

HSA's e-labelling Initiative

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E-labelling

- Product information which is distributed via electronic means, in the form of an ePI*, to healthcare professionals (HCP) in lieu of a physical paper leaflet included in the product packaging

*A digital version of the approved PI of a therapeutic product

Benefits of e-labelling

- Enables timely update and access to most up-to-date information approved by HSA
- Allows for flexibility through dissemination of country-specific information where it is not practical or feasible to produce physical PIs to meet individual country's requirements
- Eco-friendly alternative to paper copies
- Provides information through other media (eg video for instructions of use)

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Challenges

HCP and public

- Internet/network connectivity issues
- User acceptability, especially among general public if extending to non-prescription medicines

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Implementation of e-labelling pilot

- HSA embarked on a pilot programme to implement e-labelling in Q3 2019
- Pilot offered an option for companies to distribute registered product information as ePI in lieu of hardcopy leaflet.
- ePI to be accessed through a machine-readable code (e.g. QR code) or url on the product carton in lieu of printed insert accompanying the physical product.

Implementation of e-labelling pilot

- Calibrated approach using phased implementation starting with prescription medicines. On-going review for further fine-tuning as HSA gains further experience
- As of Mar 2021, a total of 270 products with e-labels implemented, with majority using QR codes directed to ePI on company webpage
- HCPs surveyed generally receptive to e-labelling for prescription medicines

Guidance for e-labelling

Companies must ensure that:

- There is a secure hosting platform in place with high availability to all users
- Product packaging carry a QR code or other machine readable code that links directly to the specific ePI of each product, or product-specific landing page
- ePI is in a machine-readable digital format that would allow optimized viewing on devices such as smartphones/laptops/tablets

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Guidance for e-labelling

- If hosted on company's website, the website must not contain any promotional information, nor carry any discussion forums/ testimonials concerning the TP
- ePI is up-to-date as approved by HSA
- Submit application to HSA to update labels with QR codes

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Sample label



Next steps

- Finalisation of guidance in April 2021
- Explore extension to non-prescription drugs