Guidance for the implementation of electronic labelling (e-labelling) for Non-prescription Therapeutic Products (Pharmacy only and General Sale List)

Background

1. E-labelling has been implemented for prescription-only therapeutic products (TP) since April 2021. HSA is assessing the feasibility of extending e-labelling to non-prescription TPs. As part of a calibrated approach and in consultation with industry stakeholders, HSA will initiate a pilot exercise from 1 April 2024. Companies are encouraged to participate in the pilot exercise for product candidates that meet the eligibility criteria.

2. This guidance should be read in conjunction with the Guidance on Electronic Labelling for Therapeutic Products.

Eligibility for participation in e-labelling pilot

3. The eligibility criteria for the e-labelling pilot are as follows:

i) The current forensic classification of the product is Pharmacy only (P) or General Sale List (GSL).

ii) 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. The electronic PIL (ePIL) may be implemented with or without a physical paper leaflet.

iii) In addition to the standard labelling requirements for the outer carton of the product/s, the following minimum safety information are 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 provide the necessary 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.

Table 1: Minimum safety information on outer carton

Section	**Description**
Indication	*Information should be consistent with current approved PIL.*
Dosing	
Contraindications	
Warnings/precautions	*Important warnings/precautions should be highlighted. Examples of cautionary statements include advising patient to consult a doctor/pharmacist if patient has existing medical conditions (e.g. high blood pressure/asthma), hepatic/renal impairment, or is pregnant/breastfeeding.*
Drug interactions	*Drug interactions that significantly impact patient safety should be highlighted. Alternatively, a general statement to inform patients to consult a doctor/pharmacist if they are taking other medicines may be proposed.*
Overdose	*May not be applicable to all TPs. A general statement to seek medical advice if patients consume more than recommended may be included.*

However, should the company decide to continue supplying the physical PIL with the ePIL during the pilot phase, the above requirement for minimum safety information is optional.

Submission of request to participate in the e-labelling pilot

4. Complete and submit the form here to notify HSA of your interest to participate. The following information is required in the submission:

i) Name of product
ii) Current forensic classification
iii) Proposed pack size
iv) Proposed artwork plan for Outer carton including machine-readable code (*Refer to Table 1 for labelling requirements*)
v) Justifications for not providing minimum safety information, if any
vi) Monitoring channels/sources (Customer reports, Adverse events reports, Website traffic) (Refer to sections 6 and 7 below)

Implementation of e-labelling during pilot phase

5. Upon HSA's acknowledgement to participate in the pilot:

i) If the current registered outer carton already meets the minimum safety information criteria as listed in Table 1:

Submit a 'Do-and-Tell' MIV-2 (Refer to Appendix 13C D12 – Update of Product Labelling) to implement e-labelling for the pilot phase.

ii) If the minimum safety information criteria are not met:

Submit a MIV-2 variation application (Refer to Appendix 13B C2 – Change of Content of Product Labelling) to update the outer carton as per paragraph 3(iii).

The duration of the pilot phase is tentatively 18 months from 1 April 2024 till 31 July 2025, subject to further review depending on industry's participation and the feedback received.

Monitoring and reporting of feedback

6. Companies are required to monitor the following events arising from the lack of a physical PIL:

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

7. Companies should notify HSA via this form if there is feedback related to 6i) and / or ii) within 15 working days from the date of incident.

Contact Us

8. For enquiries, please write in to HSA_TP_enquiry@hsa.gov.sg

References

1. ***Guidance on Electronic labelling for Therapeutic Products***