SECTION D: LABEL (MOCK-UP) FOR IMMEDIATE CONTAINER, OUTER CARTON, PROPOSED PACKAGE INSERT & PRODUCT INFORMATION LEAFLET (PIL)

D1. Label (Mock-up) for Immediate Container

D2. Label (Mock-up) for Outer Carton (Unit Carton)

Outer (Carton) & Inner/Immediate Labels, & Blister/ Strips

The following information should be present on the labelling of the product:

No.	Parameters	Unit Carton	Inner/ 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.	Expiration Date (eg: Shelf-life of the veterinary product as packaged for sale /Shelf life after first opening of container/ Shelf life after dilution)	✓	✓	✓
8.	Dosage and Administration	✓	✓	NA
9.	Storage Condition	✓	✓*	NA
10.	Country's Registration Number	✓	✓*	NA
11.	Name & Address of Manufacturer	✓	✓*	NA
12.	Name & Address of Registration Holder	✓	✓*	NA
13.	Warnings/Precautions (if applicable)	✓	✓*	NA
14.	Pack Sizes (unit/volume.)	✓	✓	NA

15.	Direction for Use	✓	✓*	NA
16.	Withdrawal Period (product for food producing animal)	✓	✓*	NA
17.	Name & content of preservative(s) where present	✓	✓	NA
18.	To declare source of ingredients derived from animal origin, including gelatin (active, excipient, and /or capsule shell)	✓	✓*	NA
19.	The words “Keep out of reach of children” or words bearing similar meaning in B.M. and English	✓	✓	NA
20.	The words “ For animal use only” or words bearing similar meaning	✓	✓	✓
21.	Disposal of containers	✓	✓*	NA
22.	Other specific labelling requirements (if applicable)	✓	✓*	NA
23.	Statement on Controlled Medicines/Ubat Terkawal for product containing Scheduled Poison only	✓	✓*	NA

NA – Not applicable

✓* Exempted for <u>small</u> labels such as used in ampoules and vials

✓ Mandatory

If the product is without an outer carton, the inner label should bear all the information that is required

D3. Proposed Package Insert

- Required for products classified as Scheduled Poisons.
- May also be submitted for OTC products.
- Following information is required to be included in the package insert:

i) Brand or Product Name

ii) Name and Strength of Active Substance(s)

iii) Product Description

iv) Pharmacodynamics/ Pharmacokinetics/ Environmental Properties
v) Indication
vi) Recommended Dosage
vii) Mode of Administration
viii) Contraindications
ix) Warnings and Precautions
x) Interactions with Other Medicaments
xi) Statement on usage during pregnancy and lactation
xii) Adverse Effects/ Undesirable Effects
xiii) Overdose and Treatment
xiv) Incompatibilities (for injections only)
xv) Withdrawal Period(s)
xvi) Storage Conditions (may be omitted if the information is stated on the label or outer carton labels)
xvii) Dosage Forms and packaging available
xviii) Name and Address of Manufacturer and Marketing Authorisation Holder
xix) Date of Revision of Package Insert

D4. Product Information Leaflet

- May be submitted as additional information for Scheduled poison and OTC products.
- Following information is required to be included in the PIL:

i) Name of Product
ii) Description of Product
iii) What is the medicine?
iv) Strength of the medicine
v) What is this medicine used for?
vi) How much and how often should you give this medicine to animal?
vii) When should you not give this medicine to animal?
viii) Undesirable effects/ side effects
ix) What other medicine or food should be avoided whilst giving this medicine to animal?
x) What should you do if you miss a dose for the animal?
xi) How should you keep this medicine?
xii) Signs & symptoms of overdose
xiii) What to do when you have given more than the recommended dosage to the animal?

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xiv) Name/logo of manufacturer/importer/marketing authorisation holder
xv) Care that should be taken when giving this medicine to animal?
xvi) When should you consult your veterinarian?