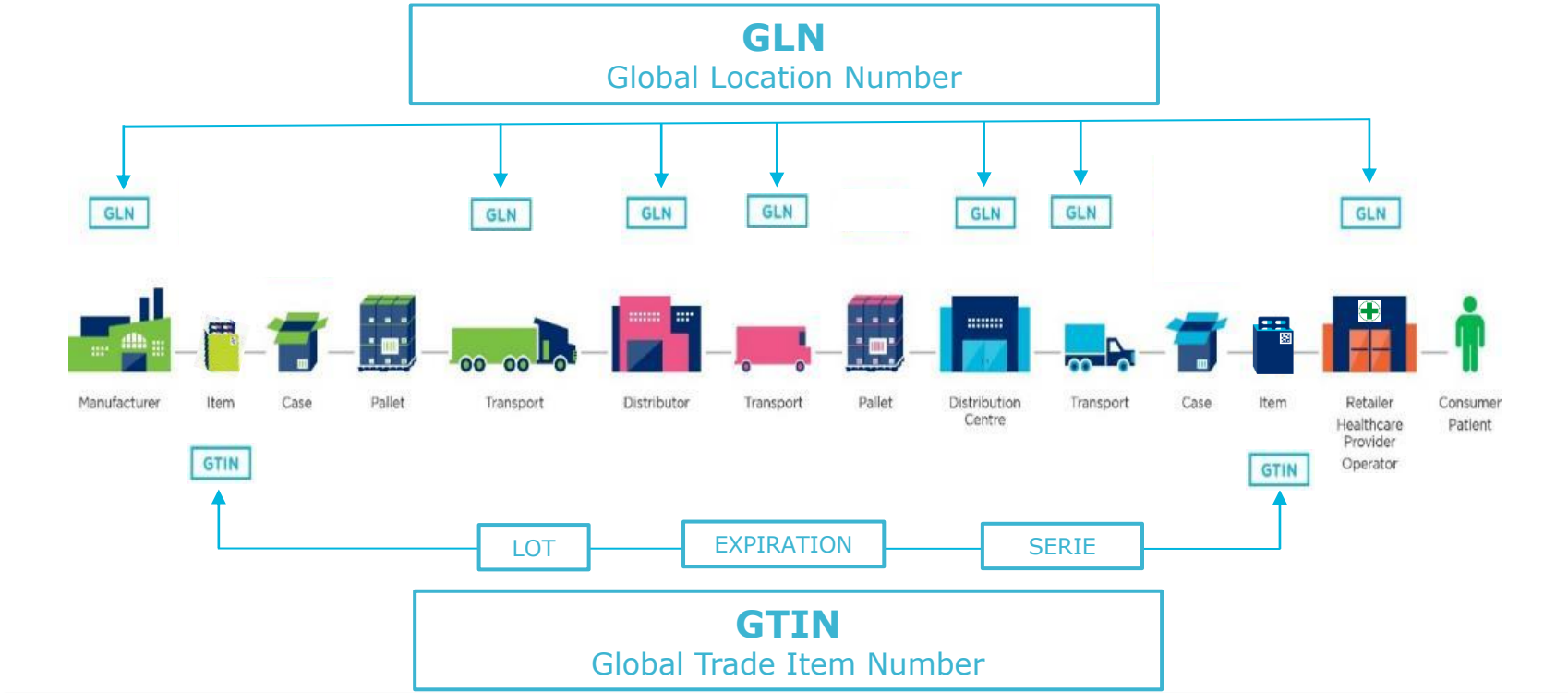
Fuente: ANMAT – Administración Nacional de Medicamentos, Alimentos y Tecnología Médica

Identification format

Secondary case

Removable die cut

Identification for products and companies



Identification keys & technologies accepted

GTIN
(01)

Lot Number
(10)

Expiration date
(17)

Serial Number
(21)

GS1 128

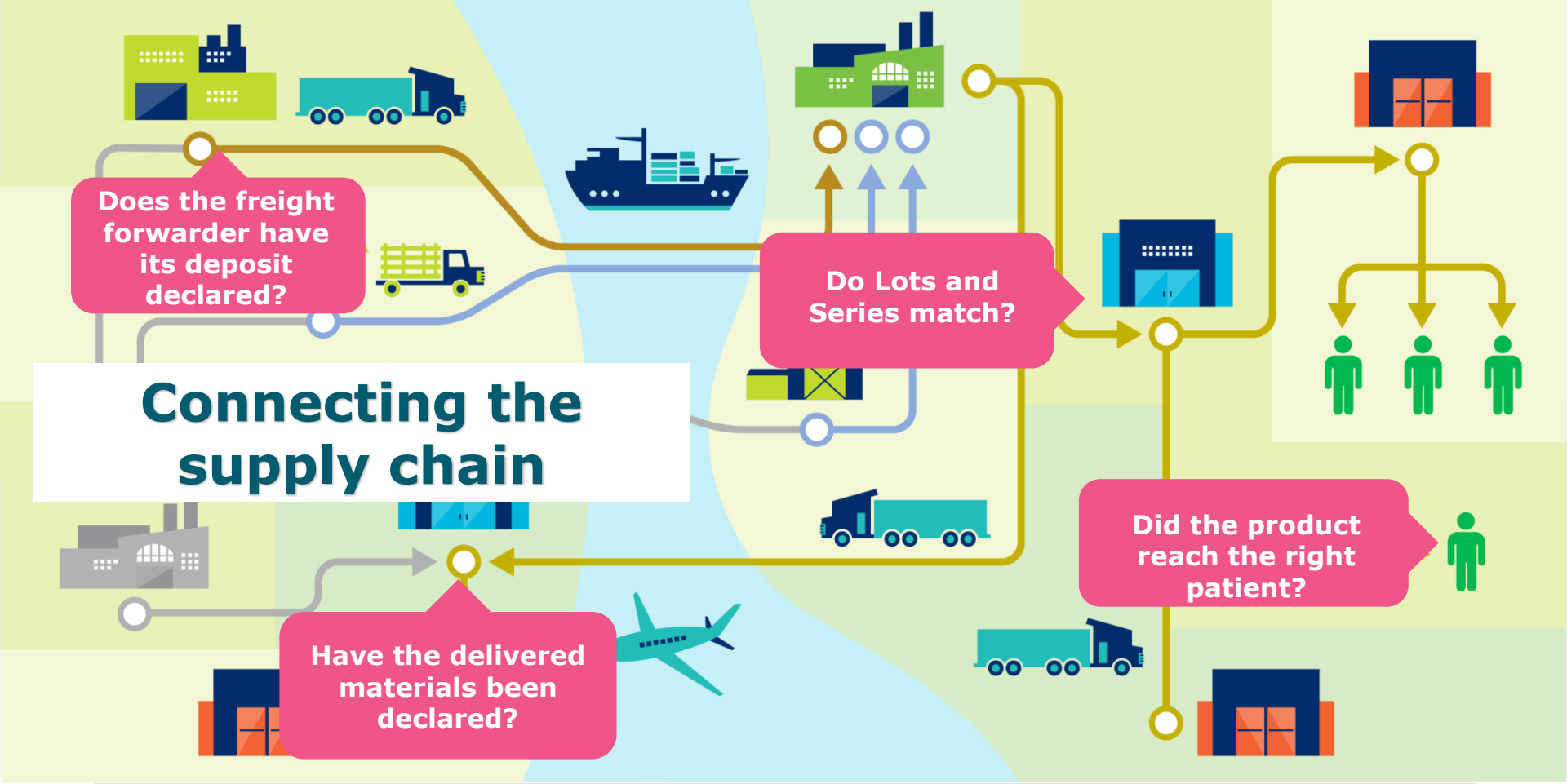
GS1 DATAMATRIX

(01) 07791234123459
(21)00010
(10)ABC123
(17)120104

100%
GS1 Datamatrix

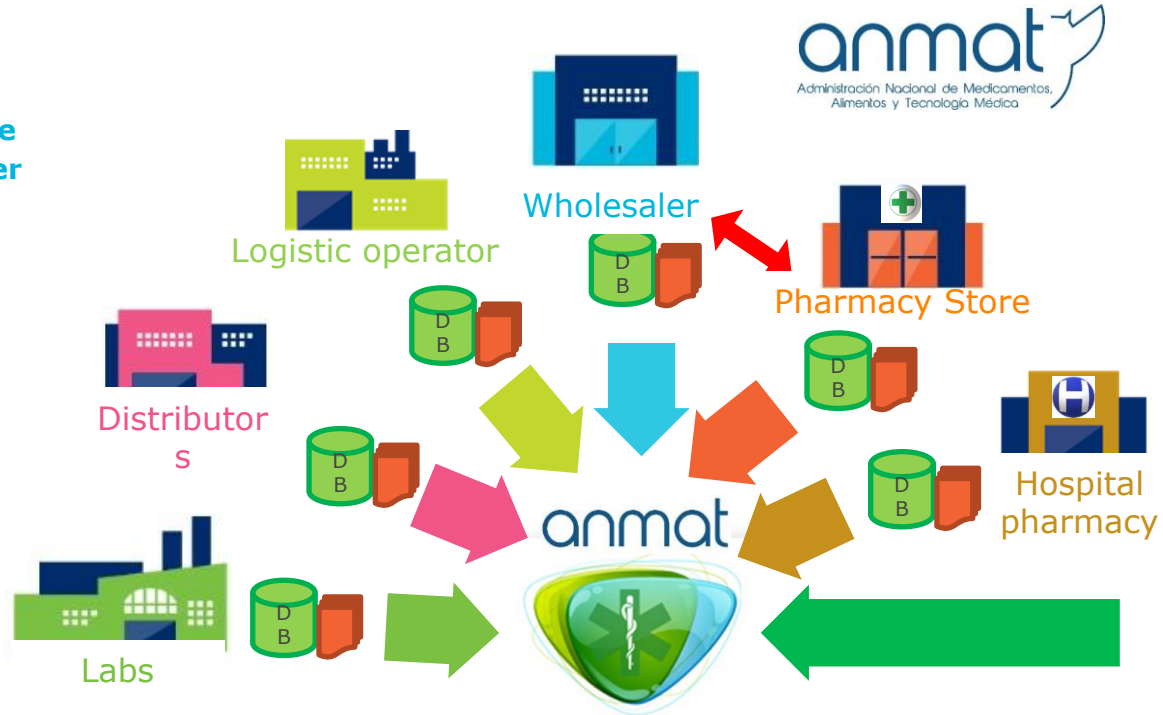
EPC/RFID

(01)07791234123459 (21)00010


Does the freight forwarder have its deposit declared?
Do Lots and Series match?
Connecting the supply chain
Did the product reach the right patient?
Have the delivered materials been declared?

National Drug Traceability System

GLN
GTIN
LOT/SERIE
Expiration date
Invoice Number
Delivery number



Trazabilidad de Medicamentos

SISTEMA NACIONAL DE TRAZABILIDAD

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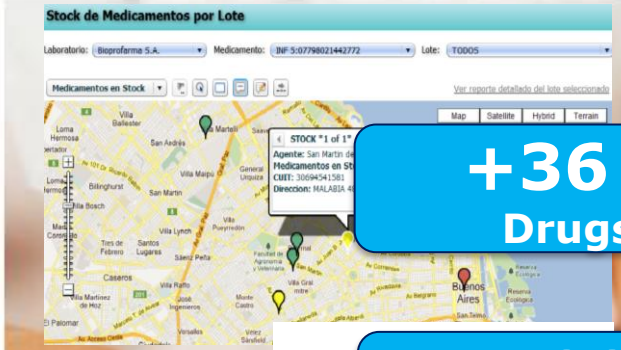
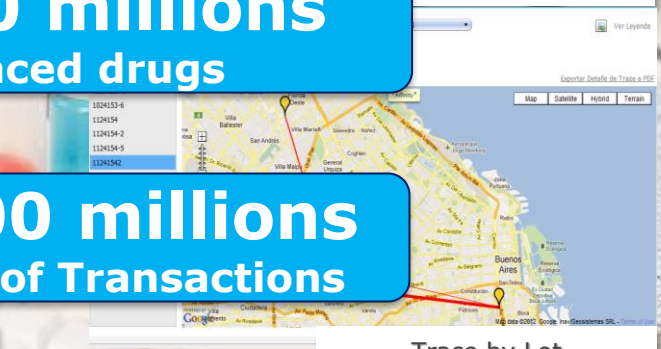


+36 millions
Drugs dispensed

+400 millions
Traced drugs

+1.000 millions
Number of Transactions

Trace by Drug



Trace by Lot

Fuente: ANMAT – Administración Nacional de Medicamentos, Alimentos y Tecnología Médica

But…
What should I do?, When? How?

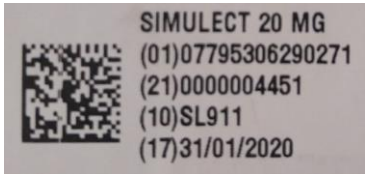
What operations must be reported

1. Sending and receiving products between customer or own warehouses.
2. Shipping and receiving quarantined products.
3. Quarantine lifting.
4. Product intended for medical sample.
5. Product intended for clinical trial.
6. Product for export.
7. Dispensing the product to the patient.
8. Damaged/destroyed code.
9. Lost/stolen item.

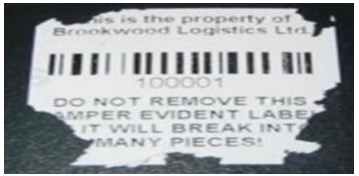
What operations must be reported

10. Expired product (informed automatically by the ANMAT NTS).
11. Sending and receiving the product as a return.
12. Return of the product to stock.
13. Product withdrawn from the market.
14. Forbiden product.

Some important requirements



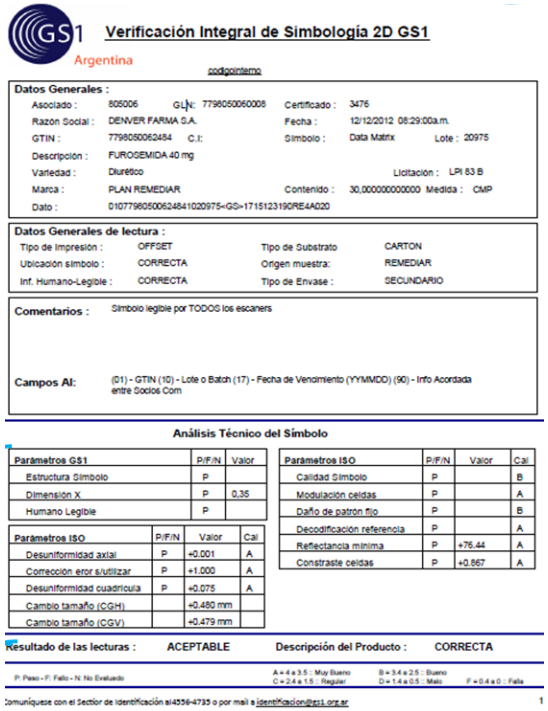
Labeling or printing on secondary packaging.



Sensitive paper evidencing the intention of illegal modification.

Protection of openings against tampering.

Some important requirements



GS1 Argentina

Verificación Integral de Simbología 2D GS1

codgointerno

Datos Generales :

Asociado :	805006	GLN: 7798050060008	Certificado :	3476	
Razón Social :	DENVER FARMA S.A.		Fecha :	12/12/2012 08:29:00a.m.	
GTIN :	7798050062484	C.I:	Simbolo :	Data Matrix	Lote : 20975
Descripción :	FUROSEMIDA 40 mg				
Variedad :	Diurético				Licitación : LPI 83 B
Marca :	PLAN REMEDIAR		Contenido :	30,000000000000	Medida : CMP
Dato :	0107798050062484102097S<GS>1715123190RE4A020				

Datos Generales de lectura :

Tipo de Impresión :	OFFSET	Tipo de Substrato	CARTON
Ubicación símbolo :	CORRECTA	Origen muestra:	REMEDIAR
Inf. Humano-Legible :	CORRECTA	Tipo de Envase :	SECUNDARIO

Comentarios : Simbolo legible por TODOS los escaners

Campos AI: (01) - GTIN (10) - Lote o Batch (17) - Fecha de Vencimiento (YYMMDD) (90) - Info Acordada entre Socios Com

Análisis Técnico del Símbolo

Parámetros GS1	P/F/N	Valor
Estructura Símbolo	P	
Dimensión X	P	0,35
Humano Legible	P	

Parámetros ISO	P/F/N	Valor	Cal
Desuniformidad axial	P	+0.001	A
Corrección error s/utilizar	P	+1.000	A
Desuniformidad cuadrícula	P	+0.075	A
Cambio tamaño (CGH)		+0.480 mm	
Cambio tamaño (CGV)		+0.479 mm	

Parámetros ISO	P/F/N	Valor	Cal
Calidad Símbolo	P		B
Modulación celdas	P		A
Daño de patrón fijo	P		B
Decodificación referencia	P		A
Reflectancia mínima	P	+76.44	A
Constraste celdas	P	+0.867	A

Resultado de las lecturas : ACEPTABLE **Descripción del Producto :** CORRECTA

P: Paso - F: Fallo - N: No Evaluado A = 4 a 3.5 : Muy Bueno B = 3.4 a 2.5 : Bueno C = 2.4 a 1.5 : Regular D = 1.4 a 0.5 : Malo F = 0.4 a 0 : Falla

Comuníquese con el Sector de Identificación al 4556-4735 o por mail a identificacion@gs1.org.ar 1

ANMAT recommends generating the **GS1 Print Quality Certificate.**

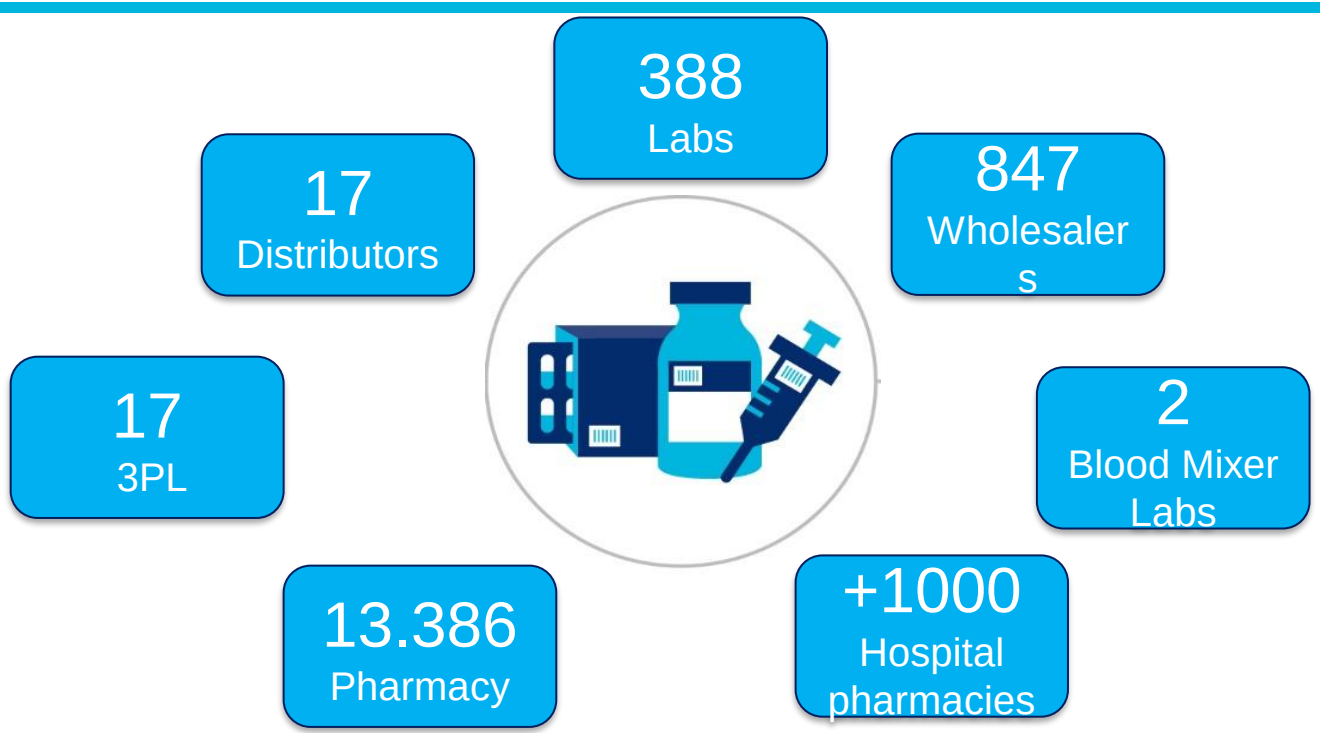
Patient data

1. Date and Time.
2. ~~First and last name.~~
3. ~~Type and number of identity document.~~
4. ~~Birthdate.~~
5. ~~Gender.~~
6. ~~Address and phone number.~~
7. Social code identification.

¡Privacy of Personal Data!

The data of the health service and the patient's affiliate number must be entered, omitting personal data of the patients, without prejudice to keeping said data in case it is necessary to contact them in order to prevent risk to their health and/or life, or carry out the recovery of units that were delivered.

Entities involved



Fuente: ANMAT – Administración Nacional de Medicamentos, Alimentos y Tecnología Médica

What did we learn?

We learned that…

Mario Abitbol
Healthcare Manager
GS1 Argentina
Fraga 1326 (C1427BUB) - CABA
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M +54 (911) 6856-7071
E mabitbol@gs1.org.ar

2ND FRANCOPHONE AFRICA GS1 HEALTHCARE SUMMIT (2023)

India’s journey towards traceability for exported products

USAID FROM THE AMERICAN PEOPLE

GS1

Amrit Garg

Senior Manager- Technical Services, GS1 India

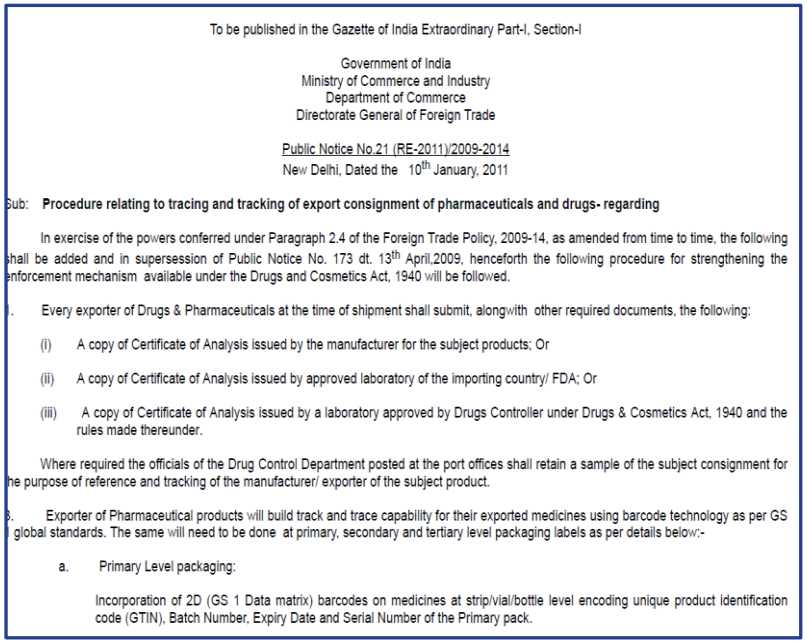
- Mr. Amrit Garg has been engaged in driving adoption of global standards and best practices in India which facilitate universal identification, track & trace, recalls management and information exchange between trading partners across Industry sector.
- Having accumulated more than 10 years of experience in promoting the adoption of global standards in India.
- Successfully organized numerous workshops focused on traceability standards. These workshops have catered to a wide range of participants, including industry professionals, solution providers, and regulatory authorities.

Agenda

- Background
- Why GS1 standards
- Supply Chain Stakeholders
- Portal Architecture
- Implementation Strategy
  - Phase wise Implementation
  - Large vs SME
- Current Status and Roadmap
- Q&A

Background

- “Pharmacy of the World”- Need a digital cum effective traceability system to safeguard “Brand India”
- Government set up a task force to determine long term approach
- January 10, 2011 – Introduction of Track and Trace regulations
- Scope- All pharmaceuticals drugs exported from India
- Impact- 3,000 + exporters from India including Manufacturers, exporters, Traders etc



To be published in the Gazette of India Extraordinary Part-I, Section-I

Government of India
Ministry of Commerce and Industry
Department of Commerce
Directorate General of Foreign Trade

Public Notice No.21 (RE-2011)/2009-2014
New Delhi, Dated the 10th January, 2011

Sub: **Procedure relating to tracing and tracking of export consignment of pharmaceuticals and drugs- regarding**

In exercise of the powers conferred under Paragraph 2.4 of the Foreign Trade Policy, 2009-14, as amended from time to time, the following shall be added and in supersession of Public Notice No. 173 dt. 13th April,2009, henceforth the following procedure for strengthening the enforcement mechanism available under the Drugs and Cosmetics Act, 1940 will be followed.

1. Every exporter of Drugs & Pharmaceuticals at the time of shipment shall submit, alongwith other required documents, the following:

(i) A copy of Certificate of Analysis issued by the manufacturer for the subject products; Or

(ii) A copy of Certificate of Analysis issued by approved laboratory of the importing country/ FDA; Or

(iii) A copy of Certificate of Analysis issued by a laboratory approved by Drugs Controller under Drugs & Cosmetics Act, 1940 and the rules made thereunder.

Where required the officials of the Drug Control Department posted at the port offices shall retain a sample of the subject consignment for the purpose of reference and tracking of the manufacturer/ exporter of the subject product.

3. Exporter of Pharmaceutical products will build track and trace capability for their exported medicines using barcode technology as per GS1 global standards. The same will need to be done at primary, secondary and tertiary level packaging labels as per details below:-

a. Primary Level packaging:

Incorporation of 2D (GS 1 Data matrix) barcodes on medicines at strip/vial/bottle level encoding unique product identification code (GTIN), Batch Number, Expiry Date and Serial Number of the Primary pack.

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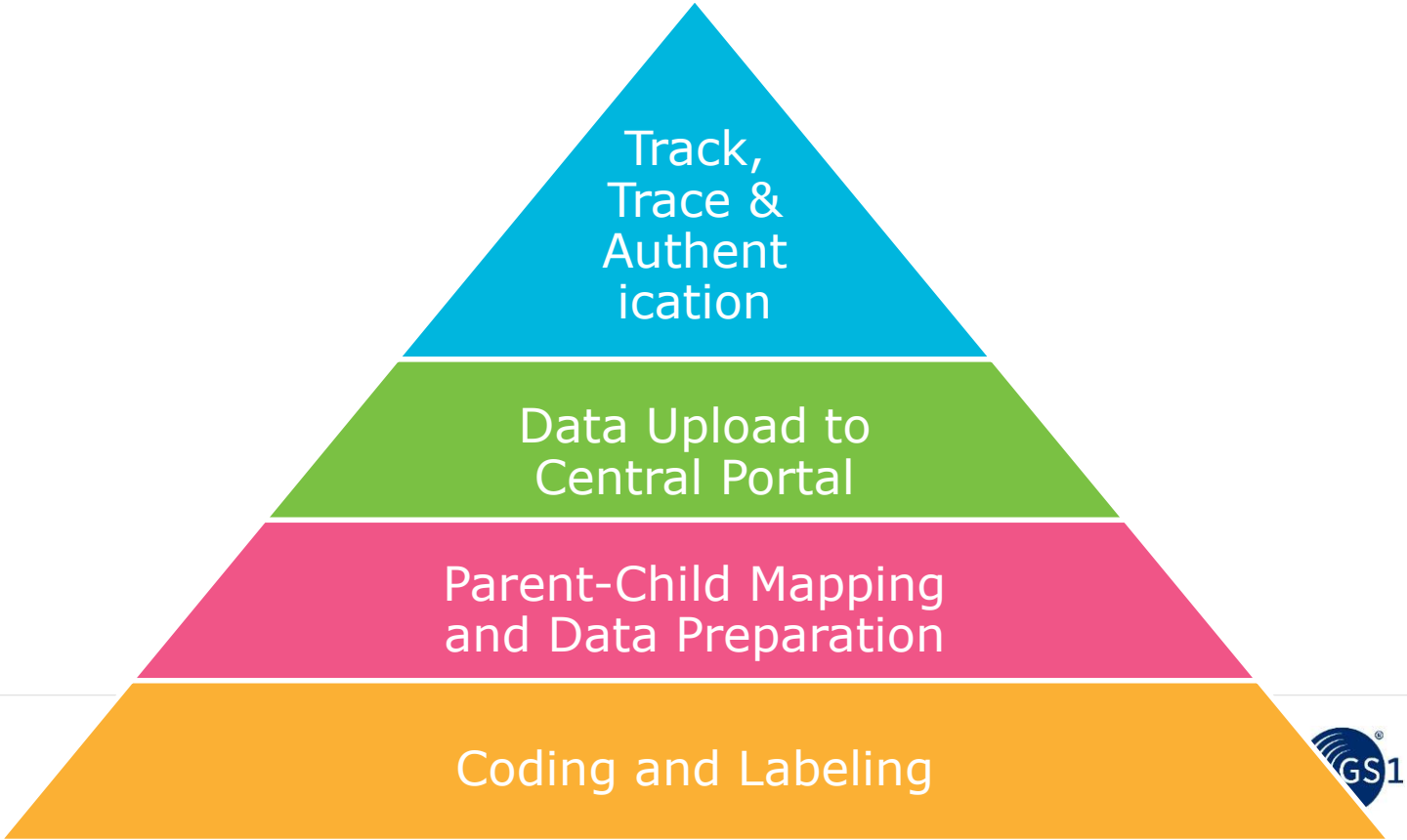
Journey


Track, Trace & Authent ication
Data Upload to Central Portal
Parent-Child Mapping and Data Preparation
Coding and Labeling

Salient Features

- Coding guidelines as per packaging levels
- Serialization across all levels of Packaging
- Data Aggregation
- Data upload on Central portal
- Authentication interface for supply chain stakeholders

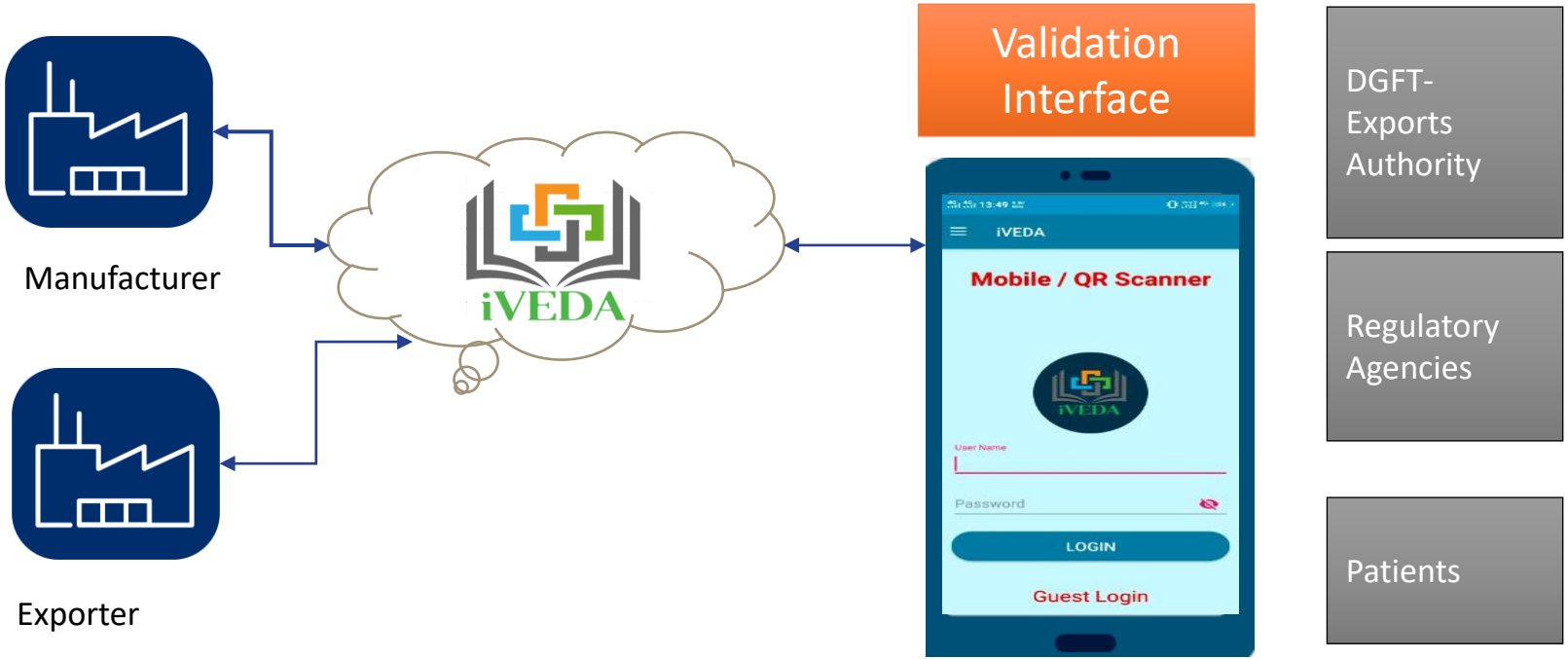
Why GS1 standards

- GoI undertook various stakeholders consultation to gather inputs and insights
- Invited Management consulting firm to advise on best practices
- Final report advised to use unified standards that are globally recognized and accepted
- GS1 codification on product packaging, interoperability between systems can be achieved
- In the future, the use of GS1 identification may facilitate a streamlined process through a "green channel" at Customs

Stakeholders

- Directorate General of Foreign Trade
- Pharmaceutical's Export Promotion Council of India
- IT agency- Central Portal
- Ministry of Health & Family Welfare
- Manufacturers/ Exporters
- CMO/ LL
- Merchant Exporters
- Solution Providers
- Importing country
- Patient
- GS1 India

iVEDA: Integrated Validation of Export of Drugs from India and its Authentication



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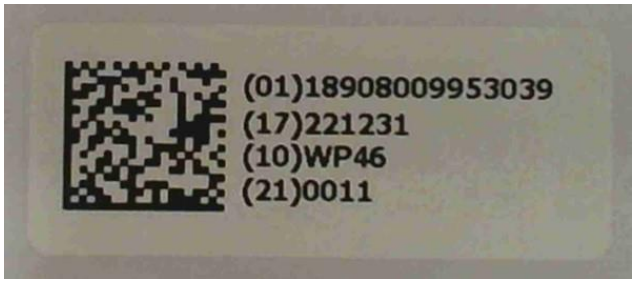
Levels of Packaging

Secondary



Tertiary

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Implementation Strategy

- Coding and labelling guidelines
- Data uploading on central portal

- Serialization
- Aggregation

- Relaxation for Micro and Small Industries
- Proposal for reimbursement of implementation cost

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Impact on Industry

- Enabled the Indian pharmaceutical industry to be well-prepared for upcoming track and trace requirements in regulated markets

- Pivotal role in catalyzing the establishment of a robust solution provider eco-system

Current Status

- Comprehensive revamp of the central portal as per Industry feedback
- Data uploading will be resumed post revamp
- Coding and labelling remains enforced

Support- GS1 India

- Implementation Guide
- Workshop & Webinar - Advanced Module
- Barcode Verification Service
- Implementation Support

Q&A

2ND FRANCOPHONE AFRICA GS1 HEALTHCARE SUMMIT (2023)

Improved Supply Chain Visibility: Why accurate product data are key for public and private healthcare supply chain digitization

July 20, 2023 | 14:30 – 14:45 GMT / 10:30 – 10:45 EDT

USAID FROM THE AMERICAN PEOPLE

GS1

Michele Francis Padayachee

Executive GS1 South Africa

Michele has 27 years' experience in Senior Business and System Integration Management, Service Delivery Management, Supply Chain Planning and Forecasting. Her career spans across both the operational implementation and strategic direction which encompasses, retail, manufacturing and financial services industries.

She has extensive general and information technology management, with corporate board experience as the GS1 South Africa Executive, supply chain, standards, and information technology businesses. An inclusive, hands on and steward leader with a passion to build high performance teams to grow and strengthen our local economies in Africa.

When product information is accessible and accurate, your healthcare supply chains wins.

It’s impossible to realize the 5 Patient rights without accurate Trusted data and Collaboration

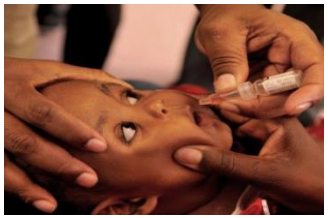
Rob Botha Chief of Party
Global Health Supply Chain
Technical Assistance at Guidehouse

There is a renewed interest in applying GS1 for health products on multiple fronts. GS1 implementation was included as one of the key priorities at the Presidential Health Summit in May 2023, including the alignment of master data databases

The right **products**, at
The right **price**, for
The right **person**, in
The right **location**, at
The right **time**

Healthcare Industry Event

Global Data Synchronization and Importance of Accurate Product Data



Why accurate product data are key for healthcare supply chain digitisation

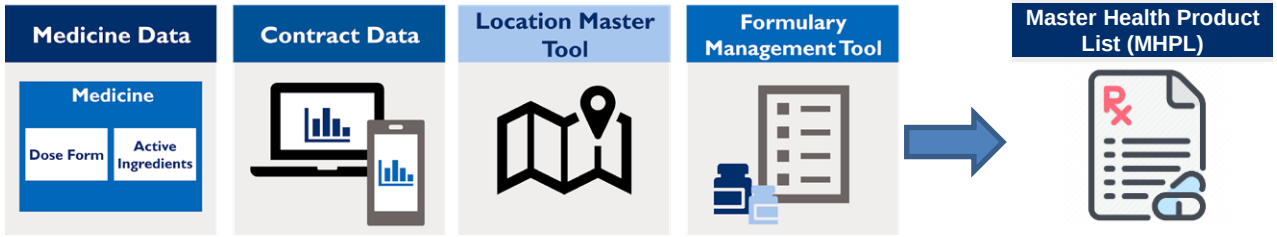
Ms K Jamaloodien
Director: Affordable Medicines
National Department of Health: South Africa

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

2030 NDP

Medicine Master Data System

- **Medicine Master Tool** – enables structuring and management of medicine data preset lists, including INN, strength and dosage form
- **Contract Master Tool** - records summary details of contracts concluded with suppliers of medicines
- **Location Master Tool** - the details of organizational units (provinces, districts, or sub-districts) and health establishments
- **Formulary Management Tool** – A formulary links a medicine to an organizational unit or establishment.



- **Master Health Product List (MHPL)** – with all products that are procured in the public sector in accordance with a transversal contract, or on a quotation basis, augmented with GS1 data received from the GDSN

AMD of the National Department of Health

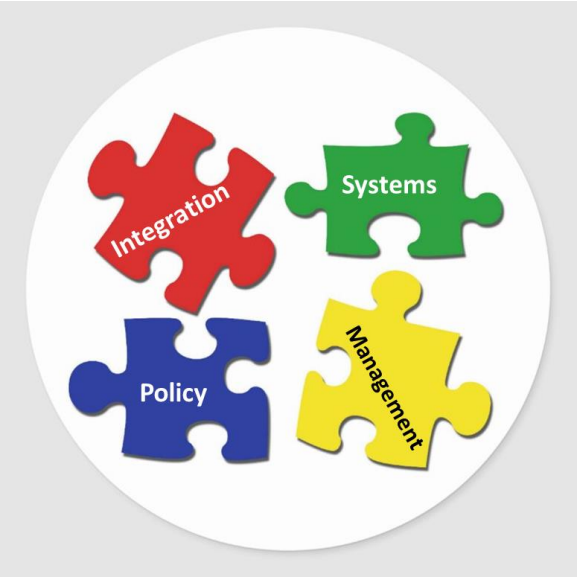
Responsible for developing systems to ensure *access to essential pharmaceutical commodities* that are affordable and of good quality

AMD provides provinces with ***strategic leadership***, a supportive ***legislative and policy*** environment and ongoing ***oversight and monitoring*** relating to medicine access.

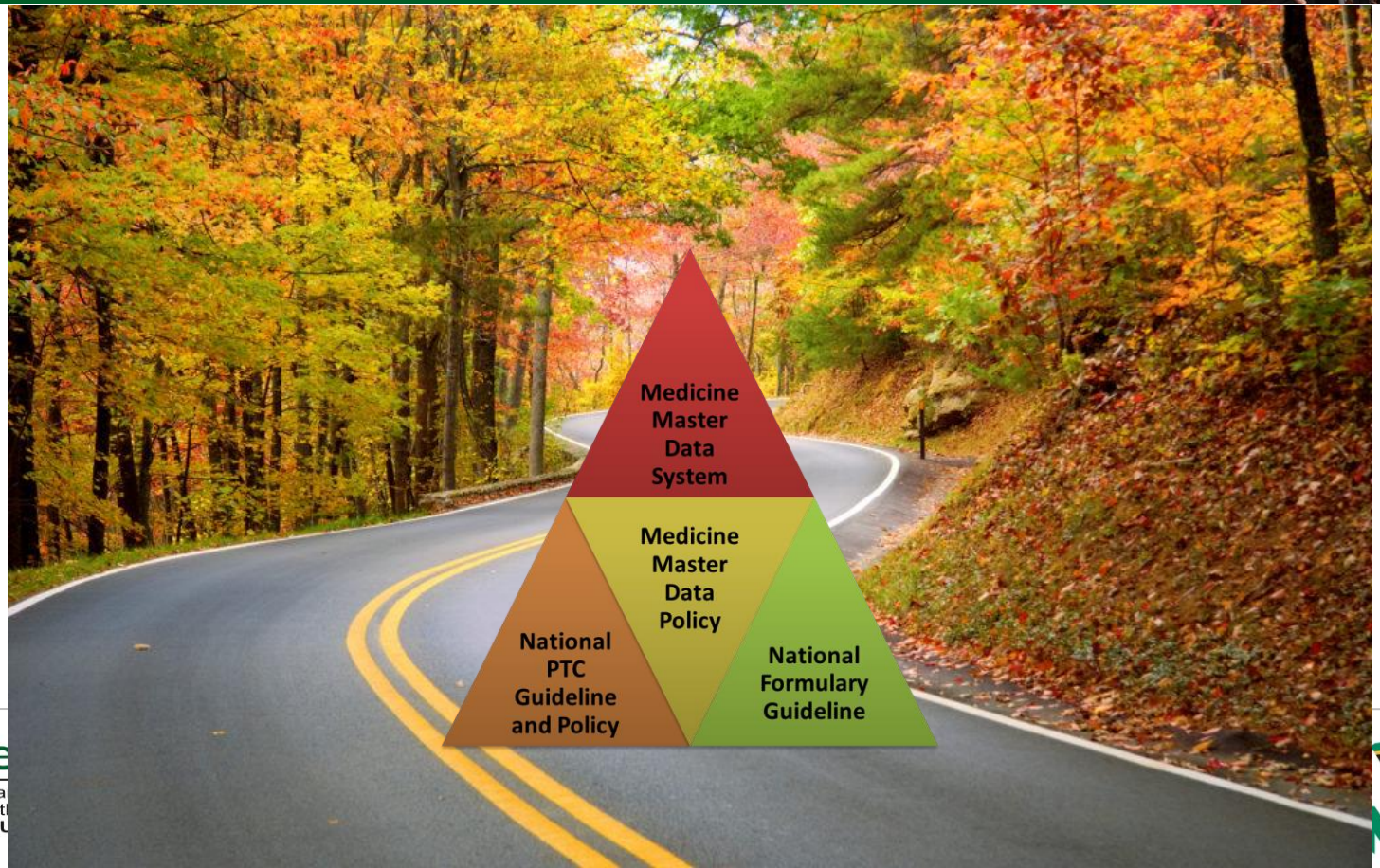
The Challenge

With **increased digitization** in the **public sector medicine supply chain** it is critical that **accurate product information** and **unique identifiers** are available to:

- **Improve interoperability** between the various system used in the supply chain;
- **Improve data quality and accuracy** for supply chain planning functions, including demand forecasting, demand planning and supply planning;
- **Improve reporting and monitoring** abilities



The Solution



Lessons Learned

- Standards need to be applied across **all medicines and health commodities** across **both public and private sectors**.
- With **increased digitization and networking** of disparate systems requires common nomenclature for **interoperability**
  - ePrescribing,
  - Inventory management,
  - Warehouse management systems
  - Dispensing applications
  - Contracting
  - Contract management
  - Supply chain planning
- **Downstream systems** need to be prepared for standards

Digitisation of Healthcare through Standards – greater emphasis on Person- centred Healthcare

Caroline Potgieter
Netcare
Ecommerce Manager

“The delivery of healthcare is increasingly being transformed by the digitisation of processes and clinical records as well as the intelligent application of data. “

Dr Richard Friedland November 2020

Product master data

0 9 5 2 4 0 0 0 0 5 9 6 0

- Brand name
- Manufacturer Name
- Manufacturer GLN
- Hierarchy level
- Child Item
- Total Quantity of Next Lower Level Trade Item
- Product description
- Functional Name
- Shelf Life from Production
- Dosage Form
- Country Of Origin

Mylan Laboratories Product Hierarchy

Dosage Form & Route of Administration

Dosage Recommendation Add Remove

Dosage Recommendation: Tablet

Language: English

Route Of Administration

Route Of Administration Add Remove

External Agency Name: Agency

External Code List Name: Oral

External Code List Version:

Prescription Type Codes

Moving into the future together to Enabling better trade

- GS1 the enabler to trade better via TrustedSource
- Better trade and speed to market
- Current status with manufacture and the project plan to move ahead
- Industry wide solution – Inclusive of E-Commerce traders
- We are setting up a portal of frequently asked questions
- **One point of contact to access accurate product data**

For any questions contact the following:

services@gs1za.org

Call: 011 777 3300

QUESTIONS & ANSWER
QUESTIONS & RÉPONSES

2ND FRANCOPHONE AFRICA GS1 HEALTHCARE SUMMIT (2023)

A Review of the WHO Digital Supply Chain Architecture Handbook

July 20, 2023 | 14:30 – 14:45 GMT / 10:30 – 10:45 EDT

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GS1

Carl Leitner

Technical Officer, WHO Digital Health and Innovation

Carl Leitner is the Technical Officer for Architecture and Informatics for WHO's Digital Health and Innovation team working on the SMART Guidelines approach. He was worked for over fifteen years in global digital health including the development and support to open-source digital health tools and standard development across a range of business domains in support of clinical health, public health and health system information needs.

Swaroop Jayaprakash

Digital Supply Chain Consultant, WHO

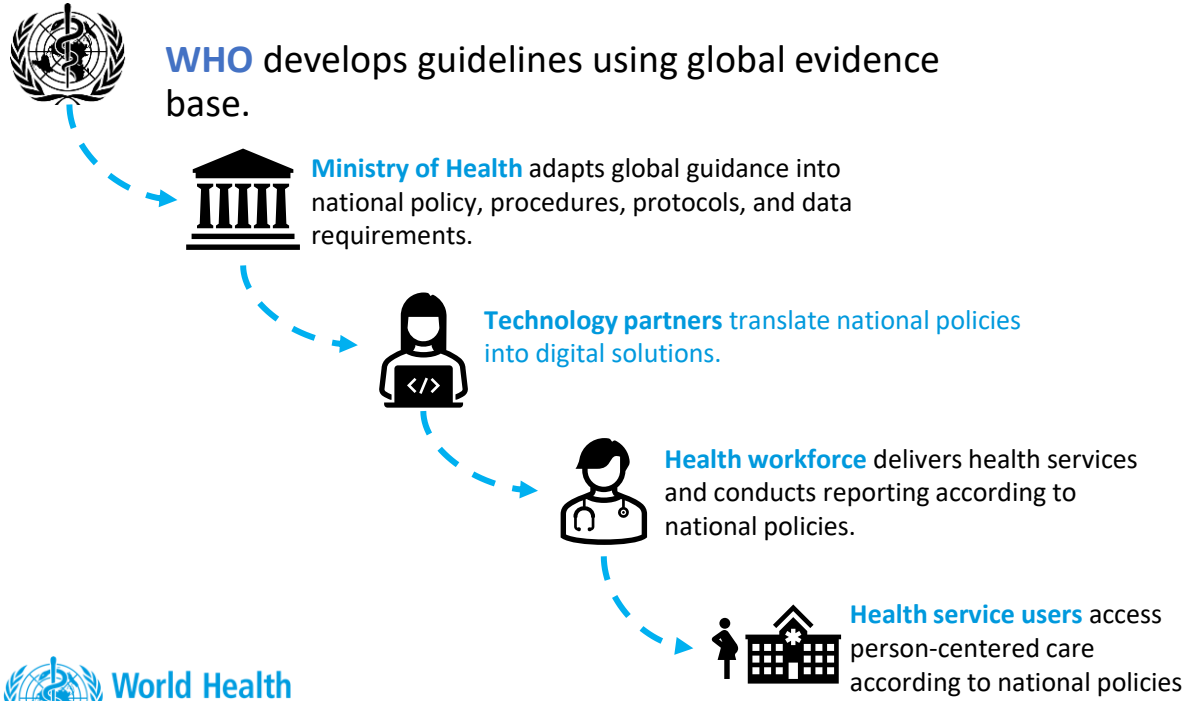
In his 22+ years of experience in IT he has designed & implemented large scale supply chain management systems for customers in retail, distribution, telecom & manufacturing. He helped design & implement ARTMIS application that facilitates procurement & distribution for USAID GHSC-PSM program. He developed the Supply Chain Information Systems Maturity Model (SCISMM) in collaboration with USAID, to help countries assess supply chain information system capabilities. He recently facilitated the development of digital supply chain strategy & architecture in Malawi & Rwanda.

Global Strategy Policy Actions

- Policy Action

- Recommends defining “a national digital health architecture blueprint or road map, adopt **open-source health data standards** and aim for **reusable systems or assets** including interoperability of health information systems both at national and international levels in order to establish an innovative integration of **different digital technologies using shared services, ensuring data are of good and comparable quality**”
- “The global strategy promotes **syntactic and semantic interoperability** with WHO norms and standards as a cornerstone of health information to enable sharing of information in a connected world.”

Digital tools can help facilitate the adoption and integration process, but if done inappropriately, can lead to questionable results

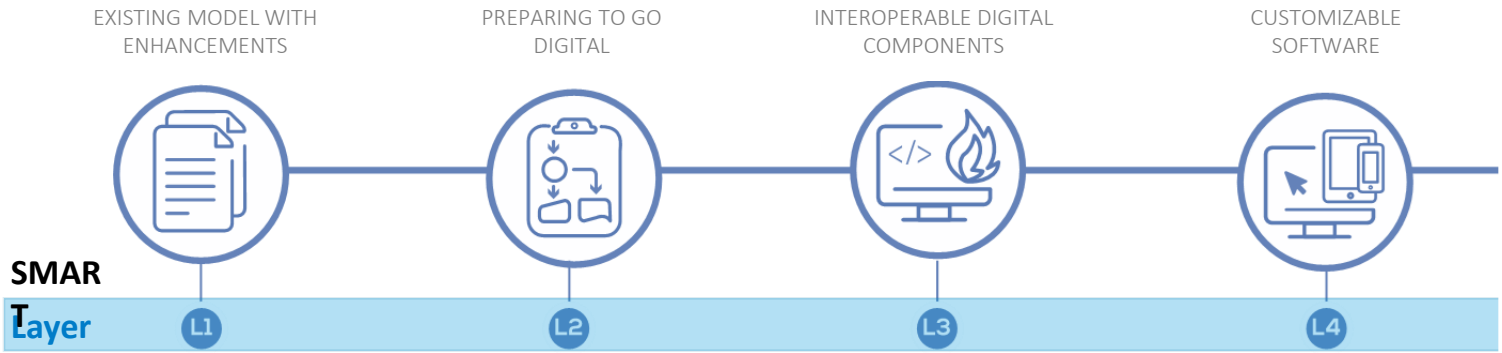


- **Difficult to operationalize** intentionally vague guideline content into digital systems with fidelity
- Infrequently digitized with **interoperability standards**, and **architectural good practice**, leading to siloed systems
- "**Black box**" digital systems become **difficult to maintain** sustainably in the long-term

World Health Organization

SMART Guidelines are health and data Content Digital Public Goods

Standards-based, **M**achine Readable, **A**daptive, **R**equirements-based, **T**estable



- Reinforce operational specificity in existing guidelines
- Digital curation of recommendations
- Panels include informatics and standards experts

- Digital Adaptation Kit (DAK) – requirements document
- Human-readable components
- Describes how a digital tool should function
- Data dictionaries mapped to ICD, LOINC

- FHIR Implementation Guide (IG) documentation
- Based on Clinical Practice Guidelines IG
- Consistent execution across systems - software as a function
- Decision support services and indicator calculations (CQL)

- Fully executable software tools
- Mechanism for real-time updates
- Interoperate with national systems

WHO SMART guidelines: optimising country-level use of guideline recommendations in the digital age - The Lancet Digital Health

WHO SMART Guidelines For Digital Supply Chain

Background

- LMICs, in pursuit of health supply chain (SC) digitalization, are investing in SC system implementations
- There is a pressing need to provide a consolidated set of resources that can inform countries to take a holistic approach to such investments
- While distinct resources such as maturity models, software standards & implementation experiences exist, use of such resources to guide SC digitalization has been low due to challenges with access, knowledge or interpretation
- In addition, accelerated adoption of global standards like HL7 FHIR & GS1 is essential to enable interoperability & traceability.
- A community (SWG) led development of aggregated guidance handbooks will benefit countries in their digital supply chain journey

WHO SMART GUIDELINES FOR DIGITAL SUPPLY CHAIN

With support from USAID, WHO will develop a handbook for digital supply chain architectural approaches that low- and middle-income countries (LMICs) can refer to during their DSC transformation journey. The handbook will also incorporate,

- Approaches to mitigating Implementation risk &
- Approaches to implementing standardized national product catalogs (NPC)

- The handbook will be developed through Digital Health & Interoperability working group's Digital Supply Chain small working group (SWG)

Key Activities

Aggregate Resources (From SWG members & partners)

- Details of past system implementations in LMICs
- Best practice & lessons learnt from implementation partners
- Challenges & risks from country stakeholders & community
- SCISMM assessment findings
- Existing systems guidance like TSS
- Details of global standards like HL7 FHIR & GS1 for alignment & adoption

Collaborate, Develop & Iterate

- Develop handbooks based on analysis of aggregated resources
- Review with community through SWG meetings & incorporate feedback iteratively
- Engage WHO regional offices & other country stakeholders for feedback

Submit for Publication

- Gather wider community & public feedback
- Incorporate feedback
- Submit for publication of handbooks
- Disseminate information about handbooks to countries for adoption & use in DHSC transformation initiatives

Guiding Principles

- Building on previous implementation experiences & best practices
- Leveraging existing resources like Target Software Standards (TSS), Supply Chain Information Systems Maturity Model (SCISMM) & Product Catalog Management Tool (PCMT)
- Utilizing open standards like HL7 FHIR & GS1 & open-source platforms
- Incorporating DHSC within the overall Digital Health Ecosystem
- Aligning with OpenHIE architecture & being software agnostic
- Collaborating with public health community through digital health & interoperability (DH&I) small working groups (SWG)
- Engaging WHO Regional Offices & public health community for inputs

Timeline (tentative)

WHO SMART GUIDELINES FOR DIGITAL SUPPLY CHAIN

If interested in contributing, please send an email to smart@who.int

This work will be done under DH&I's Digital Supply Chain SWG. To join the SWG please complete this form & select Digital Supply Chain SWG.

The SWG will meet every 2nd Wednesday of the month starting Jul 12th from 9 to 10 AM US EST