

The Republic of Ghana
Ministry for Health



Ghana Pharmaceutical Traceability Strategy



1st edition
2023 to 2028



USAID
FROM THE AMERICAN PEOPLE



**USAID GLOBAL HEALTH
SUPPLY CHAIN PROGRAM**
Procurement and Supply Management



**Republic of Ghana
Ministry of Health**

GHANA PHARMACEUTICAL TRACEABILITY STRATEGY 1ST EDITION



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**USAID GLOBAL HEALTH
SUPPLY CHAIN PROGRAM**
Procurement and Supply Management

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Pharmacy Directorate, Ministry of Health

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ACRONYMS

AIDC	Automatic Identification and data capture
FDA	Food and Drugs Authority
GHS	Ghana Health Service
GHiLMIS	Ghana Integrated Logistics Management Information System
GLN	Global Location Number
GoG	Government of Ghana
GTIN	Global Trade Item Number
ICT	Information and Communications Technology
IR	Intermediate Result
KPIs	Key Performance Indicators
LI	Legislative Instrument
MA	Marketing Authorization
M&E	Monitoring and Evaluation
MO	GS1 Member Organization
MOH	Ministry of Health
MIS	Management Information System
NHIA	National Health Insurance Authority
NHP	National Health Policy
SO	Strategic Objective
SOPs	Standard Operating Procedures
SSCC	Serial Shipping Container Code
TOR	Terms of Reference
TWG	Technical Working Group
UHC	Universal Health Coverage
USAID	United States Agency for International Development
WHO	World Health Organisation

FOREWORD

The Government of Ghana (GoG) through the Ministry of Health (MOH) is implementing strategies to ensure universal health coverage that will improve the health status of all people living in Ghana. Providing quality health services to all Ghanaians means an uninterrupted supply of safe, quality, and efficacious health commodities. Through the adoption of global standards, Ghana seeks to increase visibility within the supply chain and the ability to track and trace medicines from point of entry to the market to the patient.

Driven by these goals, GoG held a series of workshops to launch Ghana's national pharmaceutical traceability initiative. The workshops were attended by representatives from the government, private sector, and development partners in the pharmaceutical sector in Ghana. This multi-disciplinary group established the vision, strategy, and roadmap for implementing pharmaceutical traceability in Ghana through the use of global standards.

This document entitled the ***Ghana Pharmaceutical Traceability Strategy*** includes our priorities, vision, and strategy for implementing traceability in Ghana by leveraging global standards. The strategy presents a starting point to organize and operationalize the foundational work required to support traceability.

The Ministry of Health acknowledges the technical assistance, commitment, and invaluable inputs of the USAID/GHSC-PSM, GS1 Ghana office, the private sector and other development partners who supported the preparation of this document.

Finally, the Ministry also recognizes that it will take concerted efforts by all stakeholders, including consumers, to ensure that this pharmaceutical traceability strategy is fully implemented and achieves the desired impact. Indeed, we can say that this strategy belongs to all of us.



KWAKU AGYEMAN-MANU (MP)
MINISTER FOR HEALTH

ACKNOWLEDGEMENT

The Ministry of Health would like to acknowledge the diverse contributions and roles played by the various stakeholders and organizations towards the planning, execution, and finalization of the Ghana Pharmaceutical Traceability Strategy.

Special thanks to the Minister of Health, Hon. Kwaku Agyeman - Manu for his leadership role and support, and the USAID for funding and providing the technical oversight for the development of the strategy.

We are also grateful to the Steering Committee, Technical Working Group (TWG) and Secretariat for their guidance and technical expertise in the development of the strategy.

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No.	Name	Designation
1.	Hon. Kwaku Agyeman-Manu (MP)	Hon. Minister for Health
2.	Mr. Kwabena Boadu Oku-Afari	Chief Director, MOH
3.	Dr. Mrs. Martha Gyansa-Lutterodt	Former Director, Technical Coordination, MoH
4.	Dr. Baffour Awuah	Ag. Director, Technical Coordination, MoH
5.	Dr. Emmanuel Ankrah Odame	Director Policy Planning, Monitoring and Evaluation, MOH
6.	Dr. Francis Chisaka Kasolo	WHO Representative, WHO Country Office for Ghana
7.	Dr. Mrs. Joycelyn Azeez	Director, Pharmaceutical Services, MOH
8.	Dr. Bismark Attah Adjepong	Director, Pharmaceutical Services, Ghana Health Service
9.	Dr. Lydia Dsane-Selby	Former CEO, National Health Insurance Authority
10.	Prof. Alex Dodoo	Director General, Ghana Standards Authority
11.	Dr. Mrs. Delese Darko	CEO, Food and Drugs Authority
12.	Prof. Kwame Ohene Buabeng	Representative, KNUST
13.	Mr. Dan Nuer	Representative, Ministry of Finance
14.	Rev. Ammishaddai Owusu-Amoah	Commissioner General, Ghana Revenue Authority
15.	Mrs. Cecilia Senoo	Representative, Civil Society Organisation
16.	Mr. Kofi Nsiah Poku	President, Pharmaceutical Manufacturing Association of Ghana
17.	Mr. Deo Kimera	Country Director, USAID Global Health Supply Chain-Procurement and Supply Management Program
18.	Mrs. Araba Kudiabor	Director, Supplies, Stores and Drug Management, GHS
19.	Mr. Harrison Abutiate	President, Chamber of Pharmacy

Technical Working Group Members

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2.	Mr. Vigil Prah-Ashun	Food and Drugs Authority (Co-chair)
3.	Mr. Kofi Addo-Agyekum	Ghana National Chamber of Pharmacy (Co-chair)
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7.	Mrs. Adah Allotey-Pappoe	Food and Drugs Authority
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16.	Mr. Philip Tagboto	Association of Representatives of Ethical Pharmaceutical Industries
17.	Mr. Kofi Essuman	GS1 Ghana Office
18.	Mrs. Neimatu Adjabui	PQM-PLUS
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20.	Mr. Adolf Antwi	Systems for Development
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25.	Mr. Julius Fenoo	Ministry of Health
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No.	Name	Organisation
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2.	Mr. Saviour Yevutsey	Ministry of Health
3.	Dr. Brian Adu Asare	Ministry of Health
4.	Mrs. Ivy Amankwah	Ministry of Health
5.	Dr. Emmanuella Abassah-Konadu	Ministry of Health
6.	Ms. Angela Odoi	USAID Global Health Supply Chain-Procurement and Supply Management Programme
7.	Ms. Abigail Oye Ayisi	Ministry of Health
8.	Mrs. Portia Arri	Ministry of Health
9.	Mrs. Diana Edusei	Ministry of Health

EXECUTIVE SUMMARY

The *Ghana Pharmaceutical Traceability Strategy* was developed in support of the Ministry of Health's (MoH) National Health Policy (2020). This policy seeks to ensure the availability and appropriate use of quality medicines and medical products to improve the health status of all people living in Ghana.

In support of this mission, the MoH, together with the Food and Drugs Authority (FDA) began to assess how global standards in health care can improve pharmaceutical traceability and data visibility in the supply chain. In 2018, the MoH and GHS began an initiative to roll out an integrated GhiLMIS that can identify, capture, and exchange product and facility location data throughout the national public health supply chain. From 2019 to 2021, the Government of Ghana (GoG) continued to raise awareness for the use of GS1 global standards to support national health care objectives. This included a training workshop for major stakeholder groups covering the foundational elements of GS1 standards, their applicability to the Ghana health sector, and their relevance to enabling pharmaceutical traceability.

In February and May 2021, the MoH hosted a series of collaborative workshops with strategic private and public sector partners to develop the *Ghana Pharmaceutical Traceability Strategy*. The multi-disciplinary team with members across the public and private sectors established this strategy and a high-level roadmap for implementing global standards to “promote, restore, and maintain good health for all people living in Ghana.”

The following strategic objectives were defined as needed to advance toward this goal:

Strategic Objective 1: A functional governance framework that is sustainable and accountable for the implementation and evaluation of the traceability strategy

Strategic Objective 2: Enhanced regulatory framework for verification and traceability of pharmaceutical products

Strategic Objective 3: Efficient public and private supply chain systems using standardised identification, capture, and reporting of high-quality supply chain data

Strategic Objective 4: Information and communications technology (ICT) leveraged to ensure effective management of health commodities through identifying, capturing, sharing, and effectively using data

Strategic Objective 5: Appropriate skill mix of health care providers empowered with the right information and technology to provide quality health services

The *Ghana Pharmaceutical Traceability Strategy* was developed using a results-based approach as a planning system. Through this approach, stakeholders established strategic objectives that linked to intermediate outcomes and results that directly relate to the country's vision for traceability. The strategy document recognises that adopting standards to enable traceability is a multi-year endeavour that requires

broad stakeholder engagement. As such, it defines priorities and decisions that must be made to advance the strategic objectives that have been identified. The document does not represent a detailed or costed implementation plan for the illustrative activities and outputs described, which must be informed by further market analysis and refinement of the implementation scope. It includes a high-level roadmap with illustrative activities to be implemented beginning in 2023. These timelines will be refined through the course of implementation, including a result of preliminary risk analyses, assessments of market readiness, and the selection of a traceability model.

A costed implementation plan has been completed to serve both as an advocacy tool for the mobilisation of funds for the implementation of the Strategy.

Summary Budget

Strategic Objective	Cost (GHS)	Cost (US\$) @GHS8.27 per US\$
Governance	10,922,750.00	1,320,767.84
Policy and Regulation	1,677,750.00	202,871.83
Supply Chain Operations	2,585,700.00	312,660.22
Systems and Technology	7,407,300.00	895,683.19
Service Delivery	1,467,800.00	177,484.89
Total	24,061,300.00	2,909,467.96

These are subject to change based on emerging issues.

INTRODUCTION

The Government of Ghana (GoG) through the Ministry of Health (MoH) is committed to Universal Health Coverage (UHC) to improve the health status of all people living in Ghana. This vision is interpreted through the Ministry of Health's National Health Policy (NHP) (2020). The policy provides a strategic framework, notably, strategy 3.1.4, **“Ensure the availability and appropriate use of quality medicines and medical products,”** which states in part:

This policy, without prejudice to the various forms of medicines and medical products, used by different forms of medical practice (orthodox, alternative, traditional, etc.), will ensure that misuse and abuse [are] curtailed. In addition, the availability, affordability, efficacy and overall quality of medicines and medical products for all recognised forms of medical practice, will be pursued. This will be done through strengthened regulation and the promotion of local production of these medicines and medical products as well as working within the One Health strategic framework to combat antimicrobial resistance.

The *Ghana Pharmaceutical Traceability Strategy* is anchored on the NHP. It also aligns with the National Medicines Policy, 3rd Edition 2017 with respect to access to quality-assured medicines. The strategy is a plan to leverage global standards to strengthen the health system through improving data quality and traceability of health commodities. This plan will enable access to safe, effective, and quality medicines, which are key contributors to Ghana's UHC goals.

The *Ghana Pharmaceutical Traceability Strategy* was developed through multi-stakeholder consultative processes. This was built upon a series of initiatives in Ghana focused on creating an enabling environment for adopting global standards. These initiatives include the rollout of a GS1-supported Ghana Integration Logistics Management Information System (GhiLMIS).

The multi-sector stakeholders prioritised the implementation of pharmaceutical traceability policies, processes, and systems and the adoption of global standards in Ghana to create an environment that:

- Addresses substandard and falsified pharmaceutical products detected in the legitimate supply chain
- Improves efficiency of inventory management and distribution
- Enables the visibility of the location of products within the supply chain

To achieve these priorities, key stakeholders across government agencies and the private sector identified the five strategic objectives (SOs) below. These SOs focus on

building towards the stated NHP vision through adopting global standards and working towards traceability implementation.

Strategic Objective 1: A functional governance framework that is sustainable and accountable for the implementation and evaluation of the traceability strategy

Strategic Objective 2: Enhanced regulatory framework for verification and traceability of pharmaceutical products

Strategic Objective 3: Efficient public and private supply chain systems using standardised identification, capture, and reporting of high-quality supply chain data

Strategic Objective 4: Information and communications technology (ICT) leveraged to ensure effective management of health commodities through identifying, capturing, sharing, and effectively using data

Strategic Objective 5: Appropriate skill mix of health care providers empowered with the right information and technology to provide quality health services

The *Ghana Pharmaceutical Traceability Strategy* represents a starting point for the MoH and stakeholders to jointly organize and operationalise the foundational work that needs to be undertaken to support traceability implementation. It is focused on realistic near-term initiatives that can be achieved in the current context while recognising that it will be a “living document” to be updated over time.

SCOPE

The following is the scope of the *Ghana Pharmaceutical Traceability Strategy* document:

- National traceability priorities and vision statement
- A *National Pharmaceutical Traceability Results Framework*, a performance-based approach to measuring expected change from traceability implementation at each level of implementation, including Mission, Vision, Strategic Objectives, Intermediate Results, and Outputs
- The *Ghana Pharmaceutical Traceability High-Level Roadmap*, an illustrative implementation plan with initiative owners at the output level and timelines for implementation

This strategy is intended to be a dynamic document that can be expanded to include additional scope details following assessments and key decisions to be made by the governance body. The strategy document may be amended over time to include:

- The choice of traceability model - Traceability systems generally take on one of three models—verification, track, and trace, or both, with a refined implementation scope and further defined people, processes, and technology requirements for traceability including:
 - Refined scope of products and locations that global standards-based identifiers will be applied to
 - Determination of requirements and initiatives that will apply to the private sector, public sector, or both
- A detailed and costed implementation plan, including required people, process, and technology resource inputs

APPROACH

OVERVIEW

Achieving the defined strategic objectives in the Ghana supply chain will require long-term investment and an integrated implementation plan. The *Pharmaceutical Strategy* comprehensively focuses on the building blocks required to achieve the agreed-upon traceability vision and strategic objectives across governance, policy, supply chain, technology, and service delivery.

STRATEGY DEVELOPMENT PROCESS

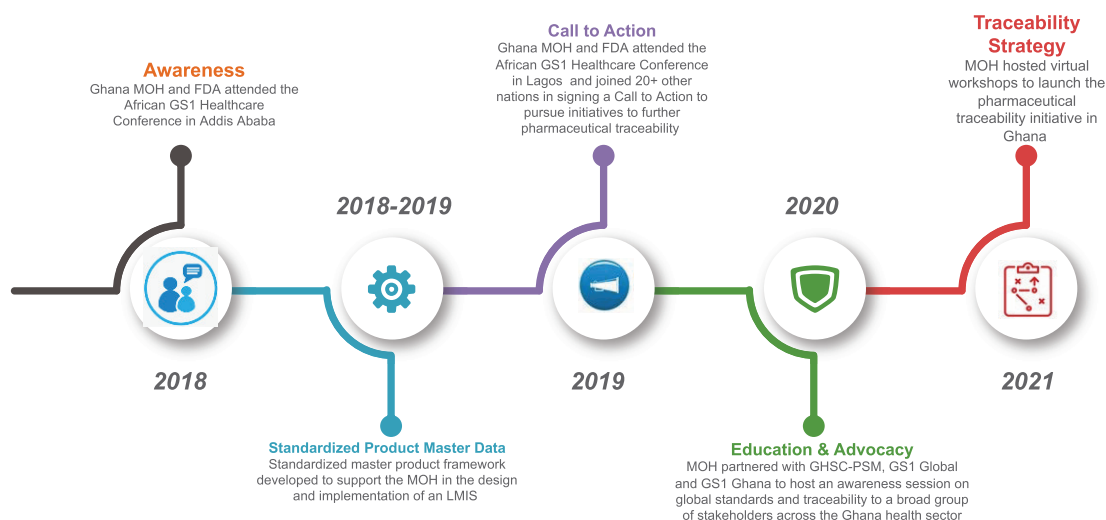
In November 2020, the Ministry of Health (MoH) led a virtual training aimed at education and advocacy among stakeholders on adopting global standards for pharmaceutical traceability. Between February and May 2021, the MoH, with its strategic private and public sector partners, hosted a series of workshops (virtual and physical) to develop the strategy. A range of stakeholders attended the workshop events, including:

- Food and Drugs Authority (FDA)
- Ghana Health Service (GHS)
- Ghana Standards Authority
- GS1 Ghana
- GS1 Global Office
- National Health Insurance Scheme
- MoH
- Pharmaceutical Manufacturers' Association of Ghana
- US Pharmacopoeia
- WHO Country Office, Accra
- UNICEF
- University of Ghana, School of Pharmacy
- USAID Global Health Supply Chain Program—Procurement and Supply Management Program (GHSC-PSM)
- USAID Promoting the Quality of Medicines Plus

TRACEABILITY PLANNING FRAMEWORK

The Ghana MoH and other stakeholders leveraged an illustrative Traceability Planning Framework to systematically organise the work of developing, operationalising, and executing a vision and strategy for pharmaceutical traceability based on GS1 standards, in support of improved supply chain security and data visibility.

Figure 1. Traceability Planning Framework¹



In 2018, the MoH and GHS began an initiative to roll out an integrated GhiLMIS that has the capability of identifying, capturing, and exchanging product and facility location data throughout the national public health supply chain. A key component of this initiative was developing a standardised master data framework for all relevant products in the Ghana health value chain. By December 2020, a structured GhiLMIS master data structure was completed which will enable alignment between Global Trade Item Numbers (GTIN) and GhiLMIS Stock Keeping Units (SKUs) to GoG priority codes, including National Health Insurance Authority (NHIA) codes, health commodity codes, and FDA registration codes to stakeholders in the health supply chain.

¹ Guidelines: Guidance for Tracing Pharmaceuticals: Leveraging GS1 Global Standards (2019). Retrieval from <https://www.ghsupplychain.org/implementation-guidance-pharmaceutical-traceability-leveraging-gs1-global-standards>

Throughout 2019 and 2020, the GoG continued to raise key stakeholders' awareness for use of GS1 global standards to support national health care objectives. This phase included representation from major stakeholder groups at GS1 Global Health Care Conferences and the organisation of national training in November 2020 hosted by GS1 Ghana and GS1 Global. The training covered the foundational elements of GS1 standards, their applicability to the Ghana health sector, and their relevance in enabling pharmaceutical traceability. Education and awareness about traceability and how it is enabled through adopting global standards for product and location identification, data capture, and data exchange will continue to be an ongoing effort in building capacity through the implementation phases and including the continued rollout of GhiLMIS.

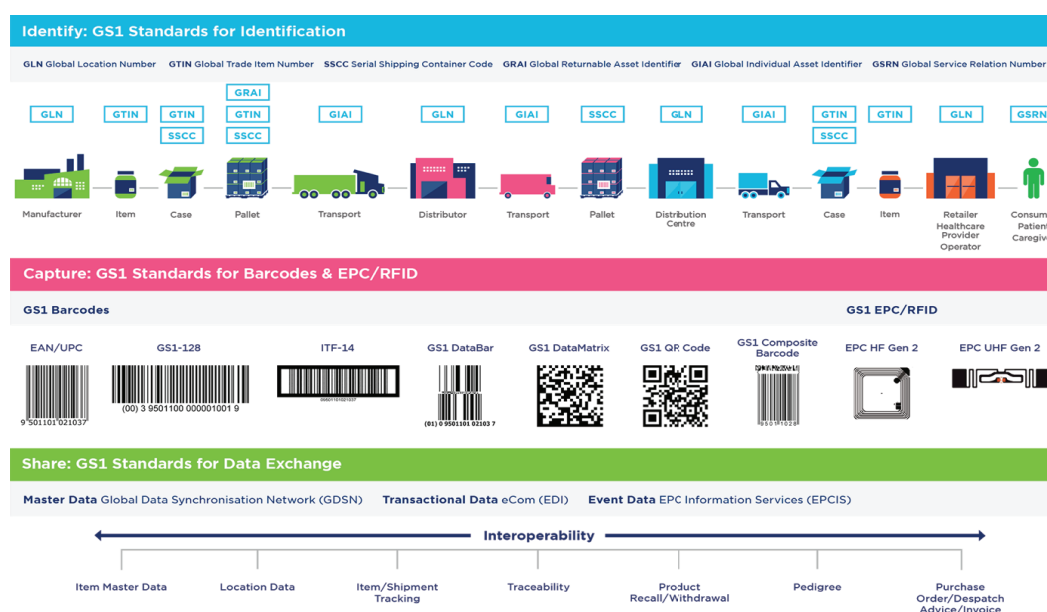
GLOBAL STANDARDS ADOPTION

The foundation for all traceability implementations is adopting a common business language—a global standard—that all trading partners can use to identify, capture, and share information about pharmaceuticals and their movement in the supply chain right from the manufacturer to the dispenser.

Without these standards, trading partners and systems (e.g., purchasing, inventory management, logistics, reporting) each use their own identifiers and data formats. This approach does not facilitate the connection between those systems, creating a high-maintenance, error-prone environment that adds complexity, inaccuracy, and cost and can be prohibitive for traceability implementation. Standards enable systems to be used collectively in enhancing the quality and quantum of data available to support operational processes. These capabilities and the associated benefits are the reasons why standards are such an integral part of data-driven industries such as grocery and retail and why the effort to adopt standards and implement them in Ghana's health sector presents such a tremendous opportunity.

GS1 health care standards provide a framework for global and national stakeholders interacting with the health sector in Ghana to use the same business language to identify products, locations, and legal entities in a common way; capture supply chain data through consistent use of standard data carriers (i.e., barcodes); and share a common set of data in a common format among trading partners, as summarised in Figure 2 below.

Figure 2. Summary of the GS1 System of Standards: Identify, Capture, and Share



TRACEABILITY MODELS

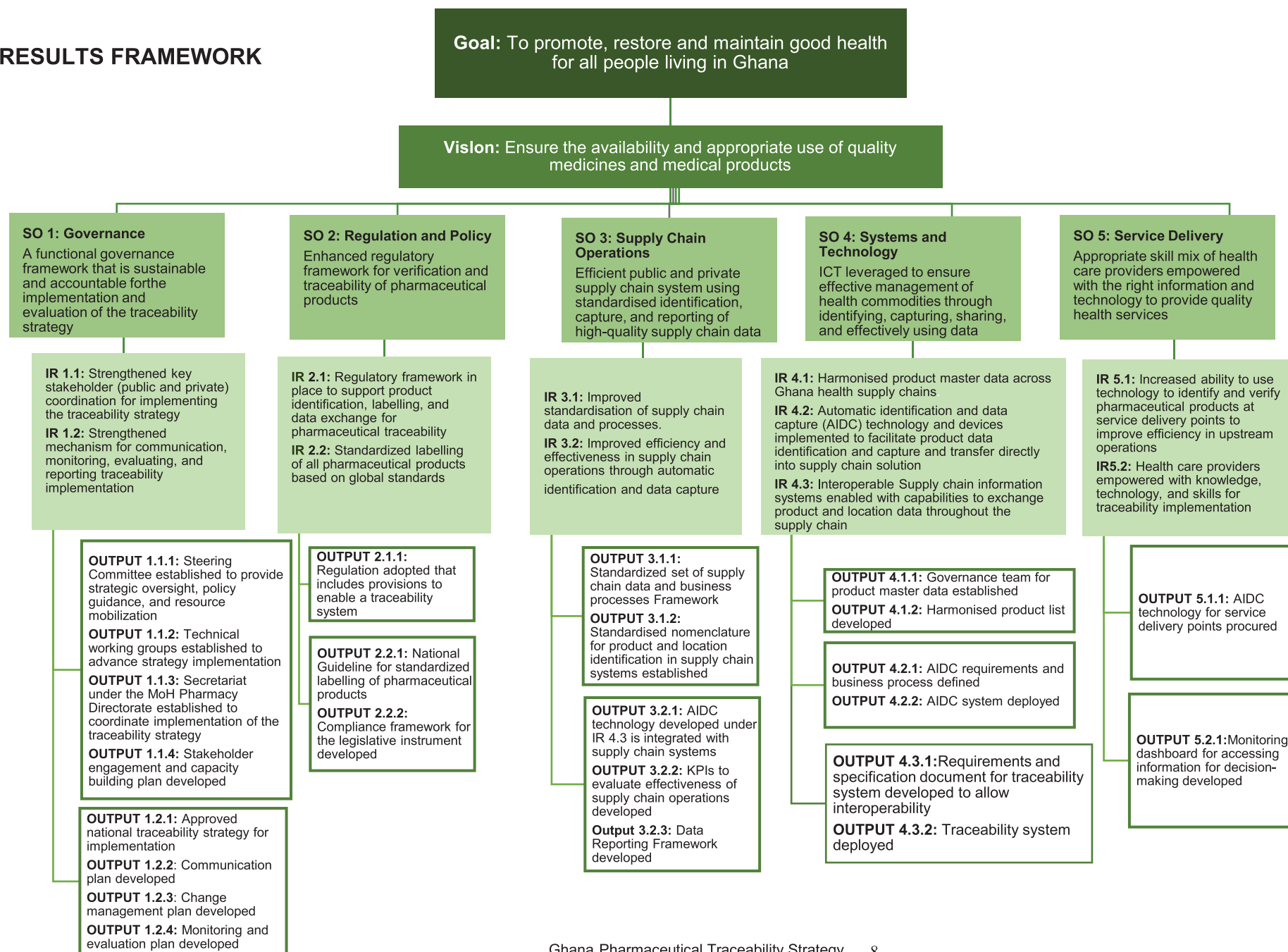
A traceability system maintains the flow of data about the product, including the master, transaction, and event data related to an item in the supply chain. However, the design and scope of any given traceability system implementation are dependent on what a specific context aims to achieve. Traceability systems generally take on one of three models—verification, track, trace, or both. This strategy, as written, assumes that one of these three models will be selected.

A verification model refers to checking at a single point in the supply chain that the identification data held in the barcode is assigned by the manufacturer of the product.

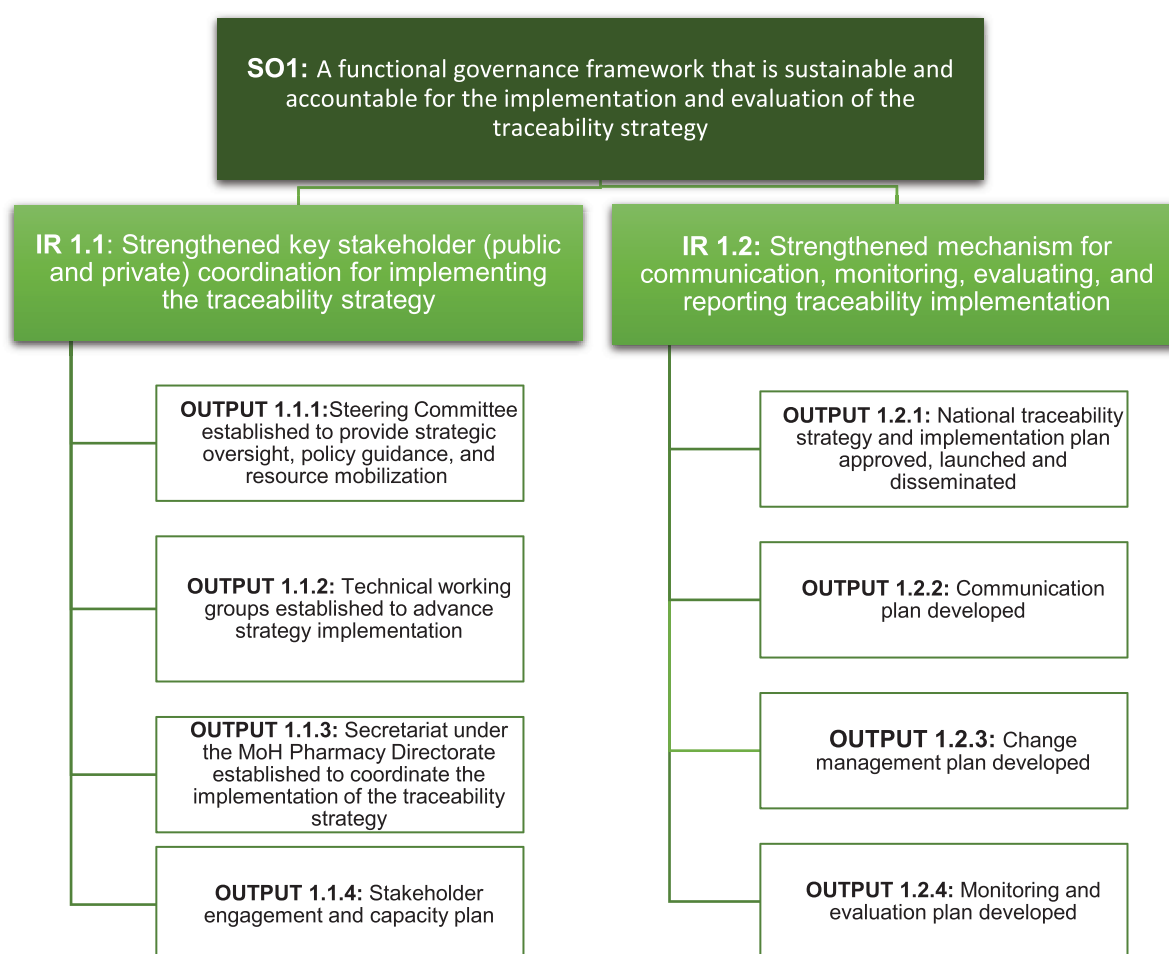
A track and trace model supports the capture of data from trading partners as the product moves through the supply chain, from the manufacturer to the end-user. In addition to the traceability model, countries need to identify which information technology infrastructure model² will be implemented to support the established reporting requirements.

²For more information on the various traceability models, please see the APEC Track and Trace Systems Workshop materials, part of the APEC Supply Chain Security Toolkit: http://www.nifds.go.kr/apec/SupplyChain/APEC_SupplyChainToolkit_170317.pdf

RESULTS FRAMEWORK



STRATEGIC OBJECTIVE 1: GOVERNANCE



Overview of SO1

This SO focuses on developing a sustained governance and monitoring mechanism for implementing the *Ghana Pharmaceutical Traceability Strategy*. The governance mechanism, consisting of a Steering Committee and supporting technical working groups (TWGs), under the leadership of the MoH, will oversee and guide a coordinated approach for mobilising financial and human resources, processes, and technologies required to advance work toward the strategy's vision. Under this SO, the Steering Committee will be instituted to provide strategic direction and oversight, risk management, and resource allocation. This committee is expected to be supported by TWGs that will bring together a diverse group of stakeholder representatives with appropriate technical expertise to advance specific outcomes and activities defined within the strategy.

Key Implementation Decisions

- Determine the composition and structural makeup of the Steering Committee and TWGs
- Determine the organisations and individuals that need to be engaged in buying into and implementing the strategy
- Determine mechanisms for resource mobilisation for strategy implementation

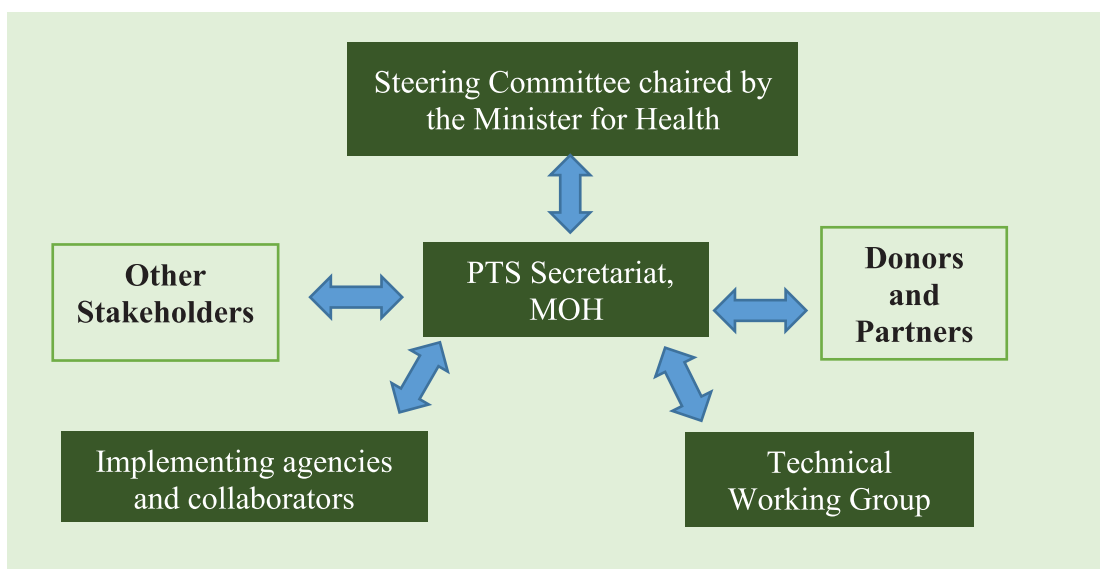
Key Dependencies

- Commitment and buy-in from relevant organisations and individuals implementing the strategy
- Availability of resources to implement initiatives presented in this strategy

INTERMEDIATE RESULTS AND OUTPUTS

IR 1.1: Strengthened key stakeholder (public and private) coordination for implementing the traceability strategy

A robust governing mechanism established through a Steering Committee supported by technical working groups will engage public and private sector partners in advancing the implementation of strategic objectives.



Output.1.1.1: Steering Committee established to provide strategic oversight, policy guidance, and resource mobilisation

The Steering Committee will be chaired by the Minister for Health or his/ her designee and will make strategic scope decisions, mobilise support, and provide the human and financial resources needed to enable implementation. The Steering Committee may establish formal relationships with a GS1 Member Organization, regional coordinating bodies, consultants etc., to provide technical assistance in implementation. The Steering Committee will have articulated Terms of Reference (TORs) to formalise its scope and objectives, designate leadership, and define membership, roles and responsibilities, and operational norms.

Output 1.1.2: Technical working group established to advance strategy implementation

The technical working group will be operationalised under the direction of the Steering Committee to inform and execute decisions this committee makes, including developing requirements and implementation approaches and providing technical recommendations for scale-up. Implementation of identification and labelling requirements based on global standards will impact private and public sector stakeholders alike, including, but not limited to, GoG agencies, donor communities, manufacturers, importers/distributors/wholesalers, and market authorisation holders, procurement agents, and financing institutions. Representatives and technical experts from these stakeholders may be represented in the TWG for the implementation of discrete outputs.

Output 1.1.3: Secretariat under the MoH Pharmacy Directorate was established to coordinate the implementation of the traceability strategy

A secretariat will be established under the MoH Pharmacy Directorate to coordinate all activities relating to the implementation of the traceability strategy.

Output 1.1.4: Stakeholder engagement and a capacity-building plan developed

A capacity-building plan will detail the skills required by each stakeholder group with a role in the implementation and a strategy for developing those skills through identified capacity-building approaches. This will be achieved through identifying the skills or competencies required to achieve goals under each strategic objective, including:

- Workforce adequately trained and mentored in Automatic identification and data capture (AIDC) implementation under SOs 3, 4, and 5
- A workforce trained on the capture and use of data to meet defined traceability mandate (track and trace or verification system) under IR 4.2

IR 1.2: Strengthened mechanism for communication, monitoring, evaluating, and reporting traceability implementation

The Steering Committee will institute and operationalize a monitoring and evaluation mechanism based on an approved *National Pharmaceutical Traceability Strategy*.

Output 1.2.1: National traceability strategy and implementation plan approved

A *National Pharmaceutical Traceability Strategy* endorsed by the MoH designated authority will enable the formal launch of activities and establish a benchmark for measuring progress and success.

Output 1.2.2: Communication plan developed

A communication plan will be developed to help identify and align information sharing with all stakeholders. This will ensure leveraging on existing communication channels to align and communicate goals and key information to all.

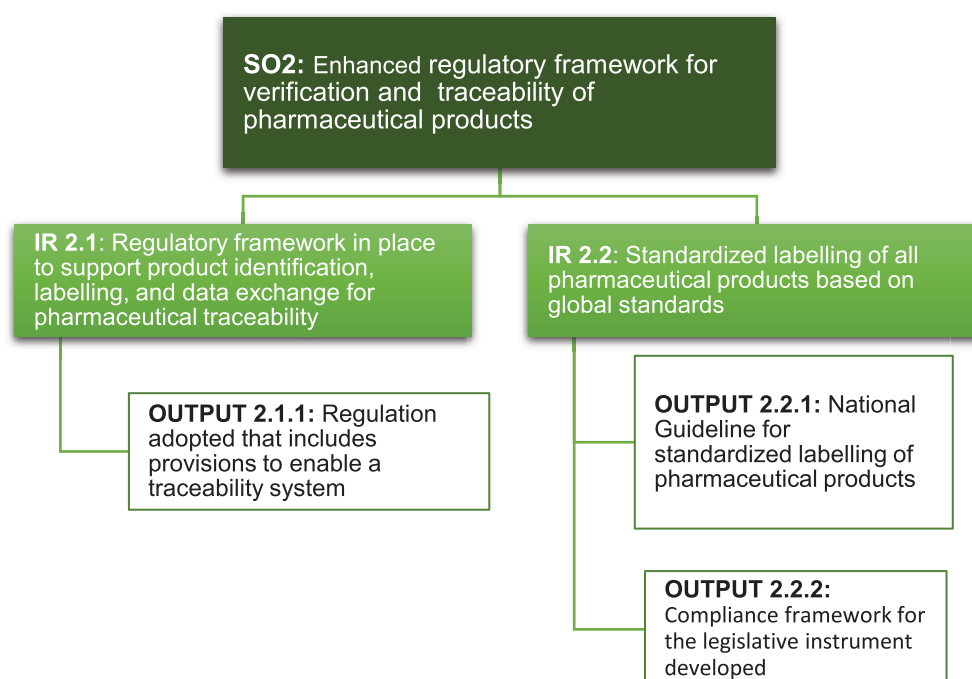
Output 1.2.3: Change management plan developed

The Steering Committee will develop a traceability change management plan to help manage the change process and ensure control of budget, schedule, scope, and resources. The change management plan will minimise the impact a change can have on the existing supply chain business processes and entitled stakeholders.

Output 1.2.4: Monitoring and evaluation plan developed

The Steering Committee will develop a monitoring and evaluation (M&E) plan through a consultative process. It will be grounded on key performance indicators (KPIs) that measure performance against defined levels of change. During the exercise, the committee will conduct assessments of current-state baselines and research on global benchmarks for each KPI. Once the KPIs are established, the committee will develop an M&E plan detailing who is responsible for M&E, the approach to calculating the value for each, and the frequency at which these data will be captured.

STRATEGIC OBJECTIVE 2: POLICY AND REGULATION



Overview of SO2

A robust regulatory framework will provide the foundation needed to define and enforce requirements to enable traceability. As specified in Section 81 of the 2012 Public Health Act, it is the mandate of the Food and Drugs Authority to provide and enforce standards for medicines and medical devices distributed on the Ghanaian market. Under this authority, this SO will incorporate global standards for the necessary product identification, labelling, and data exchange regulations, policies, and guidelines for advance verification in the tracking and tracing of products.

This will be informed by an assessment of existing regulations, policies, and local and regional labelling guidelines that govern the identification and labelling of pharmaceutical products and the exchange of information within the health sector. Also, it will identify gaps and the ability of these existing mechanisms to enable the adoption of global standards. Building on this foundation, in consultation with key stakeholders (e.g., industry, wholesalers, product users) and taking into consideration the current capacity of the market to comply, appropriate regulations, policies, standards and guidelines will be drafted, implemented, and enforced.

Key Implementation Decisions

- Determine which products are in scope for identification, labelling, and data exchange requirements
- Develop a communications strategy for engaging the industry in developing requirements and disseminating information
- Determine the timeline for manufacturers, market authorisation holders, and/or other impacted entities to adhere to labelling, identification, and data exchange requirements based on global standards
- Determine requirements for demonstrating compliance and consequences of non-compliance and roles and responsibilities for enforcing compliance

Key Dependencies

Market analyses of manufacturer and market authorisation holders' capabilities, third-party logistics providers, distributors, and other relevant market factors

Identification of target supply chain operations under SO4 that will leverage the identification and labelling requirements

INTERMEDIATE RESULTS AND OUTPUTS

IR 2.1: Regulatory framework in place to support product identification, labelling, and data exchange for pharmaceutical traceability

Informed by market analysis of the current state, this IR will strengthen Ghana's legislative instruments (LIs) with sufficient provisions in place for Ghana FDA to govern product identification, labelling, and data exchange (master data and event data) for pharmaceuticals available in the market to enable a future-state verification and/or track and trace systems.

Output 2.1.1: Regulation adopted that includes provisions to enable a traceability system

Led by the Ghana FDA, the Steering Committee will develop a framework that details product and location identification and data-sharing requirements that require regulation. The committee will assess existing regulations, other legislative instruments, and existing policies for their alignment with global standards for traceability and will develop new regulation(s) to fill gaps in consultation with stakeholders.

IR 2.2: Standardised identification and labelling of all pharmaceutical products based on global standards

This IR specifies how entities subject to regulations in IR 2.1 (importers, market authorisation holders, manufacturers, etc.) will implement that regulation in accordance with good global practices that leverage GS1 standards. This will be achieved through providing standards and guidelines on the identification and labelling, submission of the

master, transaction, and event data and specifying the responsibilities of trading partners across the supply chain. Enforcement mechanisms will ensure compliance with the guidelines.

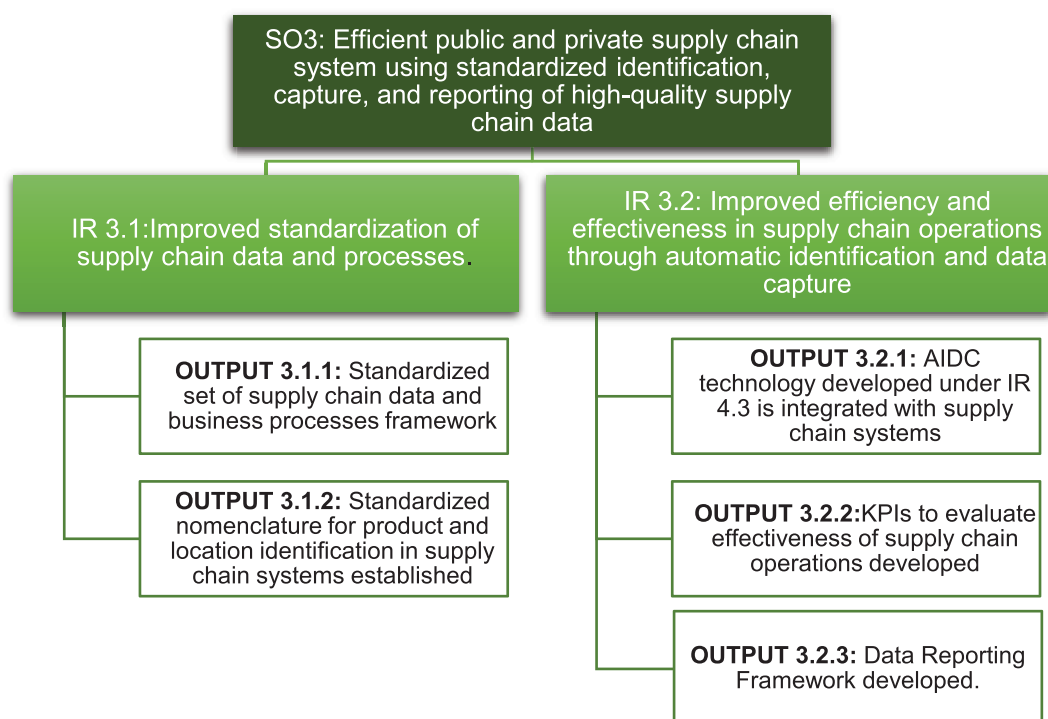
Output 2.2.1: National standards and guidelines for labelling pharmaceutical products

A guideline will be published that will guide market authorization holders on how to comply with national standards and legislative instruments identified or developed under IR 2.1. The guideline will specify identifiers and data carriers that must be assigned by brand owners on product packaging as well as timelines that compliance must be demonstrated. The guideline will be developed in broad consultation with stakeholders through soliciting feedback from manufacturers, importers, and other market authorisation holders. Additional guidelines may be developed to support other traceability requirements and functions, such as master data, event, and transactional data exchange.

Output 2.2.2: Compliance framework for the legislative instrument developed

Once regulations have been implemented and/or amended, a mechanism for enforcement must be established with clearly defined roles, responsibilities, and processes and the resources required to enforce compliance.

STRATEGIC OBJECTIVE 3: SUPPLY CHAIN OPERATIONS



Overview of SO3

This SO aims to strengthen visibility in the movement of products and improve supply chain processes with automatic identification and data capture (AIDC) technology. The SO will introduce a standardized approach to identifying products and locations within the supply chain and capturing this data through mechanisms such as barcodes to verify and monitor the flow of products more effectively. Interventions under this SO when ultimately implemented will be informed by assessments of the current state of targeted supply chain tools and processes (procurement, warehousing, distribution etc) to determine readiness and identify gaps for AIDC implementation. As currently envisioned, the SO focus will be on:

- Improving efficiency and effectiveness in supply chain operations through automatic identification and data capture.
- Improved standardization of supply chain data and processes
- Increased capacity of the health supply chain workforce to promote improved supply chain operations

Key Implementation Decisions

Determine which supply chain processes interventions to target in Ghana

Key Dependencies

SO3 will be dependent on SO 1.1.4, which will develop a capacity-building plan to strengthen the capacity of the health supply chain workforce (both public and private) to promote improved supply chain operations through AIDC implementation under IR 3.2.

SO3 will be dependent upon SO2, which will develop regulation, policy, standards, and guidelines for product identification, labelling, and data exchange to enable the interventions under SO3 to be implemented.

SO3 will be supported by SO4 and inform the implementation of SO5.

INTERMEDIATE RESULTS AND OUTPUTS

IR 3.1: Improved standardisation of supply chain data and processes

This IR is focused on the review of existing data structures in the supply chain (both paper and systems-based) to assess where standards-based identification can replace or supplement existing information to provide better data quality in support of visibility and traceability. The adoption of global standards-based product and location identifiers and data-sharing processes is foundational to increasing supply chain data visibility, quality of reporting data, and increased ability to aggregate data across the different supply chain stakeholders.

This IR will be tied closely to IR 4.1 and IR 4.2, which will increase the ability of information systems to use standards-based data and multiple product identification hierarchies.

Output 3.1.1: Standardised set of supply chain data and business processes framework

Coordinated by the Steering Committee as defined under SO1, a TWG will be established to develop a framework for implementing a well-defined, harmonised, and standardised product identification and product data management structure in Ghana. The TWG will review existing data structures and business processes supported across the supply network. A people, process, and technology approach to the framework will be required to successfully maintain how product information is generated, maintained, stored, accessed, and integrated with external systems such as the FDA system and GhiLMIS.

Key Implementation Decisions

- Determine which products are in scope for identification, labelling, and data exchange requirements
- Develop a communications strategy for engaging the industry in developing requirements and disseminating information
- Determine the timeline for manufacturers, market authorisation holders, and/or other impacted entities to adhere to labelling, identification, and data exchange requirements based on global standards
- Determine requirements for demonstrating compliance and consequences of non-compliance and roles and responsibilities for enforcing compliance

Key Dependencies

Market analyses of manufacturer and market authorisation holders' capabilities, third-party logistics providers, distributors, and other relevant market factors

Identification of target supply chain operations under SO4 that will leverage the identification and labelling requirements

INTERMEDIATE RESULTS AND OUTPUTS

IR 2.1: Regulatory framework in place to support product identification, labelling, and data exchange for pharmaceutical traceability

Informed by market analysis of the current state, this IR will strengthen Ghana's legislative instruments (LIs) with sufficient provisions in place for Ghana FDA to govern product identification, labelling, and data exchange (master data and event data) for pharmaceuticals available in the market to enable a future-state verification and/or track and trace systems.

Output 2.1.1: Regulation adopted that includes provisions to enable a traceability system

Led by the Ghana FDA, the Steering Committee will develop a framework that details product and location identification and data-sharing requirements that require regulation. The committee will assess existing regulations, other legislative instruments, and existing policies for their alignment with global standards for traceability and will develop new regulation(s) to fill gaps in consultation with stakeholders.

IR 2.2: Standardised identification and labelling of all pharmaceutical products based on global standards

This IR specifies how entities subject to regulations in IR 2.1 (importers, market authorisation holders, manufacturers, etc.) will implement that regulation in accordance with good global practices that leverage GS1 standards. This will be achieved through providing standards and guidelines on the identification and labelling, submission of the

Output 3.1.2: Standardised nomenclature for product and location identification in supply chain systems established

Standardisation of data will require aligning and agreeing on a common nomenclature to use for product and location descriptions and identifiers such as GTINs and GLNs and establishing scalable and sustainable master, transactional, and event data management processes, supported by regulation and policy established under SO2, to be used uniformly across the Ghana health sector. The Steering Committee will establish a TWG to define the nomenclature and classification that will be required for reporting data. The committee will also develop standard operating procedures (SOPs) for data standardisation and maintenance.

IR 3.2: Improved efficiency and effectiveness in supply chain operations through automatic identification and data capture

The Ghana Supply Chain Master Plan identified improving information systems and processes as a key supply chain thematic area of focus with emphasis on modern automated information systems for managing health commodities. In the current state, automation of data collection and exchange in Ghana's national supply chain and data visibility for managers outside of their site needs to be improved. This IR will provide the foundational capability required to enable automation of data capture to improve data accuracy and ultimately contribute to end-to-end data visibility for all products.

Output 3.2.1: AIDC developed under IR 4.3 is integrated with supply chain systems

This output will support the integration of AIDC barcode technology with existing warehouse management systems to improve inventory handling processes. The integration will allow for an automated, systematic, and accurate warehouse management cycle that reduces error increases efficiency and is updated in near real-time. Not all processes and supporting systems will require integration with the AIDC system, and even those in scope will be prioritised to ensure that rollout is gradual, starting with those processes and systems that could be most impacted through automation.

Output 3.2.2: KPIs to evaluate the effectiveness of supply chain operations developed

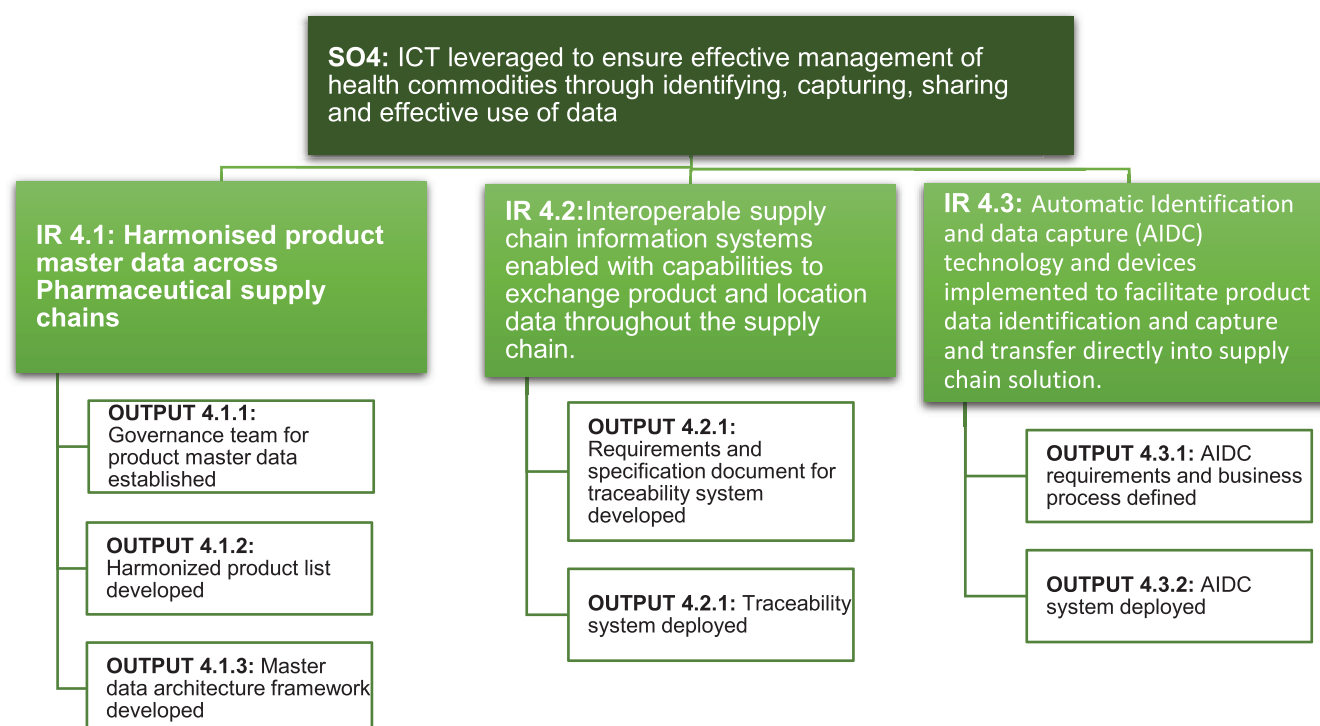
The Steering Committee will review KPIs to measure improved supply chain operations achieved through introducing AIDC into supply chain processes. The committee will use these KPIs to conduct a gap analysis that will establish a baseline for current-state efficiency metrics. Results of the gap analysis will help to understand the baseline availability of GS1-compliant barcodes on inventory to inform regulation and policy activities under SO2. It could also facilitate documentation of opportunities for using standards-based barcodes for data capture in Ghana medical store operations (e.g., receiving, picking, packing, shipping, inventory management). The committee will assess systems such as the

FDA system, GhiLMIS and others that may support GS1 data standards on capabilities to support barcode scanning.

Output 3.2.3: Data reporting framework developed

The Steering Committee will develop a data reporting framework to guide the types of reports required to effectively monitor AIDC implementation. The framework will include SOPs with defined parameters of compliance with AIDC implementation goals. As AIDC technology is deployed, a deliberate effort will be made to assess how conformance metrics can be managed through leveraging technology and supporting systems. This will include identifying users of the technology, structure, how, when, and what information they are reporting against conformance thresholds.

STRATEGIC OBJECTIVE 4: SYSTEMS AND TECHNOLOGY



Overview of SO4

The Ghana e-Health strategy calls for a well-defined e-Health structure, one that supports the interoperability of the disparate information systems and defined data standards to support identification, capture and sharing across the health sector.

The e-Health Strategy defines the current state of health information systems in Ghana as systems in “silos” running on different operating systems, generating different reporting formats, and working off different data sets. Data from one system cannot be interfaced with any other.³ This SO aims to support the exchange of information across the supply chain systems in support of pharmaceutical traceability by enabling these systems to “speak the same language” by adopting standards. A key focus of this capability will be standards-based product and location identification, data capture and data sharing to enable verification, track, and trace, or both.

³ Ghana National e-Health Strategy, p. 25. Retrievable from https://www.isfteh.org/files/media/ghana_national_ehealth_strategy.pdf

Key Implementation Decisions

- Determine legacy health information systems and reporting requirements in scope for aligning with GS1 standards and interoperability in support of IR 4.1
- Determine the capability of existing systems such as the FDA data system to serve as a National Product Catalogue

Determine a phased approach to AIDC rollout starting with central and regional medical stores or facilities with structured master data as aligned with GS1 standards in support of IR 4.3 and technology including necessary hardware and software (or upgrades) required to implement AIDC at service delivery points

Key Dependencies

- Close alignment of SO4 with SOs 2, 3, and 5.
- SO4 will be dependent on Output 1.1.4, which will develop a capacity-building plan to strengthen the capacity of the health supply chain workforce to meet the defined traceability mandate (track and trace or verification system) and to implement AIDC under IR 4.2 and IR 4.3 respectively.

INTERMEDIATE RESULTS AND OUTPUTS

IR 4.1: Harmonised product master data across Ghana health supply chains

This IR will support the institution of a standardised product master data program in Ghana enacted through a National Product Catalogue. As a foundational element, the IR will work towards structured master data that can be exchanged among trading partners through adopting a GTIN and GLN. Conformance with the GTIN standard for trade items and the GLN standard for locations and legal entities associated with that trade item enables interactions with external trading partners (e.g., manufacturers, distributors, procurement agents, donors, and export clients). This allows for interoperability across disparate systems by supporting a common reference key across different systems.

A national product catalogue will build upon the current state of product master data to leverage GS1 standards through capturing trade items (the level of identification employed for inventory management and fulfilment) along with their aggregation to products (the level of identification employed for ordering) throughout the supply chain. At its highest level of maturity, the GoG is expected to leverage the GS1 standards for master data exchange, the GS1 Global Data Synchronization Network™, or GDSN®, to access and exchange real-time product master data.

Output 4.1.1 Technical working group for product master data established

For Ghana, having a well-functioning product master data management program will require a robust and flexible governance structure. This program would have defined roles and responsibilities for the different individuals and stakeholders required to maintain it as well as a forum for aligning stakeholder priorities.

Functionally, the governance framework will capture the “what?” “who?” and “how?” of instituting a master data management program.

Output 4.1.2: Harmonised product list developed

In the current state and as a part of GhiLMIS deployment, a product master data file structure has been developed that enables GTINs to be mapped to other national classification codes (e.g., NHIA code, MoH health commodity code) as an attribute. The Steering Committee will expand this data file to include all targeted product lists in Ghana and develop SOPs for the collection and maintenance of this data over time.

Output 4.1.3: Master data architecture developed

The Steering Committee will develop a National Product Catalogue logical architecture, taking into consideration various systems in the existing landscape and how product master data will be used across the supply chain. The architecture will include data security in line with the Ghana Data Protection Act. The committee will conduct an assessment to determine whether the FDA data system or any other system could serve as a National Product Catalogue (product master source of truth) for the Ghana supply chain. Ultimately, all supply chain systems in Ghana, including private sector systems, will leverage this repository for product master data to be used in their operations so that all supply chain levels are referring to the same product identifier and its associated details.

IR 4.2: Automatic identification and data capture (AIDC) technology and devices implemented to facilitate product data identification and capture and transfer directly into supply chain solution.

The GoG aims to improve supply chain operational efficiencies by deploying technology to support barcode scanning for automatic data capture in its central medical store processes. This system will leverage GS1-based barcodes already existent on trade items enabled through policy under SO2 and supported by a strong master data management system, for the identification, capture, and exchange of that information automatically between relevant parties. The information captured from barcodes such as the GTINs will be mapped to national trade item identifiers such as the FDA registration numbers with all their fixed descriptive attributes, such as brand name, unit of measure, net content, and shelf life, as well as operational data such as expiry information.

Output 4.2.1 AIDC requirements and business process defined

The GoG acting through the MoH, its agencies and all relevant stakeholders will conduct a requirement-gathering exercise to inform how AIDC technology will be used to identify products and locations and capture data through mechanisms such as barcodes to monitor the flow of products through the supply chain and enhance existing data capture processes. This assessment will review the current state of procurement, warehousing, and distribution requirements related to the use of global standards, including item identification and barcode technology. It will also identify gaps in these processes that need to be addressed in implementation. This will incline the evaluation of existing warehouse management processes and tools for their ability to consume and use standards-based data on trade items. An inventory audit will be conducted on a sample of existing inventory to determine the current availability of GS1-compliant packaging in AIDC targeted warehouses.

Output 4.2.2: AIDC system deployed

Informed by defined business processes and requirements in Output 4.2.1, GoG will select, procure, and deploy an AIDC system. The selected AIDC system will be tested, configured, and deployed. The workforce will be trained to use this system as defined under SO 1.1.4

IR 4.3: Interoperable supply chain information systems enabled with capabilities to exchange product and location data throughout the supply chain.

This IR is aimed at removing technological barriers to effectively implement traceability. Recognising the diverse e-Health ecosystems in Ghana with different stakeholders deploying different health solutions that are fragmented, the IR will support system integration by adopting global standards reference keys to link disparate supply chain systems.

Through this IR, Ghana will work towards aligned and coordinated information systems in support of the traceability vision and priorities. This will be done through well-packaged systems, processes, and technologies to guide the conversion of legacy systems to effectively exchange event, transactional, master product, and location data as required by the selected traceability implementation model. Guidance on system architecture will include specific frameworks to support the deployment and/or scale-up of systems to support an enabling environment for end-to-end data visibility.

Output 4.3.1: Requirement and specification document for traceability system developed

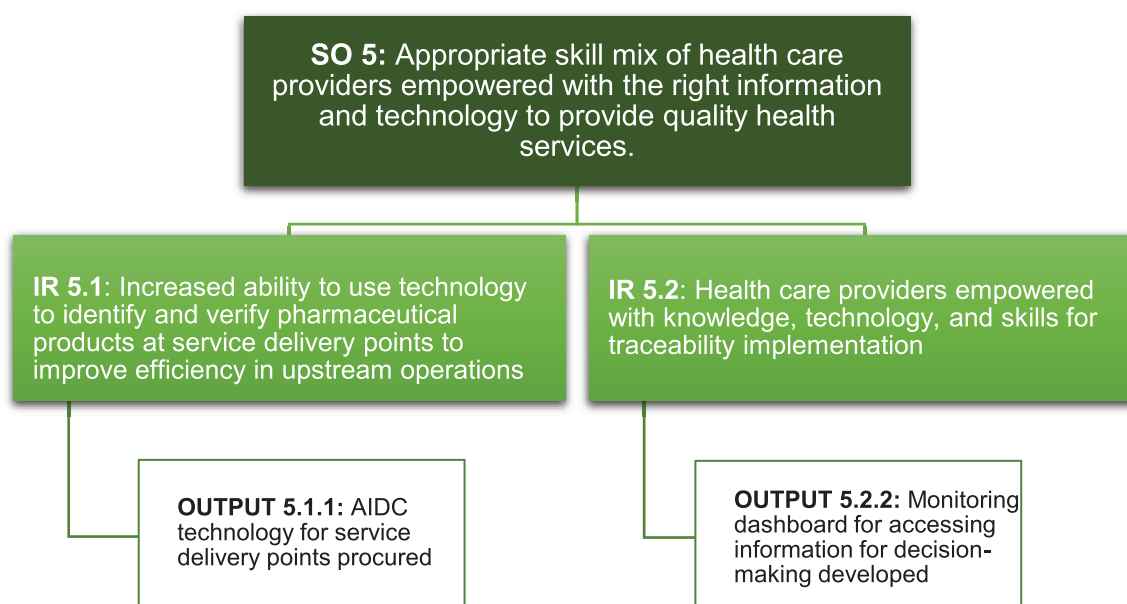
The Steering Committee will conduct a specification and requirements gathering exercise for an information system to implement the chosen traceability model(s) as described under SO2, including supply chain systems requirements, data flows, and architectures to support implementation across all in-scope trading partners. The committee will develop a report to detail recommendations based on current capabilities, identify areas for increased interoperability, and recommend requirements for a future-state architecture to support traceability implementation. The

technology will need to support global standards for item identification, data capture and data sharing for master, transaction, and event data, and be accessible by all trading partners in scope for traceability implementation.

Output 4.3.2: Traceability system deployed

Informed by 4.2.1, the Steering Committee will select an application and configure it as needed to support defined requirements. The committee will test the system against requirements, deploy access for stakeholder groups, and use a phased approach for targeted system integration with the traceability system.

STRATEGIC OBJECTIVE 5: SERVICE DELIVERY



Overview of SO5

Through this SO, the GoG will leverage global standards to address challenges of data integrity and visibility about pharmaceutical products in a way that enables health care providers to provide safe, quality pharmaceutical products and services to clients through identification and verification initiatives.

Key Implementation Decisions

Priority sites for AIDC rollout

Key Dependencies

- SO5 will be supported by activities under IR 3.1 and SO 4.3
- SO5 will be supported by the AIDC capacity-building plan developed under SO1.1.4

INTERMEDIATE RESULTS AND OUTPUTS

IR 5.1: Increased ability to use technology to identify and verify pharmaceutical products at service delivery points to improve efficiency in upstream operations

Using global standards for product identification and AIDC, the GoG will implement verification initiatives for effectively identifying pharmaceutical products in health facilities at the point of dispensing. By using AIDC technology, health care providers can more confidently:

- Manage the inventory
- Recall expired and suspicious medicines
- Dispense authentic and quality medicines to clients

Output 5.1.1: AIDC technology for service delivery points procured

Health care providers will be empowered with people, process, and technology capabilities that will support increased efficiencies in inventory management and dispensing by using AIDC technology to dispense quality commodities more confidently to clients.

IR 5.2: Health care providers empowered with knowledge and skills for traceability implementation

Health care providers: hospitals, clinics, pharmacies, over-the-counter medicine sellers, etc., will need to be supported to ensure high-quality service delivery. This can be done by equipping them with the skills and tools to implement AIDC as a foundation for increased efficiencies in delivering the right product to the right patient. This will result in effective recalls and national reimbursement processes among other benefits. Capacity-building initiatives will focus on how to use barcode scanning to automate the capture of data about products, improve inventory management, and capture and report dispensing data where that technology is available at the point of dispensing. Guidance and tools will be provided around AIDC hardware and software specifications. A capacity-building plan to support AIDC implementation at service delivery points will be implemented as defined under SO 1.1.4.

Output 5.2.1: Monitoring dashboard for accessing information for decision-making developed.

Design, develop, test, and deploy an AIDC database to track supply chain metrics in a single display or interface. The database will enable analytics on AIDC-captured data on verified recalled or falsified products scanned at the point of service. The collected data will be used to make decisions on process improvements.

ROADMAP

Level and Description	The owner (Output) and Timeline (Activity)		
	Year 1	Year 2–3	Year 4+
STRATEGIC OBJECTIVE 1: A functional governance framework that is sustainable and accountable for the implementation and evaluation of the traceability strategy			
INTERMEDIATE RESULT 1.1: Strengthened key stakeholder (public and private) coordination for implementing the traceability strategy			
OUTPUT 1.1.1: Steering Committee established to provide strategic oversight, policy guidance, and resource mobilization	MoH		
Activity 1.1.1.1: Consultative meeting with key stakeholders to develop criteria for the constitution of the Traceability Steering Committee	X		
Activity 1.1.1.2: Draft, circulate for review, and revise TOR for Traceability Steering Committee	X		
Activity 1.1.1.3: Appoint and inaugurate the Steering Committee	X		
Activity 1.1.1.4: Provide orientation to Steering Committee members	X		
OUTPUT 1.1.2: Technical working groups established to advance strategy implementation	MoH Steering Committee		
Activity 1.1.2.1: Identify TWGs required, and skill sets that must be represented in TWGs	X		
Activity 1.1.2.2: Appoint and inaugurate the TWGs	X		
Activity 1.1.2.3: Provide orientation to the TWGs/Steering Committee	X		
OUTPUT 1.1.3: Secretariat under the MoH Pharmacy Directorate established to coordinate the implementation of the traceability strategy	MoH		
Activity 1.1.3.1: Develop TORs for the secretariat	X		
Activity 1.1.3.2: Identify required skill sets to implement statement of work and resource secretariat	X		
Activity 1.1.3.3: Appoint and inaugurate the secretariat	X		
OUTPUT 1.1.4: Stakeholder engagement and capacity building plan developed	MoH		
Activity 1.1.4.1: Determine skills profile required by stakeholder group based on role in the implementation	X		
Activity 1.1.4.2: Conduct market analyses of manufacturer and market authorisation holders' capabilities, third-party logistics providers, distributors, and other relevant stakeholders to implement traceability requirements			
Activity 1.1.4.3: Landscape analysis to determine the tools needed for implementation based on Activity 1.1.4.2			
Activity 1.1.4.4: Develop a plan for capacity building for each stakeholder group	X		
1.1.4.5: Training of stakeholder groups	X	X	
INTERMEDIATE RESULT 1.2: Strengthened mechanism for monitoring, evaluating, and reporting traceability implementation			

Level and Description	The owner (Output) and Timeline (Activity)		
	Year 1	Year 2–3	Year 4+
OUTPUT 1.2.1: National traceability strategy and implementation plan approved, launched and disseminated	MoH		
Activity 1.2.1.1: Finalize national traceability strategy inclusive of stakeholder feedback	X		
Activity 1.2.1.2: Present strategy to the Ministry of Health for endorsement	X		
Activity 1.2.1.3: Launch of the national traceability strategy and disseminated			
OUTPUT 1.2.2: Communication plan developed	MoH		
Activity 1.2.2.1: Develop Social and Behavioural Change Communication (SBCC) materials for targeted groups in a stratified public education campaign.	X		
Activity 1.2.2.2: Print SBCC materials for dissemination			
Activity 1.2.2.3: Create toolkit of training materials for circulation			
Activity 1.2.2.4: Train the media and CSOs on pharmaceutical traceability			
Activity 1.2.2.5: Share information through social media (facebook,twitter etc) or on an organization's website distribution of program materials, such as flyers, guides, pamphlets and Videos			
Activity 1.2.2.6: Stakeholder engagements with organized groups (Christian Council,Traditional rulers, Muslim clerics etc)			
Activity 1.2.2.7: Present at national conferences and meetings of professional associations as part of CPDs			
OUTPUT 1.2.3: Change management plan developed	MoH		
Activity 1.2.3.1: Develop a change management plan	X		
Activity 1.2.3.2: Implement a change management plan	X	X	X
OUTPUT 1.2.4: Monitoring and Evaluation plan developed			
Activity 1.2.4.1: Hold meeting with key stakeholders to develop key performance indicators to measure the success of implementation against the stated intermediate results	X		
Activity 1.2.4.2: Establish baselines, and benchmarks, and use the baseline to develop an M&E plan	X		
Activity 1.2.4.3: Conduct continuous M&E	X	X	X
STRATEGIC OBJECTIVE 2: Enhanced regulatory framework for verification and traceability of pharmaceutical products			
INTERMEDIATE RESULT 2.1: Regulatory framework in place to support product identification, labelling, and data exchange for pharmaceutical traceability			
OUTPUT 2.1.1: Regulation adopted that includes provisions to enable a traceability system	MoH and FDA		
Activity 2.1.1.1: Review existing regulation for inclusion of appropriate mandates and/or labelling requirements to enable pharmaceutical traceability	X	X	

Level and Description	The owner (Output) and Timeline (Activity)		
	Year 1	Year 2–3	Year 4+
Activity 2.1.1.2: Conduct stakeholder consultations, draft and circulate draft LI for public comment	X	X	
Activity 2.1.1.3: Revise LI based on public comment		X	
Activity 2.1.1.4: Present LI for parliamentary approval		X	
Activity 2.1.1.5: Revise labelling guidelines and templates		X	
INTERMEDIATE RESULT 2.2: Standardised labelling of all pharmaceutical products based on global standards			
OUTPUT 2.2.1: National Standards and Guidelines for labelling pharmaceutical products developed	MoH and FDA		
Activity 2.2.1.1: Determine which products and entitled parties are in scope for identification, labelling, and data exchange requirements	X		
Activity 2.2.1.2: Draft guidance based on market assessments	X		
Activity 2.2.1.3: Circulate guidance document for public comment		X	
Activity 2.2.1.4: Revise guidance based on public comments		X	
Activity 2.2.1.5: Publish guidance		X	
OUTPUT 2.2.2: Compliance framework for the legislative instrument developed	FDA		
2.2.2.1: Develop compliance monitoring strategy in collaboration with relevant stakeholders		X	
STRATEGIC OBJECTIVE 3: Efficient public and private supply chain system using standardised identification, capture, and reporting of high-quality supply chain data			
INTERMEDIATE RESULT 3.1: Improved standardisation of supply chain data and processes			
OUTPUT 3.1.1: Standardised set of supply chain data and business processes framework	Steering Committee/TWGs		
Activity 3.1.1.2: Establishment of TWGs to develop SOPs for data standardisation		X	
Activity 3.1.1.3: Training on SOP		X	
OUTPUT 3.1.2: Standardized nomenclature for product and location identification in supply chain systems established	Steering Committee/TWGs		
Activity 3.1.2.1: Stakeholder meeting to develop nomenclature for reporting of product and location data in the supply chain		X	
Activity 3.1.2.2: Stakeholder engagement meetings for buy-in		X	
INTERMEDIATE RESULT 3.2. Improved efficiency and effectiveness in supply chain operations through automatic identification and data capture			
OUTPUT 3.2.1: AIDC developed under IR 4.3 is integrated with supply chain systems	MOH Procurement Unit and Development Partners		

Level and Description	The owner (Output) and Timeline (Activity)		
	Year 1	Year 2–3	Year 4+
Activity 3.2.1.1: TWG will develop a framework for implementing a well-defined, harmonised, and standardised product identification and product data management structure in Ghana	X		
Activity 3.2.1.2: Develop requirements for targeted system integration with the AIDC system		X	
Activity 3.2.1.3: Implement requirements and evaluate against set KPIs in output 3.1.2		X	X
OUTPUT 3.2.2: KPIs to evaluate the effectiveness of supply chain operations developed	Steering Committee/TWGs		
Activity 3.2.2.1: TWG to develop KPIs	X		
Activity 3.2.2.2: KPIs approved by traceability Steering Committee	X		
OUTPUT 3.2.3: Data reporting framework developed	Steering Committee/TWGs		
Activity 3.2.3.1: TWG to develop reporting framework to provide guidance on the types of reports required to effectively monitor implementation of AIDC		X	
Activity 3.2.3.2: TWG to develop mechanism for data reporting			
Activity 3.2.3.3: Stakeholder engagement meetings on data reporting requirements			
STRATEGIC OBJECTIVE 4: Information Communication Technology leveraged to ensure effective management of health commodities through identifying, capturing, sharing and effective use of data			
INTERMEDIATE RESULT 4.1: Harmonised product master data across pharmaceutical chains.			
OUTPUT 4.1.1: Governance team for product master data established	MoH ICT and MoH pharmacy, FDA		
Activity 4.1.1.1: Identify and engage various stakeholders on the harmonisation of product master data	X		
Activity 4.1.1.2: Develop TORs for the TWG on master data development and implementation governance team	X		
OUTPUT 4.1.2: 4.1: Harmonised product master data across pharmaceutical supply chains	MoH (coordinator) FDA, NHIA, IHS (contributors)		
Activity 4.1.2.1: Data mapping across various stakeholder's product lists in the supply chain	X		
OUTPUT 4.1.3: Master data architecture developed	FDA		
Activity 4.1.3.1: Define hosting architecture for master data	X		
Activity 4.1.3.2: Assess the capability of the FDA data system and other data management systems against master data hosting architecture	X		
INTERMEDIATE RESULT 4.2: Automatic Identification and Data Capture (AIDC) technology and devices implemented to facilitate product data identification and capture and transfer directly into supply chain solution			
OUTPUT 4.2.1: AIDC requirements and business process defined	MoH/GHS		
Activity 4.2.1.1: Define requirements and business processes (procurement, warehousing, distribution, etc.) to support AIDC		X	
Activity 4.2.1.2: Conduct an inventory audit to determine the availability of GS1-compliant packaging in AIDC targeted warehouses			

Level and Description	The owner (Output) and Timeline (Activity)		
	Year 1	Year 2–3	Year 4+
OUTPUT 4.2.2: AIDC system deployed	MoH/GHS		
Activity 4.2.2.1: Select and procure the AIDC system		X	
Activity 4.2.2.2 AIDC system tested, configured, and deployed (including training of users):		X	
INTERMEDIATE RESULT 4.3: Interoperable supply chain information systems enabled with capabilities to exchange product and location data throughout the supply chain.			
OUTPUT 4.3.1 Requirement and specification document for traceability system developed to allow interoperability.	MoH ICT		
Activity 4.3.1.1: Develop technical, business process, and functional requirements for data management systems to support interoperability and traceability		X	
Activity 4.3.1.2: Perform landscape assessment of existing system capability to integrate with traceability systems		X	
OUTPUT 4.3.2: Traceability system deployed	MoH/GHS Procurement & Supply		
Activity 4.3.2.1: Define specifications for various functionalities for the desired traceability system			
Activity 4.3.2.2: Select and procure traceability system informed by type of traceability model selected (track and trace, verification, or both)			X
Activity 4.3.2.3: Testing, configuration of system			X
Activity 4.3.2.4: Perform integration of targeted data management systems, including legacy systems with traceability system			X
Activity 4.3.2.5: Conduct training on traceability systems for all stakeholders			
STRATEGIC OBJECTIVE 5: Appropriate skill mix of health care providers empowered with the right information and technology to provide quality health services.			
INTERMEDIATE RESULT 5.1: Increased ability to use technology to identify and verify pharmaceutical products at service delivery points to improve efficiency in upstream operations			
OUTPUT 5.1.1: AIDC technology for service delivery points procured	MoH/GHS		
Activity 5.1.1.1: Assessment of facilities targeted for AIDC rollout			X
Activity 5.1.1.2: Procurement of AIDC technology for all service delivery points			X
INTERMEDIATE RESULT 5.2: Health care providers empowered with knowledge and skills for traceability implementation			
OUTPUT 5.2.1: Monitoring dashboard for accessing information for decision-making developed	MoH/GHS		
Activity 5.2.1.1: Develop a monitoring dashboard for AIDC data at service delivery points			X

GLOSSARY

Term	Definition
Automatic identification and data capture (AIDC)	A technology used to automatically capture data. AIDC technologies include barcodes, smart cards, biometrics, and radio frequency identification devices.
Barcode*	A symbol that encodes data into a machine-readable pattern of adjacent, varying width, parallel, rectangular dark bars, and pale spaces.
Batch/lot*	The batch or lot number associates an item with production information that the manufacturer considers relevant for the traceability of the trade item. The data may refer to the trade item itself or items contained in it.
DataMatrix	A standalone, two-dimensional (2D) matrix symbology that is made up of square modules arranged within a perimeter finder pattern. Data Matrix symbols are read by two-dimensional imaging scanners or vision systems.
Expiration date	The date up until which the drug manufacturer can guarantee that the medicine is fully potent and safe to use take based on scientifically sound product testing.
Global Trade Item Number (GTIN)	The GS1 identification key is used to identify trade items. The key comprises a GS1 Company Prefix, an item reference, and a check digit.
GS1	A neutral, not-for-profit, global organisation that develops and maintains the most widely used supply chain data standards in the world.
GS1 Application Identifier	The field of two or more digits at the beginning of an element string that uniquely defines its format and meaning.
GS1 Member Organization	A member of GS1 is responsible for administering the GS1 system in its country (or assigned area). This task includes, but is not restricted to, ensuring user companies make correct use of the GS1 system; have access to education, training, promotion, and implementation support; and the opportunity to play an active role in the Global Standards Management Process.
Pharmaceutical	Any substance or mixture of substances: a) Used in the diagnosis, treatment, and mitigation. or prevention of human disease, disorder, abnormal physical or mental state, or the symptoms thereof b) Used in restoring, correcting, or beneficial modification of organic or mental functions in humans c) That is an article other than food, intended to affect the structure or any function of the body of humans d) That includes articles intended for use as a component of any articles specified in clauses (a), (b), or (c)
Serial number	A numeric or alphanumeric sequence of a maximum of twenty (20) characters, is generated by a deterministic or a non-deterministic randomisation algorithm.
Trade item	Any item (product or service) that presents the need to retrieve predefined information that may be priced, ordered, or invoiced at any point in any supply chain.
Unique identifier	A numeric or alphanumeric string is captured in a machine-readable data carrier and human-readable form on the label of the pharmaceutical package that is associated with a single product or product group.

SUMMARY BUDGET

Intermediate Result	Output	Activity	Lead Implementer	Collaborators	Indicative Budget (GHS)	Indicative Budget (US\$)	Budget Narrative	Source Of Funding
Strategic Objective 1: A functional governance framework that is sustainable and accountable for the implementation and evaluation of the traceability strategy								
Total Budget Strategic Objective 1: = GHC 10,922,750.00 / USD 1,320,767.84 @8.27								
1.1: Strengthened key stakeholder (public and private) coordination for implementing the traceability strategy	1.1.1: Steering Committee established to provide strategic oversight, policy guidance, and resource mobilization	1.1.1.1: Consultative meeting with key stakeholders to develop criteria for the constitution of the Traceability Steering Committee	MOH (Pharmacy Directorate)	FDA, GNCOP, PSGH, PMAG, AREPI, NHIA, GSA, CSO, GHS, WHO, KNUST, MOF, GRA, USAID	13,500.00	1,632.41		GOG / Development Partners / Private Sector
		1.1.1.2: Draft, circulate for review, and revise TOR for Traceability Steering Committee		FDA, GNCOP, PMAG, AREPI, NHIA, GSA, CSO, GHS	13,500.00	1,632.41		
		1.1.1.3: Appoint and inaugurate the Steering Committee			5,000.00	604.59		
		1.1.1.4: Provide orientation to Steering Committee members		FDA, GHS	215,000.00	25,997.58		
	1.1.2: Technical working groups established to advance strategy implementation	1.1.2.1: Identify TWGs required, and skill sets that must be represented in TWGs		FDA, GNCOP, PSGH, PMAG, AREPI, NHIA, GSA, CSO, GHS, WHO, KNUST, MOF, GRA, PSM	116,500.00	14,087.06		
		1.1.2.2: Appoint and inaugurate the TWGs		FDA, GNCOP, PSGH, PMAG, AREPI, NHIA, GSA, CSO, GHS, Teaching Hospitals, WHO, KNUST, MOF, GRA, PSM, GAQHI, CHAG, GS1 Ghana, CPPA, Pharmacy Council	13,000.00	1,571.95		
		1.1.2.3: Provide orientation to the TWGs/Steering Committee		GHS, NHIA, MOF, GRA, CSO, PMAG	35,000.00	4,232.16		
	1.1.3: Secretariat	1.1.3.1: Develop TORs for the secretariat		TWG	2,750.00	332.53		

Intermediate Result	Output	Activity	Lead Implementer	Collaborators	Indicative Budget (GHS)	Indicative Budget (US\$)	Budget Narrative	Source Of Funding
	under the MoH Pharmacy Directorate established to coordinate implementation of the traceability strategy	1.1.3.2: Identify required skill sets to implement statement of work and resource secretariat (linked to 1.1.2.1)			1,260,000.00	152,357.92		
		1.1.3.3: Appoint and inaugurate the secretariat		FDA, NHIA, PMAG, GNCOP, AREPI, NHIA etc	8,000.00	967.35		
	1.1.4: Stakeholder engagement and capacity building plan developed	1.1.4.1: Determine skills profile required by stakeholder group based on role in implementation		GHS, Teaching hospitals, private Sector (GNCOP/ PMAG)	51,000.00	6,166.87		
		1.1.4.2: Conduct market analyses of manufacturer and market authorisation holders' capabilities, third-party logistics providers, distributors, and other relevant stakeholders to implement traceability requirements		FDA, GNCOP, PSGH, PMAG, AREPI, NHIA, GSA, CSO, GHS, Teaching Hospitals, GAQHI, CHAG, GS1 Ghana, CPPA, OTCMS	174,850.00	21,142.68		
		1.1.4.3: Landscape analysis to determine the tools needed for implementation based on Activity 1.1.4.2			149,100.00	18,029.02		
		1.1.4.4: Develop plan for capacity building for each stakeholder group			84,000.00	10,157.19		
		1.1.4.5: Training of stakeholder groups			1,779,000.00	215,114.87		
	1.2.1: National traceability strategy and implementation plan approved, launched and disseminated	1.2.1.1: Finalize national traceability strategy inclusive of stakeholder feedback		FDA, GNCOP, PSGH, PMAG, AREPI, NHIA, GSA, CSO, GHS, WHO, KNUST, MOF, GRA, USAID	11,500.00	1,390.57		
		1.2.1.2: Present strategy to the Ministry of Health for endorsement			-	-		
		1.2.1.3: Launch of the national traceability strategy and disseminated		FDA, GNCOP, PSGH, PMAG, AREPI, NHIA, GSA, CSO, GHS, Teaching Hospitals, GAQHI, CHAG, GS1 Ghana, CPPA	157,000.00	18,984.28		

Intermediate Result	Output	Activity	Lead Implementer	Collaborators	Indicative Budget (GHS)	Indicative Budget (US\$)	Budget Narrative	Source Of Funding
	1.2.2: Communication plan developed	Activity 1.2.2.1: Develop Social and Behavioural Change Communication (SBCC) materials for targeted groups in a stratified public education campaign. (Publish program or policy briefs on website of public and private institutions)		Health Promotion Div of GHS/FDA/PSGH/OTCM S /NMC/MDC/HEFRA	599,000.00	72,430.47		
		Activity 1.2.2.2: Print SBCC materials for dissemination		MOH(PRD and Procurement Unit)	1,060,000.00	128,174.12		
		Activity 1.2.2.3: Create toolkit of training materials for circulation		FDA/Pharmacy Council/Media Commission	25,000.00	3,022.97		
		Activity 1.2.2.4: Train the media and CSOs on pharmaceutical traceability			126,250.00	15,266.02		
		Activity 1.2.2.5: Share information through social media(facebook,twitter etc) or on an organization's website distribution of program materials, such as flyers, guides, pamphlets and Videos		Ministry of Education/General Public/CSOs/Local Government/Telcos	850,000.00	102,781.14		
		Activity 1.2.2.6: Stakeholder engagements with organized groups (Christian Council,Traditional rulers, Muslim clerics etc)		Health Professional Bodies Pharmacy Council/MDC/NMC/PS GH,GMA/ GRNMAetc	-	-	Leverage existing group meetings of the stakeholders to engage them	
		Activity 1.2.2.7: Present at national conferences and meetings of professional associations as part of CPDs				-	Leverage on already existing conferences of professional bodies	
	1.2.3: Change management plan developed	Activity 1.2.3.1: Develop change management plan		FDA, GNCOP, PSGH, PMAG, AREPI, NHIA, GSA, CSO, GHS, Teaching Hospitals, CPPA	88,000.00	10,640.87		

Intermediate Result	Output	Activity	Lead Implementer	Collaborators	Indicative Budget (GHS)	Indicative Budget (US\$)	Budget Narrative	Source Of Funding
		Activity 1.2.3.2: Implement change management plan		FDA, GNCoP, PSGH, PMAG, AREPI, NHIA, GSA, CSO, GHS, Teaching Hospitals, GAQHI, CHAG, GS1 Ghana, CPPA, OTCMS	1,002,400.00	121,209.19		
	1.2.4: Monitoring and Evaluation plan developed	Activity 1.2.4.1: Hold meeting with key stakeholders to develop key performance indicators to measure success of implementation against the stated intermediate results	MOH	FDA, GNCoP, PSGH, PMAG, AREPI, NHIA, GSA, CSO, GHS, Teaching Hospitals, GAQHI, CHAG, GS1 Ghana, CPPA, OTCMS	136,400.00	16,493.35		
		Activity 1.2.4.2: Establish baselines, benchmarks, and use baseline to develop an M&E plan	MOH	FDA, NHIA, PMAG, GNCoP, AREPI, NHIA etc	99,000.00	11,970.98		
		Activity 1.2.4.3: Conduct continuous M&E	MOH		2,848,000.00	344,377.27		
Strategic Objective 2: Enhanced regulatory framework for verification and traceability of pharmaceutical products								
Total Budget Strategic Objective 2: GHC 1,677,750.00 / USD 202,871.83 @8.27								
2.1: Regulatory framework in place to support product identification, labelling, and data exchange for pharmaceutical traceability	OUTPUT 2.1.1: Regulation adopted that includes provisions to enable a traceability system	Activity 2.1.1.1: Review existing regulation for inclusion of appropriate mandates and/or labelling requirements to enable pharmaceutical traceability	MOH(Legal)	FDA, GSA, Pharmacy Council, GHS, Teaching Hospitals, Ghana Chamber of Pharmacy, PMAG, GRA	193,000.00	23,337.36		GOG / Development Partners / Private Sector
		Activity 2.1.1.2: Conduct stakeholder consultations, draft and circulate draft LI for public comment			188,000.00	22,732.77		
		Activity 2.1.1.3: Revise LI based on public comment			-	-	This will be included in the SOW of the consultant working on the previous activity	
		Activity 2.1.1.4: Present LI for parliamentary approval			499,250.00	60,368.80		
		Activity 2.1.1.5: Revise labelling guidelines and templates	MOH (FDA)		204,000.00	24,667.47		

Intermediate Result	Output	Activity	Lead Implementer	Collaborators	Indicative Budget (GHS)	Indicative Budget (US\$)	Budget Narrative	Source Of Funding
2.2: Standardised labelling of all pharmaceutical products based on global standards	2.2.1: National standards and Guidelines for labelling pharmaceutical products developed	Activity 2.2.1.1: Determine which products and entitled parties are in scope for identification, labelling, and data exchange requirements			122,000.00	14,752.12		
		Activity 2.2.1.2: Draft guidelines based on market assessments			204,000.00	24,667.47		
		Activity 2.2.1.3: Circulate guidelines document for public comment			-	-	Circulated via emails/existing channels to relevant stakeholders for their review and input	
		Activity 2.2.1.4: Revise guidelines based on public comments			125,500.00	15,175.33		
		Activity 2.2.1.5: Publish guidelines			10,000.00	1,209.19		
	2.2.2: Compliance framework for the legislative instrument developed	2.2.2.1: Develop compliance monitoring strategy in collaboration with relevant stakeholders			132,000.00	15,961.31		
	Strategic Objective 3: Efficient public and private supply chain system using standardised identification, capture, and reporting of high-quality supply chain data							
Total Budget Strategic Objective 3: GHC 2,585,700.00 / USD 312,660.22 @8.27								
3.1: Improved standardisation of supply chain data and processes	3.1.1: Standardised set of supply chain data and business processes framework	Activity 3.1.1.1: Establishment of TWGs to develop SOPs for data standardisation	MOH (Pharmacy Directorate)	FDA, GNCOP, PSGH, PMAG, AREPI, NHIA, GSA, CSO, GHS, Teaching Hospitals, GAQHI, CHAG, GS1 Ghana, CPPA, OTCMS	113,350.00	13,706.17		GOG / Development Partners / Private Sector
		Activity 3.1.1.2: Training on SOP			1,002,400.00	121,209.19		
	3.1.2: Standardized nomenclature for product and location	Activity 3.1.2.1: Stakeholder meeting to develop nomenclature for reporting of product and location data in the supply chain	MOH (FDA)		107,300.00	12,974.61		

Intermediate Result	Output	Activity	Lead Implementer	Collaborators	Indicative Budget (GHS)	Indicative Budget (US\$)	Budget Narrative	Source Of Funding
	identification in supply chain systems established	Activity 3.1.2.2: Stakeholder engagement meetings for buy-in			159,200.00	19,250.30		
3.2. Improved efficiency and effectiveness in supply chain operations through automatic identification and data capture	3.2.1: AIDC developed under IR 4.3 is integrated with supply chain systems	Activity 3.2.1.1 TWG will develop a framework for implementing a well-defined, harmonised, and standardized product identification and product data management structure in Ghana	MOH (Pharmacy Directorate)	FDA, GNCOP, PSGH, PMAG, AREPI, NHIA, GSA, CSO, GHS, Teaching Hospitals, GAQHI, CHAG, GS1 Ghana, CPPA, OTCMS	251,700.00	30,435.31		
		Activity 3.2.1.2: Develop requirements for targeted system integration with the AIDC system			83,450.00	10,090.69		
		Activity 3.2.1.3: Implement requirements and evaluate against set KPIs in output 3.1.2			-	-	The budget for this activity is captured under SO4	
	3.2.2: KPIs to evaluate effectiveness of supply chain operations developed	Activity 3.2.2.1: TWG to develop KPIs	MOH (Pharmacy Directorate)		102,000.00	12,333.74		
		Activity 3.2.2.2: KPIs approved by traceability Steering Committee			30,600.00	3,700.12		
	3.2.3: Data reporting framework developed	Activity 3.2.3.1: TWG to develop reporting framework to provide guidance on the types of reports required to effectively monitor implementation of AIDC			175,900.00	21,269.65		
		Activity 3.2.3.2: TWG to develop mechanism for data reporting			-	-	No Budget Input (This activity is to be captured in the scope of work for the consultant working on Activity 3.2.3.1)	
		Activity 3.2.3.3: Stakeholder engagement meetings on data reporting requirements			559,800.00	67,690.45		

Intermediate Result	Output	Activity	Lead Implementer	Collaborators	Indicative Budget (GHS)	Indicative Budget (US\$)	Budget Narrative	Source Of Funding
Strategic Objective 4: Information Communication Technology leveraged to ensure effective management of health commodities through identifying, capturing, sharing and effective use of data								
Total Budget Strategic Objective 4: GHC 7,407,300.00 / USD 895,683.19 @8.27								
4.1: Harmonised product master data across Pharmaceutical supply chains	4.1.1: Governance team for product master data established	Activity 4.1.1.1: Identify and engage various stakeholders on the harmonisation of product master data	MOH ICT	FDA, GHS, NHIA, PIWA, PMAG, Chamber of Pharmacy, AREPI, CPPA, Pharmacy Council, PSGH	14,650.00	1,771.46		GOG / Development Partners / Private Sector
		Activity 4.1.1.2: Develop TORs for the TWG on master data development and implementation governance team	MOH (Pharmacy Directorate)	FDA, TWG	25,500.00	3,083.43		
	4.1.2: Harmonised product list developed	Activity 4.1.2.1: Data mapping across various stakeholder's product lists in the supply chain			91,500.00	11,064.09		
	4.1.3: Master data architecture developed	Activity 4.1.3.1: Define hosting architecture for master data	FDA	FDA, NHIA, NMSC, GHS, Private Sector	69,000.00	8,343.41		
		Activity 4.1.3.2: Assess capability of the FDA data system and other data management systems against master data hosting architecture			208,000.00	25,151.15	* 1 Systems and technology consultant * 1 Management alignment consultant	
4.2: Automatic Identification and Data Capture (AIDC) technology and devices implemented to facilitate product data identification and capture and transfer directly into supply chain solution	4.2.1: AIDC requirements and business process defined	Activity 4.2.1.1: Define requirements and business processes (procurement, warehousing, distribution, etc.) to support AIDC	TWG	GS1 Ghana, FDA, MOH Procurement	150,000.00	18,137.85		
		Activity 4.2.1.2: Conduct an inventory audit to determine availability of GS1-compliant packaging in AIDC targeted warehouses	TWG subgroup	GHS, Private sector, Faith-based, GS1 Ghana	140,500.00	16,989.12		
	4.2.2: AIDC system deployed	Activity 4.2.2.1: Select and procure AIDC system	MOH Procurement /FDA	All relevant stakeholders	2,032,500.00	245,767.84		
		Activity 4.2.2.2 AIDC system tested, configured, and deployed (including training of users)			770,400.00	93,155.99		

Intermediate Result	Output	Activity	Lead Implementer	Collaborators	Indicative Budget (GHS)	Indicative Budget (US\$)	Budget Narrative	Source Of Funding
4.3: Interoperable supply chain information systems enabled with capabilities to exchange product and location data throughout the supply chain.	4.3.1 Requirement and specification document for traceability system developed to allow interoperability	Activity 4.3.1.1: Develop technical, business processes, and functional requirements for data management systems to support interoperability and traceability	MOH (Pharmacy Directorate)	TWG, USAID, NHIA, NMSC, GHS, Private Sector	50,000.00	6,045.95		
		Activity 4.3.1.2: Perform landscape assessment of existing system capability to integrate with traceability systems	PTS Secretariat MOH		124,000.00	14,993.95		
	4.3.2: Traceability system deployed	Activity 4.3.2.1: Define specifications for various functionalities for the desired traceability system	TWG		50,000.00	6,045.95		
		Activity 4.3.2.2: Select and procure traceability system informed by type of traceability model selected (track and trace and verification)	MOH		2,990,000.00	361,547.76		
		Activity 4.3.2.3: Testing, configuration of system	FDA/MOH	NHIA, NMSC, GHS, Private Sector, GRA	-	-	No budget allocation (implemented under activity 4.2.2.2)	
		Activity 4.3.2.4: Perform integration of targeted data management systems, including legacy systems with traceability system			322,500.00	38,996.37		
		Activity 4.3.2.5: Conduct training on traceability systems for all stakeholders		NHIA, NMSC, GHS, Private Sector, GRA, GS1 Ghana, Teaching Hospitals, Disease programmes	368,750.00	44,588.88		

Intermediate Result	Output	Activity	Lead Implementer	Collaborators	Indicative Budget (GHS)	Indicative Budget (US\$)	Budget Narrative	Source Of Funding
Strategic Objective 5: Appropriate skill mix of health care providers empowered with the right information and technology to provide quality health services.								
Total Budget Strategic Objective 5: GHC 1,467,800.00 / USD 177,484.89 @8.27								
5.1: Increased ability to use technology to identify and verify pharmaceutical products at service delivery points to improve efficiency in upstream operations	5.1.1: AIDC technology for service delivery points procured	Activity 5.1.1.1: Assessment of facilities targeted for AIDC rollout	MOH(Pharmacy Directorate)	FDA, Pharmacy Council, HEFRA, NMC, MDC, TH/GHS, Private Health Facilities, Quasi Govt Facilities	-	-	<i>To be decided from Activity 1.1.4. 1 Report</i>	<i>GOG / Development Partners / Private Sector</i>
		Activity 5.1.1.2: Procurement of AIDC technology for all service delivery points			-	-		
5.2: Health care providers empowered with knowledge and skills for traceability implementation	5.2.1: Monitoring dashboard for accessing information for decision-making developed	5.2.1.1: Develop monitoring dashboard for AIDC data at service delivery points			1,467,800.00	177,484.89		
Total Budget					GHC24,061,300.00	\$2,909,467.96		

KEY PERFORMANCE INDICATORS FOR GHANA NATIONAL PHARMACEUTICAL TRACEABILITY PRIORITIES

Traceability Priority Outcome	Indicators	Definition	Formula	Data Inputs	
				Data Sources	Data Requirements
Detection of substandard and falsified pharmaceutical products detected in the legitimate supply chain	Percentage of suspicious medicines identified at service delivery points	This indicator measures the percentage of trade items that are found to be suspicious and therefore flagged for further investigation. This indicator will be measured through scanning of products at service delivery points and verifying against a verification repository of trusted health product information to confirm the authenticity of health product information. The trade item is considered “suspicious” when a GTIN is not found in the verification repository.	$\left(\frac{\text{Number of medicines reported as suspicious after verification scan}}{\text{Total Number of medicines verified}} \right) * 100$	Verification Information System	List of in-scope trade items List of point of scan locations
	Percentage of suspicious medicines confirmed to be falsified	This indicator measures the percentage of medicines reported as suspicious confirmed to be falsified/fraudulently misrepresent their identity, composition, or source.	$\left(\frac{\text{Number of medicines confirmed to be falsified}}{\text{Total number of medicines reported as suspicious after verification scan}} \right) * 100$	Verification Information System Pharmacovigilance reports Quality assurance reports	Verification program documents

Traceability Priority Outcome	Indicators	Definition	Formula	Data Inputs	
				Data Sources	Data Requirements
Improve efficiency and accuracy of inventory management and distribution	Warehouse Order Processing Time	This indicator measures the average amount of time (e.g., minutes, hours, days, weeks) from the moment an order is received at the storage facility until the time the order is shipped to the client. The order processing/Pick-to-Ship time can be calculated for a specific shipping facility averaged across orders or on average for orders to a specific client or for a specific product.	$\frac{((\text{Date and time order is shipped} - \text{date and time shipping order was received}) / \text{Total number of orders processed})}{1}$	Packing lists order/requisition forms	Actual delivery date Expected delivery date Issue date Total orders processed
	Inventory Accuracy	This indicator measures whether stock balances recorded on a stock ledger, bin card, or automated system (LMIS) are the same as the actual inventory on hand. This indicator can be calculated for any facility that manages the items in question and can be calculated whenever a physical inventory is taken.	$\frac{(\text{Number of items where stock record count equals physical stock count} / \text{total number of items counted}) * 100}{1}$	Stock card and inventory reports from information systems Physical inventory report	Inventory discrepancy calculation Total number of warehouses under review Established minimum/maximum tolerable limits
Enable visibility of the location of products within the supply chain	Traceability data shared with relevant authorities prior to circulation in the country (capture)	Pertinent to the assumptions made of product shipments being serialized (the unique identifier with associated traceability information when they receive and distribute the product), this indicator measures the percentage of products that electronically capture and share	$\frac{(\text{Number of unique trade items manufactured for the Ghana market circulated to which traceability data has been shared with the authority} / \text{Total of unique trade items imported into the market in scope for the national traceability mandate}) * 100}{1}$	National Traceability Information System	Traceability regulations and guidelines

Traceability Priority Outcome	Indicators	Definition	Formula	Data Inputs	
				Data Sources	Data Requirements
		with the Agency. This indicator may be measured differently for locally manufactured trade items for the Ghana market vs. imported trade items	(Number of unique trade items circulated on the market to which traceability data has been shared with the authority / Total of unique trade items imported into the market in scope for the national traceability mandate) * 100	Import Records	List of in-scope products List of supply chain partners required to submit data
	Traceability data shared with relevant authorities prior to circulation in the country (circulation mapping)	Traceability event data shared with the authority during distribution in country. Measures to what degree traceability is happening based on the expected number of event data exchanges for a product upon entry of product to market.	(Number of unique trade items where predefined traceability events are captured and reported to the authority / Total number of unique trade items in scope of the traceability mandate) * 100	National Traceability Information System	Traceability regulations and guidelines In-Scope product scope
Improved efficiency of “reverse” logistics processes (e.g., returns, recalls)	Reverse logistics turn-around time	This indicator measures the average amount of time in days it takes from when a recall is issued to when all recalled trade items are in the authority’s custody after the discovery of safety issues or product defects. The use of the GTIN paired with batch and serial number will increase the precision of product identification allowing for a more targeted and effective process.	(Date when all trade items are in authority’s custody - Date when recall is issued)	Recall reports	Date and time recall was issued Date and time log for each trade item returned

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