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Saudi Arabia: Understanding the Compliance Requirements



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

On January 7, 2019, the Saudi Food and Drug Authority (SFDA) began enforcement of reporting requirements that affect all companies producing medicines for the Saudi Arabia market—and more deadlines will be coming later this year. This infographic provides a high-level overview of key deadlines, roles and responsibilities, packaging elements, and more, to help you understand the requirements and how they will impact your business.

As the trusted compliance partner of more than 1,000 companies around the world, TraceLink closely monitors regulatory laws and guidance to deliver purpose-built solutions for meeting today's—and tomorrow's—track and trace regulations.

SAUDI ARABIA

Understanding the Compliance Requirements



A guide to the requirements affecting companies producing medicines for the Saudi Arabia market.



The Saudi Food & Drug Authority (SFDA) oversees the Saudi Drug Track and Trace System (RSD), where companies, stakeholders, and drugs must be registered and supply chain events reported.

Key Deadlines



WHICH PRODUCTS ARE INCLUDED?

All drugs manufactured in or imported into Saudi Arabia are subject to the requirements:



Prescription drug products



Over the counter (OTC) products



Veterinary pharmaceutical products

KEY REQUIREMENTS

Registration



Company, stakeholder, and product

Serialization



Serial numbers are generated by the manufacturer

Reporting



Core transactions reported include: commission, sale/ship, buy/receive, dispense/decommission

STAKEHOLDER EVENT REPORTING

As of January 2019, Saudi Arabia law requires the tracking of events which vary based on the manufacturer's business operations.

OPERATION	MANUFACTURERS	DISTRIBUTORS	HOSPITALS/ DISPENSE CENTERS	PHARMACIES
REGISTER products manufactured in Saudi Arabia	●			
REGISTER products imported into Saudi Arabia	●	●		
DISPATCH product to another stakeholder	●	●		
ACCEPT product from a stakeholder	●	●	●	●
DEACTIVATE Identifier in the system	●	●	●	●
EXPORT product	●	●		
RETURN product back from recipient to the sender	●	●	●	●
TRANSFER product between locations			●	●
NOTIFY when medicine is dispensed			● Use of a medicine	● Retail Sale

WHAT INFORMATION IS REQUIRED?

Pharmaceutical manufacturers must apply a serialized barcode to the packaging of their products at the secondary (saleable unit) and tertiary (case) levels. This is a 2D Data Matrix barcode and must include 4 data elements:



1. Product code / GTIN-14
2. Serial number
3. Lot number
4. Expiration Date



Aggregation will be required by October 1, 2019.

HOW DOES IT WORK?



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TraceLink is already helping more than 1,100 customers across the supply chain achieve compliance in the U.S., EU, and other markets around the world.



Country-specific compliance software for more regulated geographies than any other provider.

Experts dedicated to following developments to Saudi Arabia track and trace requirements



A purpose-built solution that incorporates market-specific business logic, reporting workflows, and user controls.

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