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Integrate-Once, Interoperate-with-Everyone™: A Practical Guide to Egypt Traceability Compliance



Egypt's pharmaceutical traceability regulation is progressing, with industry and regulatory authorities working together to establish the systems and processes required for compliance. A law establishing the track-and-trace system was published in August 2025, followed by updates in December that introduced key deadlines for both imported and locally manufactured products. At the same time, technical specifications, reporting mechanisms, and the centralized regulatory system are still taking shape.

Companies are being asked to act in this environment. Under **Egyptian Drug Authority (EDA) Decree No. 475**, imported products were required to meet initial milestones beginning in February 2026, while locally manufactured products must be prepared for broader registration and reporting requirements by August 2026. As these requirements are introduced, organizations must be ready to support both current expectations and what comes next.

Organizations should begin preparing to support a defined set of capabilities across serialization, aggregation, and data exchange. These include:

- Serialization of pharmaceutical products at the unit level
- Aggregation across packaging hierarchies, including case and pallet

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- Capture and management of key supply chain events, including commissioning, packing, shipping, receiving, and decommissioning
- Sharing of serialized and aggregated data across supply chain partners
- Alignment of data with physical product movement across importers, distributors, and downstream stakeholders
- Preparation for phased reporting, including structured file-based submissions with strict validation rules

These requirements extend across a fragmented supply chain that includes foreign and domestic manufacturers, CMOs, importers, distributors, and healthcare providers. In particular, foreign manufacturers are expected to provide serialized and aggregated data to local importers, who are responsible for reporting to the national system. This makes partner-to-partner data exchange a necessary part of execution as requirements are implemented.

In this environment, compliance depends on more than meeting a reporting requirement. It requires the ability to share data across a network of companies, support operational workflows, and adapt as requirements change over time.

Start with a single integration to exchange serialization data across all partners

The most effective place to begin is by enabling fully interoperable data exchange with partners through a single integration to a scalable digital network platform. This is where progress can be made immediately and it is the foundation for maintaining compliance as requirements continue to evolve.

Foreign manufacturers must provide serialized and aggregated data to local importers. Importers depend on that data to manage inbound operations and prepare for reporting. Distributors and downstream partners rely on the same information to execute receiving, inventory, and fulfillment workflows. Without the ability to integrate seamlessly with partners, compliance cannot be executed

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consistently.

Organizations can begin making progress now by focusing on a defined set of actions:

- Establish the ability to exchange serialized and aggregated data with importers, distributors, and other trading partners.
- Onboard supply chain partners to a digital network platform, avoiding point-to-point integrations.
- Enable visibility into inbound and outbound serialized shipments across the network.
- Support receiving, shipping, and reconciliation workflows that align physical product with digital data.
- Prepare to provide data in required formats, including structured file-based submissions in early phases.
- Validate data before exchange to reduce the risk of rejection and operational disruption.

These steps are not dependent on the central system being fully available. They reflect how supply chains must operate under the regulation and represent a proven approach that can be applied immediately.

By starting with a digital network platform, organizations create the foundation needed to execute consistently today and adapt as Egypt’s requirements and reporting structure take shape.

Ensure Egypt compliance with TraceLink—one integration, interoperable data exchange at scale

TraceLink’s digital network platform links hundreds of thousands of supply chain entities across life sciences and healthcare—enabling real-time exchange of serialized data, transactions, and operational events across all partners. With just

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one integration, companies can interoperate across their entire supply chain through TraceLink's Integrate-Once, Interoperate-with-Everyone™ capability—eliminating costly and difficult-to-maintain point-to-point integrations.

For foreign manufacturers already using TraceLink for track and trace, this approach extends a global compliance platform strategy—enabling Egypt compliance without introducing separate, country-specific systems.

Backed by deep experience supporting global traceability regulations, the TraceLink team understands how to operationalize compliance across complex supply chains. Our Network Success team works directly with your organization to onboard partners at no additional cost—ensuring you can onboard partners quickly and execute consistently. This approach enables not only initial compliance, but continuous compliance as requirements change over time.

Required capabilities to support Egypt traceability compliance

To ensure compliance with Egypt's traceability requirements, organizations need to establish a set of core capabilities:

- **Interoperable data sharing** across all trading partners to share serialized and aggregated product data
- **An integration model** that eliminates point-to-point connections and supports rapid partner onboarding
- **End-to-end visibility and control** across inbound and outbound serialized product flows
- **Operational workflows** for receiving, shipping, and reconciliation of serialized product
- **Serialized product scanning capabilities** to rapidly capture, verify, and reconcile product data across receiving, handling, and shipping
- **Exception management and cross-company coordination** to resolve issues quickly and keep product moving

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- **Verification and data quality controls** to ensure accuracy before submission and reporting

How TraceLink enables these capabilities

TraceLink delivers these capabilities through a proven digital network platform that links supply chain partners, systems, and processes. With TraceLink, organizations can share serialized data, execute workflows, and coordinate with partners in real time—without the need for custom, point-to-point integrations.

This includes exchanging serialized and aggregated shipment data, supporting all partner formats without custom development, enabling receiving, shipping, and reconciliation workflows aligned with serialized data, and coordinating cross-company processes with full visibility into issue resolution.

How TraceLink does it better

TraceLink's approach is differentiated by its architecture, network scale, and deep expertise in global traceability:

- **Integrate-Once, Interoperate-with-Everyone™**—TraceLink's unique one-to-many integration model that enables you to establish a single link and share data seamlessly across all supply chain partners, eliminating the cost, complexity, and ongoing maintenance of point-to-point integrations
- **A proven digital network of 291K+ life sciences and healthcare supply chain entities**, where many of your partners are already participating—reducing onboarding effort and accelerating time to value
- **Network Success team-led onboarding and maintenance**, provided at no additional cost, reducing IT burden and accelerating time to value
- **Deep life sciences and global traceability expertise**, enabling organizations to operationalize compliance across complex supply chains

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- **Industrial-grade, GxP-compliant platform**, designed to support secure, validated operations in highly regulated environments

Together, these capabilities enable companies to move beyond manual processes and reactive workflows—keeping product flowing and resolving issues quickly. With the expertise of the TraceLink team and a proven approach to global traceability, organizations maintain continuous compliance throughout each phase of Egypt's traceability requirements.

Contact TraceLink for your Egypt Traceability Assessment today.

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Fill out the form to contact us now.

Thank you for contacting us; we'll be in touch shortly.

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