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

GLOBAL SELF-CARE FEDERATION

# INDIA

## Country summary

**1.4 billion** population

**692 million** internet users

**48.7%** internet penetration rate

## E-labelling infrastructure

**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)

## Regulatory framework

**E-labelling provision**

Not mandatory.

**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).

**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.

# E-labelling implementation

**Current format**

Dual system: paper leaflet required for new products.

Fully electronic for locally manufactured old drugs.

## Implementation roadmap

**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.

## Unique opportunities

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.**