MINISTRY OF HEALTH MALAYSIA

NATIONAL PHARMACEUTICAL REGULATORY AGENCY

GUIDELINE ON ELECTRONIC LABELLING (E-LABELLING) FOR PHARMACEUTICAL PRODUCTS IN MALAYSIA

Second edition, August 2025

PREFACE

This guidance document is issued by the Senior Director of Pharmaceutical Services under Regulation 29, Control of Drugs and Cosmetics Regulations 1984.

This document is intended to provide general guidance. Although great care has been taken in compilation and preparation of this publication to ensure the accuracy, National Pharmaceutical Regulatory Agency (NPRA) cannot in any circumstances accepts liability for any errors or omission in this document, or any action/decision taken or not taken as a result of using this document. In the event of any contradiction between the contents of this document and any written law, the latter should take precedence.

CONTACT INFORMATION

For further information, please contact:

National Pharmaceutical Regulatory Agency (NPRA)
Ministry of Health Malaysia
Lot 36, Jalan Profesor Diraja Ungku Aziz,
46200 Petaling Jaya, Selangor

Email: sdps@npra.gov.my
Contact no.: +603-7883 5400
Website: https://www.npra.gov.my

ABBREVIATIONS

The following abbreviations are used in this document:

DCA	Drug Control Authority
DRGD	Drug Registration Guidance Document
HCP	Healthcare Professionals
IPRP	International Pharmaceutical Regulators Programme
ICDRA	International Conference of Drug Regulatory Authorities
NPRA	National Pharmaceutical Regulatory Agency
PI	Package insert
PIL	Patient Information Leaflet
PRH	Product Registration Holder
RiMUP	Consumer Medication Information Leaflet

TABLE OF CONTENT

1. BACKGROUND

Medical product information (here after product information) is a document providing officially approved information for healthcare professionals and patients on a medicine. The product information includes the summary of product characteristics, package information leaflet and labelling. The information is based on clinical development and post-marketing data, translated into descriptive text suitable for Healthcare Professionals (HCPs) and for the patients, respectively.

Product information plays a pivotal role in ensuring patients' understanding of their treatments while also supporting HCPs in their decision making. For product information to become more effective, new, digital-enabled tools are key components in enabling more effective use of available treatments and helping raise overall health literacy. These tools will facilitate a swifter access, better understanding and improved usability.

One emerging trend that fits in this category is electronic labelling, or e-labelling. E-labelling is defined as the dissemination of approved product information for medicinal products in a dynamic digital format allowing for the development of personalized product information based on the needs of the patients and healthcare professionals

Approximately half of the countries in Asia have published product information in PDF format on their Health Authority (HA) websites. In Malaysia, e-labelling is proposed by industry since 2019 to be line with the healthcare digitalization initiatives which was discussed in International Pharmaceutical Regulators Programme (IPRP) and International Conference of Drug Regulatory Authorities (ICDRA) where e-labelling and reliance have been the main topic discussed. The implementation of e-labelling is in line with the global advancement in digital healthcare and e-labelling has become one of the emerging trends that is moving at different speeds around the world. Several countries have adopted e-labelling as means to provide patients and HCPs easy access to the latest product information.

Currently, Malaysia has adopted the use of e-labelling for COVID-19 therapeutics and vaccines based on the global packs which has been evaluated and approved in the Drug Control Authority (DCA) reference countries. This is to ensure that the needed information is distributed swiftly with the rapid distribution of the products nationwide in the time of the COVID-19 pandemic.

2. OBJECTIVE

This document serves as a guide for the implementation of voluntary e-labelling. The document shall be reviewed when necessary.

3. DEFINITION

E-labelling is defined as the provision of an approved product information that includes the package insert (PI) and/or Consumer Medication Information Leaflet (RiMUP) electronically via a machine readable Quick Response (QR) code on the outer carton/inner label of the product that links to the NPRA QUEST system.

When PI and/or RiMUP is distributed via e-labelling, physical printed copies may also be distributed with the product. It is the responsibility of the Product Registration Holder (PRH) to provide the physical printed copies when it is required.

4. GENERAL GUIDANCE AND CONDITIONS FOR E-LABELLING

4.1 Products eligible for e-labelling

The implementation of e-labelling is voluntary and applies to new drug products, biologics, and generic products containing scheduled poisons and non scheduled poisons for human use only. Extension of e-labelling to other product categories will need to be further reviewed.

4.2 Acceptable e-labelling formats

E-labelling shall be presented in a QR code on the outer carton/inner label of the product that translates to NPRA QUEST3+ page which displays the same product information in a pdf format. The format would allow optimized viewing on any electronic devices such as smartphones/ laptops/ tablets.

Product information in video format is currently not allowed

Note: The maximum capacity of product information (e-labelling) to be uploaded and hosted in QUEST3+ system shall not exceed 5MB

4.3 Accessibility of e-labels

The approved e-label content shall not be modified by any means. The product information used shall be approved by DCA. A partially extracted package insert of DCA-approved product is not allowed.

PRH may display the QR code on the outer packaging (e.g. outer carton) of the products or where there is no outer packaging, on the inner label.

The QR code may be printed or affixed onto the outer carton/inner label using a stick-on label. If the stick-on label method is used, the following criteria should be met:

a) The stick-on label shall not cover any information on the outer carton or inner label.
b) The stick-on label shall be made from good quality materials and is not easily torn or peeled off.
c) This activity shall be carried out in a licensed secondary repacker facility that complies with Good Manufacturing Practice (GMP)/Good Distribution Practice (GDP) requirements.

4.4 PRH's roles and responsibilities

PRH are responsible for ensuring that the product information that appears in the QUEST3+ system are aligned to the most up-to-date PI/RiMUP information as approved. Upon approval of any label update, the e-labelling should be updated immediately.

PRH may include proposals for e-labelling in the dossier submission for new product registrations. The process remain the same as submission for new product registration.

Changes to current approved labels solely to incorporate e-labelling without any changes to the approved product information may be submitted as 'Minor Variation Notification (MiV-N): E-labelling Verification' using the current variation procedure.

The purpose of this variation category is solely to confirm the accessibility and readability of the submitted e-labelling.

4.5 E-labelling requirements

The use of e-labelling is subjected to the product labelling requirements as stipulated in the current edition of the Drug Registration Guidance Document (DRGD). Failure

to comply with the requirements of e-labelling may result in regulatory actions.

5. REFERENCES

i. Asia-Pacific Economic Cooperation Secretariat. (2017). *www.apec.org.* Retrieved from Best Practices for Electronic Labelling: https://www.apec.org/Publications/2017/11/Best-Practices-for-Electronic-Labeling

ii. Health Sciences Authority. (2022, June). *www.hsa.gov.sg.* Retrieved from Guidance on Therapeutic Product Registration in Singapore: https://www.hsa.gov.sg/docs/default-source/hprg-tpb/guidances/guidance-on-therapeutic-product-registration-in-singapore_jun22.pdf

iii. IFPMA. (2022). *www.ifpma.org.* Retrieved from IFPMA Position Paper- Use of Electronic Labelling Imporving Patient Safety and Health Systems Resilience through the Use of Electronic Labelling: https://www.ifpma.org/resource-centre/position-paper-use-of-electronic-labeling/

iv. Malaysian Variation Guideline For Pharmaceutical Products, National Pharmaceutical Regulatory Agency, 2nd Edition, July 2022