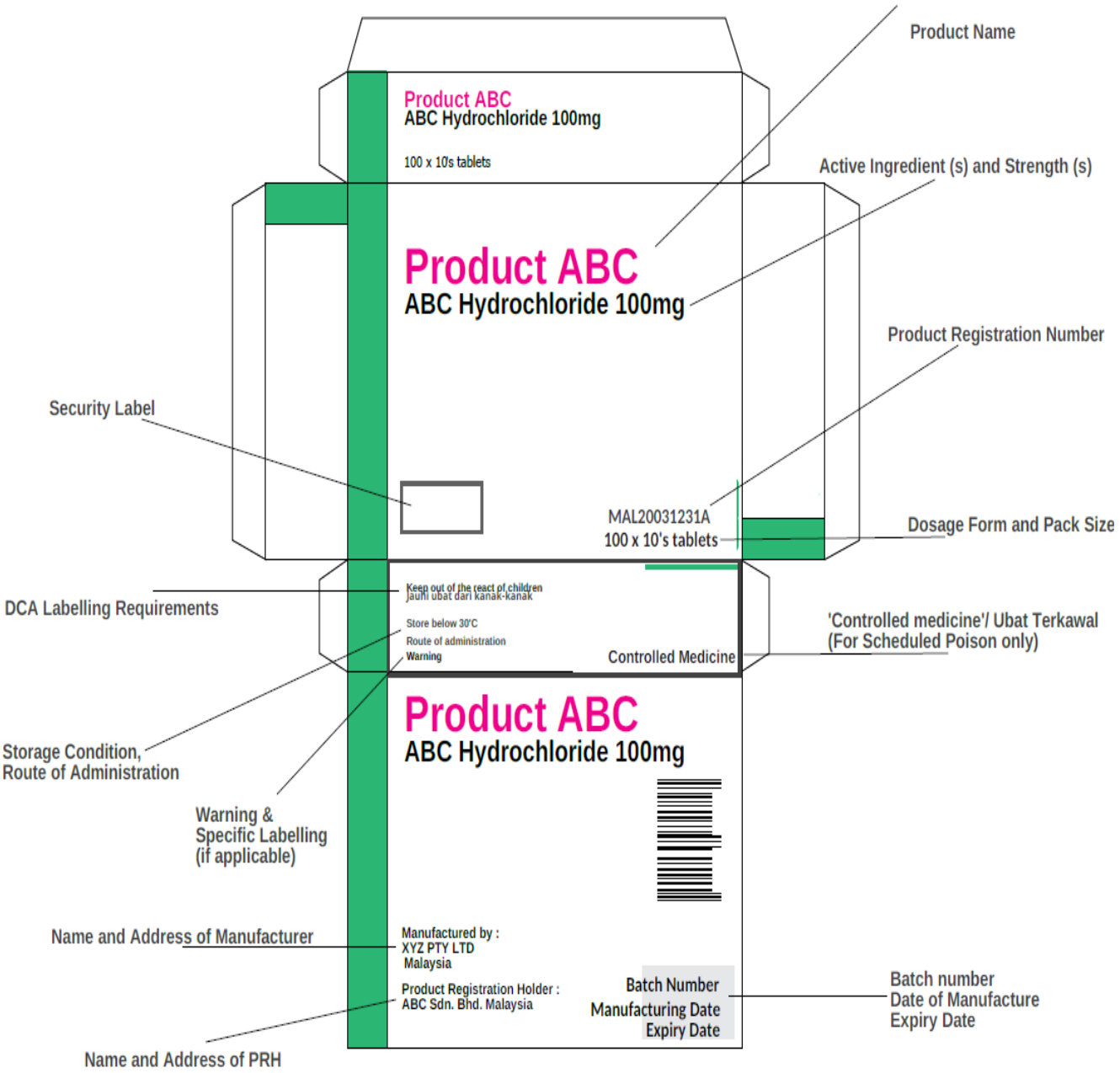
APPENDIX 19

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 (active and excipient) including starting materials and gelatine	✓	✓	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

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) Only a single label artwork is permitted for all pack sizes of a registered product.

f) No stick-on label is permitted. Any usage of stick-on label shall have prior approval by the Authority. The label shall be made from good quality material and not easily torn or peeled off. The Authority will only consider the following situations:

Stick-on label of such information is permitted:

Words with "Controlled Medicine", "*Ubat Terkawal",* "Keep out of reach of children" and *"Jauhkan daripada capaian kanak-kanak"*, PRH information, and Malaysia Specific Labelling Requirements (if any) shall be printed in a single label.

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 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 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.

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.

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)