

**PRODUCT LITERATURE STANDARD (PLS) FOR VETERINARY MEDICINAL PRODUCTS:
GUIDANCE FOR INDUSTRY**

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1. Introduction

The information in the Product Literature Standard (PLS) will assist applicants in creating product labels that will help them get it right first time. Taking note of the sections below will greatly enhance applicants' chances of presenting the right information on product labels.

2. What information should appear on the label?

The table below shows the minimum amount of information which should appear on the package leaflet, primary or immediate packaging as well as secondary packaging materials. If it is not practical to include all of the information on the immediate or outer packaging, a package leaflet must be included and the statement 'Read the package leaflet before use' should appear on the outer and immediate packaging.

It is important that the information on a blister pack remains available to the user up to the point when the last dose is removed. Often it is not possible to display all the information over each blister pocket. Random displays of information should appear frequently. It is acceptable to apply the batch number and expiry date at the end of the blister.

a. Particulars to Appear on the Immediate/ Primary Packaging Material (for product containing a Package Insert)

- Brand name of Veterinary Product
 - Generic name of Veterinary Product
 - Dosage form
 - Strength of active substance(s)
 - List of excipients
 - Content by weight, volume, number or doses
 - Indications (For non-prescription products)
 - Target species
 - Withdrawal period for the individual foodstuffs e.g. meat, eggs, milk
 - Storage instructions
 - Batch number, manufacturing and expiry dates
 - The statement 'For Veterinary Use Only'
 - The statement 'Keep out of reach and sight of children'
 - In-use storage conditions (where applicable)
- Keep out of reach and sight of children'

b. Particulars to Appear on the Immediate/ Primary Packaging Material (for product containing no Secondary Package and Package Insert)

- Brand name of Veterinary Product
- Generic name of Veterinary Product
- Dosage form
- Strength of active substance(s)
- List of excipients

- Content by weight, volume, number or doses
- Indications (For non-prescription products)
- Target species
- Dosing
- Mixing instructions (product for reconstitution)
- Method/ route of administration
- Withdrawal period for the individual foodstuffs e.g. meat, eggs, milk
- Storage instructions
- Warnings and precautions
- Disposal advice
- Batch number, manufacturing and expiry dates
- The statement 'For Veterinary Use Only'
- The statement 'Keep out of reach and sight of children'
- In-use storage conditions (where applicable)
- Name and full address of finished product manufacturer (s)

c. Particulars to Appear on the Immediate/ Primary Packaging Material (Blisters)

- Brand name of Veterinary Product
- Generic name of Veterinary Product
- Strength of active substance(s)
- Storage instructions
- Batch number, manufacturing and expiry dates
- The statement 'Keep out of reach and sight of children'
- Name of manufacturer

Finished products in blisters should always be packed in secondary packaging materials with a package insert in the pack.

d. Particulars to Appear on a Secondary Package

- Brand name of Veterinary Product
- Generic name of Veterinary Product
- Dosage form
- Strength of active substance(s)
- List of excipients*
- Content by weight, volume, number or doses
- Indications (For non-prescription products)
- Target species
- Dosing*
- Method/ route of administration*
- Mixing instructions (product for reconstitution)*
- Withdrawal period for the individual foodstuffs e.g. meat, eggs, milk

- Storage instructions
- Warnings and precautions*
- Disposal advice
- Batch number, manufacturing and expiry dates
- The statement 'For Veterinary Use Only'
- The statement 'Keep out of reach and sight of children'
- In-use storage conditions (where applicable)
- Name and full address of finished product manufacturer (s)

****Applicable when product has no package insert***

e. Particulars to Appear on the Package Insert

- Brand name of Veterinary Product
- Generic name of Veterinary Product
- Dosage form
- Strength of active substance(s)
- List of excipients
- Content by weight, volume, number or doses
- Indications (For non-prescription products)
- Target species
- Dosing
- Method/ route of administration
- Mixing instructions (product for reconstitution)
- Withdrawal period for the individual foodstuffs e.g. meat, eggs, milk
- Storage instructions
- Warnings and precautions
- Disposal advice
- The statement 'For Veterinary Use Only'
- The statement 'Keep out of reach and sight of children'
- In-use storage conditions (where applicable)
- Name and full address of finished product manufacturer (s)
- Date of approval/ review of package insert

f. Particulars to Appear On the Immediate Diluent Label

- Name of diluent
- Chemical composition
- Content by volume
- Route(s) of administration
- Storage conditions
- Batch number, manufacturing and expiry dates
- The words "For animal treatment only"

4. How to present the Strength and Total Content of a product

- Applicant may need to include both quantity per unit volume and total quantity per total volume where applicable.
- Different strengths of the same product should be expressed in the same format e.g. 100 mg, 500 mg, 1000 mg.
- Unless space is limited micrograms should be spelt out in full, not abbreviated.
- Trailing zeros should not be used e.g. 2.5 mg not 2.50 mg.

5. Labeling Requirements for Multilingual Labels

- All labels and packaging must be in English. They may also contain other languages provided the legibility of the English text is not compromised.

6. Readability of label

The following should be taken into consideration during the design of labels:

a. Type Style and Size

- The type of font should be easy to read. Stylised fonts which are difficult to read should not be used.
- Choose a font that clearly distinguishes between similar characters e.g. “i”, “l” and “1”.
- *Italics* should be used for Latin terms e.g. citing correct nomenclature and microorganisms.
- The font size should be as large as possible and must be clearly legible and understood by the end user.

Type of Packaging	Recommended Font Size	Minimum Font Size
Small Immediate Pack	Not less than 7	6
Immediate Packaging	Not less than 8	7
Outer packaging	Not less than 9	8
Package insert	Not less than 9	8

If you can't use the recommended font size, please include a justification for this when submitting application.

b. Use of Colours

- Colours should have a good contrast between the text and the background.
- The legibility of information should not be compromised by the colours chosen such as the use of similar colours being used for the text and background, use of different colours that makes the product name more difficult to identify.
- Preferably, dark text should be printed on a light background.

c. Design and Layout

- Legibility of information should not be compromised by design.
- Where possible, line spaces should be kept clear.
- Related information should be kept together so that information flows from one column to the next.
- Multilingual labels should have a clear separation between the different languages.

7. Headings

- Headings help users navigate the text.
- Bold type and different colours help this information stands out.
- Spacing above and below the headings should be consistent throughout the packaging.
- The use of multiple headings/ combining headings should be avoided as much as possible as this may cause confusion.

8. Changes Requiring Variations

- Changes to the colouring of the product literature, use of different colours etc.
- New corporate design of packaging
- New container type / size
- Changes to the layout of the package
- Introduction of multilingual packs for an already approved product

9. Definitions

Immediate Packaging: The container or any other form of packaging that is in direct contact with the Veterinary Medicinal Product (VMP) e.g. vials, ampoules, bottles, blister packs, etc. The immediate packaging does not include capsules which are administered as part of the product.

Outer Carton: The packaging into which the immediate packaging is placed e.g. cartons, boxes, packets, etc.

Label: Information on the immediate or outer packaging.

Package Leaflet: The leaflet that contains information for the user which accompanies the VMP.

Summary of Product Characteristics (SPC)

Contains information on the VMP as agreed during the course of the assessment process

Mock-up A flat artwork design in full colour, presented so that it provides a full size replica of both the immediate, outer packaging and package leaflet so that the three dimensional presentation of the label text is clear.