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

[Image -1x668 to 596x843]

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.
- **Approval & update process for ePILs**
  - The introduction of ePILs is regarded as a variation.
  - The industry is responsible for updating the ePILs.
- **Products excluded / included in e-labelling provisions**
  - None.
- **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.

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

**Steps taken:**
1. Self-Care Association of South Africa built an online directory for all OTC PIs and PILs.
2. The association submitted a white paper to the regulator supporting the case for QR codes on packs.
3. Obtained buy-in from OTC companies to launch directory.
4. Promoted the directory: developed a toolkit, launched a PR campaign and made the site zero-rated.
5. 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).

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

**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.

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