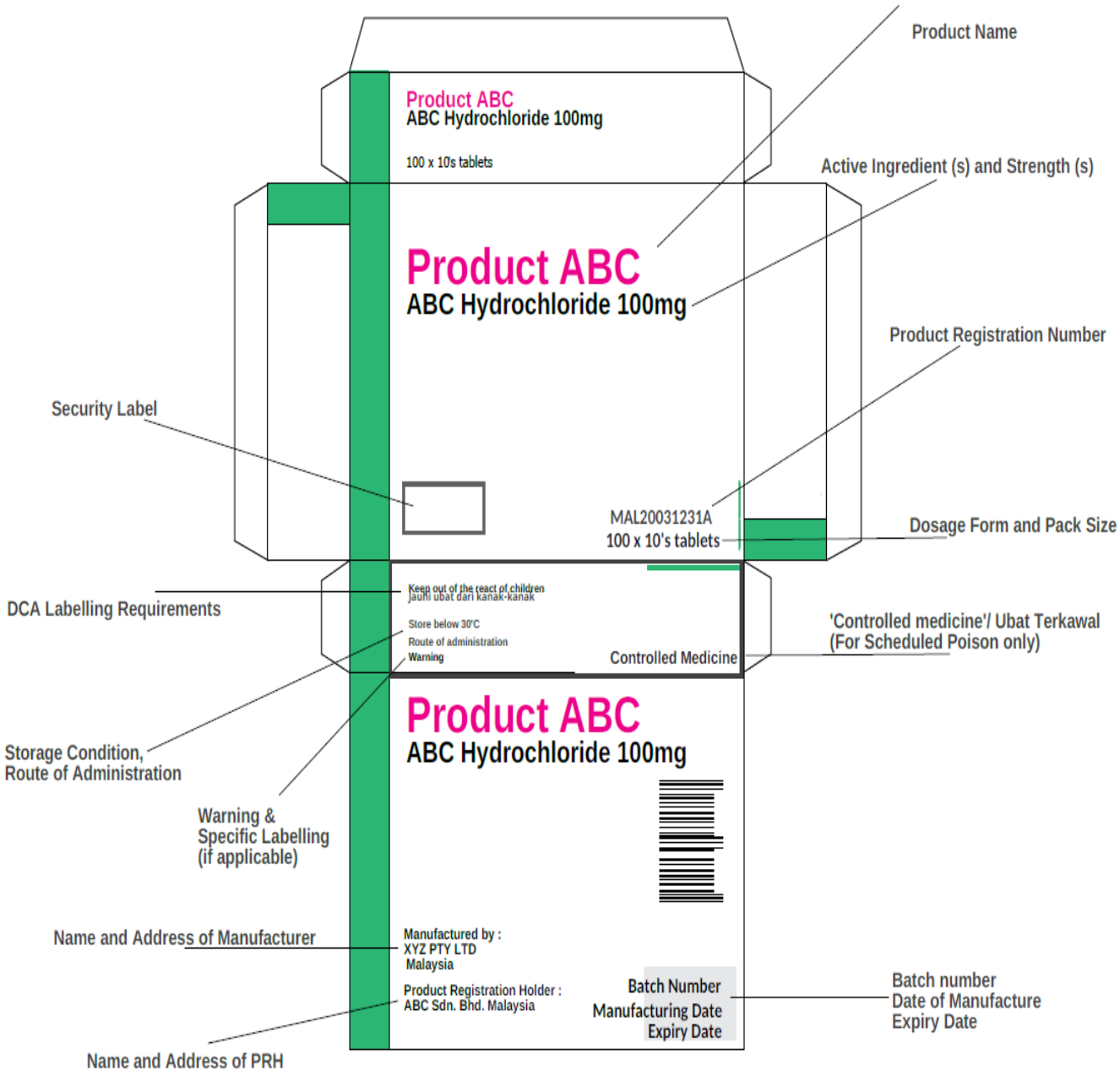
# APPENDIX 19

# GENERAL LABELLING REQUIREMENTS

## 1. LABEL FOR IMMEDIATE CONTAINER AND OUTER CARTON



The following information in **Table 1** below shall be present on the label of a product at the outer carton, immediate container or blister/ strips:

| No. | Parameters | Outer Carton (Unit Carton) | Immediate Labels | Blister/ Strips |
|---|---|---|---|---|
| 1. | Product Name | ✓ | ✓ | ✓ |
| 2. | Dosage Form | ✓ | ✓* | NA |
| 3. | Name of Active Substance(s) | ✓ | ✓ | ✓** |
| 4. | Strength of Active Substance(s) | ✓ | ✓ | ✓** |
| 5. | Batch Number | ✓ | ✓ | ✓ |
| 6. | Manufacturing Date | ✓ | ✓* | NA |
| 7. | Expiry Date | ✓ | ✓ | ✓ |
| 8. | Route of Administration | ✓ | ✓ | NA |
| 9. | Storage Condition | ✓ | ✓* | NA |
| 10. | Country's Registration Number | ✓ | ✓* | NA |
| 11. | Name & Address of Product Registration Holder (PRH) | ✓ | ✓* | Name/ Logo of Manufacturer/ Product Owner |
| 12. | Name & Address of Manufacturer | ✓ At least name of town/ city and country of manufacturer | ✓* At least name of town/ city and country of manufacturer | NA |
| 13. | Warnings and/or Specific Labelling (if applicable) | ✓ | ✓* | NA |
| 14. | Pack Sizes (unit/ volume) | ✓ | ✓ | NA |
| 15. | Name & content of preservative(s) where present | ✓ | ✓* | NA |
| 16. | Name & content of alcohol, where present | ✓ | ✓* | NA |
| 17. | To declare source of ingredients derived from animal origin, unless a satisfactory confirmation can be provided verifying the absence of animal materials in the final product. | ✓ | ✓* | NA |

| No. | Parameters | Outer Carton (Unit Carton) | Immediate Labels | Blister/ Strips |
|---|---|---|---|---|
| 18. | To declare the source of capsule shell (if applicable) | ✓ | ✓ | NA |
| 19. | Recommended daily allowance (RDA) for vitamins/ multivitamins/ mineral preparations used as dietary supplements (optional) | ✓ | ✓ | NA |
| 20. | The words "Keep medicine out of reach of children" or words bearing similar meaning in both *Bahasa Malaysia* & English | ✓ | ✓* | NA |
| 21. | Other country specific labelling requirements (if applicable) | ✓ | ✓* | NA |
| 22. | The words "Controlled Medicine" or "*Ubat Terkawal*" (For scheduled poison only) | ✓ | ✓* | NA |
| 23. | Security Label (Hologram) | ✓ # | - | NA |
| 24. | Presence of tartrazine (if any) E.g. This product contains Tartrazine/ FD & C Yellow No. 5/ MA Yellow A-2/ Aluminic Lake | ✓ | ✓ | NA |

*NA: Not Applicable*

* Exempted for small labels (i.e. 5ml and less*)* used for ampoules/ cartridge, vials, eye drops, ear drops, and nose drops.

** For multi-vitamins and minerals preparations, it is suggested to be labelled as "multi-vitamins and minerals".

\# i. If the product does not have an outer carton, the security label shall be affixed onto the immediate label.

ii. For large volume parenteral (LVP) products defined as containers labelled as containing more than 100mL [based on the United States Pharmacopeia (USP)], the security label (hologram) shall be affixed on the immediate label of each unit of the product.

iii. The security label (hologram), however, shall not be affixed to the outer shrink wrap of the product.

iv. The following are exempted from the security label requirement:

- Small labels (i.e. volume of 5mL and less). E.g. ampoules/ cartridges/ vials.
- Radiopharmaceutical with short half-life, temperature-sensitive and cold chain products. E.g. vaccines, etc.
- It is sufficient for the security label (hologram) to be affixed to the outer carton / unit of sale for small volume parenteral (SVP) products [defined as packaged in containers and labelled as containing 100mL or less based on the United States Pharmacopeia (USP)].

No. 15, 20, 22 and 23 of the above are country specific requirements for Malaysia.

**Additional Requirements:**

a) All labels and package inserts must be in *Bahasa Malaysia* or English. In addition to this, translation to another language is allowed.

b) If the product is without an outer carton, the inner label shall bear all the required information.

c) The link to the official company website or website for any purpose of product promotion by the PRH/ product owner/ manufacturer is not allowed to be printed on the product label (applicable to all product categories, including imported products). However, the company email address is permitted on the label.

d) The label colours shall differentiate the different strengths of the product as well as products containing different active ingredients that belong to the same PRH.

e) A registered product is required to have the same label artwork for all pack sizes, but may have **minor** differences in colour code to differentiate pack sizes.

f) Stick-on label refers to an additional label affixed onto an approved immediate label (D1) and/or outer carton (D2). The stick-on label shall not cover any information on the approved immediate label (D1) or outer carton (D2). The stick-on label shall be made from good quality material and not easily torn or peeled off.*

Stick-on label of the following is permitted:*

i. 'Controlled Medicine/*Ubat Terkawal*' (For scheduled poisons only), 'Keep out of reach of children', '*Jauhkan daripada capaian kanak-kanak*' (reiterations that are similar in meaning is allowed), and Product Registration Holder information. These statements shall be printed on a single label.

ii. Malaysia-specific label requirements such as name and content of preservative(s)

iii. Specific labelling requirements of a product according to **Appendix 20: Specific Labelling Requirements**

iv. '*Diimport/diedarkan oleh…*'

v. 'Halal logo' according to 7.14 *Halal* Logo

vi. Security label (hologram)

vii. 'Sample Not For Sale', 'Physician's sample not for sale', or 'Professional sample not for sale'

viii. Barcode (inventory management)

ix. QR Code (e-labelling/ inventory management)

x. Security seal (tamper-evident feature)

xi. Recommended Distributor's Price (RM)/ Recommended Retail Price (RM) (Optional)

** The terms above should be read in its entirety and together with **Appendix 32: Explanatory Notes for Repackers** to ensure full understanding and correct implementation.*

No other stick-on label is permitted. Any usage of stick-on label other than the above shall require prior approval by the Authority.

g) The registration number shall be printed permanently on the product (inkjet) and it is not allowed to be printed on the stick-on label.

h) Use of QR code/barcode is permitted only for the purpose of monitoring inventory of the product, such as batch number, expiry date and manufacturing date, BUT NOT for linkage to any website. The addition of QR code/barcode for this purpose on registered product labels without variation approval from NPRA may be considered only if that is the only proposed change to the currently approved labels.

The use of a QR Code for the purpose e-labelling is permitted in accordance with the Guideline on Electronic Labelling (E-Labelling) for Pharmaceutical Products in Malaysia.

i) The label of a registered product containing any Scheduled Poison shall not have colourful artwork or graphics that can be misleading or will adversely influence caregivers'/patients'/children's perceptions of the appropriateness of the medication.

j) Font size of the product name on the label, including alphabets and numbers, shall be equal.

k) For a product containing two (2) or more active ingredients, the font of each active ingredient that is highlighted on the inner/outer carton must be of equal size and prominence.

- This does not refer to the product name, but the statement made on the label.

- Justification for highlighting only certain ingredients on the product name/label must be provided and is subject to approval by the Drug Evaluation Committee.

l) Declaration of nutrition information per serving (e.g. energy, carbohydrate, protein and fat) is not permitted on a health supplement product label.

m) For information regarding **e-labelling**, refer to:

(i) **Directive No. 3, 2023**. *NPRA.600-1/9/13(21) Jld.1 Direktif Berkenaan Pelaksanaan Electronic Labelling (E-labelling) Ke Atas Produk Farmaseutikal Di Malaysia*

(ii) **Directive No. 11, 2025**. *NPRA.600-1/9/13 (58) Jld.1 Direktif Berkenaan Peluasan Skop Produk Yang Melaksanakan Electronic Labelling (E-Labelling) Kepada Kategori Produk Generik Bukan Racun Berjadual (Over-The-Counter, OTC)*

(iii) Guideline on Electronic Labelling (E-labelling) for Pharmaceutical Products in Malaysia, Revision 2 August 2025

## 2. PROHIBITED VISUAL/ GRAPHICS/ STATEMENTS ON LABEL

The list of prohibited visual/ graphics/ statements on label are as specified in **Appendix 19A: Prohibited Visual/ Graphics/ Statements On Label**.

Also refer to:

- **Appendix 6: Guideline on Registration of Health Supplements**
  Table 7: Prohibited Visual/ Graphics on Label
- **Appendix 7: Guideline on Registration of Natural Products**
  Table 11: Prohibited Visual/ Graphics/ Statement on Packaging Materials (Label, Box, Package Insert or Consumer Medication Information Leaflet)