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VETERINARY MEDICINES DIRECTORATE

GUIDELINES FOR LABELLING OF VETERINARY PHARMACEUTICALS

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INTRODUCTION

Labelling includes any printed, stenciled marked, embossed or impressed text or graphic matter on the immediate container, on the outer pack, and any other printed material supplied together with the veterinary medicinal product.

PURPOSE

a) To describe and identify the product
b) To avoid medication errors
c) To contribute towards optimal therapeutic outcome
d) To achieve proper handling and storage of the product
e) To allow the product to be traced in the event of a concern such as a quality issue

SCOPE

The document will serve as a guide to establish minimum requirements for content in labels with reference to specific dosage forms and requirements for product information leaflets according to category of the medicine.

DEFINITIONS

Primary label – label upon the immediate container, i.e. container in direct contact with the product

Secondary label – label on the outer pack immediate to the container holding the product

Product information leaflet/Package insert (PI) – a leaflet accompanied with the medicinal product containing specific information about the product

Summary of Product Characteristics (SPC) – a document approved as part of the marketing authorization of each medicine. It contains more information than the product information leaflet

REQUIREMENTS

Label the container of every veterinary medicine imported, manufactured, processed or packed locally or sold or exposed for sale shall have a label bearing the following information in English language.

(a) The official or generic name[1] of the medicinal product followed by its pharmaceutical form[2] and strength[3]. If applicable, abbreviations for the official pharmacopoeia or formulary[4] in which specifications of the drug product are described in a monograph shall be included prior to the strength; e.g. Albendazole[1] bolus[2] B.P.[4] 500mg[3]

Where the product contains up to three active substances, the international non-proprietary name (INN) or any other commonly used official name such United States Approved Name (USAN) or British Approved Name (BAN) shall be included. If there are more than one official name for an active substance, the name that has been used most commonly in Kenya shall be preferred. For products containing more than three active substances, name descriptive of the true nature of the medicinal product shall be used. (E.g. Multivitamin)

(b) If conformity with a pharmacopoeial monograph is claimed for a product, relevant labeling requirements given in both general and specific monographs shall be adhered to.

(c) The brand/proprietary name. The brand name should not be already registered for another product. Also, VMD reserves the right to refuse a brand name which is partially similar to an existing product and could lead to mix up with another medicine, or a brand name deemed inappropriate due to reasons such as exaggeration of its action.

(d) A statement of the active substance(s) showing quantitative particulars:

i. The quantity of each active ingredient, identified by its appropriate non-proprietary name, in each dosage unit of the medicinal product expressed in terms of weight, volume, capacity or units of activity; or
ii. where there is no dosage unit, the quantity of each active ingredient identified by its appropriate non-proprietary name, in the container of the medicinal product expressed in terms of weight, volume, capacity or units of activity or percentage by weight or volume of the total quantity; For active substances present as salts, they should be clearly indicated. E.g. each suspension contains Amoxicillin trihydrate equivalent to Amoxicillin 250mg

(e) Pack size: the number of doses, weight, or volume contained in the pack

(f) Excipient(s) known to have undesirable effects and any other ingredients specified by the Authority. Particularly, presence of the following ingredients should be indicated:

(i) Colourant(s) contained in the formulation of any medicinal product
(ii) Sweeteners used as inactive ingredients (quantity in milligram per dosage unit)
(iii) Alcohol content in oral liquids (as a percentage)
(iv) Presence of benzyl alcohol in parenteral preparations.
(v) Preservatives contained in ophthalmic products. (as a percentage)
(vi) Any added microbial preservatives in parenteral preparations. (as a percentage)

(g) The dosage form

(h) The route of administration for injectable products

(i) Storage temperature and, other special storage precautions if any

(j) A special warning that the product must be stored out of reach of children.

(k) Specific instructions if the product needs to be reconstituted, diluted, or prepared by any other means prior to its use

(l) For injectable solutions, not to use if visible particles are present.

(m) Any other special warnings and precautions that may be necessary for the particular medicinal product.

(n) The date of manufacture in clear terms (month/year)

(o) The date of expiry in clear terms (month/year)

(p)The batch or lot number assigned by the manufacturer, and

(s) The period for which the medicine can be used after opening of the container or after reconstitution of the product, if applicable.

(t) Specific precautions related to disposal of unused quantities of the product, if applicable. (u) The name of the manufacturer and address of the manufacturing site. When the product owner is different to the manufacturer, the label shall indicate in the following manner: 'manufactured by (name and address of actual manufacturer) for (name and address of product owner)'.

Exemptions for smaller labels

Primary labels on smaller containers such as a blister strip, an ampoule or vial with a volume of 10 ml or less shall contain the following minimum information.

(a) the generic or common name,

(b) the brand name (where applicable),

(c) the strength of the drug,

(d) lot or Batch number,

(e) the date of manufacture and expiry

(f) the name or logo of the manufacturer or the product owner. In addition, route of administration shall be indicated for injections. This may be indicated in abbreviations. The information exempted on the primary label should be included on the outer carton and/or the leaflets. Where practicable, the name and strength of the product should appear over each blister pocket or be oriented centrally across the pack. It is important that the particulars remain available to the user up to the point at which the last dose is removed from the blister pack.

General

Information provided in the labels should be consistent with the information submitted in the application dossier.

All information required to be indicated on the label shall be displayed prominently, legibly and distinctly. Information that is required should be printed on the labels and use of over-stickers is not allowed. The outer carton labels for products with different strengths, dosage forms, or formulations of the same manufacturer should be adequately differentiated (e.g. by using different colour schemes) to minimise confusion and medication errors. The draft artworks, specimens or mock-ups of outer cartons and primary labels submitted in the dossier should be consistent with the formats, designs and colours of the original labels that would be used on commercial packs to be marketed. Handwritten information on the artworks, specimens, or mockups are not acceptable. QR codes or 2D barcodes on the product's labelling which are intended for logistics control are allowed. However, the inclusion of QR codes or 2D barcodes with links to promotional internet websites or other information sources is not allowed. Indication of website addresses is not allowed.

Product Information Leaflet / Package Insert (PI)
The container of every medicine classified under Category I, II and III of the VMD regulations shall be accompanied by a printed insert containing information drawn up in accordance the summary of product characteristics. It shall contain the particulars specified below:

(a) Generic or official name of the drug product, the dosage form, and the strength.

(b) Net content of the active substance(s). When an active substance is present as a salt, this should be clearly indicated.

(c) Brand or proprietary name.

(d) For products to be reconstituted before use, the appearance before reconstitution should be stated.

(e) For tablets/boluses designed with a score line, information on the purpose of the score-line should be given, e.g. 'the score line only serves to facilitate breaking for ease of swallowing and does not divide the tablet into equal half-doses', or 'the tablet can be divided into equal halves.

(f) Excipients contained in the product, of which the knowledge of presence is important for the safe and effective use of the medicinal product. (e.g. preservatives, colourants, antioxidants etc.)

(g) Pharmacodynamics/Pharmacokinetics – information to be mentioned in this section include:

(i) The pharmaco-therapeutic group and if available, the ATC code
(ii) Mechanism of action of each drug substance
(iii) Pharmacokinetic properties of each drug substance
(iv) Clinical trial information relating to clinical efficacy and safety; and
(v) Relevant pharmacogenetic information from clinical studies with data showing a difference in benefit or risk to a particular genotype or phenotype.

(h) Indication and usage – the therapeutic indication(s) of the product. Information shall include a concise statement of each of the medicine's approved indications, briefly noting any major limitations of use for any or all of its indications. If multiple indications exist, the information be presented in a bulleted format.

(i) Dosage and administration – the information required include, as appropriate:

(i) A concise summary of the recommended dosage regimen (e.g., starting dose, dose range, route of administration)
(ii) Maximum recommended/tolerated daily dose and the maximum dose for an entire course of therapy;
(iii) Monitoring requirements: advices relevant for dosage adjustment from monitoring of clinical symptoms and signs and/or laboratory investigations, when appropriate.

(j) Method/Route of Administration – only standard abbreviations should be used.

(k) Contraindications – situations where animals should never or generally not be treated with the medicine.

(l) Warnings and Precautions – circumstances where caution is required to ensure the safe and efficacious use of the product.

(m) Interactions – forms of interactions with other medicines.

(n) Use during Pregnancy/Lactation

(o) Adverse Effects/Undesirable Effects – a description of the adverse reactions under normal use of the medicine and, if necessary, action to be taken by the veterinarian. Provide an indication of severity, clinical importance and frequency, whenever possible.

(p) Overdose and Treatment – symptoms, signs and recommended treatment of overdose or accidental poisoning.

(q) Method of preparation – if applicable, the complete method of reconstitution or dilution should be stated. If not accompanied with the product, the names of suitable diluents or solvents to be indicated. The appearance of the product after reconstitution should be stated. As appropriate, the information on in-use shelf-life after dilution or reconstitution or first opening should be provided in this section or the section "Shelf life".

(r) Incompatibilities (for injections only)

(s) Storage Condition - The storage condition must be consistent with the conclusion of the stability testing and the conditions stated on the product label and/or outer carton.

(t) Shelf Life -The shelf life must be based on stability data furnished in the dossier and consistent with that stated on the product label and/or outer carton. The information on in-use shelf-life after dilution or reconstitution or first opening should be provided.

(u) Available pack size(s) - All pack sizes intended to be marketed should be listed. Reference should be made to the primary container closure system (e.g. glass vials, PVC/Aluminium blister, Alu/Alu blister, HDPE bottle, ampoule, etc.).

(v) Any other components accompanying the product should be indicated (e.g. solvent, syringe, measuring cup, needles, etc.). The primary container closure system of the diluent/solvent provided with the drug product should also be described.

(w) The name and address of the manufacturer, product owner and /or distributor. The site address should be compatible with the address indicated in the COPP and labels.

(x) The date on which the leaflet was last revised.