HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

AUGUST 2022

GUIDELINES ON VOLUNTARY ELECTRONIC LABELLING FOR COMPLEMENTARY HEALTH PRODUCTS

The information in these Guidelines may be updated from time-to-time. For the latest version of the Guidelines, please refer to our website at www.hsa.gov.sg.

HSA
Health Sciences Authority

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1. Introduction

1.1 Electronic labelling (e-labelling) refers to product information which is distributed via electronic means, such as through a machine-readable code (e.g. QR code) or URL on the product outer packaging, that links to a secure online system which publishes the product information in digital format. Presently, e-labelling for Complementary Health Products (CHP) is applicable to the product leaflet[1] (PL) only.

1.2 The objective of e-labelling is to facilitate consumers' access to updated product information in a timely manner.

1.3 CHP dealers who have a secure online system may distribute the PL in the form of an e-PL. The e-PL may be distributed with or without physical printed copies contained in the products.

2. General Guidance for E-labelling

Acceptable e-labelling formats

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

Accessibility to product information

2.2 CHP dealers which opt to adopt e-labelling should ensure that the host website (i.e. website of individual companies or industry associations) has in place the necessary infrastructure and support system to allow users to access the e-label online.

2.3 The information should preferably be accessible to all users via a direct link to the e-label pertaining only to the CHP of interest. Alternatively, a landing webpage with information on that CHP may be considered, provided that the time spent by the user navigating the page (e.g. clicking links, scrolling) is minimised. Users should not be asked for their personal information or be required to log in or register with the site before they can access the e-label.

2.4 Companies may state the URL (shortlink preferred), QR code, or other machine-readable code on the outer packaging (e.g. outer box) of the product. Appropriate instructions on how to access the e-labels should also be included.

Roles and responsibilities of companies

2.5 Companies are responsible for ensuring that the e-labels published online are aligned with the most up-to-date PL. The websites that are used to host the e-labels must not contain information that is false or misleading, and must comply with the Medicines Act, Medicines (Advertisement and Sale) Act and their subsidiary legislation.

[1] A product leaflet is a document packed with the product to provide additional details, such as safety information, to the consumer.

Chinese Proprietary Medicines (CPM)

2.6 For dealers who are interested to implement e-labelling, please inform HSA by submitting the online form here. Please note that you will be requested to submit the following information in the online form:

- List of CPM that will incorporate e-labelling
- A letter of undertaking that there are no other changes to the product labels, except the addition of the e-labelling (e.g. URL/QR code)
- Proposed image(s) or document of the e-label for each product

2.7 Companies are not required to submit CPM amendment applications via PRISM for any changes to current approved CPM labels solely to incorporate QR code or URL to the e-labels. For other changes to the product labels, the e-labels should be updated within 30 days of approval of any label update.

Other Complementary Health Products (CHP)

2.8 Other CHP such as Health Supplements and Traditional Medicines are currently not subject to pre-market approval by HSA. For dealers who are interested to implement e-labelling, please inform HSA by submitting the online form here. Please note that you will be requested to submit the following information in the online form:

- List of products that will incorporate e-labelling
- Proposed image(s) or document of the e-label for each product

2.9 For questions and answers on voluntary e-labelling for CHP, please refer to Appendix 1.

2.10 For other enquiries related to e-labelling, please email HSA_CHP@hsa.gov.sg

Appendix 1 – Questions and Answers on Voluntary Electronic Labelling for Complementary Health Products

1. Is it mandatory to incorporate electronic labelling (e-labelling) for Complementary Health Products (CHP)?

The e-labelling initiative for CHP is currently on a voluntary basis.

2. What are the types of CHP that are considered for this e-labelling initiative?

E-labelling may be used on all types of CHP. Currently, CHP include Chinese Proprietary Medicines (CPM), Health Supplements (HS), Traditional Medicines (TM) and any other CHP as determined by the Health Sciences Authority (HSA).

3. Do I have to inform HSA when I want to implement e-labelling for my CHP?

Dealers who are interested to implement e-labelling are required to inform HSA prior to implementation.

4. What should I do if I have further label updates after I have implemented e-labelling for my listed CPM?

Approval of label updates by HSA is required for CPM via CPM amendment applications in PRISM. The e-labels should be updated within 30 days of approval of any label update.

5. Do I have to inform HSA when I stop using e-labelling for my CHP?

Dealers who have decided to stop using e-labelling are required to inform HSA via email: HSA_CHP@hsa.gov.sg

6. Can I omit information on my product's outer packaging if I incorporate e-labelling for my CHP?

Please ensure that the product labels fulfill the relevant labelling requirements. You may refer to the following websites for the respective labelling requirements for CPM, HS and TM:

- For CPM, please click here
- For HS and TM, please click here

HEALTH SCIENCES AUTHORITY

Health Products Regulation Group
Blood Services Group
Applied Sciences Group

www.hsa.gov.sg

Contact information
Complementary Health Products Branch
Medicinal Products Pre-Market Cluster
Health Products Regulation Group
Health Sciences Authority

11 Biopolis Way
Singapore 136667
www.hsa.gov.sg
Email: hsa_chp@hsa.gov.sg

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