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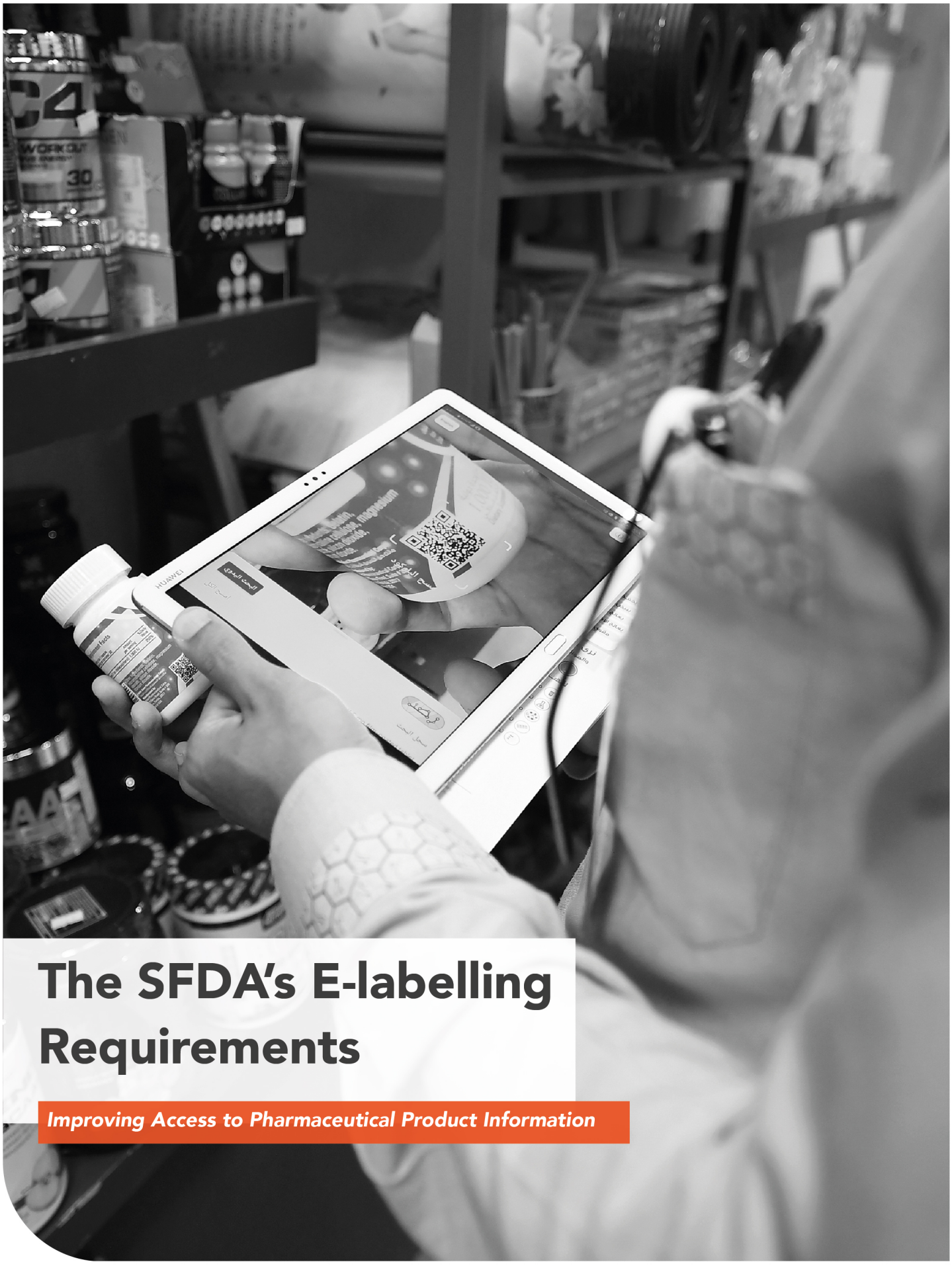
Saudi Food & Drug Authority



The SFDA's E-labelling Requirements

Improving Access to Pharmaceutical Product Information

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Improving Access to Pharmaceutical Product Information

As part of efforts to improve its services, the SFDA is introducing measures to make information about pharmaceutical products more accessible to patients and the health care industry. One way the SFDA has done this is by introducing e-labelling, or electronic labelling, for pharmaceutical products. The SFDA introduced the requirement for e-labels in 2017 and launched a system to support e-labelling in 2018 called the Saudi Drugs information system.

Saudi Arabia is the first country in the GCC and one of the first countries worldwide to introduce e-labelling requirements. This article details the background of e-labelling and provides an overview of the SFDA's labelling requirements and the Saudi Drugs information system.

E-labelling Explained

E-labelling is the provision of product information via electronic channels. It is an alternative way for manufacturers to communicate important information that would typically be stamped or attached to a product in the form of a physical label and leaflet. E-labels include the same information as a printed label.

There are a number of benefits to e-labels, particularly in an era of increasing digitisation and demand for digitally accessible information. Most importantly, e-labels offer access to important information anytime in an easy-to-read format.

Only a handful of countries have adopted e-labelling. A 2021 preliminary survey by the International Pharmaceutical Regulators Programme, which is a forum for pharmaceutical regulators to exchange information on regulatory cooperation, found that Singapore, Japan, Saudi Arabia, Switzerland and Taiwan were among the respondents who had adopted e-labelling. The survey found that Brazil, the EU, the US and Canada were among the respondents planning to introduce e-labelling.

SFDA Labelling Requirements

The SFDA now requires every pharmaceutical product entering the Saudi market to have a digital leaflet in addition to a printed leaflet. This is reviewed and approved by the SFDA during the product registration period. The SFDA requires digital information to be in the form of fully searchable text. This enables users and health professionals to easily search for and access certain information in the leaflet.

There are three components of information that manufacturers are required to display: a label, a patient information leaflet (PIL) and a summary of product characteristics (SPC). The label typically includes information such as the product name, how to use or take it, the recommended dosage, warnings, the expiry date and storage conditions. The PIL typically includes a description of what the product is and what it is used for, what a patient needs to know before taking or using it, how to take or use it, the possible side effects, how to store it and further information. The SFDA requires the PIL to be in both English and Arabic. The SPC, meanwhile, provides additional information on the product and is targeted at health care professionals, such as doctors, nurses and pharmacists. It provides a description of the medicinal product's properties and the conditions attached to its use, and explains how to use and prescribe the medicine.

The SFDA has a guide for manufacturers that details the authority's requirements to display this information. The guide is called *Templates for Labelling Information, SPC and PIL*. It is designed to ensure standardisation of product information submitted to the SFDA. It is available here.

Saudi Drugs Information System

E-labelling information in Saudi Arabia is available from two main sources. The first is the SFDA mobile app, *Tameni*, and the second is the website portal, the Saudi Drugs information system. The Saudi Drugs information system provides easily accessible information on pharmaceutical products, including documentation on variations related to drug use. It also continuously updates information related to the product, such as side effects. As part of its monitoring and evaluation efforts, the SFDA regularly conducts random searches on the Saudi Drugs information system to ensure the e-label is the same as the printed label and is available for users to access.