RESOURCES

Saudi Compliance Update: Barcode Requirements for Aggregated Products

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.

With the October 1 aggregation deadline less than two months away, pharmaceutical companies are anxiously awaiting final guidance from the Saudi Food and Drug Authority (SFDA). In July, SFDA released some new information about the country's requirements for aggregated packaging that should help manufacturers and repackagers configure their line systems for the Saudi market.

The updates in version 6.0 of the SFDA Drug Barcoding Specifications are limited to package barcoding requirements and do not include additional technical specifications for exchanging aggregation data using the Saudi Package Transfer System (PTS) or any other potential requirements for overall government compliance.

The newly released SFDA specifications follow GS1 formatting guidelines for the Serial Shipping Container Code (SSCC) barcodes used to identify a shipping container, such as a case or pallet. With aggregation, the SSCC enables companies to link to information about the contents of a case or pallet without having to open

the container, speeding up the movement and invoicing of medicines manufactured for the Saudi market.

SFDA defines six packaging levels and requires aggregation information on secondary packaging, cases, and pallets:

Level 1: Primary Packaging
This is the innermost layer of packaging that actually touches the product, for example, a blister pack or ampule. It is not generally considered a “saleable unit” and does not require a unique serial number under SFDA regulations. The manufacturer has the option to apply a 14-digit Global Trade Item Number (GTIN-14), Expiry Date, and Batch Number.

Level 2: Secondary Packaging
This is considered to be the “individual saleable unit” and, by law as of March 2017, requires a randomized serial number as part of the unique product identifier. This is the smallest unit in the aggregation hierarchy: unique “parent” identifiers at the case and pallet levels are used to infer the serial numbers of the individual “child” units. The manufacturer is **required by SFDA** to apply a GS1 DataMatrix and human readable information that contain:

- GTIN-14
- Expiry Date
- Batch Number
- Serial Number

Level 3 and Level 4: Homogeneous Bundle and Sub-Carton/Inner Pack
These intermediate packaging levels are used to package drugs of the same type in commercial configurations. These levels are not required for aggregation, but the manufacturer has the option to apply a GTIN-14, Expiry Date, Batch Number, and SSCC.

Level 5: Case/Carton/Outer Pack

A Case, Carton, or Outer Pack are different names for the basic “parent” shipping container in the aggregation hierarchy. An SSCC is **required by SFDA** for both homogeneous (medicines of the same type) and heterogeneous (mixed types of medicines) cases. For homogeneous cases, the manufacturer has the option to apply a GTIN-14, Expiry Date, and Batch Number in addition to the SSCC.

Level 6: Pallet

A pallet comprises multiple Cases, Cartons, or Outer Packs. An SSCC is **required by SFDA** for both homogeneous and heterogeneous pallets. For homogeneous pallets, the manufacturer has the option to apply a GTIN-14, Expiry Date, Batch Number in addition to the SSCC.

What is the Saudi Package Transfer System?

The SFDA Package Transfer System (PTS) provides a channel for bulk transfer of aggregated product identifiers between trade entities in the supply chain. Because aggregation does not represent a transfer of ownership or disposition of product, SFDA does not require reporting on aggregation events and PTS is considered to be a service, not a reporting system. SFDA has not defined a data format standard, so trade partners must provide their own specifications for how their data is structured when sending aggregation information.

TraceLink: Proven track and trace solutions for meeting Saudi requirements

As the leading track and trace solution for the pharmaceutical industry, TraceLink’s proven compliance platform provides pre-built business logic and workflows designed to support multi-level product aggregation—giving companies a significant advantage over implementing a customized solution.

In addition, the TraceLink network allow companies to “integrate once, interoperate with everyone” to exchange serialized product data and meet compliance requirements around the world without having to create point-to-point connections with their global trading partners.

Contact us to learn more about TraceLink's compliance solution for Saudi Arabia—and about TraceLink's Saudi Arabia Special Interest Group: the leading forum for TraceLink customers to stay up to date on SFDA regulations.

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