

Nigeria's Journey Implementing Pharmaceutical Traceability Using GS1 Standards

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

- MANDATE: regulate and control the manufacture, importation, exportation, **distribution**, advertisement, sale and use drugs, cosmetics, chemicals, detergents, medical devices and packaged water
- The NAFDAC ACT places the burden of drug **distribution, sale, use** and security on the Agency.
- This has guided the development of a 5-year traceability implementation plan in line with the Nigeria National Pharmaceutical Traceability Strategy.

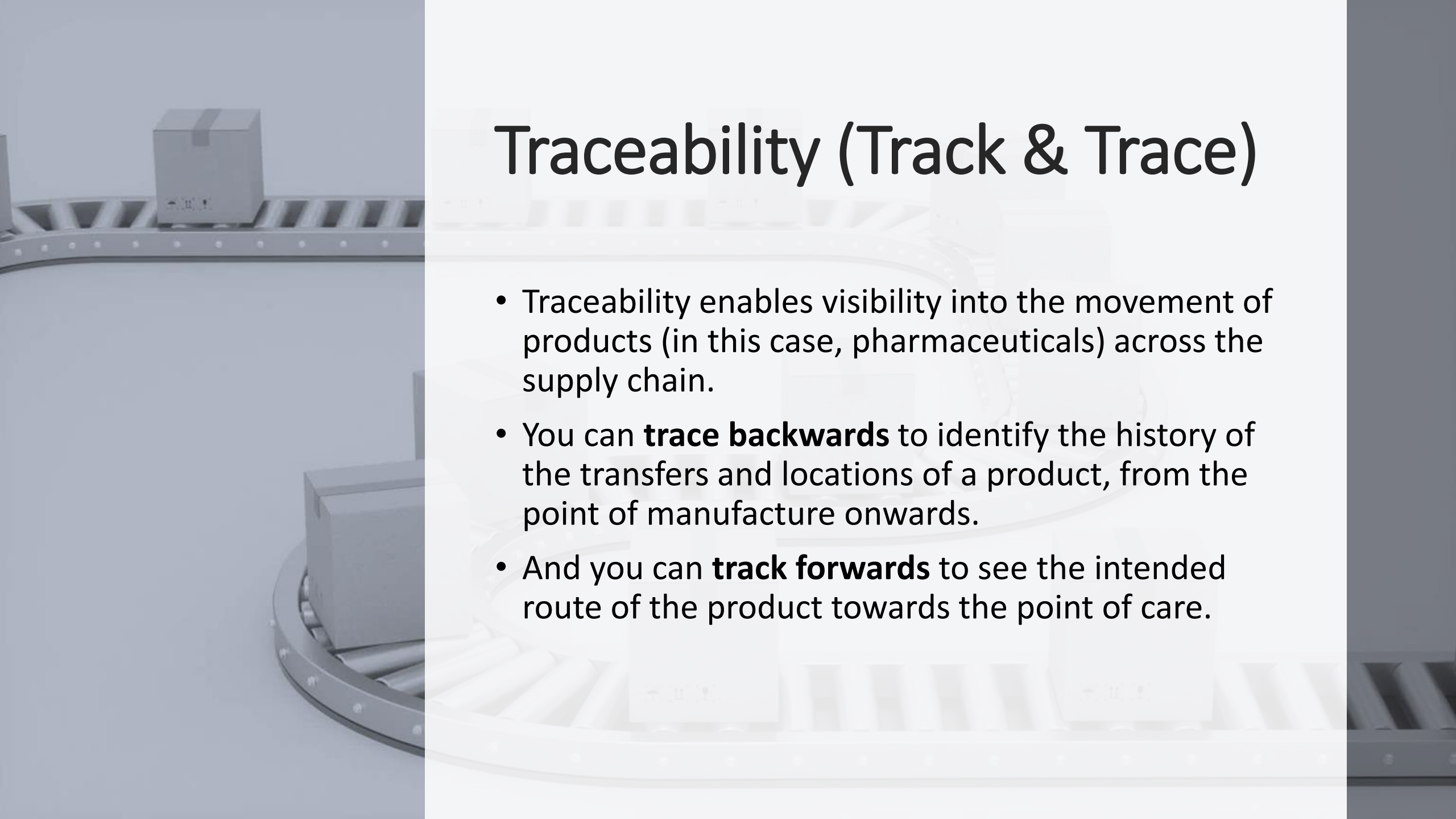
The Need for a Secured Supply Chain

- Often the supply chain is broken
- Medicines are expired or not stored correctly
- Medicines are not available when needed
- Inventory management is not optimal
- Diversion of medicines from public sector and donor supported programs
- SF medicines are still a major challenge
- Chaotic distribution system evident in Large Drug Markets



The WAY FORWARD





Traceability (Track & Trace)

- Traceability enables visibility into the movement of products (in this case, pharmaceuticals) across the supply chain.
- You can **trace backwards** to identify the history of the transfers and locations of a product, from the point of manufacture onwards.
- And you can **track forwards** to see the intended route of the product towards the point of care.

Traceability Objectives

Traceability supports many healthcare objectives, including:

- Enabling **visibility** of where the product is within the supply chain
- Improving **pharmacovigilance** and control of outcome of treatments
- Improving efficiency of **inventory** management and distribution
- Improving **visibility of product “status”** (e.g. expired, short-dated, recalled)
- Enabling **protection of brand integrity** for domestically manufactured goods
- Improving **efficiency of “reverse” logistics** processes (e.g. those used for returns, recalls)

NAFDAC's Traceability Implementation: Five-Year Plan

Major Activities		2020	2021	2022	2023	2024				
1	Establish Traceability Office at NAFDAC									
2	Establish Technical Working Group - <i>the GS1 help desk</i>									
3	Establish National Traceability Steering Committee									
4	Conduct traceability technical infrastructure gap analysis									
5	Work with stakeholders on pilot to test prototype traceability implementation									
6	Guide supply chain stakeholders on hardware and software requirements and solution providers									
7	Use pilot results for future pilots and as input for regulation									
8	Develop regulations to support traceability implementation									
9	Develop and sustain traceability system infrastructure									
10	Implement product identification									
11	Implement master data requirements									
12	Implement traceability data requirements									
13	Enable monitoring of stakeholder compliance									
14	Achieve safety and efficiency by use of traceability information									

Completed: 

In progress: 

Not yet Started: 

Nigeria's Traceability Journey at a Glance I

Participation at the 1st Africa GS1 Conference in Ethiopia driven by GSC

2018

Hosted 2nd Africa GS1 Conference in Nigeria.

Call to Action – Africa Strategy

Developed 5-year Traceability Plan

September 2019

NAFDAC and GS1 Nigeria signed MOU

November 2020

Support from International Partners

- BMGF
- USAID

3rd/4th Quarter 2021

Support from

- Global Fund
- WHO

Private Sector Pilot engagements

Sensitization of Solution Providers

1st Quarter 2022

June 2019

National Pharmaceutical Traceability Strategy development - Workshop

October 2020

Launch of Strategy and Inauguration of the National Traceability Steering Committee

March 2021

COVID-19 vaccine traceability pilots, in-country serialization

November 2021

Reliance: Ghana FDA visit to Nigeria to understudy the NAFDAC Traceability Implementation

March 2022

Reliance: SAPHRA to understudy NAFDAC – Initial Zoom Meeting

Nigeria Traceability Journey at a Glance II





Traceability Implementation Approach

- Sensitization of stakeholders on the needs and requirement for pharmaceutical traceability
- Deployment of Traceability Infrastructure – Hardware and Software
- Training of relevant stakeholders across the supply chain
- Implementation of various pilots – scalable, progressive, risk-based, etc.
- Development and dissemination of the Pharmaceutical Traceability Regulation
- Aggressive sensitization of the stakeholders and the public on requirements of traceability
- Enforcement of traceability for all pharmaceuticals

Thank you

