RESOURCES

Poll: Companies Prepping for Saudi Aggregation Despite Outstanding Guidance



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.

Companies that are manufacturing or distributing medicines in Saudi Arabia are moving ahead with their compliance planning, product aggregation, and trade partner engagement, despite the lack of final guidance from the Saudi Food and Drug Authority (SFDA). While Saudi reporting requirements have been in place since January, 2019, product aggregation was only confirmed as a requirement one month later and an October 1 aggregation deadline was established. The actual details of aggregation—including affected packaging levels and reporting requirements—have yet to be issued by SFDA.

To stay competitive and to minimize the impact of aggregation, nearly two-thirds of companies said they are already working toward or finalizing their plans to comply with Saudi track and trace requirements. Companies that delay their preparations in anticipation of final guidance from SFDA risk missing the October aggregation deadline and being penalized by the Saudi government.

More than 66% of companies currently aggregate all or some products.

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Of the companies surveyed, nearly one-third are already aggregating all of their products and more than one-third aggregate selected products to meet their distributors' requirements. An additional 20% plan to add aggregation capabilities to comply with SFDA regulations.

However, even with aggregation in place, companies are waiting to see if—or how—Saudi technical requirements might affect their current aggregation capabilities.

Most companies are already engaging trade partners on aggregation.

While it has not been determined if aggregation events will need to be reported to SFDA, aggregation data is expected to be shared between trading partners via the Saudi Package Transfer System (PTS) to facilitate product distribution. More than 55% of companies are actively working with their trading partners on defining aggregation processes and responsibilities and discussing the impact of product aggregation on their current operations—a necessary first step for any company that expects to provide medicines for Saudi Arabia.

Reduce the complexity of aggregation with TraceLink.

For companies faced with the challenge of serializing and aggregating their products for the Saudi market, TraceLink's proven compliance platform provides the scalability, tools, and workflows to handle the complexities of serialization management and aggregated packaging. And TraceLink customers can already begin to apply their aggregation hierarchies in the TraceLink system—and get a head start on their long-term serialization and reporting strategy for the Saudi Arabia market.

Contact TraceLink for information about our Saudi Arabia compliance solutions and to learn more about being part of TraceLink's Saudi Arabia Special Interest Group, the leading forum for TraceLink customers to stay up to date on SFDA regulations.

Saudi Arabia

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