Guideline

Regulatory Guideline for the Rules and Procedures Governing the Establishment and Operation of the Unified National Electronic Pharmaceutical Track-and-Trace System for Human and Biological Medical Products

Year 2025

Code: EDREX: GL.CIP/PPMA.001

Version No: First

Version date: 12/2025

Effective date: 12/2025

Table of Contents

1. Introduction

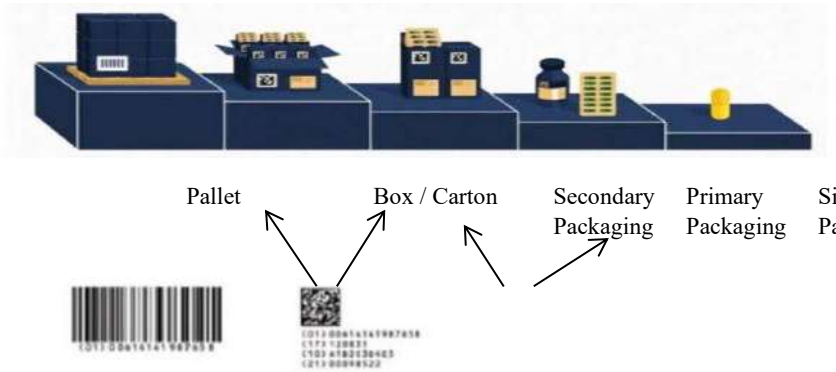
- As part of the Egyptian state's commitment to strengthening the pharmaceutical security system and ensuring the safe and effective availability of medicines, this regulatory guideline establishes the rules and procedures governing the implementation and operation of the Unified National Electronic Pharmaceutical Track-and-Trace System.
- The system aims to track the movement of human and biological medical products within the Arab Republic of Egypt throughout all stages of the supply chain, starting from manufacturing or importation, through distribution and storage, and ending with dispensing to the patient, using the latest serialization and aggregation technologies in accordance with international standards.
- The Egyptian Drug Authority affirms its full commitment to leading this national project in its capacity as the regulatory authority responsible for ensuring the safety and quality of pharmaceutical products. All stakeholders involved in the pharmaceutical supply chain are likewise obligated to fully comply with the provisions of this Guideline.
- This Guideline constitutes the official and binding reference for all stakeholders to ensure the proper implementation of the system and the achievement of its intended objectives both locally and internationally.

2. Definitions

- ✓ **Barcode:** A locally and internationally recognizable barcode used to encode a sequence of data elements through Application Identifiers (AI).
- ✓ **Application Identifiers (AI):** Numeric prefixes preceding the data encoded within the barcode that define the format and meaning of the data.
- ✓ **Trade Item Number:** A global identification key for products that uniquely identifies each product at any packaging level.
- ✓ **Location Code:** A unique identification number used to distinguish and identify different geographical locations within the pharmaceutical supply chain, such as a factory, importing company, warehouse, Distribution Company, public or private pharmacy, hospital, or any licensed logistics point.
- ✓ **Serial Shipping Container Code (SSCC):** A unique international code used to identify larger packaging or shipping units (such as cartons, boxes, or pallets). It is considered an essential component in aggregation and shipping operations within the national track-and-trace system. The SSCC enables linking a group of individual packages as one logistical unit that can be tracked throughout various transportation and storage stages without losing the details of each package contained therein.
- ✓ **Serial Number:** A unique number assigned to distinguish each package of a product identified by the Trade Item Number from all others. The combination of the Trade Item Number and the Serial Number constitutes a unique, non-duplicated identifier for each pharmaceutical package.
- ✓ **Serialization:** The process of assigning each pharmaceutical package a unique, non-duplicated Serial Number linked to the international Trade Item Number, Batch Number, and Expiry Date. This coding is used to generate and print a two-dimensional barcode (2D Data Matrix) uniquely identifying each package individually, even within the same batch.

- ✓ **Human Readable Interpretation (HRI):** Printed information on the package that can be read visually by humans, such as texts and numbers printed adjacent to the barcode, including the batch number, expiry date, Trade Item Number, and Serial Number.
- ✓ **Aggregation:** An organizational process whereby a number of individual packages (child unit) are linked within a larger packaging unit (parent — such as a carton, box, or pallet) using a unified serial number known as the Serial Shipping Container Code (SSCC).
- ✓ **De-aggregation:** The reverse process of aggregation, whereby the larger packaging unit (parent — such as a carton, box, or pallet) is unpacked and the individual component packages (child unit) are separated for the purpose of distribution or transfer independently.
- ✓ **Unified National Electronic Pharmaceutical Track-and-Trace System:** A secure electronic system for Track & Trace of pharmaceutical products, designed to record and monitor every movement of each package from the moment of manufacture or importation, through storage and distribution operations, until dispensing to the patient, exportation abroad, or destruction, as applicable.
- ✓ **2D Data Matrix:** A code capable of containing both numbers and letters, characterized by its high information storage capacity within a very small space. It is the approved method for uniquely encoding pharmaceutical packages within the Unified National Electronic Pharmaceutical Track-and-Trace System and is used at all stages of verification and tracking throughout the pharmaceutical supply chain. **The code must include**:
  - Trade Item Number
  - Unique Serial Number
  - Batch Number
  - Expiry Date
- ✓ **Primary Packaging:** The direct packaging of the product (such as a blister strip or ampoule).
- ✓ **Secondary Packaging:** An outer package containing one or more primary packages.
- ✓ **Track & Trace:** A system that enables recording and monitoring the movement of each pharmaceutical product from the moment of manufacture or importation, through storage and distribution operations, until the point of final dispensing or removal from the market (whether through exportation, destruction, or return). This system provides “complete visibility” of the path taken by each individual package and enables verification of the authenticity of the source, as well as the timing and location of each transfer point.
- ✓ **EPCIS (Electronic Trade Item Number Information Services):** A unified digital language used for recording, exchanging, and analyzing Track & Trace events among the various entities within the pharmaceutical supply chain.

- **Serialization and Aggregation Levels**



- ✓ **Batch:** A specified quantity of products manufactured, processed, or packaged under the same conditions, at the same time, and in the same location.
- ✓ **Expiry Date:** The predetermined date defining the shelf life of the product, after which it may no longer be used due to changes in its properties, loss of efficacy, or deterioration.
- ✓ **Logistic Unit:** Any item intended for transportation or storage carrying an SSCC number, such as a carton, box, or pallet.
- ✓ **Pharmaceutical Supply Chain:** All stages from manufacturing/importation until dispensing the product to the patient.
- ✓ **Product Recall:** An action undertaken by the regulatory authority or the manufacturer or importer to remove a defective, unsafe, or non-compliant medical product from the market and from patients who may already be using it.
- ✓ **Scanner:** A device that reads and decodes the barcode and transmits the data to the system.
- ✓ **Traceability:** The ability to trace a product or verify its history or location through documented data.
- ✓ **Products:** All human and Biological Medical products subject to the jurisdiction of the Egyptian Drug Authority pursuant to its establishing law, whether locally manufactured or imported.
- ✓ **Licensed Logistics Entity:** A manufacturer, importing company, marketing authorization holder in Egypt, warehouse, Distribution Company, public or private pharmacy, hospital, or company engaged in any logistics services activity at any licensed logistics point. Such entity must be a legal entity established in accordance with the relevant laws of the Arab Republic of Egypt and operating as part of the supply chain, provided that it is listed in the electronic registration records of the Egyptian Drug Authority.
- ✓ **Licensed Logistics Point:** It is one of the subdivisions within an investment zone established in accordance with the Investment Law issued under Law No. 72 of 2017.
- ✓ **Logistics Service Companies:** A company established under the relevant laws of the Arab Republic of Egypt and licensed to carry out logistics service activities, particularly storage, transportation, distribution, serialization, and aggregation of human and Biological Medical products. In general, it includes any activities related to the circulation of goods and services that fall within or are related to the scope of the Egyptian Drug Authority, such as Third-Party Logistics Providers (3PLs) and similar

entities. It is required that such companies are registered in the electronic registration records of the Egyptian Drug Authority.

- ✓ **Circulation:** Includes all operations involving production, distribution, and possession, offering for sale, display, storage, use, preservation, packaging, transportation, delivery, import, or export of products under the jurisdiction of the Egyptian Drug Authority.
- ✓ **Event:** Any operation recorded within the **Unified National Electronic Pharmaceutical Track-and-Trace System that affects the status**, location, or identity of a pharmaceutical package. These events include serialization, shipping, dispensing, export, returns, and others, and are recorded using the EPCIS protocol.
- ✓ **Non-Compliant Product:** Any pharmaceutical package that does not comply with pharmaceutical traceability requirements in terms of serialization, registration, or movement between entities.
- ✓ **ERP (Enterprise Resource Planning):** An integrated management system used by factories and companies within the pharmaceutical supply chain to manage daily operations, including inventory management, purchase and sales orders, invoicing and supply processes, performance reporting, and accounting. It must be technically capable of **integration with the Unified National Electronic Pharmaceutical Track-and-Trace System** using the **EPCIS** protocol.
- ✓ **MES (Manufacturing Execution System):** A digital system used in factories as a link between production lines and enterprise management systems such as ERP. It is responsible for monitoring and executing production and serialization processes in real time.
- ✓ **WMS (Warehouse Management System):** A specialized digital system used by distribution companies, intermediate warehouses, or storage facilities to efficiently manage logistics and storage operations within the pharmaceutical supply chain. It must be capable of sending events (such as receipt, aggregation, and de-aggregation) in EPCIS format and generating reports.
- ✓ **Operational Costs:** Financial costs borne by entities subject to the National Pharmaceutical Track-and-Trace System. These include expenses related to technical services required for system implementation (such as the central platform services, updates, and others). The categories of such costs and the obligated entities shall be determined by a decision issued by the Chairman of the Egyptian Drug Authority.

3. Objectives:

- **Local Level:**

- ✓ Ensuring the safety and efficacy of medicines, thereby strengthening trust between patients and the healthcare system.
- ✓ Enforcing full control over all stages of pharmaceutical product circulation, enhancing transparency within the supply chain.
- ✓ Reducing the infiltration of counterfeit or untraceable medicines into the supply chain and preventing their access to consumers.
- ✓ Tracking strategic stock levels to ensure fair distribution of medicines in accordance with actual consumption rates.

- ✓ Assisting the Authority in notifying relevant state bodies of any monopolistic practices that may be detected.
- ✓ Enabling rapid and accurate recall of medicines in case of manufacturing defects or health risks.
- ✓ Supporting evidence-based decision-making through accurate data on consumption and strategic inventory levels.

- **Regional and International Level:**

- ✓ Enhancing Egypt's position on the global pharmaceutical map through compliance with international standards.
- ✓ Improving supply chain efficiency and facilitating import and export operations.
- ✓ Strengthening Egypt's role as a regional leader in pharmaceutical regulation and management in Africa and the Middle East.

4. Scope of Application:

- Locally manufacturing companies of pharmaceutical products.
- Importing companies/entities of pharmaceutical products.
- Licensed distribution companies and warehouses.
- Public and private pharmacies.
- Governmental, university, educational, and private hospitals.
- Primary healthcare units and family planning units.
- Health Insurance Authority hospitals, Universal Health Insurance system hospitals, and Healthcare Authority facilities.
- Logistics service companies (3PL) and similar entities.

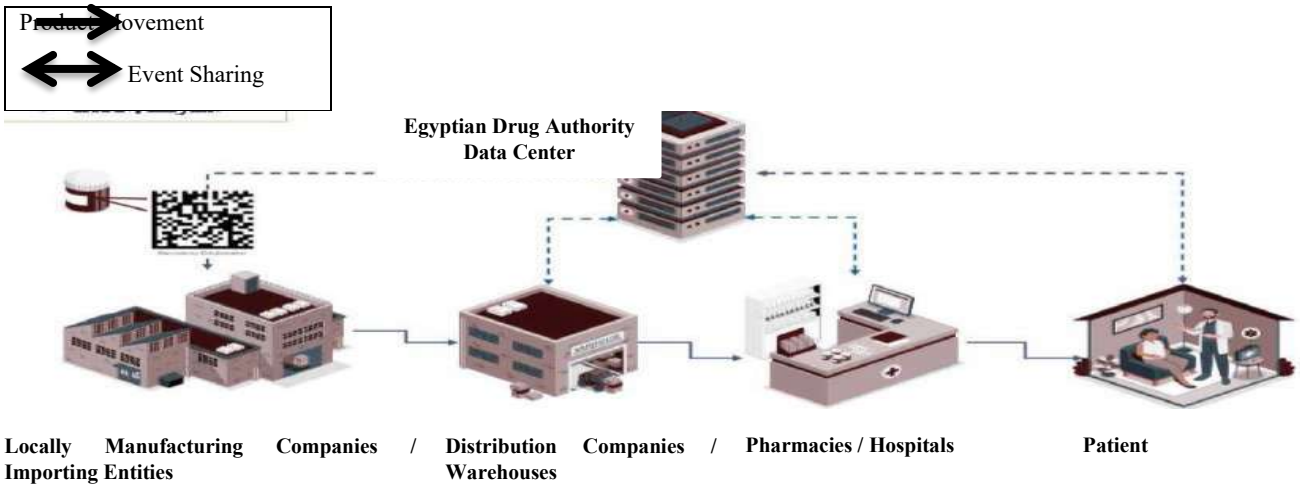
5. Products Exempted from Application:

- Unregistered imported products brought in under specific requests from entities or individuals.
- Products intended for clinical trials (Clinical Trials).
- Free medical samples or samples intended for medical or research purposes (Research & Study).

This exemption is due to the special nature of these categories, as they do not fall under the normal commercial circulation system of human and Biological Medical products in the local market, while still remaining subject to the relevant regulatory controls applicable to each category separately.

6. Package Journey within the Pharmaceutical Track-and-Trace System

- The pharmaceutical product passes through several stages within the supply chain, starting from manufacturing or importation and ending with its delivery to the patient. All of these stages are electronically recorded within the Unified National Electronic Pharmaceutical Track-and-Trace System using the EPCIS protocol, to ensure transparency and the safety of package movement.
- **Traceability Path of the Package**



7. Operational Obligations and Technical Compliance:

- The executing entities (manufacturer, importing company, warehouse, distribution company, public or private pharmacy, hospital, or any licensed logistics point) represent the operational backbone of the pharmaceutical supply chain. They are responsible for ensuring the correct and accurate flow of data within the system. These entities must fully comply with the following:

1. System Account Activation: Ensuring activation of the account on the Unified National Electronic Pharmaceutical Track-and-Trace System.

2. Location Code Acquisition: Each entity within the scope of application must update its data and obtain a unique location code for each logistics point (geographical site), and report it to the Egyptian Drug Authority according to the timelines announced on the Authority's official website.

3. Technical Compliance: Use systems or solutions compatible **with the Unified National Electronic Pharmaceutical Track-and-Trace System** using the EPCIS protocol.

4. Regulatory Compliance: Continuous monitoring of technical and regulatory updates issued by the Egyptian Drug Authority.

5. Implementation of All Regulatory Guideline Requirements: Full compliance with coding, serialization, data integration, periodic data submission, and information retention requirements in accordance with approved standards.

6. Data Protection Compliance: Ensuring the accuracy and integrity of all operational data related to the pharmaceutical institution in accordance with data protection policies.

7. **Provision of Personnel and Resources**: Allocating the necessary technical and administrative staff, as well as operational resources and equipment, to ensure continuous real-time connectivity and system integration integrity.

8. **Training and Awareness Compliance**: Participation in awareness and training programs organized by the Egyptian Drug Authority to ensure proper system operation.

9. Prohibition of Unauthorized Access Delegation: Prohibiting the delegation of system access or data access to any external party without official approval from the Egyptian Drug Authority.

10. Linking Financial Data with Events: Linking each financial transaction (e.g., sales invoice) associated with a product identified by a Trade Item Number to the corresponding traceability events recorded on the platform to ensure transparency and regulatory alignment.

11. Cooperation with Regulatory Authorities:

Full cooperation with inspection and audit activities, including providing required data within specified timelines.

12. Immediate Reporting: Immediate notification to the Authority of any technical failures, security breaches, or data errors to enable corrective action.

13. Dedicated Technical Contact Point: Assigning a dedicated technical responsible person to handle system-related matters, including technical support, emergencies, and inspections.

8. Operational and Technical Obligations of Locally Manufacturing Companies Registered with the Egyptian Drug Authority for Finished Human and Biological Medical Products:

- Manufacturers represent the first point in the traceability chain and are responsible for initiating product serialization and ensuring the accuracy and integrity of production data. With the implementation of the **Unified National Electronic Pharmaceutical Track-and-Trace System, manufacturers are required to comply with the following:**

✓ **Obtaining the Trade Item Number:** Updating the data of human and Biological Medical products and obtaining a unique Trade Item Number for each commercial package of the same product according to its different pack sizes, and notifying the Egyptian Drug Authority accordingly.

✓ **Embedding the Unique Serial Number within the 2D Data Matrix:** Complying with the requirement to print a **2D Data Matrix** on the outer packaging of the product containing:

- Trade Item Number
- Unique Serial Number
- Expiry Date
- Batch Number

✓ **Verification of Each Production Process on the System upon Registration of a Commissioning Event:** Ensuring verification that the Trade Item Number and Serial Number combination is not duplicated, without causing any disruption to the factory production process or product availability.

✓ **Performing Aggregation Operations:** Linking individual packages to higher packaging levels using the unified SSCC code.

✓ **Production Line Integration (L1–L2):** Equipping production lines with internal systems compatible with the EPCIS protocol and documenting every production event in real time.

✓ **Technical Compliance:** Using ERP and MES systems capable of integration with **the Unified National Electronic Pharmaceutical Track-and-Trace System** through the EPCIS protocol.

✓ **EPCIS Data Upload:** Submitting all events to the Unified National Electronic Pharmaceutical Track-and-Trace System in EPCIS format.

✓ **Real-Time Reporting Compliance:** Delays in sending events are prohibited, including the mandatory accurate identification of the receiving entity during the shipping event, in order to ensure technical coordination with distribution companies and warehouses, maintain uninterrupted package traceability, and prevent package loss at any stage, thereby avoiding legal liability for the manufacturer.

- ✓ **Bearing Operational Costs**

In cases where a manufacturer performs Toll Manufacturing, both the manufacturer and the Marketing Authorization Holder/Product Owner must fully comply with all requirements of the Unified National Electronic Pharmaceutical Track-and-Trace System, including all technical and regulatory requirements issued by the Egyptian Drug Authority.

- ✓ **Obtaining the Trade Item Number:** The **product-owning company** shall register the data related to human and Biological Medical products and obtain a unique Trade Item Number for each commercial package of the same product according to its different pack sizes, and notify the Egyptian Drug Authority accordingly.

✓ **Embedding the Unique SERIAL NUMBER within the 2D Data Matrix:**

The manufacturer shall be committed to printing a 2D Data Matrix on the outer packaging of the pharmaceutical product containing the following:

- Trade Item Number
- Unique SERIAL NUMBER
- Expiry Date
- Batch Number

✓ **Uploading EPCIS Data:**

The Marketing Authorization Holder/Product Owner shall ensure that the manufacturer has registered all events on the Unified National Electronic Pharmaceutical Track-and-Trace System in EPCIS format for each produced batch.

✓ **Performing Aggregation Operations:**

The manufacturer shall link individual packages to higher packaging levels using the unified SSCC code.

In cases where the company/entity obtains an export approval, companies shall fully comply with the requirements of the Unified National Electronic Pharmaceutical Track-and-Trace System, including all technical and regulatory requirements issued by the Egyptian Drug Authority.

✓ **Aggregation and Shipping Units:**
- All shipping units intended for export must bear a clear and electronically scannable SSCC.

✓ **Sequence of Traceability Events (EPCIS Events):**
- Traceability events shall be recorded through the national system according to a logical sequence compliant with EPCIS standards, for example: Commissioning → Packing → Shipping
- The company/entity shall enter the description "Exported" as well as the importing country on the system when recording the Shipping Event.

✓ **Handling Returned Quantities:** In the event that any quantities are rejected or returned by the importing entity, a "Return" event must be recorded on the system with the description "from Export", along with documentation of the product status.

✓ **Prior Coordination with the Egyptian Drug Authority:** Prior coordination with the Egyptian Drug Authority is required for the implementation of any additional requirements imposed by importing countries (such as serialization requirements or packaging design requirements).

✓ **Prevention of Manipulation or Leakage:** It is strictly prohibited to enter inaccurate data related to shipping details, dates, or distribution routes, in order to ensure transparent and accurate traceability until the shipment leaves the country.

✓ **Immediate Reporting of Technical Failures or Operational Challenges:** Immediate reporting is required for any technical malfunction or operational challenge that may affect the accuracy of traceability data.

9. Operational and Technical Obligations of Importing Companies/Entities Registered with the Egyptian Drug Authority for Finished Human and Biological Medical Products.

- ✓ **The importing company/entity shall bear full responsibility** for implementing serialization and electronic traceability requirements **in accordance with** the Unified National Electronic Pharmaceutical Track-and-Trace System, in a manner that **ensures the integrity of the traceability chain and transparency of pharmaceutical product movement from the moment of shipment until local distribution. These obligations include the following**:
- ✓ **Serialization and Compliance with System Requirements**
  - The importing company/entity shall ensure that every package imported into the Arab Republic of Egypt carries serialized coding including the following data:
    - Trade Item Number: the global trade number used to identify the pharmaceutical product.
    - Unique Serial Number.
    - Expiry Date.
    - Batch Number.
  - Compliance with printing 2D Data Matrix on the outer packaging before shipment to the Arab Republic of Egypt.
  - In the event of importation from countries that do not follow international serialization standards, the importing company/entity shall be responsible for ensuring that the product packaging is serialized in accordance with the requirements of the Egyptian Drug Authority before circulation in the local market.
  - During the transitional period (from 01/02/2026 to 01/08/2026), the use of an electronic label (NFC) shall be permitted when direct printing is not feasible, provided that printing of the 2D Data Matrix becomes mandatory by the end of the transitional period.
- ✓ **Shipment Data Entry Prior to Importation**: The foreign/exporting company shall **prepare and provide the importing companies/entities with the following electronic data before departure from the country of origin**:
  - Serialized Product List at the individual package level.
  - Aggregation data at the carton/box/pallet level.
  - Generation and printing of the Serial Shipping Container Code (SSCC) for each shipping unit.
  - **Commissioning & Packing Events** shall be executed in the country of origin (at the manufacturing site), and the importing company/entity shall be provided with the electronic file (EPCIS/XML) for uploading to the system.
- ✓ **Event Registration in Egypt:**
  - The importing company/entity shall upload shipment data to the national traceability system before the shipment arrives, provided that the first official event recorded on the system shall be the "Receiving" event, which is registered by the receiving entity upon arrival of the shipment.
- ✓ **Registration of Temporary Storage Locations:** Entering the location code for all intermediate warehouses to ensure real-time and accurate documentation of all internal and external inventory movements.

- ✓ **Bearing Operational Costs.**

10. Operational and Technical Obligations of Distribution Companies and Warehouses/Storage Facilities Registered with the Egyptian Drug Authority for Finished Human and Biological Medical Products.

Distribution companies and intermediate storage companies bear a fundamental responsibility for maintaining data accuracy and the integrity of traceability operations through verification of serialization, event recording, and ensuring effective continuous traceability within the system. Their obligations include the following:

- ✓ **Recording Receiving Events**: Documenting all receiving operations from manufacturers or importers within the system and linking each receiving transaction to SSCC codes and the location code of the source entity, while verifying the validity of the codes and confirming the presence of a SERIAL NUMBER.
- ✓ **Recording Shipping Events:** Uploading shipping events for all receiving entities (sub-distributors, public or private pharmacies, hospitals), including the destination location code and shipment code (SSCC). Recording the event in real time at the moment of shipment is mandatory.
- ✓ **Verification of Aggregation Hierarchy**: Reviewing the accuracy of aggregation levels before any shipping or de-aggregation process to ensure that no SERIAL NUMBER is lost within the shipment.
- ✓ **Real-Time Synchronization:** Electronic scanning (Scan) and registration of the Receiving Event must be completed within the permitted timeframe specified from the date of shipment registration (maximum 48 hours from the actual receipt of the shipment). **Failure to perform the scan within the specified period shall constitute a breach of the system and shall trigger an alert to the regulatory authorities**.
- ✓ **Status Update:** Updating shipment status within the system upon any actual change in location, logistical status, or transfer to another entity, with documentation of the corresponding event.
- ✓ **Inventory Management:** Providing an electronic inventory management system integrated with the traceability system, reflecting actual quantities, returns, and pending quantities, thereby enabling the Egyptian Drug Authority to directly extract reports.
- ✓ **Technical Integration:** Achieving full integration between internal ERP or WMS systems and the traceability system using the approved EPCIS protocol, while ensuring compatibility with technical updates issued by the Authority.
- ✓ **Bearing Operational Costs.**

11. Operational and Technical Obligations of Public and Private Pharmacies Licensed by the Egyptian Drug Authority for Finished Human and Biological Medical Products

- ✓ Public and private pharmacies represent the lawful dispensing point within the traceability chain and bear significant responsibility in ensuring that every dispensed package is properly documented and monitored within the national traceability system. Their obligations include the following:
- ✓ **Technical Compliance:** Using systems or solutions compatible with the **Unified National Electronic Pharmaceutical Track-and-Trace System** using the EPCIS protocol.

- ✓ **Recording Receiving Events:** Documenting all pharmaceutical receiving operations within the system and linking each receiving operation to the aggregation code (SSCC) and the location code of the source entity, while verifying the validity and integrity of serialization data.
- ✓ **Mandatory Verification Prior to Dispensing:** No pharmaceutical package may be dispensed unless the validity of the traceability code has been verified on the system.
- ✓ **Recording Dispensing Events (Dispense):** Uploading dispensing events to the system in real time, linked to the dispensing location code, and accurately recording the date and time of the transaction.
- ✓ **Real-Time Update Compliance:** Electronic scanning (Scan) and registration of the dispensing event must be performed in real time. Failure to register the event **shall constitute a breach of the system and may result in legal liability.**
- ✓ **Partial Dispensing:** In cases of partial dispensing of the contents of a pharmaceutical package, the 2D Data Matrix must be scanned during each dispensing transaction until the final dosage unit has been dispensed. Accordingly, the package bearing the 2D Data Matrix must be retained until the last pharmaceutical unit is dispensed.
- ✓ **Reporting Non-Compliant Packages:** Dispensing of any package containing a non-verifiable code must be suspended, and the Authority must be notified immediately to take the appropriate action.
- ✓ **Dispensing Records:** Maintaining accurate digital dispensing records reflecting actual quantities, returns, pending quantities, and quantities seized by the Authority, enabling reference during inspections or in the event of complaints.

12. Operational and Technical Obligations of Governmental, University, and Private Hospitals for Finished Human and Biological Medical Products.

- ✓ These include public hospitals, university hospitals, educational hospitals, and institutions affiliated with ministries and governmental authorities. **The obligations of these entities include the following**:
- ✓ **Technical Compliance:** Using systems or solutions compatible with the Unified National Electronic Pharmaceutical Track-and-Trace System using the EPCIS protocol.
- ✓ **Recording Receiving Events:** Documenting all pharmaceutical receiving operations within the system and linking each receiving operation to the aggregation code (SSCC) and the location code of the source entity, while verifying the validity and integrity of serialization data.
- ✓ **Mandatory Verification Prior to Dispensing:** No pharmaceutical package may be dispensed unless the validity of the traceability code has been verified on the system.
- ✓ **Recording Dispensing Events (Dispense):** Uploading dispensing events to the system in real time, linked to the dispensing location code, and accurately recording the date and time of the transaction, while taking into consideration that in cases of partial dispensing of the contents of a pharmaceutical package, the 2D Data Matrix must be scanned during each dispensing transaction until the final pharmaceutical unit has been dispensed. Accordingly, the package bearing the 2D Data Matrix must be retained until the last pharmaceutical unit is dispensed.
- ✓ **Real-Time Update Compliance:** Electronic scanning (Scan) and registration of the dispensing event must be performed in real time. Failure to register the event **shall constitute a breach of the system and may result in legal liability.**

- ✓ **Integration of Human and Biological Medical Dispensing Systems:** Integration of hospital management systems or enterprise resource management systems with the national traceability system.
- ✓ Recording Receiving, Dispensing, and Return Events: (Recording Receiving, Dispense, and Return) events on the national traceability system in accordance with the EPCIS system to ensure traceability of pharmaceutical product movement.
- ✓ **Reporting Non-Compliant Packages:** Dispensing of any package containing a non-verifiable code must be suspended, and the Authority must be notified immediately to take the appropriate actio

13. Registration and Accreditation Mechanisms for Each Event-Executing Entity

- ✓ Official registration and accreditation constitute the first and fundamental step for any entity joining the pharmaceutical traceability system. The objective is to verify the legal identity and operational location of each entity, link each entity to an approved standardized location code, and ensure the entity's readiness to interact with the system.
- ✓ The registration process shall be implemented through specific mechanisms according to the type of pharmaceutical institution or institution, including technical integration preparations and acknowledgment of the obligation to register all movements within the system without delay. This includes:
  - Manufacturers
  - Importing companies/entities
  - Distribution companies and warehouses
  - Pharmacies
  - Hospitals and governmental entities

Description	Manufacturers	Toll Companies	Importing Companies / Entities	Distributors / Wholesalers / Warehouses / 3PL	Publ Priv Phar es
Obtaining the Trade Item Number	√	√	√ (Product License Holder)		
Obtaining a Location Code for Sites	√	√	√	√	√
Registering the Trade Item Number & Location Code to Ensure Updating and Approval of Master Data	√	√	√	√	√
Preparing the Production Line for Printing 2D DataMatrix	√	√ (Manufacturer)			

Preparing the Enterprise Resource Management System to Generate EPCIS Files	√	√ (Manufacturer/ Distributer)		√	√
Obtaining the Required 2D Scanners	√	√ (Manufacturer/ Distributer)		√	√
Compliance with aggregation procedures and obtaining the required aggregation equipment	√	√ (Manufacturer/ Distributer)		√	

14. Proposed Phased Implementation Plan for the National Pharmaceutical Traceability System

Implementation shall apply to all imported finished pharmaceutical products effective from 01/02/2026, and to products that are locally packaged and/or filled and/or manufactured effective from 01/08/2026, all in accordance with the implementation timetable issued by the Chairman of the Authority. In all cases, batches manufactured or imported up to these dates shall remain in circulation within the market until their consumption date.

15. Penalties and Sanctions for Non-Compliance

- The Central Administration for Inspection of Pharmaceutical Institutions shall seize and impound pharmaceutical products manufactured or imported after the dates stipulated in Article Five of Decision No. 475 of 2025 in violation of the provisions of this Decision and the Regulatory Guideline.
- The Head of the Central Administration for Inspection of Pharmaceutical Institutions may, based on a technical memorandum from the competent administration, issue a decision to destroy the non-compliant pharmaceutical products or approve a corrective action plan for reintroducing them into circulation after rectifying the causes of non-compliance, provided that the prescribed service fees for monitoring implementation of the corrective action plan are paid.

- All entities within the pharmaceutical supply chain shall fully comply with the requirements of the Unified National Pharmaceutical Track-and-Trace System. In the event of non-compliance or breach of any technical or regulatory requirements, **the following penalties shall apply, without prejudice to any criminal or disciplinary liability**:
  1. **An official written warning** from the Egyptian Drug Authority requiring correction of the violation within a specified period.
  2. **Temporary suspension of circulation of the pharmaceutical products subject to the violation** until completion of the requirements of the Unified National Pharmaceutical Track-and-Trace System.

3. **Temporary suspension of pharmaceutical product supply** to the violating entity until approval of a corrective action plan.
4. **Imposition of financial penalties** in accordance with the applicable penalties and violations regulations.

16. Guiding Table for Traceability Events

The following illustrative table serves as a guiding reference for the sequence of traceability events, which each event-executing entity shall be required to record according to the actual workflow within the pharmaceutical supply chain. This is intended to ensure accurate event registration and its reflection within the Unified National Electronic Pharmaceutical Track-and-Trace System, thereby achieving integration and compliance with regulatory standards. (Traceability Event Sequence Chain)

#	Functionalities/ Features	EPCIS Event	Description	Manufacturer/ Applicant	Importer/ Exporter	Distributor/ Wholesaler/ Warehouse/ 3PL	Hospital/ Pharmacy
1	Production	Commission	This is to report creating (Trade Items Number + Serial Number) & SSCCs	√	√ **(SSCC) only**	√ **(SSCC) only**	√ **(SSCC) only**
2	Product Cancellation	Commission Error Declaration	This is to report cancelling creating (Trade Item Number + Serial Number) & SSCCs	√	√ **(SSCC) only**	√ **(SSCC) only**	√ **(SSCC) only**
3	Production Withdrawal	Recall	This is to report a recall / withdrawal	√	√		

			transaction				
4	Production Withdrawal Cancellation	Recall Error Declaration	This is to cancel reporting a recall / withdrawal transaction	√	√		
5	Packaging	Packing	This is to report an aggregation transaction	√	√	√	√
6	Packaging Cancellation	Packing Error Declaration	This is to cancel reporting an aggregation transaction	√	√	√	√
7	Shipment/Exportation/ Return Shipment	Shipping	This is to report a shipping transaction (inside borders or cross-borders)	√	√	√	√
8	Shipment Cancellation/ Exportation Cancellation/Return Shipment cancellation	Void Shipping	This is to report cancelling a shipping transaction (inside borders or cross-	√	√	√	√

			borders)				

#	Functionalities/ Features	EPCIS Event	Description	Manufacturer/ Applicant	Importer/ Exporter	Distributor/ Wholesaler/ Warehouse/ 3PL	Hospital/ Pharmacy
9	-	Void Shipping Error Declaration	This is to report cancelling a void shipping transaction (inside border or cross-borders)	√	√	√	√
10	Shipment Receipt/ Importation/ Return Shipment Receipt	Receiving	This is to report receiving shipment (inside borders or cross-borders)	√	√	√	√
11	Shipment Receipt/ Cancellation/ Importation Cancellation/ Return Shipment Receipt Cancellation	Receiving Error Declaration	This is to cancel reporting receiving shipments (inside borders or cross-borders)	√	√	√	√
12	Dispensation	Dispensing	This is to report dispensing a pack(s) of Medication to a patient				√
13	Dispensation Cancellation	Dispensing Error Declaration	This is to cancel reporting dispensing a pack(s) of Medication to a				√

			patient				
14	Partial Dispensation	Partial Dispensing	This is to report dispensing partially a pack(s) of Medication to a patient				√

15	Partial Dispensation Cancellation	Partial Dispensing Error Declaration	This is to cancel reporting dispensing partially a pack(s) of Medication to a patient				√
16	Decommission	Decommission	This is to report a normal removal of the pack serial no. from the supply chain	√	√	√	√
17	Decommission Error Declaration	Decommission Error Declaration	This is to Cancel reporting the normal removal of the pack serial no. from the supply chain	√	√	√	√
18	Destruction	Destruction	This is to report a damaged pack(s)	√	√	√	√
19	Destruction Cancellation	Destruction Error Declaration	This is to cancel reporting a damaged pack(s)	√	√	√	√

20	Sampling	Sampling	This is to report picking a sample(s) from a batch(es)	√	√	√	√
21	Sampling Cancellation	Sampling Error Declaration	This is to cancel reporting picking a sample(s) from a batch(es)	√	√	√	√
22	Missing	Missing	This is to report a lost pack(s)	√	√	√	√

#	Functionalities/ Features	EPCIS Event	Description	Manufacturer/ Applicant	Importer/ Exporter	Distributor/ Wholesaler/ Warehouse/ 3PL	Hospital/ Pharmacy
23	Missing Cancellation	Missing Error Declaration	This is to cancel reporting a lost pack(s)	√	√	√	√
24	De-aggregation	Unpacking	This is to report opening a package (of any packaging level)	√	√	√	√
25	De-aggregation Cancellation	Unpacking Error Declaration	This is to cancel reporting opening a package (of any packaging level)	√	√	√	√
26	Stolen	Stolen	This is to report a stolen pack(s)	√	√	√	√
27	Stolen Cancellation	Stolen Error Declaration	This is to cancel reporting a stolen pack(s)	√	√	√	√

28	Return	Return	This is to report a return pack(s) as batches from customer				√
29	Return Cancellation	Return Error Declaration	This is to cancel reporting of a return pack(s) as batches from customer				√
30	Receiving Returning	Receiving Returning Event (Full/Partial)	This is to report a receiving pack(s) as batches				√

❖ Table of Abbreviations Used in the Guideline

Abbreviation	Full Term
SSCC	Serial Shipping Container Code
2D Data Matrix	Two-Dimensional Data Matrix
EPCIS	Electronic Product Code Information Services
ERP	Enterprise Resource Planning
MES	Manufacturing Execution System
WMS	Warehouse Management System
HRI	Human Readable Interpretation