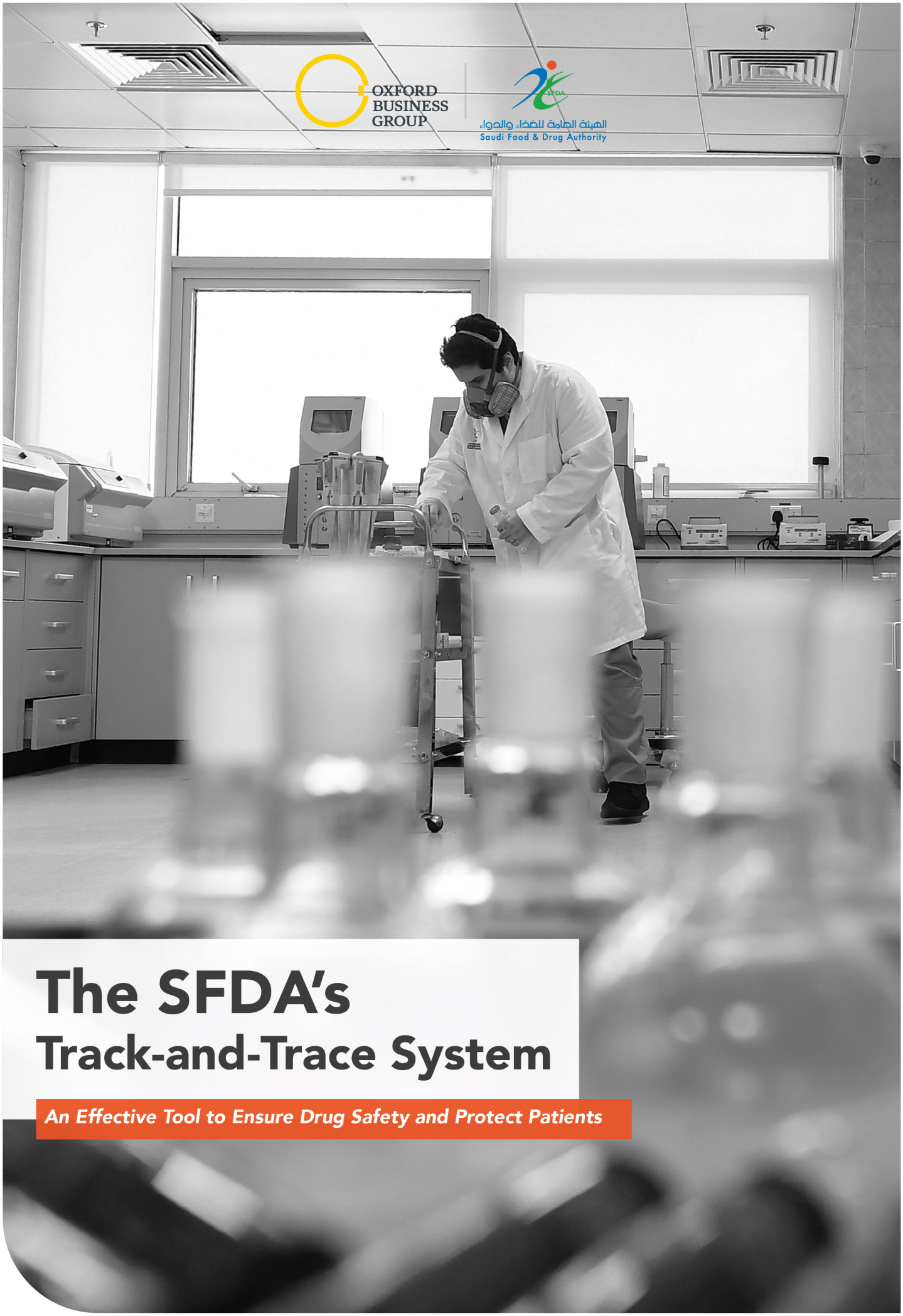

The SFDA's Track-and-Trace System

An Effective Tool to Ensure Drug Safety and Protect Patients

The SFDA's Track-and-Trace System:
An Effective Tool to Ensure Drug Safety and Protect Patients

In 2018 the SFDA introduced a new track-and-trace system to monitor all human pharmaceutical products that are manufactured in Saudi Arabia and imported from abroad. The system is helping to advance Saudi Arabia's health sector and enables the SFDA to ensure the safety of drugs consumed within the Kingdom.

Drug track-and-trace systems allow regulators to protect society and guarantee the safety of medications by knowing their location from the moment of production to the point of consumption. Such systems serve to assist various stakeholders across the supply chain, including manufacturers, distributors, pharmacies, hospitals, health care staff and patients.

The SFDA's new system, which is known by the acronym RSD, is one of the authority's key strategic initiatives. It supports Vision 2030 by transforming Saudi Arabia's health care sector and improving coordination among sector entities. This article provides an overview of the RSD system, detailing its benefits and objectives.

Benefits of Track-and-Trace Systems

A track-and-trace system allows users to pinpoint any item's current and past location in a supply chain. Such systems are used in a variety of industries for various purposes. Perhaps the most well-established example is postal and delivery track-and-trace systems. Applying a track-and-trace approach to pharmaceuticals brings a range of benefits. It essentially allows users of the system to see everywhere a box of medication goes. Key benefits include preventing counterfeit, adulterated or expired medications from entering the supply chain; protecting against theft and diversion; ensuring products remain safe; and enhancing supply chain efficiency and speed.

By following the trail of products in the supply chain, regulators like the SFDA are able to act more efficiently and monitor more effectively the products in the market they regulate. This is especially important for product recalls. Track-and-trace systems also help to build consumer confidence.

SFDA System

The SFDA's track-and-trace system, RSD, has three major objectives:

1. **Preventing Counterfeit Drugs**: In order to ensure only authorised products enter the supply chain, the RSD system requires a unique, randomly generated serial number on each box of drugs, making it very difficult to counterfeit.
2. **Ensuring Drug Availability**: By tracking the number of products in the supply chain and on the market, the RSD system enables the SFDA to monitor the pattern of in-demand medication and assess if there is likely to be a shortage of any product. At any one time it allows the SFDA to see how many boxes of a certain type of medication are inside the Kingdom. It also enables the authority to see if there is a sudden increase in demand, at which time the SFDA can implement measures such as asking manufacturers to increase production or asking pharmacies to restrict the dispensation of the drug. During the height of the Covid-19 pandemic, the RSD system was particularly important in helping Saudi Arabia avoid shortages of certain types of drugs, especially in cases where there was panic-buying of drugs such as paracetamol.
3. **Achieving Drug Safety**: If a quality or safety issue is identified with a certain drug, it may need to be recalled and returned to the manufacturer to be destroyed. The RSD system allows users to know the exact location of each drug, and makes it easier to perform a recall and prevent the

drug from reaching patients. It also helps hospitals and pharmacies by letting them know which patients a drug has been sent to and how many boxes have been sent, enabling them to act on recalls more effectively. Recalls may originate from manufacturers that detect a fault or receive customer reports of defects, or from the SFDA as a result of drug sample analysis. There are different levels of recalls depending on the severity of the issue. For example, a product may be recalled from hospitals but not from patients, or patients may be required to return the product.

Establishing A System

There are different types of track-and-trace systems and a variety of approaches are used across countries. The two main types of track-and-trace systems are end-to-end tracking and full track and trace. The SFDA chose to implement a full track-and-trace system. This type of system is harder to develop and more complex, but ultimately yields greater benefits.

In 2014 the SFDA saw a need to develop a drug track-and-trace system. Part of its consultations included organising local workshops for the stakeholders involved in the drug supply chain, in addition to participating in global workshops and speaking with international manufacturers to understand international best practices for establishing a system. Between 2014 and 2018 the SFDA worked to draft the requirements for tracking products before sharing this with stakeholders. It then mandated that all products entering the supply chain were trackable. Once most of the products in the supply chain were trackable, the SFDA launched a test version of the RSD system at the beginning of 2018. The SFDA proceeded to collect feedback on the system from users so any necessary adjustments could be made. The completed system was launched at the end of 2018 and stakeholders started using it at the beginning of 2019.

More than 6000 stakeholders were registered on the RSD system between January 2019 and the end of 2021. The SFDA continues to register new stakeholders on a daily basis. Since its launch, the system has proved effective, having recorded more than 3bn operation transactions and recalled 15m boxes of medication as of end-2021.

Stakeholders

Establishing a track-and-trace system for medications is a complex and gradual process. Significant coordination and alignment among stakeholders is needed, spanning manufacturers, distributors, pharmacies and hospitals. Each stakeholder has a different set of needs and workflows, and it is important to take all their requirements into account to build a system that works for all. The SFDA implemented a step-by-step approach for users to adopt and absorb changes in their business, upgrade their systems and become familiar with RSD requirements. Since 2014 the SFDA has been running specialist workshops targeting different stakeholders to raise awareness of RSD. The authority also regularly asks for feedback from stakeholders to modify, fix and upgrade the system.

Barcode

The SFDA built the RSD system according to local and international GS1 standards, standardising the label on each box of medication. This is a 2D barcode that contains four key pieces of information: expiry date; batch number; global trade item number, which is a unique number for that particular drug; and serial number, which is a unique number for that box of medication that allows users to track it. Aggregating information into a single barcode helps manufacturers and warehouses register and track drugs in their system by simply scanning the outer barcode and getting all the relevant information without inputting the data manually, which may lead to errors. This supports

operational efficiency. Using the SFDA app, members of the public are also able to scan the barcode on their medication and check the product status – for example, whether it has been recalled.

Reporting

Stakeholders are required to conduct reporting on RSD by integrating their own local computer system with the RSD system. This helps to eliminate human error when recording transactions. A pharmacy linking its computer system with the RSD system, for instance, allows for a seamless flow of information. While new stakeholders modify their systems to prepare for this integration, the SFDA allows users to conduct reporting temporarily through an online portal where users are required to log in with a username and password and record transactions.

For more information on RSD, please visit our website:
Arabic: https://rsd.sfda.gov.sa/
English: https://rsd.sfda.gov.sa/index-en.html

or contact us by email at tracking.drug@sfda.gov.sa