

□ BRAZIL

Country summary

 **203.1 million** population  **162.5 million** internet users  **80%** internet penetration rate

E-labelling infrastructure



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.

Regulatory framework



E-labelling provision

Mandatory submission of ePIL.

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



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.



Guidelines

RDC 47/09 published in 2009.
Law No. 14,338/2022 that prompted a review of RDC 47/09.

E-labelling implementation



Current format

Dual system since 2009.



Stakeholders

Health Authorities, Industry / trade association, consumers.

Implementation roadmap



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.



Unique opportunities

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.



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