SPOTLIGHT: PROGRESS IN THE ADOPTION OF E-LABELLING FOR NON-PRESCRIPTION MEDICINES

GLOBAL SELF-CARE FEDERATION

SAUDI ARABIA

Country summary

36.6 million
population

36.3 million
internet users

99% internet penetration rate

E-labelling infrastructure

Health Authority website
ePIL hosting platform

QR Code
ePIL format (technology means used)

Data uploaded on NashraTech platform
Provision of label information (format)

Regulatory framework

E-labelling provision
Not mandatory.

Products excluded / included in e-labelling provisions
For all centrally registered medicines.

Approval & update process for ePILs
The introduction of ePILs is regarded as a variation.

Guidelines
The GCC Guidelines for Variation Requirements.

E-labelling implementation

Current format

Dual system pilot.

Stakeholders

E-labelling advocacy: MENAP-SMI.

E-labelling implementation:
Gulf Cooperation Council, SFDA.

Implementation roadmap

2021

MENAP-SMI (Middle East, North Africa, Pakistan Self Medication Industry) developed an industry position paper on e-labelling.

2022

The paper was submitted to Saudi Arabia authority followed by several meetings with Saudi Food & Drug Authority (SFDA) / Gulf Cooperation Council (GCC) authority.

May 2023

SFDA / GCC issued guideline for Variation Requirements, to include “Addition of Electronic patient leaflet variation”.

Following the move by SFDA, other GCC countries are also adopting e-labelling.

Overview of the GCC NASHRATECH project timeline for GCC Countries

2023

Jun - Dec: Registration in the system and issuance of the QR code mandatory for centrally registered pharmaceutical products.

2024

Jan - Jun: Adding QR code on the outer pack mandatory for centrally registered pharmaceutical products.

Apr - Jun: Evaluate Gulf society and industry satisfaction, recommend Nashratech implementation for peripheral pharmaceuticals, and obtain Member States' regulatory approval for the transition.

Jul - Dec: Registration in the system and issuance of the QR code mandatory for peripherally registered pharmaceutical products.

2025

Jan - Jun: Adding QR code on the outer pack is mandatory for peripherally registered pharmaceutical products.

Jul - Sep: Assess Gulf society and manufacturing companies' satisfaction and recommend removing the paper leaflet after a successful trial period.