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

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.

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**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**.