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

GLOBAL SELF-CARE FEDERATION

COUNTRIES OVERVIEW

Country summary

GUATEMALA

17.1 million population

8.7 million internet users

65% internet penetration rate

SAUDI ARABIA

36.6 million population

36.3 million internet users

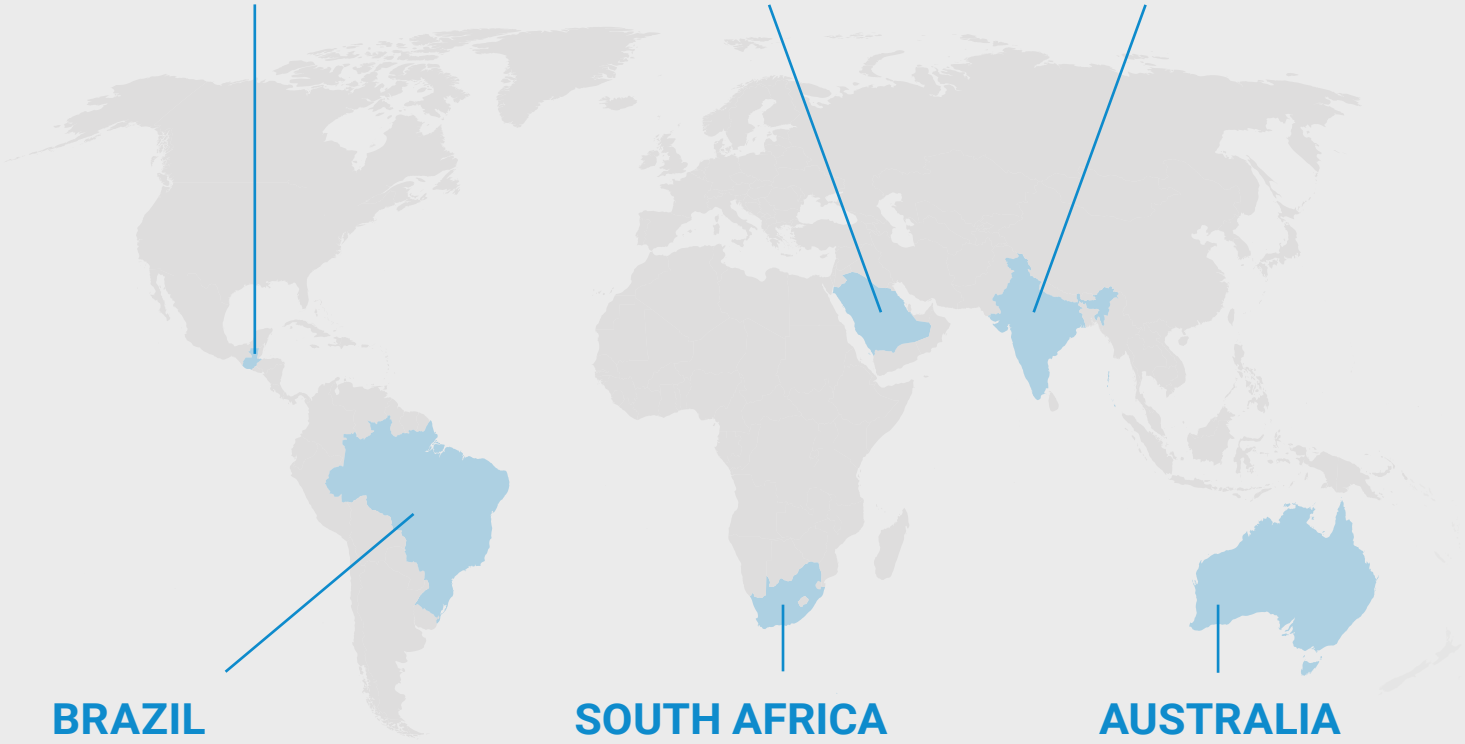
99% internet penetration rate

INDIA

1.4 billion population

692 million internet users

48.7% internet penetration rate



BRAZIL

203.1 million population

162.5 million internet users

80% internet penetration rate

SOUTH AFRICA

60.14 million population

43.48 million internet users

72% internet penetration rate

AUSTRALIA

25.69 million population

23.93 million internet users

89.60% internet penetration rate

E-labelling infrastructure

GUATEMALA

Marketing Authorisation holder website

ePIL hosting platform

QR Code

ePIL format (technology means used)

HTML

Provision of label information (format)

SAUDI ARABIA

Health Authorit website

ePIL hosting platform

QR Code

ePIL format (technology means used)

Data uploaded on NashraTech platform

Provision of label information (format)

INDIA

Marketing Authorisation holder website

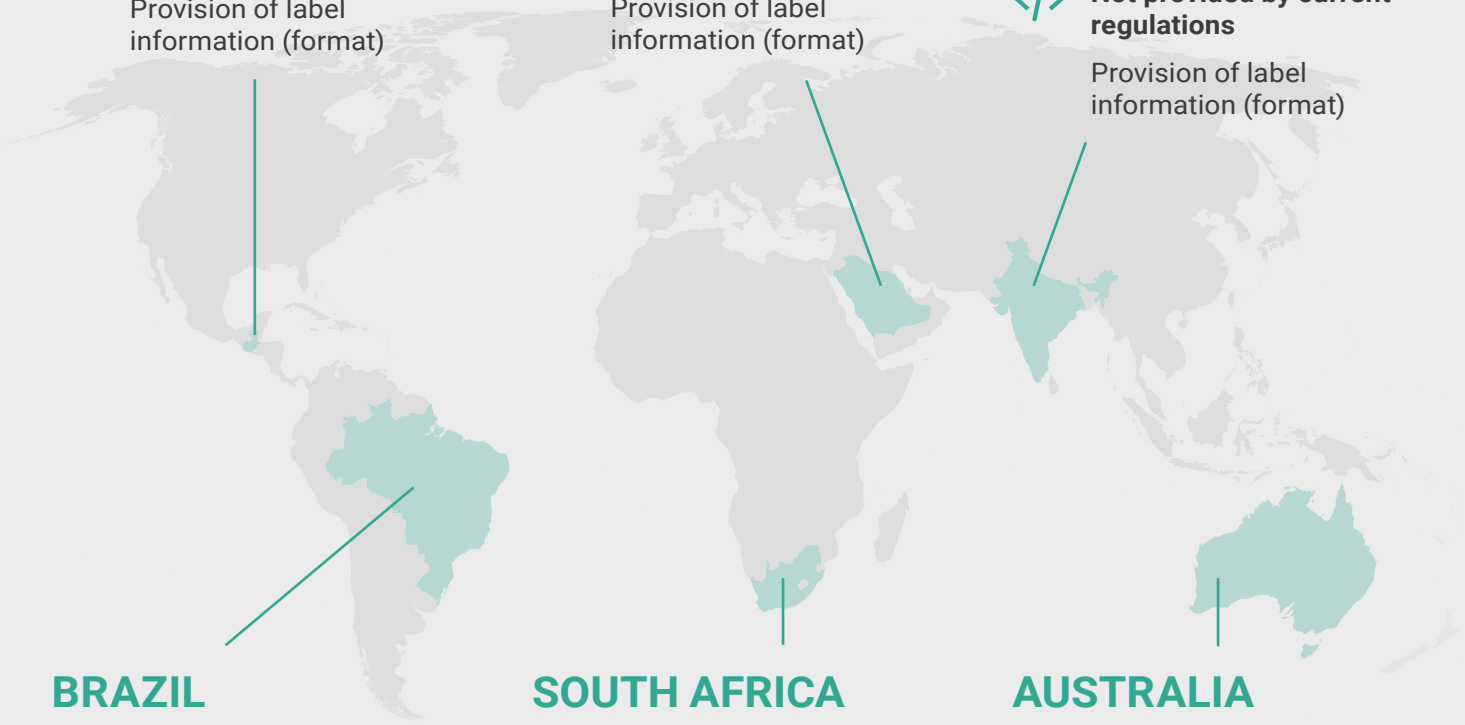
ePIL hosting platform

QR Code and website information on pack

ePIL format (technology means used)

Not provided by current regulations

Provision of label information (format)



BRAZIL

Health Authority & Marketing Authorisation holder websites

ePIL hosting platform

QR Code

ePIL format (technology means used)

Under evaluation.

Provision of label information (format)

- ANVISA (Brazilian Health Regulatory Agency) assesses EU electronic standard (premature discussion).
- Formats being explored include: unstructured PDF, semi-structured HTML / XML and other formats adapted for electronic use.

SOUTH AFRICA

Health Authorit website

ePIL hosting platform

QR Code

ePIL format (technology means used)

PDF

Provision of label information (format)

AUSTRALIA

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

GUATEMALA

E-labelling provision

Not mandatory.

SAUDI ARABIA

E-labelling provision

Not mandatory.

Guidelines

The GCC Guidelines for Variation Requirements.

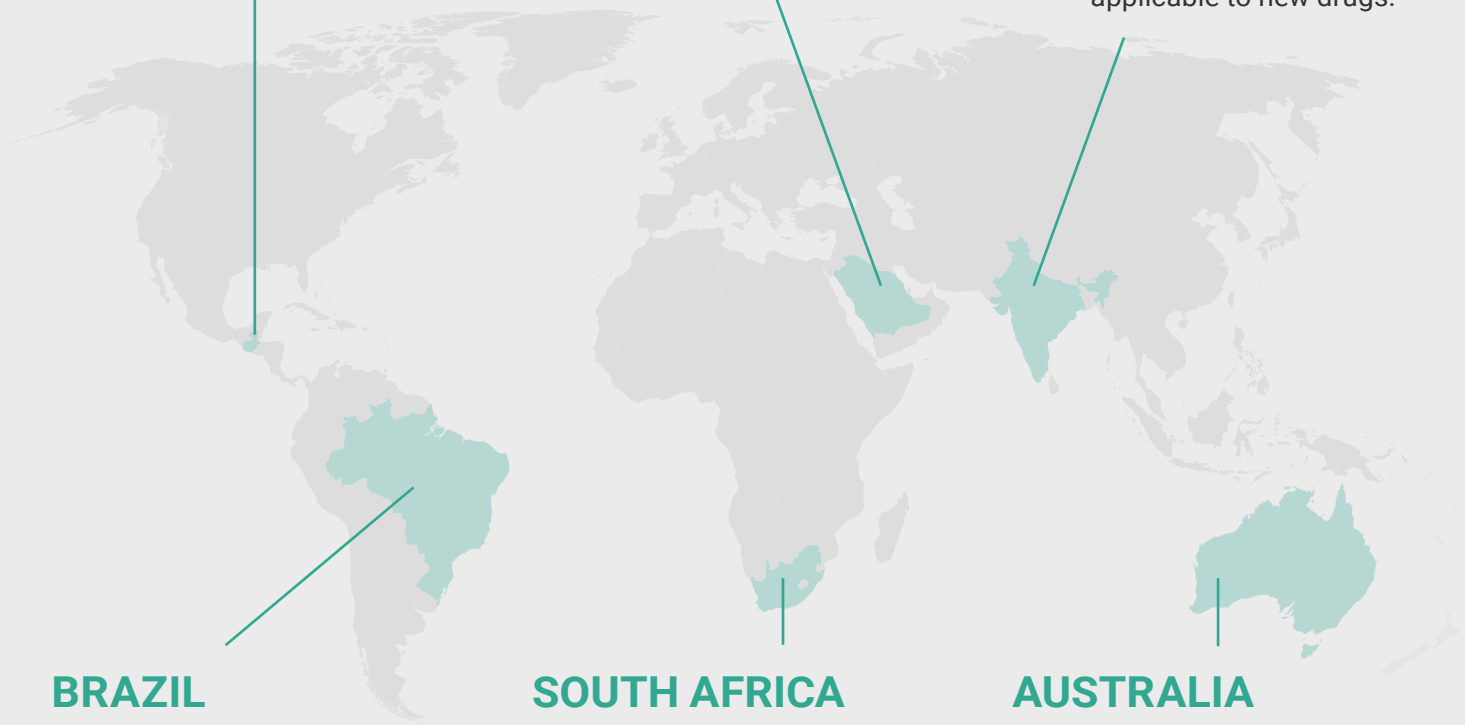
INDIA

E-labelling provision

Not mandatory.

Guidelines

The format w.r.t. content is specified in the 3rd schedule of New Drugs and Clinical Trial Rules-2019 which is only applicable to new drugs.



BRAZIL

E-labelling provision

Mandatory submission of ePIL.

Companies have the option to make ePILs available on their websites, after submission to the HA.

Guidelines

RDC 47/09 published in 2009.

Law No. 14,338/2022 that prompted a review of RDC 47/09.

SOUTH AFRICA

E-labelling provision

Not mandatory.

Guidelines

No specific guidelines.

These are combined with labelling guidelines and regulations.

AUSTRALIA

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.

Guidelines

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

GUATEMALA

Products excluded / included in e-labelling provisions

Only approved for small pack size OTC medicines.

Approval & update process for ePILs

Proposed labelling for e-labelling is assessed by the health authority for approval, which takes 5-6 months.

The Marketing Authorization Holder is responsible for updating the website.

SAUDI ARABIA

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.

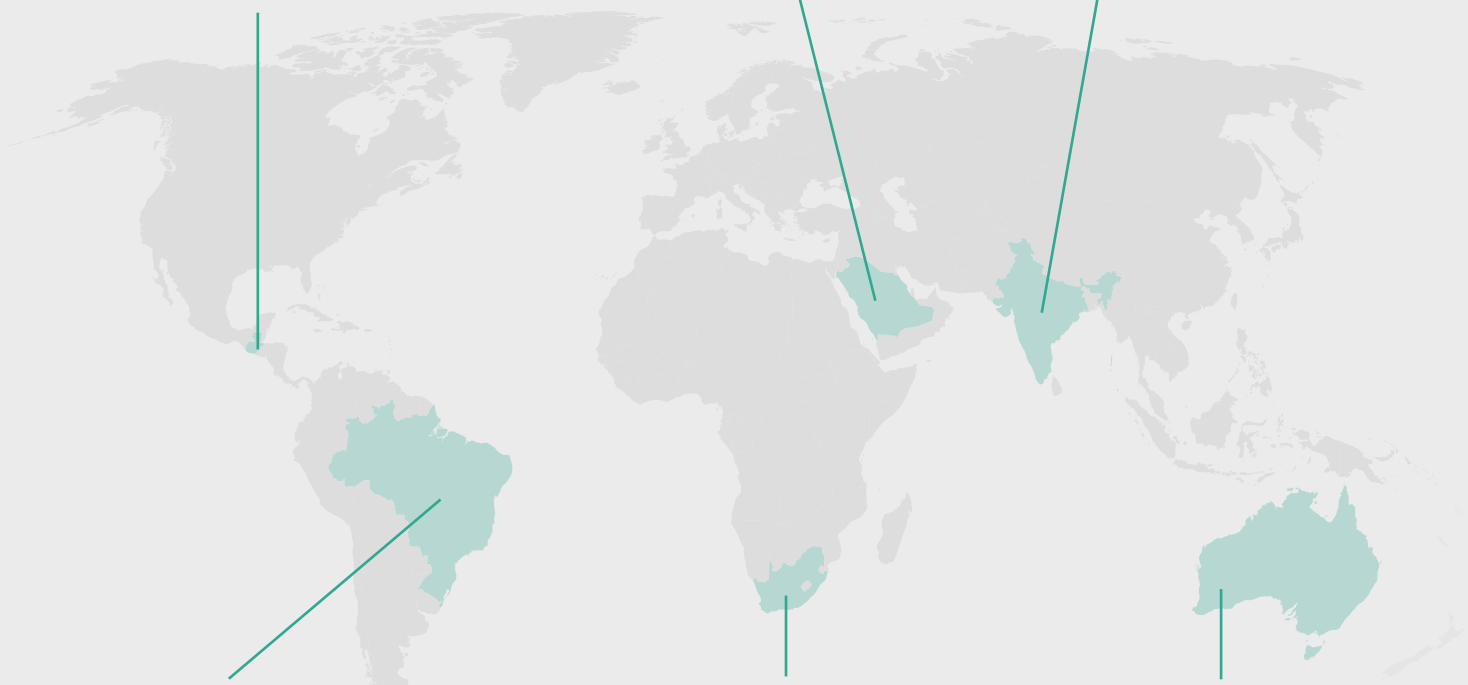
INDIA

Products excluded / included in e-labelling provisions

New Drugs: the PIL has to be included in the dossier submission for approval and uploaded online.

Approval & update process for ePILs

Both the company and marketing authorization holder are responsible for ensuring up-to-date product information (both paper & ePIL).



BRAZIL

Products excluded / included in e-labelling provisions

QR Code approved for all products.

Approval & update process for ePILs

No specific guidelines, update in a timely manner once approved.

SOUTH AFRICA

Products excluded / included in e-labelling provisions

None.

Approval & update process for ePILs

The introduction of ePILs is regarded as a variation.

The industry is responsible for updating the ePILs.

AUSTRALIA

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.

Approval & update process for ePILs

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

E-labelling implementation

GUATEMALA

Current format

Dual system (complementary to paper PILs).

ePILs not accepted as a replacement for paper PILs.

Stakeholders

E-labelling advocacy and implementation: Consumer Health Division at Bayer, Health Authority in Guatemala.

SAUDI ARABIA

Current format

Dual system pilot.

Stakeholders

E-labelling advocacy: MENAP-SMI.

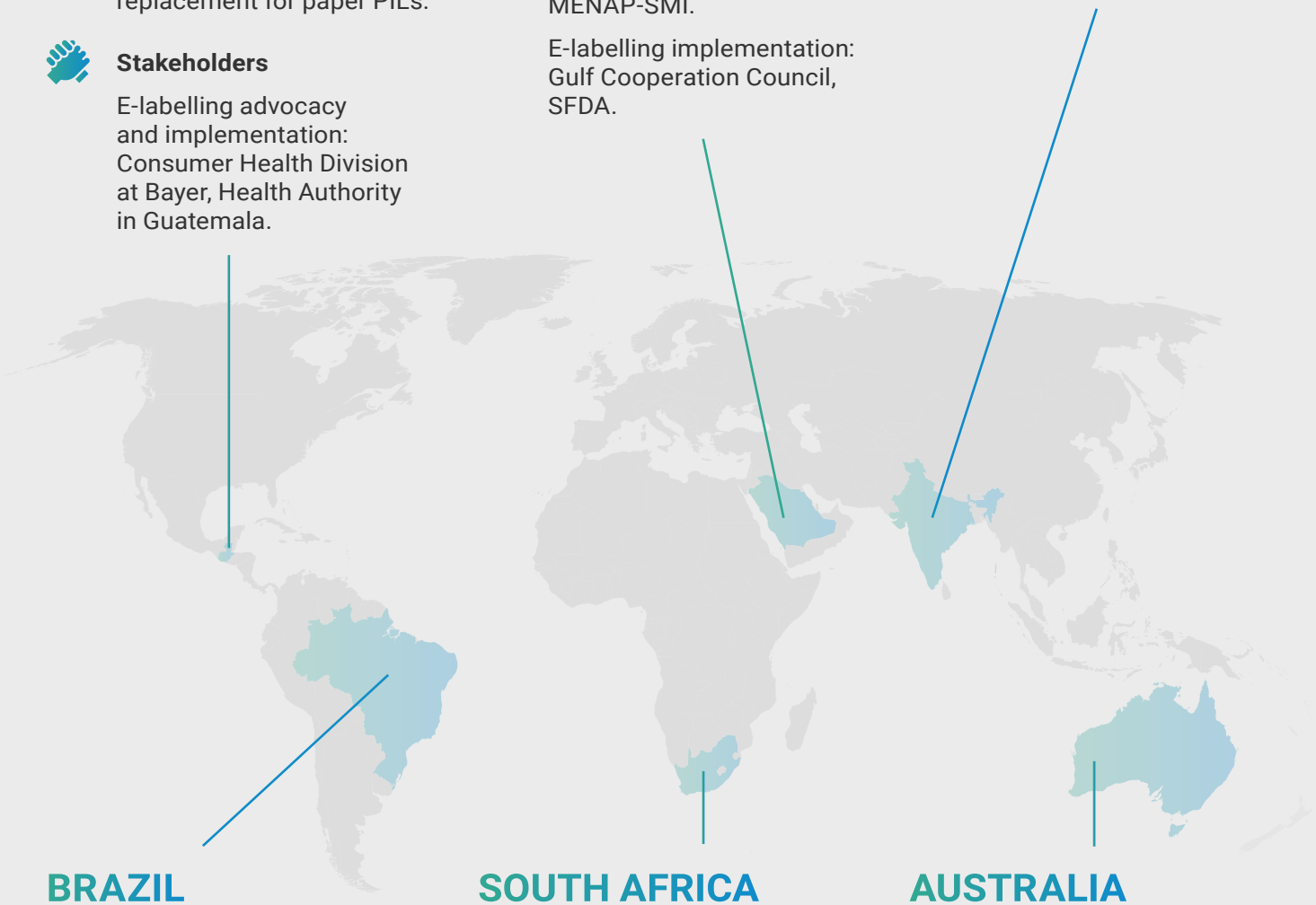
E-labelling implementation: Gulf Cooperation Council, SFDA.

INDIA

Current format

Dual system: paper leaflet required for new products.

Fully electronic for locally manufactured old drugs.



BRAZIL

Current format

Dual system since 2009.

Stakeholders

Health Authorities, Industry / trade association, consumers.

SOUTH AFRICA

Current format

Dual System with a plan to fully transition to e-labelling.

Professional Information (PI) does not need to be on the pack, can be electronic.

Patient Information leaflet (PIL) must be in / on the pack in two languages.

Stakeholders

E-labelling advocacy: SAHPRA, Pharmacy Council, HPCSA, industry.

E-labelling implementation: SAHPRA, industry.

AUSTRALIA

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

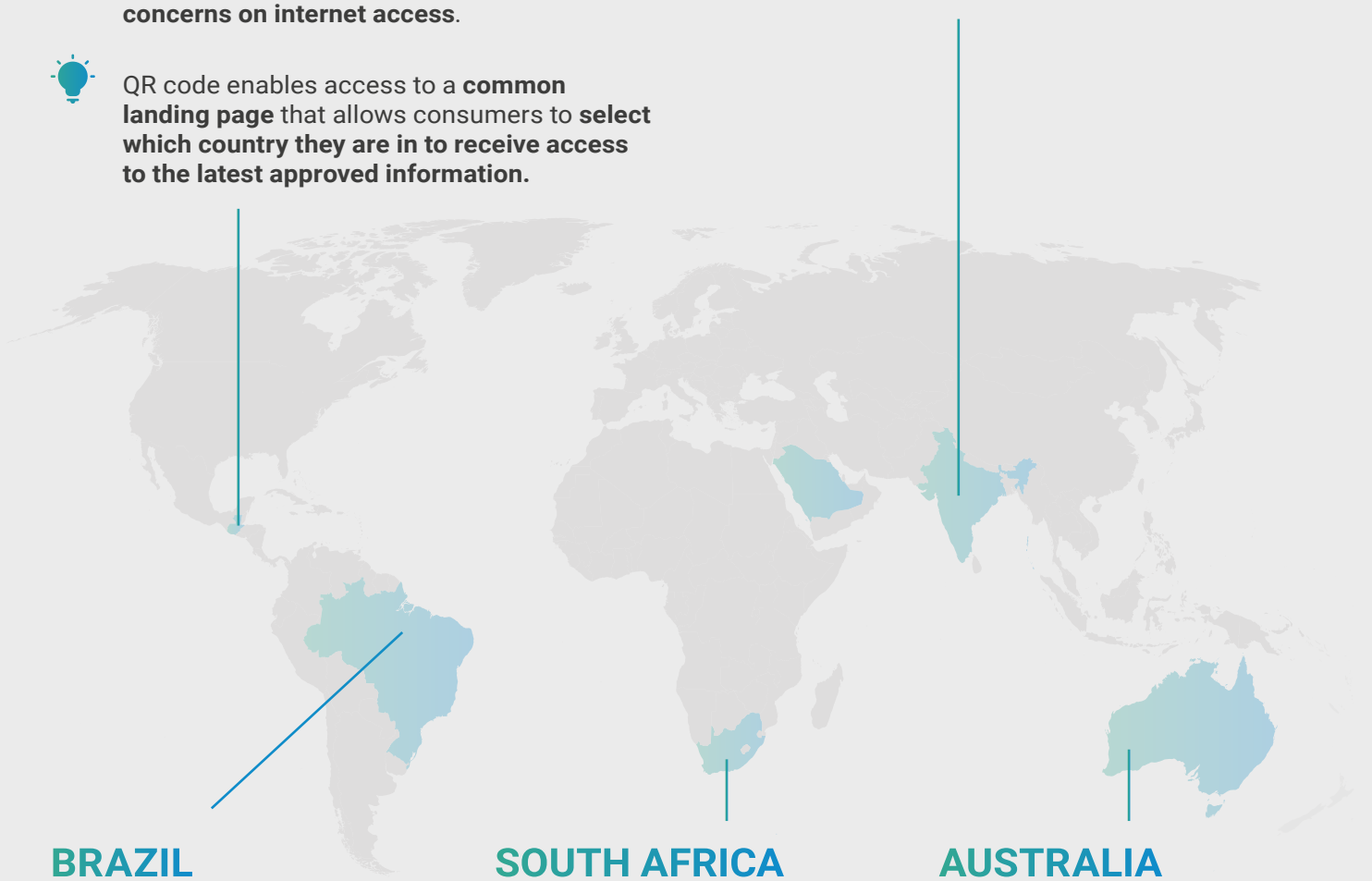
GUATEMALA

Data supported by the telecommunication industry and local mobile phone company providers on mobile phone ownership, usage and access to the internet **alleviated HA concerns on internet access**.

QR code enables access to a **common landing page** that allows consumers to **select which country they are in to receive access to the latest approved information.**

INDIA

As per current regulations, paper leaflet is only mandatory for new drugs. Hence, for all other products, **paper leaflet can be transformed to e-leaflet.**



BRAZIL

Some low-risk Prescription-free medicines (MIPs) are exempted from paper PILs by the HA if the mandatory information is listed on the product packaging.

MIPs sold directly in primary packaging have **paper PILs available in pharmacies** if the consumer requests and a survey from Brazilian Institute of Public Opinion and Statistics showed only 1% of the population asks for the PIL.

Challenge:
Lack of 100% internet access is a barrier to full transition.

SOUTH AFRICA

Zero rating the website **addressed the issue of access in regard to data costs.**

The self-care association of South Africa built trust by developing an **online directory for the HA**. Phase 2 of the directory will include RX products.

Challenge:
12 languages are spoken in South Africa.

AUSTRALIA

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

Implementation Roadmap

GUATEMALA

2021

Small pack sizes with ePILs were first launched.

Challenge:

Products are dispensed and sold in unit doses to be affordable for low-income consumers.

Solution:

- Adopt e-PILs to ensure access to full information for the small pack sizes.
- QR code proposal also enabled access to a common landing page.

Steps taken:

- Developing proposals for the health authority on the benefit of e-labelling.
- Discussions / meetings with the health authority on the challenge and proposed solutions.

Impact of COVID 19

- Accelerated the adoption of e-labelling.
- Influenced changes in consumer behaviour and fostered consumers' familiarity of using QR codes.
- Adoption of QR codes increased across multiple sectors to support social distancing.

SOUTH AFRICA

Currently in the planning phase of a pilot to remove PILs in schedule 0 products.

Steps taken:

Self-Care Association of South Africa built an online directory for all OTC PIs and PILs.

The association submitted a white paper to the regulator supporting the case for QR codes on packs.

Obtained buy-in from OTC companies to launch directory.

Promoted the directory: developed a toolkit, launched a PR campaign and made the site zero-rated.

Obtained buy-in on the pilot: from both the regulator and the industry.

Piloting e-PILs.

Piloting e-PILs:

1. Identify and obtain regulatory exclusions.
2. White paper on ePIL pilot developed and signed off by regulator.
3. Shortlist products to be piloted and establish a working committee.
4. Conduct consumer research on the number of people who use paper PILs. Compare results before and after the pilot.
5. Develop video content for pilot products (how to use the product).

SAUDI ARABIA

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.

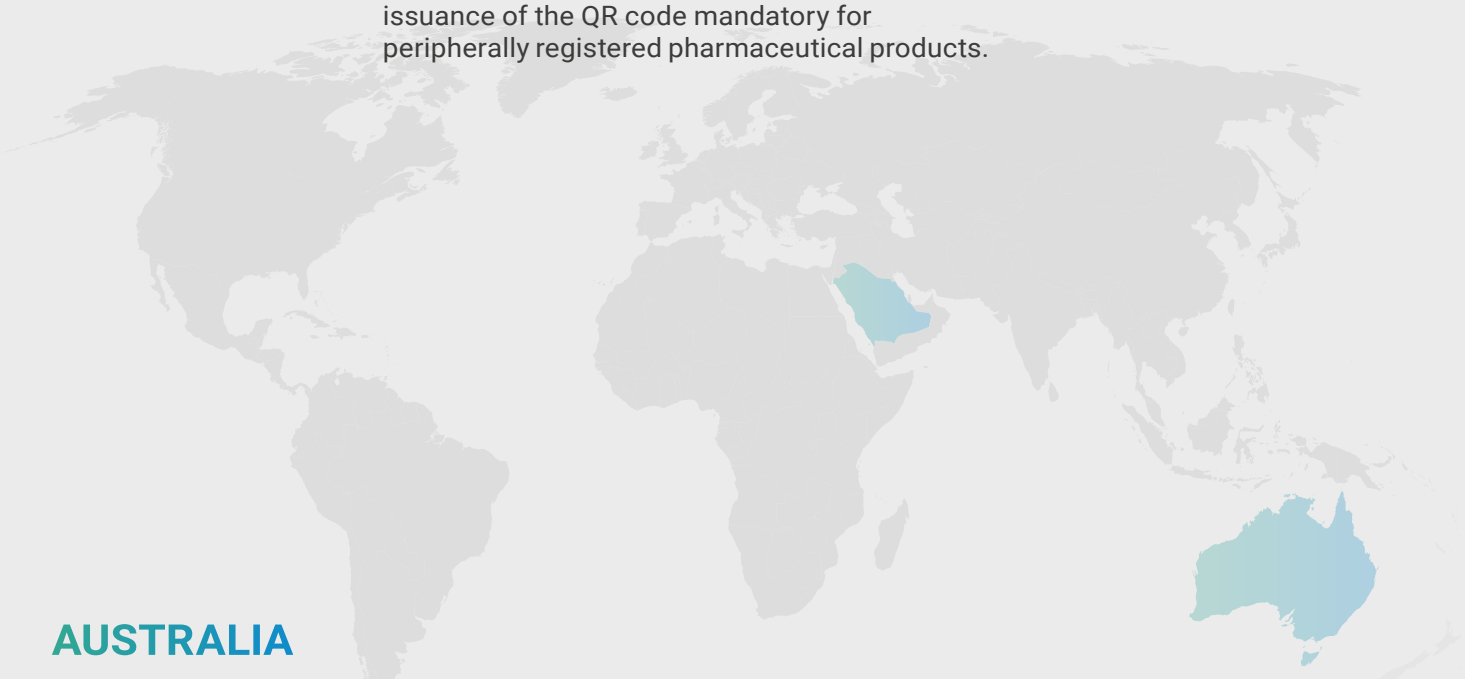
2024
Jan - Jun: Adding QR code on the outer pack mandatory for centrally registered pharmaceutical products.

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.



AUSTRALIA

The Therapeutic Goods Regulations 1989 donot 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).

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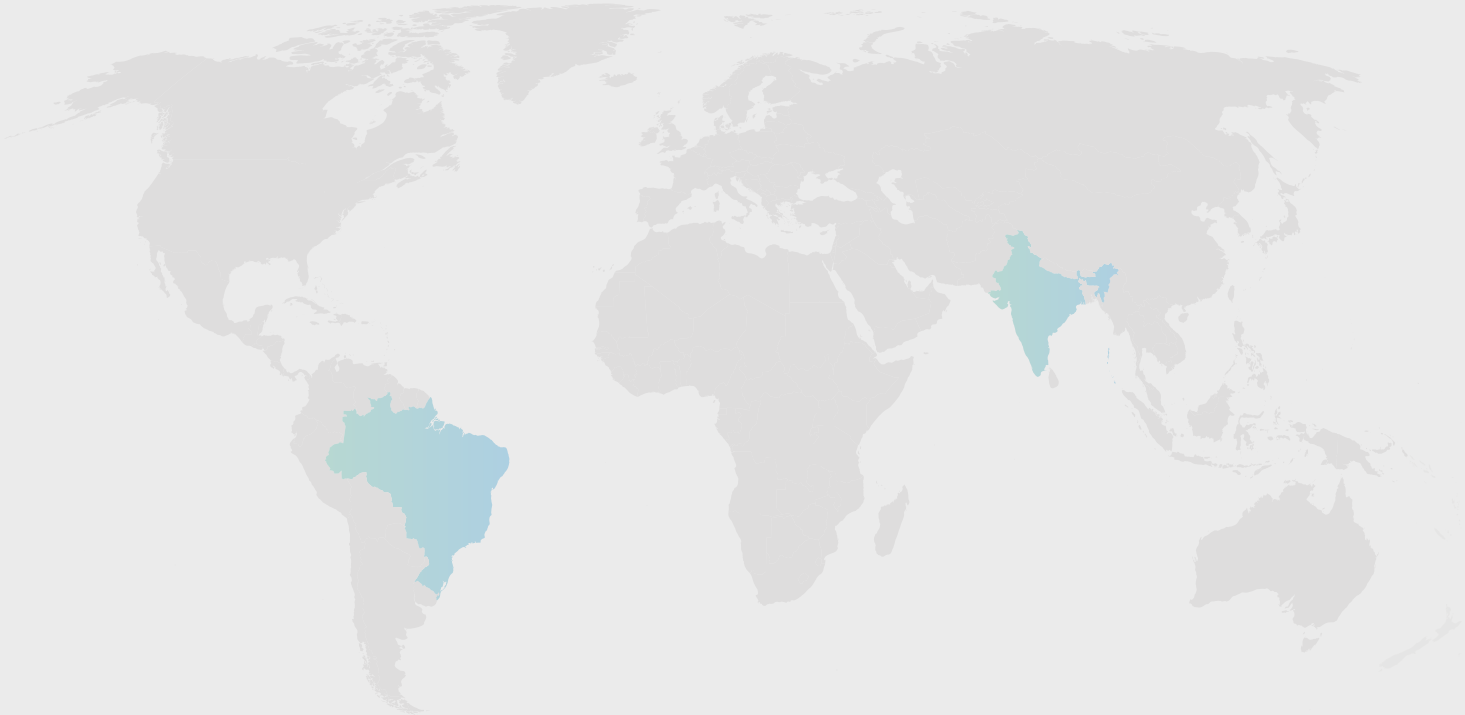
January 2021
The new templates were implemented and are now mandatory, with all registered medicines required to transition to the new format **by 30 December 2025**.

INDIA

OTC regulations are under development.

Draft regulations did not have any mention of using e-labelling provisions, but industry provided comments to include this provision instead of paper leaflets.



BRAZIL

2009

RDAC 47/2009.

Regulation that mandated companies to submit a digital version of the PIL in PDF to be stored in the HA electronic repository; in a file format that allows for conversion to audio and source magnification.

2019

HA had discussions on the expansion of access to the digital package leaflet with the revision of the medicine labelling standard.

2022

Law No. 14,338/2022 prompted HA to review RDC 47/2009.

- New labelling framework published in 2022 mandating companies to place digital codes i.e. QR codes, on package inserts.
- HA has opened a regulatory process to review the regulatory framework of package inserts, which will include: Regulatory Impact Analysis and Public Consultation.

Currently, the HA is working on the standardization of digital leaflets.