


□ GUATEMALA

Country summary


 **17.1 million**
population

 **8.7 million**
internet users

 **65%** internet
penetration rate


E-labelling infrastructure


 **Marketing Authorisation holder website**
ePIL hosting platform


 **QR Code**
ePIL format
(technology means used)

 **HTML**
Provision of label information (format)

Regulatory framework

 **E-labelling provision**
Not mandatory.

 **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.

E-labelling implementation



Current format

Dual system (complementary to paper PILs).

ePILs not accepted as a replacement for paper PILs.



Stakeholders for E-labelling advocacy and E-labelling implementation

Consumer Health Division at Bayer.

Health Authority in Guatemala.

Implementation roadmap

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.

Unique opportunities



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.**



For more info visit:
datos.bancomundial.org