2nd African GS1 Healthcare Conference

Track and trace for access to safe medicines

Day 1| Tuesday 17 September

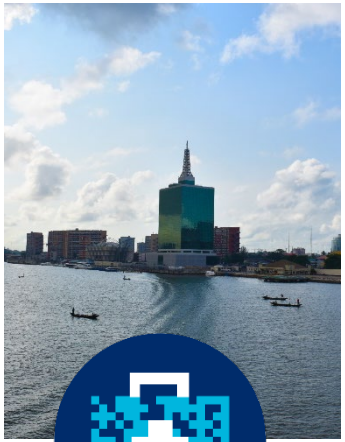
The Global Language of Business

Welcome to the Conference

2nd African GS1 Healthcare Conference
Lagos, Nigeria

Ulrike Kreysa, Senior Vice President GS1 Healthcare

September 17, 2019



Ulrike Kreysa

Senior Vice President
Healthcare

GS1 Global Office

Ulrike is responsible for the Healthcare sector at the GS1 Global Office and works with her local colleagues in 114 countries to develop and implement GS1 standards in the healthcare industry

Having started her career as a Pharmacist she manages GS1 Healthcare, the global GS1 user group, formed by the stakeholders in the healthcare supply chain, including pharmaceutical and medical device manufacturer, wholesaler/distributor, GPO's, hospitals, pharmacies, logistic providers, governmental and regulatory bodies and associations

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Welcome to the conference!

Thanks to our co-host NAFDAC

and conference partners IFPMA TheGlobalFund THE WORLD BANK USAID

Anti-Trust Caution

- GS1 operates under the **GS1 anti-trust caution**. Strict compliance with anti-trust laws is and always has been the policy of GS1.
- The best way to avoid problems is to remember that the purpose of the group is **to enhance the ability of all industry members to compete more efficiently**.
- This means:
  - There shall be no discussion of prices, allocation of customers, or products, boycotts, refusals to deal, or market share
  - If any participant believes the group is drifting toward impermissible discussion, the topic shall be tabled until the opinion of counsel can be obtained.
- The full anti-trust caution is available via the link below, if you would like to read it in its entirety: http://www.gs1.org/gs1-anti-trust-caution

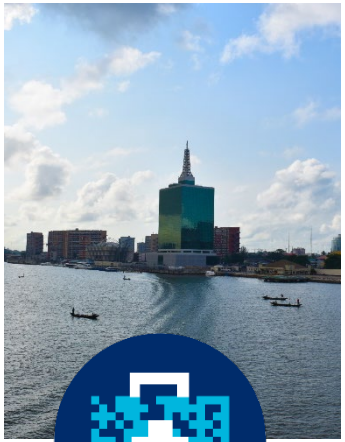
The Global Language of Business

Opening of the Plenary

2nd African GS1 Healthcare Conference
Lagos, Nigeria

Marianne Timmons, President Industry Engagement & Standards Development, GS1

September 17, 2019



Marianne Timmons

President, Industry Engagement

Marianne Timmons is the President of Industry Engagement at GS1 Global Office where she is responsible for global activities in Retail, Healthcare, Food Service, Transport and Logistics, technical Industries, Financial Services and related sub-sectors. Marianne has spent the past 30 years in and around the Retail and Consumer Products Industries as both a consultant and a practitioner. Her consulting experience spans sectors and industry but has been concentrated in Grocery, Mass, Specialty Retail, Electronics, DIY and Drug. As a practitioner at Wegmans Food Markets Marianne held senior leadership roles in Store Operations, Merchandising, Supply Chain and e-Commerce (including GDSN, RFID, EDI, Data Quality)

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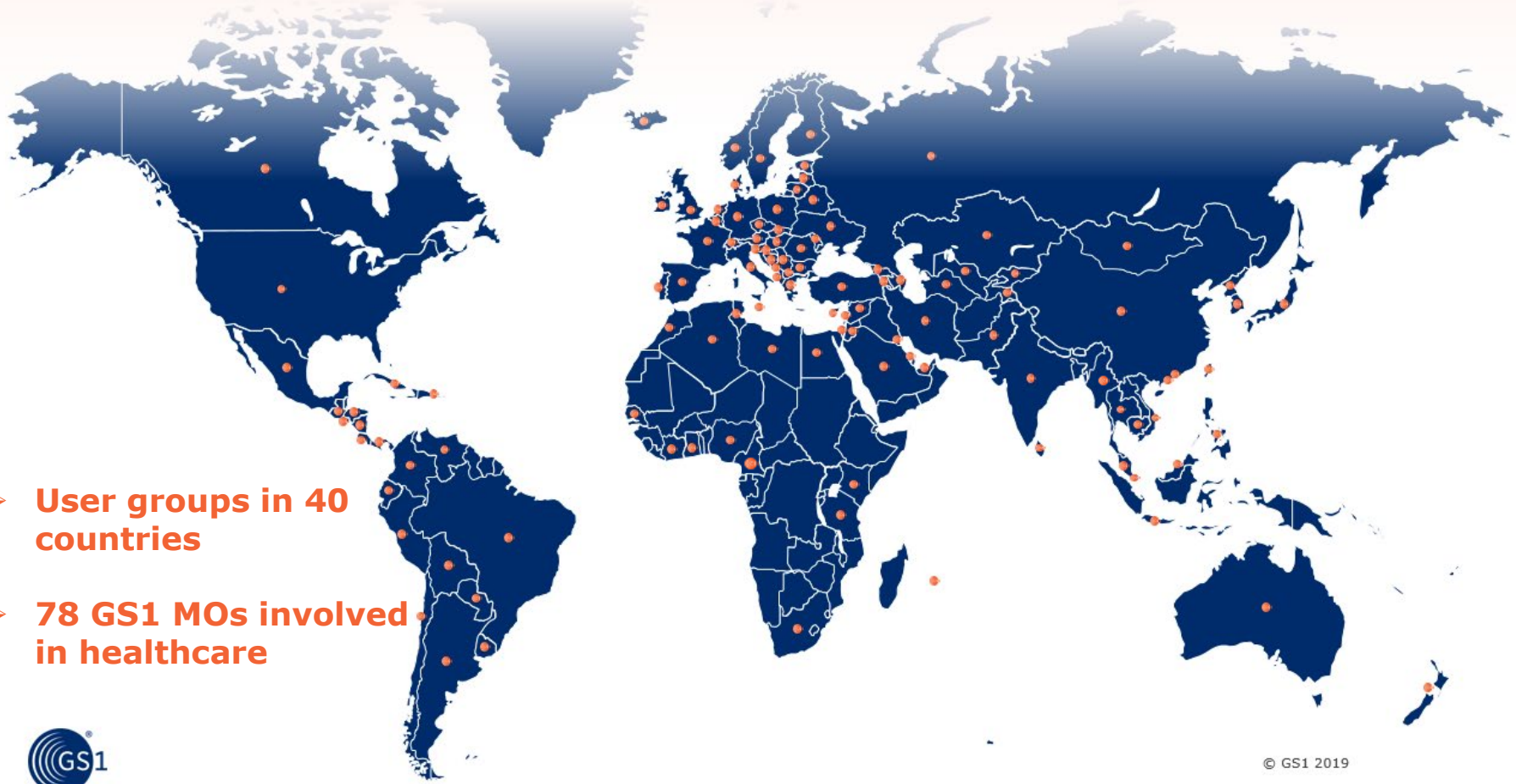
GS1 – The Global Language of Business

GS1 is an international global standards organisation

- Neutral and not-for-profit
- User-driven and governed
- Global and local
- Inclusive and collaborative

Working with 114 GS1 Member Organisations across the world



- **User groups in 40 countries**
- **78 GS1 MOs involved in healthcare**

We need to fight the spread of fake drugs

1 in 10 medical products in developing countries is **substandard or falsified**[1]

About
100,000 deaths/ year
in Africa linked to **counterfeit drug trade**[1]

Counterfeit medical goods can form up to 30% of the market in parts of Asia, Africa and Latin America[2]

>1 million people die each year from counterfeit drugs[2]

Millions of patients at risk for adverse drug events

Tens of billions of dollars' worth of counterfeit drugs could be blocked with help of standards[3]

$160-280 billion lost due to inefficiencies and errors[3]

Sources: 1. World Health Organization; 2. Interpol, 3. McKiinsey

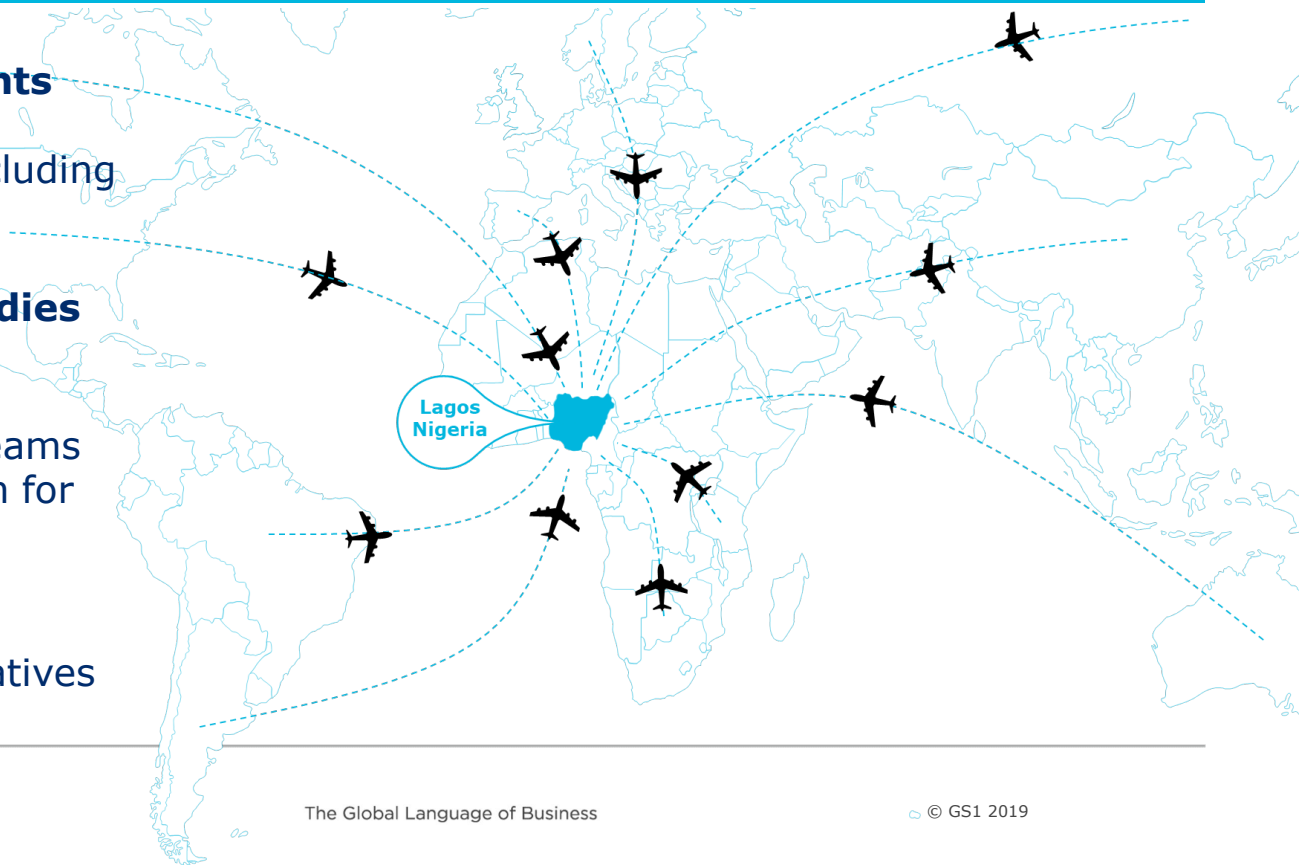
Track & trace for access to safe medicines

GS1 standards are key to improving patient safety, fighting falsified medicines, and increasing visibility and efficiency in the supply chain

The world is heading towards a **globally standardised approach in healthcare** which will be less complex and costly

Our conferences and community – to learn, share best practices, ask questions, network…

- ✓ More than **300 participants** from **44 countries** from all over the world including **35 African countries**
- ✓ **Over 110 regulatory bodies** representatives
- ✓ **3** plenaries**, 4** parallel streams and **one** dedicated session for **YOUR** questions
- ✓ More than **70 donor organisations** representatives



Learn, ask questions, network …and enjoy!







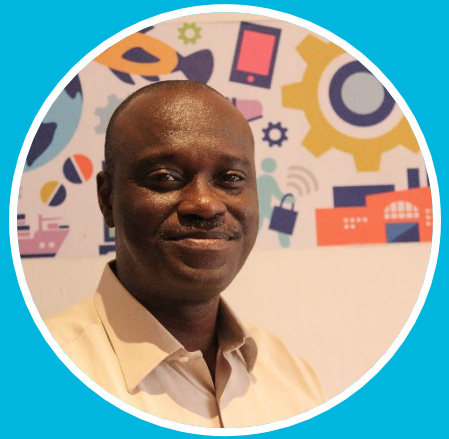
The Global Language of Business

Welcome to the Conference

2nd African GS1 Healthcare Conference
Lagos, Nigeria

Tunde Odunlami, CEO – GS1 Nigeria

September 17, 2019



Tunde Odunlami

CEO, GS1
Nigeria

Tunde Odunlami is a highly seasoned computer programming and networking expert from the University of Lagos with experiences in point of sales equipment, control retail outlet start-ups and hardware solutions for barcoding implementations as well as AutoID.

He holds several certifications in electronic identification functions and is Senior Partner at the POS Shop Limited, a privately-owned firm reputed for first class sales of POS equipment (hardware and software) and supply chain management solutions.

He has championed several astounding projects including the identification solutions for Murtala Mohammed International Airport staff and World-Bank-assisted billing system for NEPA. He has attended various exhibitions, trainings and management programs in Lebanon, USA, UK, Belgium, UAE, Jordan and more.

Possessing several certifications and demonstrated knowledge in GS1 standards and solutions, he spearheads several projects such as the ongoing GS1 Healthcare, EPCIS and barcode build in Nigerian retail stores, among others.

Tunde leads the Management team in GS1 Nigeria and Board member. He is the Chair of the Sub-Saharan African member organizations of GS1, a cluster group of the GS1 MEMA region. He is a member of POS global networking and solutions.

E-mail
Twitter
LinkedIn

Outlook of Healthcare in Africa and in Nigeria in particular

Continuous Disease Burden and Dampened Economic outlook will lead to **focus on more cost effective products**

Donor Agencies will place more emphasis on **supply chain efficiency**, **traceability** and **cost saving initiatives**

Regulatory Agencies will **intensify the fight against fake and counterfeit drugs**

Outlook of Healthcare in Africa and in Nigeria in particular

Standard treatment protocols for diseases of public sector interest will **continue to be implemented** in private sector healthcare

Business models specific to the African continent will be implemented

Communicable diseases such as HIV/AIDS and malaria will continue **to be public sector and donor agency priority areas.**

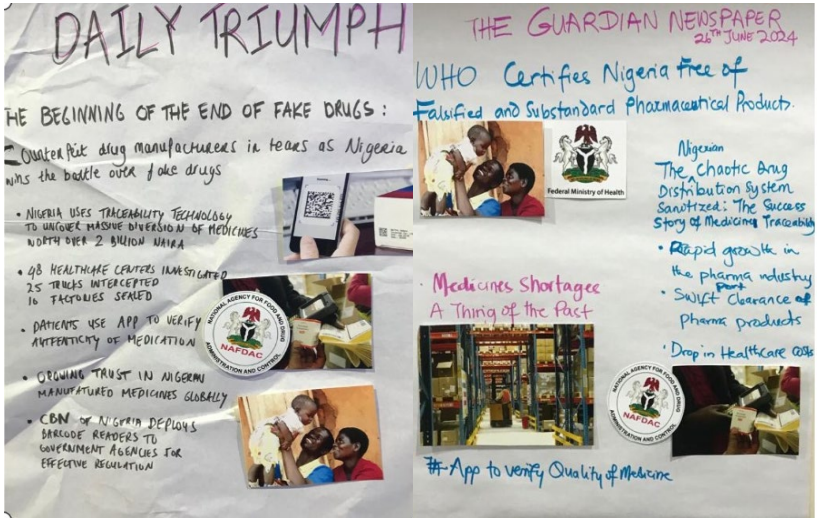
Present status / Progress made since 1st African GS1 Healthcare Conference

TRACEABILITY WORKSHOP JULY 2019

Led to the Development of a **Nigeria National Pharmaceutical Traceability Strategy**

Stakeholders involved included **NAFDAC, FMOH,USAID, GHSC-PSM, PMG-MAN, NIGERIAN CUSTOMS, PCN, PSN, SON** and other relevant stakeholders

OBJECTIVES CAPTURED AT THE WOKSHOP



Global Standards Technical Implementation Guideline for Global Health Commodities

- ✓ Endorsed by the Global Drug Facility, Global Fund, UNDP, UNFPA and USAID
- ✓ Provides guidance on the implementation of global standards for product and location identification, labeling, and data exchange
- ✓ GS1 General Specification as primary reference document for technical specifications to meet the requirement in accordance with GS1 global standards

The future African Healthcare we love to see

Data enabled healthcare system at every point in the chain.

This made possible GS1 identification standards for the healthcare industry.

Integrated Data Capture

- Data Capture
- Visibility
- Authentication
- End-to-end Traceability
- Recall readiness
- Transparency
- Trust
- Patient-safety
- Improved regulation by government
- Increased revenue for all parties

Interagency Supply Chain Group (ISG)
Adoption of global GS1 standards

From the Interagency Supply Chain Group:

Visibility for Health Systems: Adoption of Global Data Standards (GS1)

About the ISG

The broad purpose of the Interagency Supply Chain Group (ISG) is to share information and seek greater alignment across supply-chain investments to bring more impact to individual agency supply chain strategies. The group promotes coordination both globally across programs, and locally through national leadership with the overall aim of improving the efficiency and effectiveness of in-country supply chains. The ISG is an informal partnership of 15 major actors involved in providing supply chain support to countries: Bill and Melinda Gates Foundation, DFID, Global Affairs Canada, the Global Drug Facility, KfW, the Global Fund, Gavi, NORAD, UNDP, UNFPA, UNICEF, USAID, World Bank, WFP and WHO.

Boxes of medical supplies are sorted before being distributed among the mobile health brigades at the Chibuabuabe District hospital in Maputo, Mozambique, in July 2016. ©UNICEF/Rich.

Background

Medicines supply chain execution and responsiveness require synchronization of supply and demand, as well as the orchestration of three flows of commerce, that are the movement of goods, information and funds, across an increasing number of logistics and trading partners, spanning a wide (if not global geographic) region. Whilst the implementation of traceability systems has been identified by National Regulatory Authorities as a useful and efficient tool to combat falsification and illicit distribution of medical products, only some countries have issued progressive traceability regulation. Many have not, and are still assessing various implementation mechanisms, alternatives or otherwise have not approached this topic at all[1]. The international community has recognized the need to support countries in determining what these best approaches are. Since 2014, the international development community has promoted the use of global data standards (GS1) to provide a wider and harmonized framework for supply chain visibility, strengthening anti-counterfeiting measures and sharing of data between parties. The Interagency Supply Chain Group recognizes the value for advocating for both effective and sustainable solutions to enable traceability and safe passage of medicines through national supply chains and have committed to strengthening this response accordingly.

Current activities of the ISG

- Strengthen global and country advocacy for the adoption of GS1 standards and traceability systems with countries, in collaboration with other relevant stakeholders.
- Accelerate the understanding and adoption of an open and global supply chain standard, globally, through technical support, education, and collaboration with manufacturers.
- Collaborate to improve donor procurement guidelines, including the requirement for the use of GS1 standards for identification and barcoding on the different packaging levels, and coordinate with manufacturers on an implementation timeline.
- Develop a roadmap & timeline for the adoption of GS1 standards in labeling all health commodities and products.
- Provide technical assistance to several countries in defining parameters necessary to implement National Traceability Systems. These include development and finance implementation plans for barcoding of health commodities for member states. e.g. support to the Government of Ethiopia to implement a nation-wide adoption of barcoding technology.

[1] Fourth meeting of the member state mechanism on substandard/spurious/falsely-labelled falsified/counterfeit medical products, 13 November 2015, provisional agenda item 4C. Existing technologies and 'track and trace' models in use and to be developed by member states. Draft document submitted by Argentina.

August 2017:

Position paper on the adoption of GS1 standards committing to the process of transitioning to include established, global data standards as part of their procurement requirements and support country uptake of these standards.

The importance / the role of Regulatory bodies in Africa

Over 100 regulatory bodies representatives from **39 countries** present are seeking ways to **ensure patient safety**

Our support / commitment moving forward

Work with NAFDAC to **develop a workable regulatory framework tailored** to the **Nigerian Healthcare delivery system**

Develop a **working group** with stakeholders **to pilot the standard implementation process leveraging on learnings from GS1 African membership organiza**tions

Commitment to **increase patient safety** and **supply chain transparency and efficiency** through the use of our standards

To provide **standards that ensure effective Traceability**

Dr. Tedros Adhanom Ghebreyesus

Director-General of the World Health Organization

" My friends, we have a ***historic opportunity*** *to make* ***transformational improvement*** *in world health.*
Let's do it.

Let us do it ***for every woman and child who died when they didn't have to die.*** *And for* ***every child who failed to reach her full potential****. […]*

Let us ***dedicate ourselves to them****.*

Let us stand ***together for a healthier world****."*


Together,
let's build
a healthy future
in AFRICA
Thank you!

Moji Christianah Adeyeye

Director-General,
NAFDAC

About Me

Professor Adeyeye is the founding Chair of Biopharmaceutical Sciences and Professor of Pharmaceutics and Drug Product Evaluation at the College of Pharmacy, Roosevelt University in Schaumburg, Illinois. She was Professor of Pharmaceutics and Manufacturing for 21 years at Duquesne University in Pittsburgh, PA. She is a Senior Fulbright Scholar and Specialist and 2008 AAPS Fellow. She earned her B.S., and M.S., and PhD from the University of Nigeria, Nsukka, Nigeria and University of Georgia, Athens, GA, respectively.

Her research interests include pre-formulation, early phase development of solid, semisolid and liquid dosage forms, and IND-based and intellectual property-driven late phase development or bench-to-bedside translational research. She has mentored over 15 PhD and M.S candidates. She has 5 patents, 55 peer-reviewed manuscripts, book chapters and books, and more than 140 scientific presentations. She is the founder of a socially conscious start-up company – Elim Pediatric Pharmaceuticals. She uses her university lab for the early phase R&D and partners with contract manufacturing organizations for the clinical and registration batches.

PHARMACEUTICAL TRACK & TRACE IN NIGERIA: A TIMELY IMPERATIVE

Professor Christianah Mojisola Adeyeye, FAAPS, FAS

Director General, NAFDAC

National Agency for Food and Drug Administration and Control (NAFDAC)

NAFDAC was established by Decree 15 of 1993 as amended by Decree 19 of 1999 and now the National Agency for Food and Drug Administration and Control Act Cap N1 Laws of the Federation of Nigeria, 2004.

This Act mandates NAFDAC to regulate and control the manufacture, importation, exportation, distribution, advertisement, sale and use of food, drugs, cosmetics, chemicals, detergents, medical devices and packaged water (known as regulated products).

BACKGROUND

Why is Track and Trace Timely?

- Drug and medical products distribution system in Nigeria for the most part is unstructured and poses a serious threat to the National Drug Policy.
  - Open drug markets
  - As a result, the country has introduced the concept of coordinated wholesale centers (CWC) across th six geo-political zones
  - In addition to this a well-coordinated system of tracking and tracing of pharmaceutical products Is needed to ensure an end-to-end safety in the drug value chain.

Why is Track and Trace Timely?

- Substandard and Falsified Medicines (SFs) and Counterfeits
  - WHO estimates that 10.5% of medicines worldwide are substandard or falsified
  - Most of the burden falls on low- and middle-income countries (LMICs) due to poor pharmaceutical governance and supply-chain management
  - Nigeria, studies conducted have consistently shown declining incidence of SFs
  - Prior to 2001, it was reported that 40% of medicines circulating in the Nigerian pharmaceutical supply chain were substandard, fake, or counterfeited (Ogundipe, 2011; Bate et al, 2009)

Substandard and Falsified Medicines (SFs) and Counterfeits

- A study conducted in 2005 by NAFDAC in collaboration with WHO and DFID showed a remarkable decrease in the circulation of counterfeit medicines from 40% in 2001 to 16.7% in 2005.
- The national survey on quality of medicines using the Truscan® device conducted by NAFDAC across 29 states including the FCT from January 2010 to April 2012 revealed a failure rate of 19.6% for antimalarial medicines
- March 2019 survey results (Round 5) showed a a failure rate of 1.3% for antimalarials
  - This is a result of the Mobile Authentication System (MAS) that will be discussed next
- The current estimate of SFs in the country is about 17%. Too high!!
- We strive for a much lower figure!
  - That is why Traceability in the supply chain is needed and the Conference timely

NIGERIA DRUG POLICY (NDP) AND SAFE MEDICINES

Goals:

- Make available at all times to the Nigerian populace adequate supplies of drugs that are effective, affordable, safe and of good quality
- Ensure the rational use of such drugs
- Stimulate increased local production of essential drugs

- As reflected in the central goals, the federal government is committed to ensuring safe, effective and affordable medicines to the citizenry.
- NAFDAC, as the custodian of the mandate of safeguarding the health of the nation constantly seeks to partner with organizations to achieve this task
  - The drive was part of the reason for adoption of MAS
- This is why the co-hosting of the GS1 Conference is timely

ENSURING QUALITY AND SAFE MEDICNES: PAST EFFORTS

THE MOBILE AUTHENTICATION SERVICE (MAS)

- In 2010, NAFDAC in a pilot study deployed the MAS scheme as one of the anti-counterfeiting strategies to detect SFs medical products.
  - The scheme uses scratch codes and Short Messaging Service (SMS) to empower consumers to verify the authenticity of medicines at the point of purchase: (putting the power of detecting counterfeit in the hands of consumers)
  - The consumer scratches a panel on the product which reveals a unique, one-time use PIN

ENSURING QUALITY AND SAFE MEDICINES: PAST EFFORTS

- Following the success of the pilot study, NAFDAC deployed the MAS Scheme in January 2012, across **anti-malarial** and **antibiotic medicines** imported or manufactured in Nigeria
  - Experience during pilot phase positioned the Agency to work closely with national and international partners
  - This will be valuable during the pilot phase of GS1 in Nigeria
- MAS is still in place in the country till date for enforcing the quality of anti-malarial and antibiotic medicines
- Moving to the next level, the time is right for traceability in the supply chain using global standards
- This is why the GS1 Conference is happening

THE GLOBAL STANDARDS

- Adopting a common business language – a global standard – that can be used by all trading partners, from manufacturer to dispenser/patient
- Goal is to identify, capture, and share information medical products and their movement in the supply chain.

GLOBAL STANDARDS

- NAFDAC's partnership with GS1 Nigeria to deploy a more effective and robust means of securing the medicines supply chain
  - To keep up with the Agency's mandate…control and regulate distribution, sale and use of its regulated products
- In June 2019, the FMoH and NAFDAC, with the support of the United States Agency for International Development (USAID) Global Health Supply Chain – Procurement and Supply Management (GHSC-PSM) Project, hosted a workshop to launch the pharmaceutical traceability initiative.
- The event was attended by a range of stakeholders, and it was to be a prelude to this conference.

NIGERIA'S TRACK & TRACE VISION

- Nigeria seeks to implement pharmaceutical traceability using global standards.
- The implementation of pharmaceutical traceability policies, processes, and systems will create an environment that provides visibility of product status from plant to patient.
- Positive outcomes requires strong regulatory governance, collaborative execution, and accountability through effective monitoring and evaluation
- NAFDAC will collaborate across government agencies and the private sector to meet the following strategic objectives

TRACEABILITY VISION

- **Strategic Objective 1:** Establish a governance structure for advocacy, collaboration, responsible resource mobilization, and oversight of global standards and traceability implementation.
- **Strategic Objective 2:** Strengthen the regulatory environment to include legal frameworks that enable traceability of quality pharmaceuticals through the legitimate supply chain.
- **Strategic Objective 3:** Create efficiencies in the public and private health supply chains through standardized identification, automated data capture, and reporting.

TRACEABILITY VISION

- **Strategic Objective 4:** Build and sustain technology to support interoperability of health information systems and implementation of traceability to improve data visibility.
- **Strategic Objective 5:** Enable use of standards to support identification and authentication of commodities dispensed to end-users at service delivery points in the public and private sectors.

NIGERIA'S TRACEABILITY ROADMAP

- NAFDAC set a five-year strategic plan to achieve the stated objectives.
  - Estimated ten companies already using GS1 bar coding system for verification only
  - Traceability is capital intensive project, funding is a major determinant.
  - Positive indicators of international support from donor agencies and development partners.
- **Expectation:** By the end of the fifth year, Nigeria would have achieved at least 70% implementation of all NAFDAC-regulated medical products

5-YEAR PLAN

NAFDAC's Planned Scalable Project Using GS 1

Goals:

- Demonstrate that tse of global standards for traceability can provide a Nigerian national product identification and classification structure
- The use will provide a common language that can be used efficiently among stakeholders in the supply chain to exchange ideas or carry such forth in the tracking and tracing a health commodity
  - E.g., NAFDAC, manufacturers, distributors, pharmacists, health systems
- Track and trace will be a basis for global trade in terms of identification, verification and data exchange of commodities

NAFDAC's Planned Scalable Project Using GS 1

- **Option 1:** The manufacturer will share product master data and serialized product information for the secondary package. The patient/ healthcare provider will use an app to verify if that serial number really comes from the manufacturer.
- **Option 2**: The manufacturer will share product master data and serialized product information for the secondary package (and possibly logistic item).
- The wholesaler and/or distributor will capture traceability information during receipt and distribution of the products. The healthcare provider will capture receipt and dispense information.

NAFDAC's Planned Scalable Project Using GS 1

Option 1: Verification – identification of falsified products by the patient

- Secondary package needs GS1 DataMatrix with GTIN + expiry date + serial number
- Manufacturers need to be able to upload serialized information to a centralized database
- A mobile app needs to be available to scan the GS1 DataMatrix and do the verification
- Dashboard needs to show reporting of all the activities
- Cyber security to protect the data and data exchange

- Manufacturer (Options 1 and 2): International manufacturer that does serialization
- Commodities: Essential medicines (antiretroviral drug and antimalarial)

Planned Scalable Project

Option 2: Traceability – capture information at more points along the supply chain

- Secondary package and logistic item needs GS1 DataMatrix with GTIN + expiry date + serial number / GS1-128 with GTIN + serial number
- Manufacturers need to be able to upload serialized information to a centralized database
- The database needs to be in place to receive serialized product information and verify while a patient scans the GS1 DataMatrix.
- A mobile app needs to be available to scan the GS1 DataMatrix and do the verification.
- Dashboard needs to show reporting of all the activities.
- Cyber security to protect the data and data exchange.

CONCLUSIONS

- Implementation and success of the scalable project becomes a reference template for stakeholders in the supply chain in modeling and lessons learned
- Implementation of GS1 standards in Nigeria will tremendously advance our regulatory efficiency as we strive to reduce the scourge of SF medicines.
- This will probably be one of the greatest legacies to bequeath to the future Nigeria and Africa

NATIONAL AGENCY FOR FOOD AND DRUG ADMINSTRATION AND CONTROL

NAFDAC

Thank you