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Saudi Regulations are in Force: How Are You Complying?

Regulatory update: The Saudi government has notified registered users of the goverment's drug track and trace system (RSD) that the deadline for aggregation of medicines is now August 20, 2020.

As of January 7, 2019, the Saudi Food and Drug Authority (SFDA) has initiated reporting requirements that affect all companies producing medicines for the Saudi Arabia market. While SFDA track and trace regulations affect the entire supply chain, manufacturers have specific concerns about the full impact of the SFDA mandates on their businesses as they seek to understand how they can comply immediately with the latest requirements.

Following the March 2017 serialization deadline and February 2018 deadline for registering factory and warehouse locations, SFDA indicated that the final reporting deadline would be approved by the end of 2018. However, companies were not expecting the compressed interval between the government’s announcement on

October 30, 2018 and the January 2019 deadline.

SFDA has made it clear that all companies are expected to be in compliance, but has made allowances for them to meet the regulations using interim methods while they implement and test more sustainable solutions. It is critical that any company producing, distributing, or dispensing medicines in Saudi Arabia make every effort to understand their options for complying with the SFDA regulations. Here is what you need to know:

Deadlines Have Passed on 3 Primary Requirements.

Since March 2017, serialized product identifiers have been required for all human and veterinary products sold in Saudi Arabia: a 14-digit Global Trade Item Number (GTIN-14), serial number, lot number, and expiration date.

Beginning in March 2018, companies have been required to register factory and warehouse locations via their Global Location Numbers (GLNs).

As of January 2019, organizations, stakeholders, and GTINs for imported products and product manufactured in Saudi Arabia must be registered through the SFDA's track and trace system as a requirement for reporting on a range of supply chain operations. For manufacturers and distributors, these operations include:

1. Supply: identify products manufactured in Saudi Arabia
2. Import: identify products imported into Saudi Arabia

3. Dispatch: send a product to another stakeholder
4. Accept: receive a product from another stakeholder
5. Deactivate: remove an identifier from the system
6. Export: export product previously identified in the system
7. Return: Send product back to the sender

The SFDA registration and reporting systems are live.

The official name of the SFDA track and trace system is **RSD**. Company and product (GTIN-14) registration are completed through the RSD **Stakeholder Management Portal**. Once registered, companies can use one of 3 methods for reporting supply chain events:

1. Automated product data exchange through an integrated connection.
2. Product data uploaded as a CSV file through the RSD **Stakeholder Operation Portal** .
3. Product data uploaded manually through the RSD Stakeholder Operation Portal.

To achieve immediate compliance, many companies are relying on CSV or manual uploads, often using a local company to determine the exact shipment information that needs to be extracted from the larger set of batch-level data. In many cases, these local organizations must break apart cases to scan, capture, and upload the secondary

product package identifiers.

As SFDA continues to work with companies producing medicines for the Saudi supply chain to streamline the management and reporting of product data, the expectation is that organizations are working toward implementing an integrated connection with the RDS system to enable automated event reporting. In addition to reducing errors and increasing warehouse efficiency, automated reporting gives companies continued visibility of their product once it enters the Saudi supply chain—and control over a key component of their global compliance operations.

Aggregation will be required in October 2019.

In anticipation of the logistical difficulties inherent in reporting secondary-level product identifiers of products shipped in cases, aggregation was strongly recommended by the SFDA in its circular of October 31, 2018. On February 13, 2019, the SFDA issued a circular indicating that product aggregation would be required beginning on October 1, 2019. SFDA has not yet issued guidance indicating if aggregation events will need to be reported through RSD.

TraceLink: your Saudi compliance partner.

TraceLink's compliance platform and integrated supply network provides a purpose-built foundation for meeting Saudi regulations and gives companies a significant advantage over implementing a customized solution. As your compliance partner, TraceLink monitors updates and addendums to Saudi law and guidance—ensuring that

your solution will conform to any changes in reporting requirements or workflows, while giving you full visibility into product movements and disposition.

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