


□ SOUTH AFRICA

Country summary

 **60.14 million**
population

 **43.48 million**
internet users

 **72%** internet
penetration rate

E-labelling infrastructure



**Health Authority
website**

ePIL hosting
platform



QR Code

ePIL format
(technology
means used)



PDF

Provision of
label information
(format)

Regulatory framework



E-labelling provision

Not mandatory.



**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.



Guidelines

No specific guidelines.

These are combined with
labelling guidelines and
regulations.

E-labelling implementation



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.

Implementation roadmap

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:

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).

Unique opportunities



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.

