NEW INITIATIVES FOR REGISTRATION OF THERAPEUTIC PRODUCTS

Dear Industry Stakeholders,

The Therapeutic Products Branch (TPB), Health Products Regulation Group is pleased to share the following new initiative.

Electronic labelling (e-labelling) for Therapeutic Products

TPB, in consultation with industry stakeholders, is introducing a new initiative to enable the distribution of package insert (PI) and patient information leaflet (PIL) for therapeutic products (TP) through electronic means, i.e. e-labelling.

The PI is an official document that specifies the regulatory approval which HSA has granted for a TP with respect to its clinical use, efficacy and safety. Companies/product registrants have the responsibility to ensure that the PI contains the most current approved information as it is the official reference for communicating with healthcare professionals.

The objective of e-labelling is to facilitate efficient and timely dissemination of the latest approved PI/PIL in an eco-friendly manner. Companies may use machine-readable code or url (shortlink preferred) on the product carton that links to a secure online system that publishes the product information in digital format, instead of relying on the printed hardcopy which is usually contained inside the physical packs of the TP.

The initial implementation will start with PI and PIL (if available) of prescription-only medicines (POM) only. During this trial period, TPB will work closely with industry stakeholders to assess the reliability and feasibility of the e-PI/PIL, and review in 6 months following first implementation. Participating companies should have communication plans in place to ensure that healthcare professionals to whom the TP are supplied are informed in advance of the changes that may occur with e-labelling.

For more information on e-labelling format, requirements and registrant's roles and responsibilities, please refer to the Guidance for Electronic Labelling for Therapeutic Products. Interested companies may submit their proposal to TPB via this form (or scan the QR code below) from 19 August 2019 onwards.

For enquiries, please click here

Therapeutic Products Branch
Medicinal Products Pre-Market Cluster
Health Products Regulation Group
Health Sciences Authority