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

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 NASHRATETECH 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.