Terms of Reference

National Traceability Steering Committee

July 2020

BACKGROUND

- Establishment of global standards is a fundamental undertaking that provides simplicity and consistency by promoting universal applicability and optimal functionality across the globe and industry sectors.

- Use of global standards in the supply chain of medical products significantly contribute to the mitigation of substandard and falsified or counterfeit medicines, reduction of medication errors, efficient traceability, product authentication, the dedication of more time for patient consultation and increased supply chain efficiency.

- The National Traceability Strategy Initiative (NTSI) was developed in Nigeria as a five-year plan at a workshop of multi-stakeholders in June 2019.

BACKGROUND (Cont'd)

- The aim is to establish a governance structure in order to lead the strategy, advocacy, collaboration, resource mobilization, and oversight of global standards and traceability implementation.

- In addition, The NTSI seeks to advocate among key health sector stakeholders for their participation and contributions towards achieving the vision, strategy, and roadmap toward a strong supply chain network that is powered by GS1 global standards.

- The overarching goals are:
  - Improve efficiency in the pharmaceutical supply chain.
  - Improve patient safety and safeguard the health of the nation

STRATEGIC OBJECTIVES

Having obtained approval by the Minister of Health,

the objectives are as stated below:

> **A.** Establish a governance structure to lead strategy, collaboration, outreach, and oversight of global standards and traceability implementation through the following four key administrative components

i. **NAFDAC and Ministry of Health are Co-Chairs**
   - Director of Food and Drugs (FMOH)
   - Director of Drug Registration and Regulatory Affairs (NAFDAC)

ii.   **Multi-stakeholders National Traceability Steering Committee (NTSC) comprised of the following:**

1.   National Agency for Food and Drug Administration and Control (NAFDAC)
2.   Federal Ministry of Health (FMOH)
3.   Pharmacists Council of Nigeria (PCN)
4.   Pharmaceuticals Manufacturing Group of the Manufacturers Association of Nigeria (PMG-MAN)
5.   Association of Food, Beverage & Tobacco Employers (AFBTE)
6.   Association of Pharmaceutical Importers of Nigeria (APIN)
7.   Global Health Supply Chain- Procurement and Supply Management (GHSC-PSM)
8.   Pharmaceutical Society of Nigeria (PSN)
9.   GS1 Nigeria (GS1)
10.   The Global Fund to Fight AIDS, Tuberculosis and Malaria (TGF)
11.   United States Agency for International Development (USAID)
12.   Nigeria Representation of Overseas Pharmaceutical Manufacturers (NIROPHARM)
13.   Association of Community Pharmacists of Nigeria (ACPN)
14.   African Resource Centre (ARC)
15.   The Association of Industrial Pharmacists of Nigeria (NAIP)
16.   Nigeria Customs Service (NCS)

iii. **NAFDAC Traceability Office (GS1 Desk)**

iv. **Traceability Technical Working Group (TWG)**

B. Strengthen the regulatory environment to include legal frameworks that enable traceability of quality pharmaceuticals starting with development of Master data and track and trace capability of legitimate supply channels (such as USAID, GLOBAL FUND, GAVI and UNICEF) as a scaleable model

STRATEGIC OBJECTIVES (Cont'd)

(C) Create efficiencies in in-country health supply chains through standardized GS1 traceability identification, automated data capture, and reporting of movement of commodities from local manufacturers through various stakeholders' supply chains to the end user.

(D) Build and sustain technology to support interoperability of health systems and implementation of traceability to improve data visibility

(E) Enable the use of standards to support identification and verification of commodities dispensed to end-users at service delivery points in the public and private sectors.

STRATEGIC OBJECTIVES (Cont'd)

1 Establish Governance Structure

- Lead strategy
- Advocacy
- Collaboration
- Resource Mobilization
- Oversight of implementation

2 Strengthen Regulatory Environment

- Develop and disseminate Regulation
- Publish guidelines for implementation
- Enforce compliance

3 Create Supply Chain Efficiency

- Standardized Identification
- Automated Data Capture
- Automated Reporting

4 Build and Sustain Technology

- Support interoperability of health systems
- Implement traceability
- Improve data visibility

5 Enable use of Standards

- Identification of commodities
- Authentication of commodities at service delivery points in public and private sectors.

Nigeria Pharmaceutical Traceability Strategic Objectives

RESPONSIBILITIES
The National Traceability Steering Committee (NTSC)

1. To serve as the main coordinating organ for the implementation of the Traceability Strategy

2. To provide strong leadership and accountability in executing supporting activities as contained in the Traceability Strategy

3. To advocate among key health sector stakeholders for advancement of implementation and use of global standards for trade item and location identification, data capture, and data exchange

4. To guide in all activities that will support reaching Nigeria's vision for pharmaceutical traceability implementation and the use of global standards.

5. To coordinate with donor partners to develop yearly work plans containing agreed funding and associated Key Performance Indicators

RESPONSIBILITIES
NAFDAC Traceability Office (GS1 Desk)

1. The Traceability Office (TO) at NAFDAC is responsible for day to day implementation of the Traceability Strategy and development of necessary regulatory framework

2. The GS1 Desk will be staffed by NAFDAC personnel and augmented through a donor supported technical consultant.

3. The GS1 Desk will serve as the operational lead for traceability implementation, with oversight and policy guidance from the NTSC.

RESPONSIBILITIES
Traceability Technical Working Group (TWG)

1. The joint technical team of NAFDAC and GS1 IT staff is made up of healthcare and supply chain experts and it is responsible for management of the National Traceability Information Technology (IT) infrastructure.

MEMBERSHIP OF THE STEERING COMMITTEE AND DURATION

- Federal Ministry of Health and NAFDAC will each have four representatives

- PCN, Customs, GS1 will each have two representatives

- International Partners
  - Two members each
  - Any other International Partners that have a collaborative traceability project(s) with NAFDAC will also have two representatives

- All other organizations will each have one representative

- Except for FMOH and NAFDAC that are members in perpetuity, the membership at this initial stage will be five-years in duration when full implementation is realized based on the deliverables

MEETINGS

- Meetings will be held alternately at NAFDAC and FMOH site whether it is virtual or physical.

- Frequency will be every other month.

- Each organization shall be responsible for their travel and accommodation.

QUORUM

- Seventy percent of membership.

- Excuse must be taken in writing for inability to attend a meeting.

- Organization that has less than 70% attendance shall be excused from the Committee

REPORTS

- Progress report of ongoing projects and activities shall be given at each meeting

- Financial report will be given twice a year

DELIVERABLES

a) A well-developed multi-stakeholder governance structure that is collaborative and strategic in implementing the traceability agenda

b) Trained multi-stakeholders on the adaptation of the supply chain to traceability GS1 technology

c) Development of strong regulatory environment that includes legal frameworks to enable traceability of quality products through supply channels

d) Successful implementation of track and trace using already built international supply channels such as USAID and Global Fund, as a scalable model

e) Realization of efficiencies in health supply chains through standardized GS1 traceability identification, automated data capture, and reporting of movement of commodities from local manufacturers to the end user

f) Sustainable and robust application of GSI traceability standards that support interoperability of health systems and implementation of traceability to improve end to end data visibility

g) Sixty to seventy-five percent of local manufacturers become users of track and trace GSI technology within five years

h) Use of international best practices of standards that support identification and verification of commodities dispensed to end-users at service delivery points in the public and private sectors.

i) Investment case for the track and trace program in Nigeria

j) Long term roadmap for implementation of track and trace for health products

Thank you