Egyptian Drug Authority

Notice to applicant.

Egyptian Track & Trace for Pharmaceutical (EPTTS)

Technical FAQ (Phase 1)

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1. Purpose and Scope

This document defines the mandatory technical, data, serialization, aggregation, and reporting requirements for Phase 1 of the Egyptian Track & Trace System (EPTTS). It applies to all pharmaceutical products manufactured locally or imported into the Arab Republic of Egypt.

2. Regulatory Responsibility Model

The Importing Entity is legally accountable for reporting commissioning, aggregation, shipping, and receiving events to EPTTS. Manufacturers and CMOs may generate data, but submission accountability remains with the Importer.

3. Product Identification and Serialization

EDA does not issue serial numbers. Manufacturers must generate GLOBAL STANDARDS-compliant serial numbers (AI 21). Serial numbers must be globally unique, non-reusable, and associated with approved GTINs registered with EDA prior to importation.

4. SGTIN and Packaging Rules

Serialization is mandatory at Secondary Packaging level only. SGTIN shall not be used for multipacks encoded as GTIN+SSCC. Secondary packaging is defined as the smallest saleable unit dispensed to patients.

5. Data Matrix Encoding Requirements

GLOBAL STANDARDS Data Matrix ECC 200 is mandatory. Encoded elements include (01) GTIN, (21) Serial Number, (17) Expiry Date, and (10) Batch/Lot. Expiry Date must be encoded in YYYY-MM-DDT format as mandated by EPTTS, deviating intentionally from GLOBAL STANDARDS YYMMDD format.

6. Separators and GLOBAL STANDARDS Compliance

FNC1 / GS (ASCII 29) separators are mandatory after variable-length AIs such as Batch and Serial Number. Restriction on separators applies only to special characters within data fields, not GLOBAL STANDARDS functional separators.

7. Human Readable Interpretation (HRI)

HRI is mandatory and must comply with GLOBAL STANDARDS General Specifications Release 26. AI prefixes must be printed in parentheses. Data Titles (GTIN, EXPIRY, BATCH/LOT) are acceptable.

8. Aggregation Model

EPTTS supports hierarchical aggregation from SGTIN to SSCC at Bundle, Carton, Pallet, and Container levels. No packing method is mandated, but parent-child hierarchy integrity must be preserved.

9. Aggregation and Disaggregation Events

All aggregation events affecting product traceability must be reported unless demonstrated otherwise. Disaggregation requires SSCC decommissioning. Partial unpack and partial receive events are permitted and must be reported immediately.

10. Data Submission Formats (Phase 1)

CSV is the mandatory submission format during Phase 1. XML and API-based integration will be supported in later phases. Manual uploads remain required during the initial rollout.

11. CSV Technical Constraints

Maximum 50,000 serial numbers per file and 5 batches per commissioning file are allowed. Atomic processing applies—any error will reject the entire file. VOID events are supported before custody transfer.

12. Shipment and Timing Rules

Only products physically shipped to Egypt may be reported. Reporting must be completed prior to arrival. Timelines are based on calendar hours, not business hours.

13. EPCIS Alignment Strategy

Phase 1 CSV formats deviate from GLOBAL STANDARDS EPCIS 1.2/2.0. EDA intends to align future releases with EPCIS 2.0 while maintaining backward compatibility.

14. API and Integration Roadmap

No API is available in Phase 1. API and system-to-system integration will be provided in future phases and announced by EDA officially.

15. Operational Restrictions

Serial number reuse is prohibited. Barcode printing within Egypt is permitted only at EDA-licensed facilities after batch approval. Distribution Centers are not permitted to serialize or reprint barcodes.

16. Effective Date

All requirements defined in this document apply to pharmaceutical shipments shipped on or after 1 February 2026 PLUS The stock for those drugs will be packed with the shipped drugs.