RESOURCES

Saudi Arabia Regulatory Updates

This is a compilation of the recent regulatory updates for Saudi Arabia. Every week, we post an update of what's new, which you can **view here**.

2020

- **June 28:** Users of Saudi Arabia's Drug Track and Trace System (RSD) received a government email stating that the deadline for aggregation of medicines has been pushed back to August 20, 2020.
- **April 5:** Saudi Arabia's government announced a delay in the implementation of aggregation and integrated reporting requirements. The requirements will now go into effect on June 30, 2020.

2019

- **December 29:** The Saudi Food and Drug Authority (SFDA) extended the deadline for companies that are required to connect to Saudi Arabia's track and trace system and complete aggregation of shipped products. The new deadline is March 31, 2020.
- **August 11:** The Saudi Food and Drug Authority (SFDA) circulated a letter to alert stakeholders of upcoming aggregation deadlines. The letter also reinforces the need for companies to use the Saudi Drug Track and Trace System (RSD) to comply with current track and trace requirements.
- **July 28:** The Saudi Food and Drug Authority (SFDA) published Version 6 of its

Drug Barcoding Specifications with details about multi-level packaging hierarchy requirements, including barcoding, serialization, and aggregation to the pallet level.

- **April 7:** Full guidance for the Saudi Unique Device Identifier (UDI) program is expected to be published next month.
- **March 10:** The Saudi Food and Drug Authority (SFDA) urged stakeholders to make their best efforts to be compliant. Regulators acknowledged the challenge of meeting the upcoming aggregation deadlines as guidelines for the technical requirements have yet to be published. Regulators are considering the use of Turkey's Package Transfer System (PTS) as the basis for the SFDA requirements.
- **February 24:** An aggregation circular was published that sets the deadline for medicines to be aggregated at unit/case level starting on October 1, 2019.
- **February 10:** The SFDA-GS1 joint workshop, held on February 5, reinforced that the SFDA is serious about compliance and that global pharma Marketing Authorization Holders (MAHs) will have the flexibility to do their own reporting instead of delegating it to a local distributor.
- **February 3:** An SFDA-GS1 joint workshop will take place on February 5, 2019.
- **January 27:** Formal updates have not yet been published concerning the January 7, 2019 deadline and Saudi Food and Drug Authority (SFDA) enforcement. The SFDA continues to hold individual meetings, but hasn't issued a timeframe for when formal guidance will be published.

2018

- **December 2:** The government has updated information on the v1.0.2 technical guidelines. The deadline of January 7, 2019 has yet to be finalized along with details of how the government may apply the guidelines.
- **November 25:** The government has published a new regulatory website that will be used for submission of stakeholder identification and locations and also

issued new forms to test government compliance reporting.

- **November 4:** New deadlines of July 2019 have been published for aggregation and compliance reporting.
- **October 28:** Compliance implementation guidelines were updated and published this past week. These updates did not include a listing of dates for compliance.
- **August 5:** The comment period on the draft Integration Guide for compliance has now closed. An updated Guide is expected by the end of September.
- **February 11:** The reporting of GLN codes is required by February 28 for each factory and warehouse serving the country.

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