# Guidance for Electronic Labelling for Therapeutic Products

## 1.1 BACKGROUND

Electronic labelling (e-labelling) refers to product information, including the package insert (PI) and patient information leaflet (PIL), which is distributed via electronic means, such as through a machine-readable code or url on the product carton that links to a secure online system that publishes the product information in digital format.

Registrants of Therapeutic Products (TP) who have a secure online system may distribute the HSA-approved PI and/or PIL electronically in lieu of the physical printed hardcopies.

## 1.2 GENERAL GUIDANCE FOR E-LABELLING

*TP eligible for e-labelling*

The initial implementation of e-labelling will start with PI and PIL (if available) of prescription-only medicines (POM). During this trial period, the e-PI/PIL may be distributed concurrently with printed copies contained in the physical products. The reliability and feasibility of the e-PI/PIL will be assessed based on outcome measures including number of hits/downloads of e-PI, acceptance by end users and adoption by product registrants.

Extension of e-labelling to non-prescription medicines will be reviewed after the trial phase.

*Acceptable e-labelling formats*

E-labelling should be presented in a machine-readable digital format that would allow optimized viewing on devices such as smartphones/laptops/tablets.

In addition to the PI and/or PIL, the following can be considered:

i) Online videos on instruction for use (e.g. inhalers/injectable pen devices)

ii) Tools for the visually impaired

*Accessibility of e-labels*

Product Registrants who opt to adopt e-labelling are responsible for ensuring that the hosting platform (e.g. company website) has high availability for users to access the e-label online.

The information should preferably be accessible to user via a direct link to the e-label. Alternatively, a landing webpage with information pertaining only to the TP of interest may be considered, provided that the time spent by the user navigating the page (e.g. clicking links, scrolling) is minimized. Users should not be asked for their personal information nor required to log in or register with the site before accessing the e-label.

Product registrants may state the url (shortlink preferred), QR code, or other machine readable code on the outer packaging (e.g. outer carton) of the TP. In addition, appropriate instructions on how to access the e-labels should be stated.

E-labelling should be accessible to all users, or catered to targeted users if the clinical use is restricted to certain groups of healthcare professionals.

*Registrant's roles and responsibilities*

Product registrants are responsible for ensuring that the e-labels published on its websites are the most up-to-date PI and/PIL as approved by HSA. Upon approval of any label update by HSA, the e-label should be updated within 4 weeks.

The websites that are used to host the e-labels must not contain information that is false or misleading, and must comply with the Health Products (Advertisement of Therapeutic Products) Regulations. Such websites must not contain any promotional information, nor carry any discussion forums/ testimonials concerning the TP. Registrants are reminded that advertisement of POM directed to the general public is prohibited.

**Product Registrants who have plans to implement e-labelling are required to submit their proposal to HSA using the online notification form at least 2 months prior to the actual implementation.**

**Changes to current approved labels solely to incorporate e-labelling without any changes to the approved product information may be submitted via a Do-and-Tell MIV-2 variation.**