APPENDIX 7A *GUIDANCE ON 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 in the form of an e-PI/PIL. The e-PI/PIL may be distributed with or without physical printed copies contained in the products.

1.2 GENERAL GUIDANCE FOR E-LABELLING

Acceptable e-labelling formats

E-labelling should be presented in a machine-readable digital format that would allow optimised viewing on devices such as smartphones/laptops/tablets. Additional online tools can be utilised to enhance users' experience when they access product information.

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. Users should not be asked for their personal information or required to log in or register with the site before accessing the e-label.

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 minimised.

Product registrants may state the URL (short link 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. Avoid using multiple QR codes to reduce confusion. If necessary, place each code in a separate location with clear instructions.

Registrant's roles and responsibilities

Product registrants are responsible for ensuring that the e-labels published on its websites are up-to-date and aligned with the product information registered with HSA. The e-label should be made available to users within 30 days of any update of product labelling.

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 or carry any discussion forums/ testimonials concerning the TP. Registrants are reminded that direct-to-consumer advertisement of POM is prohibited.

Labelling requirements for General Sale List (GSL) medicines

i) The products are supplied to end users as consumer packs intended for short-term treatment with product information presented in a Patient Information Leaflet (PIL) format.

ii) In addition to the standard labelling requirements for the outer carton of the product/s in accordance with Appendix 7 of the *Guidance on Therapeutic Products Registration*, the following minimum safety information is required along with the machine-readable code (e.g., QR code) directing the user to the complete product information via the ePIL. The minimum labelling requirements serve as a safeguard to ensure appropriate use of the medicine in the event that consumers are unable to access the ePIL in the absence of a paper leaflet.

   a. Indication: What the medicine is used for
   b. Dosing: How to take the medicine
   c. Important side effects, warnings or contraindications

iii) If the current approved outer carton label does not meet the minimum safety information criteria, the applicant must submit a MIV-2 variation application (Refer to Appendix 13B C2 – Change of Content of Product Labelling) to update the outer carton.

iv) Exceptions may be considered for products with small pack sizes (e.g. creams, eyedrops) on a case-by-case basis. Companies may include the necessary justification in the notification to HSA. In addition, the requirement for minimum safety information is optional if the company decides to continue supplying the physical PIL with the ePIL

Notification of e-labelling

Product registrants are required to submit the online notification form prior to actual implementation of e-labelling for registered TPs. Machine-readable codes (e.g. QR codes) may be included in the outer packaging without notifying HSA.

Monitoring and reporting of feedback (For GSL medicines only)

Companies are required to monitor the following arising from the lack of physical PIL for a period of 12 months following ePIL implementation:

i) Customers' and healthcare professionals' feedback, complaints, or requests for hardcopy PIL.
ii) Safety concerns or inappropriate use of the product.

Companies may consolidate feedback related to i) and/or ii) for affected products over the monitoring period and notify HSA via this form.