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**GUIDELINES FOR LABELLING VETERINARY PEST CONTROL PRODUCTS**

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Contents	
<b>Abbreviation</b> .....	3
<b>INTRODUCTION</b> .....	4
<b>PURPOSE</b> .....	4
<b>SCOPE</b> .....	4
<b>DEFINITIONS</b> .....	4
<b>I. The Primary package</b> .....	4
<b>II. LANGUAGE OF LABELS</b> .....	5
<b>1. Primary Label</b> .....	5
<b>2. Secondary Label</b> .....	6
<b>NOTICE TO USER</b> .....	6
<b>ILANI KWA MTUMIAJI</b> .....	6
<b>SELLER’S GUARANTEE(WARRANTY)</b> .....	6
<b>THIBITISHO</b> .....	6
<b>III. PICTOGRAMS AND COLOUR CODES.</b> .....	6
<b>IV. SMALL PACK LABELS</b> .....	7

**Abbreviation**

QR – Query code

MAH – Market Authorization Holder

## **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

### **I. The Primary package**

The following is the information that must appear and how it should appear on the primary package.

- (i) - Trade name of the products - Its physical form - Purpose of use
- (ii) Statement “READ THE LABEL BEFORE USING” Must appear prominently in capital letters.
- (iii) Statement “KEEP LOCKED OUT OF REACH OF CHILDREN” to appear prominently in capital letters.
- (vi) Nature and degree of hazard inherent in the pest control product and shown by a precautionary symbol and signal word.
- (vii) QR code
- (viii) Net content
- (ix) Name and address of Market Authorization Holder, Local Agent, Manufacturer or Distributor where applicable
- (x) Date of Manufacture
- (xi) Shelf life in original unopened container.

- (xiii) Batch No.
- b) Secondary label
  - (i) Brief description of product.
  - (ii) Directions of use that must include dosage rate in amount of formulation per the spray volume.
  - (iii) Significant hazards respecting handling, storage, and procedures to alleviate the hazards.
  - (iv) Decontamination procedures
  - (v) Disposal of product and empty containers
  - (vi) Significant hazards to things the product is to be used, and how to alleviate such hazards.
  - (vii) FIRST AID INSTRUCTIONS – in capital letters.
  - (viii) TOXICOLOGICAL INFORMATION/NOTICE TO DOCTOR.

## **II. LANGUAGE OF LABELS**

The VMD requires that information on every label shall be printed in both English and Kiswahili languages. However, due to lack of enough space especially on the small packs and non-existence of appropriate or standardized Kiswahili translation of some scientific words, the label be translated as follows, and the translations appear side by side.

### **1. Primary Label**

- (a) Trade name of product – English
- (b) Physical form(formulation) - English
- (c) Purpose of product - English/Kiswahili. The translation of this should be simple e.g. insecticide “kiuwa dudu”. A descriptive translation can be given on the secondary label
- (d) KEEP LOCKED OUT OF THE REACH OF CHILDREN - English/Kiswahili
- (e) Nature and degree of Hazard - English/Kiswahili
- (f) READ LABEL BEFORE USING - English/Kiswahili
- (i) QR code. - English
- (j) Net Contents - English
- (k) Name and Address of MAH, Manufacturer, Agent distributor - English
- (l) Manufacture/formulation date - English
- (m) Shelf life (in original unopened containers). - English/Kiswahili-translate as “Maisha Rafuni”
- (n) Batch No. - English

## **2. Secondary Label**

- (a) Brief description of product - English/Kiswahili
- (b) Directions for use - English/Kiswahili
- (c) Significant hazards respecting handling, storage and how to alleviate the hazards. - English/Kiswahili
- (d) Decontamination procedures - English/Kiswahili
- (e) Disposal of product & empty containers - English/Kiswahili
- (f) Significant hazards to things products to be used, public health, animals, plants or environment and how to alleviate the hazards. - English/Kiswahili
- (g) First aid instructions - English/Kiswahili as (“maelezo ya huduma ya kwanza”)
- (h) Toxicological information - English
  - Antidotes & remedial measures - English
  - Symptoms of poisoning - English
  - Ingredients that may affect treatment - English
  - Notice to doctor - English

Although this entire section on Toxicological information will be in English, a finishing line in Kiswahili should be added to read: PELEKA MJERUHI KWA DAKTARI.

### **NOTICE TO USER**

This pest control product is to be used only in accordance with the directions on this label. It is an offence under the VMD regulations to use or store a pest control product under unsafe conditions.

### **ILANI KWA MTUMIAJI**

Dawa hii sharti itumiwe kulingana na maangizo yaliyo kwenye kibandiko. Ni hatia chini ya sheria za madawa ya kuangamiza wadudu waharibifu kutumia au kuhifadhi dawa hii katika hali isiyo salama.

### **SELLER'S GUARANTEE(WARRANTY)**

Seller's guarantee is limited to the terms set out on the label and subject thereto, the buyer assumes the risk to persons or property arising from the use or handling of this product and accepts the product on that condition.

### **THIBITISHO**

Dhamana ya muuzaji ni maelezo yaliyo kwenye kibandiko ambayo ni lazima yafuatwe kikamilifu. Mnunuzi lazima akubali hatari zozote zinazoweza kutokana na matumizi ya dawa hii kwa binadamu au mali na lazima aikubali dawa hii katika hali hiyo.

## **III. PICTOGRAMS AND COLOUR CODES.**

1. Pictograms and colour codes shall be included on the primary package in all labels.
2. Pictograms so included must relate to the product text. Material safety data sheet (MSDS)

3. Minimum size of pictograms shall be 7mm x 7 mm.
4. Storage and wash after use pictograms must appear in every label.
5. Starting from the center, the activity pictogram shall precede followed by advice pictograms boxed together e.g. mixing followed by relevant pictograms.
6. The hazard symbol and word shall be symmetrically placed within the toxicity colour band, separating storage and mixing pictograms from spraying, washing and others if necessary.
7. Face shield shall be used instead of eye goggles, overalls sleeves worn over gumboots other than sleeves tucked inside boots, and running water instead of basin water.
8. Colour codes shall be used to band the pictograms on all labels and the colour so used shall relate to the toxicity of the product as follows; -
  - (i) Red (very toxic & toxic)
  - (ii) Yellow(Harmful)
  - (iii)Blue(Caution)
  - (iv) Green(Caution)
9. The colour band so used shall not be repeated elsewhere on the main panel.

#### **IV. SMALL PACK LABELS**

- (i) All pesticide packages of whatever size and by extension label must be approved by the VMD.
- (ii) Glass packages should be avoided for pesticides unless there is no alternative.
- (iii) Leaflets should be used if all the information cannot fit onto the package.
- (iv) The print size should be at least size 7.
- (v) The leaflet must be firmly attached to the package.
- (vi) Where the label information is in leaflet, the primary package should contain the words in capital letters, "READ THE ATTACHED LEAFLET BEFORE USE" prominently displayed.

Pack sizes are divided as follows;

##### 1. 500ml/gm – 100ml/gm

- (i) All the information from the primary panel should be on the package.
- (ii) Statement: "Read the attached leaflet before use".
- (iii) All the information from the secondary package should be on leaflet attached to packages.

##### 2. Below 100gm/ml

The package should have;

- (i) Name of product and formulation
- (ii) Registration No. Net Contents
- (iii) Read the label before using
- (iv) Keep locked out of reach of children
- (v) Hazard symbol and precautionary words

(vi) Read the attached information leaflet before use

The rest of the label information should be on the leaflet or brochure.