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

GLOBAL SELF-CARE FEDERATION

AUSTRALIA

Country summary

25.69 million population

23.93 million internet users

89.60% internet penetration rate

E-labelling infrastructure

Both Health Authority (HA) & Marketing Authorisation Holder (MAH) websites

PIL may also be hosted on Doctors' prescribing software and Pharmacists' dispensing software platforms

ePIL hosting platform

QR Code and website addresses

ePIL format (technology means used)

A mandatory template provided by The Australian Therapeutic Goods Administration (TGA)

Provision of label information (format)

Regulatory framework

E-labelling provision

Not mandatory to be done via an on-pack QR code.

Digital format can link to promotional content as well. However, the ePIL must not contain promotional content. Promotional material must be clearly distinguishable from the ePIL material.

Products excluded / included in e-labelling provisions

Medicines that must have a PIL may provide this electronically if they wish. However not all OTC medicines require a PIL.

Guidelines

The ePIL template and guidelines for Consumer Medicines Information (CMI) for non-prescription medicines .

Approval & update process for ePILs

The TGA and the MAH are responsible for updating their respective website content.

E-labelling implementation

Implementation roadmap

The Therapeutic Goods Regulations 1989 do not specify how the Product Information (PI) and Consumer Medicine Information (CMI) should be distributed.

2019

The Australian Government established a TGA-facilitated stakeholder working group to review previous research and user testing of CMI undertaken by the University of Sydney and the Electronic Distribution Working Group (EDWG).

The work done by this group resulted in a **revised format for CMI.**

It featured new separate templates for prescription and non-prescription medicines, which have improved readability, reduced complexity, and are more suitable for reading on electronic devices by allowing use of hyperlinks and digital functionality.

January 2021

The new templates were implemented and are now mandatory, with all registered medicines required to transition to the new format **by 30 December 2025**.

Current format

Dual system (paper & digital).

ePIL is accepted, if all the required information is provided on the pack label.

Stakeholders

Advocacy: industry, consumers, health professional and government representatives.

Implementation: Health Authority

Unique opportunities

The removal of paper leaflets when all mandatory information is included on the pack label.

For more info visit:
tga.gov.au