الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Labeling Information and Package Leaflet for Veterinary Medicinal Products

Version 1

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Version 1

Saudi Food & Drug Authority

Drug Sector

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Saudi Food and Drug Authority

Vision and Mission

Vision

To be a leading international science-based regulator to protect and promote public health

Mission

Protecting the community through regulations and effective controls to ensure the safety of food, drugs, medical devices, cosmetics, pesticides and feed

Document Control

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I. INTRODUCTION

This guideline is adapted from the EMA Notice to applicants for veterinary medicinal products, volume 6C.

- **Objective**

The guideline is intended to guide the applicants on how to present the information for:

  - Labeling information.
  - Package leaflet (PL).

It provides advice on the principles of presenting information. Applicants should maintain the integrity of each section of the document by only including information in each section, which is relevant to the section heading. However, some issues may need to be addressed in more than one section and in such situations the individual statements may cross-refer to other sections when these contain relevant additional information.

When submitting a new application for registration, renewal or variation, the information presented by the applicant regarding the PL and labeling must follow this guidance.

- **Related guidelines**

These guidelines should be read in conjunction with the following guidelines (depend on the type of the product):

  - Summary of product characteristics for veterinary immunological products, or
  - Summary of product characteristics for veterinary pharmaceutical products.

II. LABELING

A separate text for the labelling of the outer and immediate packaging should be provided unless the particulars to appear on the outer and immediate packaging are the same. Separate labelling documents should be prepared for each strength and pharmaceutical form. However, different package sizes of the same strength can be presented in one document. Where the same text for outer and immediate packaging is used, this should be clearly indicated in the heading and in {nature/type}.

Grey shading: Text appearing in grey shading will ONLY appear in the template but NOT on the mock-ups and on the final printed materials.

However, it should be noted that in some sections of this template, grey-shading has an alternative purpose and can also be used to indicate wording that will appear only on the relevant mock-up and on the related final printed material.

For example, in case of a combined labelling text covering different package sizes of the same strength where the different package sizes are included in grey-shading. In these cases, the information in grey-shading should appear on the relevant mock-ups and on the related final printed materials for that particular package size.

Bracketing convention:

{text}: Information to be filled in.

<text>: Text to be selected or deleted as appropriate.

A. Particular to appear on the <outer packaging> <and> < immediate packaging> {nature/type}

If no outer package, all the particulars will have to appear on the immediate package.

Headings are provided to help applicants when completing the template; they should remain in the opinion/decision annexes. However, they are not to appear in the final printed packaging materials (mock-ups/specimens).

1. Name of the veterinary medicinal product

{(Invented) name of veterinary medicinal product <strength> pharmaceutical form} {Active substance(s)}

Name of the veterinary medicinal product, followed by its strength (if applicable) and pharmaceutical form. The common name shall appear if the medicinal product contains only one active substance and its name is an invented name, as it appears in the SPC guidance under section 1 (name of the veterinary medicinal product).

2. Statement of active and other substance(s)

Expressed qualitatively and quantitatively per dosage unit or according to the form of administration for a given volume or weight, using the common names. Where the active substance is present as a salt, this should be clearly indicated.

e.g.: “mg X” or “mg Y-hydrochloride (equivalent to mg Y)”.

Excipients, including adjuvants, can be stated here in exceptional cases but must be justified and discussed on a case by case basis.

Express qualitatively those excipients known to have a recognized action or effect.

However, where justified for space considerations, abbreviations for excipient names may appear on the labeling, on condition that these abbreviations together with the full name are also included in section (6.1) of the SPC and section (3) of the package leaflet.

3. Pharmaceutical form

The pharmaceutical form has to be mentioned on the outer package only.

4. Package Size

By weight, by volume or by number of doses of the veterinary medicinal product (i.e. content of bottle; pack size, including a reference to any ancillary items included in the pack such as needles, swabs etc…).

In case of a combined labeling text covering different pack-sizes of the same strength, further

pack-size(s) should be included in grey shading.

e.g. *28 tablets*

56 tablets

100 tablets

5. Target species

As in SPC, section 4.1.

On the printed material, the target species should appear displayed close to the name.

In addition to the wording, a pictogram can be used.

6. Indication(s)

Indication to be included only for medicinal products not subject to medical prescription. Information to be included for immunologicals only.

In case of space restriction and if the indication is clear from the name of the product, the indication should not be repeated.

7. Method and route(s) of administration

This section should include information on directions for proper use of the veterinary medicinal product (e.g. “shake well before use”).

In all cases, and especially if full details cannot be included on the outer packaging itself, a reference to the package leaflet must be included (read the package leaflet before use).

If the route of administration is already mentioned in the name of the veterinary medicinal product, it should be repeated here in grey shading (i.e. it will appear in the template text but NOT on the mock-ups and on the final printed materials, e.g Oral solution).

Space shall be provided for the prescribed dose to be indicated on the label/outer carton. Route(s) of administration should be mentioned

8. Withdrawal period

Withdrawal period for veterinary medicinal products to be administered to food-producing species, for all the species concerned and for the various foodstuffs concerned (meat and offal, eggs, milk,

honey); including those for which the withdrawal period is zero.

Not applicable for non-food producing animals.

Present by species and/or food components

<Withdrawal period: > as it mentioned in SPC guidances.

If withdrawal period is not applicable, the template heading should not be deleted and clearly state that the withdrawal period is not applicable.

9. Special warning(s), if necessary

Indicate any particulars essential for safety or health protection, including any special precautions relating to use and any other warnings.

<Read the package leaflet before use.> unless already included under method and route(s) of administration or in case of space limitation.

10. Manufacturing and expiry dates

Dates should be expressed with the month given as 2 digits or 3 characters and the year as 4 digits, e.g.: 02/2010, Feb 2010. The expiry date should be taken to mean the last day of that month.

<EXP {month/year}>

< {MM/YYYY}>

< {Month YYYY}>

<Once <broached> <opened> <diluted> <reconstituted> <use by…><use within…> <use immediately.>>

Where applicable, the shelf life after reconstitution, dilution or after first opening the container should be included.

11. Special storage conditions

<Do not store above <25 °C> <30 °C>.>

<Store below <25 °C> <30 °C>.>

<Store in a refrigerator.>

<Store and transport refrigerated> [1]

<Store in a freezer>

<Store and transport frozen>[2]

<Do not <refrigerate> <or> <freeze>>

<Protect from frost>[3]

<Store in the original <container><package>>

<Keep the {container}[4] tightly closed>

<Keep the {container} [4] in the outer carton>

<in order to protect from <light> <and> <moisture>>

<Protect from light>

<Store in a dry place>

<Protect from direct sunlight>

<Not applicable>

12. Specific precautions for the disposal of unused products or waste materials, if any

This section is not required on the immediate label and should include information from section 6.6 of the SPC guidance in user-friendly wording.

In case of space limitation a shorter statement as follows:

<Dispose of waste material in accordance with local requirements.>

<Disposal: read package leaflet.>

[1] The stability data generated at 25°C/60 % RH (acc) should be taken into account when deciding whether or not transport under refrigeration is necessary. The statement should only be used in exceptional cases.

[2] This statement should be used only when critical.

[3] E.g. for containers to be stored on a farm.

[4] The actual name of the container should be used (e.g. bottle, blister, etc.)].

13. The words “veterinary use only”

For veterinary use only, <To be supplied only on veterinary prescription.> this phrase should be written in RED color.

14. The words “keep out of the reach and sight of children”

This section should include the following phrase:
“Keep out of the reach and sight of children”. However, this section is not required on the immediate label.

15. Name and address of the marketing authorization holder

{Name and address}
<{tel}>
<{fax}>
<{e-mail}>

16. Registration number

<Registration No.> {number}
Item to be completed by the marketing authorization holder once the marketing authorization has been granted.

17. Name of the manufacturer

{Name}

18. Batch number

<Batch> <Lot> <BN> {number}

B. Minimum requirements to appear on small immediate packaging units {nature/type}

Ampoules, small single-dose containers other than ampoules. On a case by case basis, the minimum particulars could also be considered for other containers (e.g. small multidose containers up to 50 ml) where it is not feasible to include all the information. Such exceptional cases have to be justified, discussed and agreed with the SFDA.

In case where the space is not enough to hold the minimum requirements, the information should be provided as a folded label.

1. Name of the veterinary medicinal product

{(Invented) name of veterinary medicinal product <strength> pharmaceutical form <target species>}
{active substance(s)}
Target species: on small immediate packaging units, the target species may be replaced with a pictogram.

2. Quantity of the active substance(s)

If the strength is already mentioned following the name of the veterinary medicinal product in section 1, it should be repeated here in grey shading (i.e. it will appear in the template text but NOT on the mock-ups and the final printed materials e.g. 20 mg/ml).
Contents by weight, by volume or by number of doses

3. Route(s) of administration

It included standard terms of small immediate packaging labeling “Intramuscular –IM, Intravenous- IV, Subcutaneous – SC”.

4. Withdrawal period

Not applicable for non-food producing animals.

Present by species and/or food components.

<Withdrawal period(s):>

If withdrawal period is not applicable, the template heading should not be deleted and clearly state that the withdrawal period is not applicable.

5. Batch number

<Batch> <Lot> <BN> {number}

6. Manufacturing and expiry dates

Dates should be expressed with the month given as 2 digits or 3 characters and the year as 4 digits. Expiry date refers to the last day of the month.

<EXP {month/year}>

<Once <broached> <opened> <diluted> <reconstituted> <use by…> <use within…> < use immediately>>

[Where applicable, shelf life after reconstitution, dilution or after first opening the container.

7. The words “veterinary use only”

<Veterinary use only > this phrase should be written in RED color.

C. Minimum requirements to appear on blisters or strips {nature/type}

1. Name of the veterinary medicinal product

{(Invented) name of veterinary medicinal product <strength> pharmaceutical form <target species>}

Target species on blisters or strips, the target species may be replaced with a pictogram.

2. Name of the marketing authorization holder

{Name} Full name or abbreviated name of the marketing authorisation holder. Company logo can be accepted on a case by case basis.

3. Manufacturing and Expiry dates

Dates should be expressed with the month given as 2 digits or 3 characters and the year as 4 digits, e.g.: 02/2010, Feb 2010.

<EXP {month/year}>

< {MM/YYYY}>

< {Month YYYY}>

4. Batch number

<Batch> <Lot> <BN> {number}

Batch number and Expiry date should be at the end of each blister strip, if technically possible this could be applied to both ends.

5. The words “for veterinary use only”

<Veterinary use only> this phrase should be written in RED color.

III. PACKAGE LEAFLET

The inclusion of a package leaflet in the packaging of veterinary medicinal products shall be obligatory unless all the information required can be conveyed on the container and the outer package.

Heading number grey shading: Grey shaded heading numbers indicate that the numbers can be omitted on the final printed material, when appropriate.

The package leaflet must contain, but is not limited to, the following items:

1. Name of the veterinary medicinal product

As it appears in the SPC under section 1 (name of the veterinary medicinal product) followed by its strength and pharmaceutical form. The common name shall appear if the product contains only one active substance and its name is an invented name.

{(Invented) name of veterinary medicinal product <strength> pharmaceutical form <target species>} {Active substance(s)}.

2. Statement of the active substance (s) and other ingredients

This section should include:

- Qualitative and quantitative composition in terms of the active substances and constituents of the excipient, knowledge of which is essential for proper administration of the veterinary medicinal product.
- Information on the description of the pharmaceutical form, e.g. “xx is a white powder containing … mg (active substance)”.
- Information on the appearance of the product before reconstitution/dilution, if applicable.

3. Indication(s)

This section should include:

- Clearly defined indications for the target species.
- A short section describing the benefits of the product and the purpose of the treatment.

4. Contraindications

This section should include information under section 4.3 of the SPC, if applicable.

5. Adverse reactions

This section should include information on adverse drug reactions attributed to the product when used as recommended. The reactions listed should be based on an assessment of all observed adverse events and all facts relevant to their causality, severity and frequency. Should also include information about any action that may be taken by the animal owner or the veterinarian in case of adverse reactions, for example immediate cessation of treatment or emergency resuscitation.

If frequencies of adverse reactions are included, the following statements should also be included at the end of the section.

< The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)>

Close this section with:

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

6. Target species

When appropriate the statement “Include any sub-categories” should be indicated.

7. Dosage for each species, route(s) and method of administration

Method of administration: directions for proper use of the veterinary medicinal product.

8. Advice on correct administration

Directions for proper use by healthcare professionals, farmer or animal owner; including practical details such as mixing instructions. A description of appearance after reconstitution, if applicable. Where appropriate, warning against certain visible signs of deterioration.

<Do not use {name} if you notice {description of the visible signs of deterioration}.>

9. Withdrawal period

This section should include information under section 4.11 of the SPC.

10. Special storage precautions

Keep out of the sight and reach of children.

This section should include:

- Keep out of the reach and sight of children.

<Do not store above <25 °C> <30 °C>.> or

<Store below <25 °C> <30 °C>.>

<Store in a refrigerator (2 °C – 8 °C).>

<Store and transport refrigerated (2 °C – 8 °C).>[5]

<Store in a freezer {temperature range}.>

<Store and transport frozen {temperature range}.>[6]

<Do not <refrigerate> <or> <freeze>.>

5 The stability data generated at 25°C/60 % RH (acc) should be taken into account when deciding whether or not transport under refrigeration is necessary. The statement should only be used in exceptional cases.

6 This statement should be used only when critical.

<Protect from frost.>[7]

<Store in the original <container><package>>

<Keep the {container}[8] in the outer carton>

<Keep the {container}[8] tightly closed>

<In order to protect from <light> <and> <moisture>.>

<Protect from light.>

<Store in a dry place>

<Protect from direct sunlight.>

<This veterinary medicinal product does not require any special storage conditions.>

<This veterinary medicinal product does not require any special temperature storage conditions.>[9]

Do not use this veterinary medicinal product after the expiry date, which is stated on the <label> <carton> <bottle> <...> <after {abbreviation used for expiry date}>. [Where a specific abbreviation for Expiry date is used on the labelling, it should be mentioned here.] <The expiry date refers to the last day of that month.>

Where applicable, shelf life after reconstitution, dilution or after first opening the container, as in SPC section 6.3.

<Shelf life after first opening the container: …..>

<Shelf life after <dilution> <reconstitution> according to directions: …..>

<Shelf life after incorporation into meal or pelleted feed: ….>

11. Special Warning(s)

Warnings from relevant sections 4.4, 4.5, 4.7, 4.8, 4.10 or 6.2 from the SPC should be included as appropriate in user-friendly wording.

Sub-headings should be used in this section to list warnings and precautions. For certain veterinary

7 E.g. for containers to be stored on a farm

8 The actual name of the container should be used (e.g. bottle, blister, etc)

9 Depending on the pharmaceutical form and the properties of the product, there may be a risk of deterioration due to physical changes if subjected to low temperatures. Low temperatures may also have an effect on the packaging in certain cases. An additional statement may be necessary to take account of this possibility.

medicinal product not all sub-headings may be relevant, in this case the heading should not be included.

For warning on accidental self-administration, etc. include statement as it appears in the SPC.

<None>

<Special warnings for each target species :>

<Special precautions for use in animals :>

<Special precautions to be taken by the person administering the veterinary medicinal product to animals :>

If the veterinary medicinal product contains mineral oil, the warnings in the SPC should be repeated here.

<Pregnancy :>

<Lactation :>

<Pregnancy and lactation :>

<Lay :>

<Fertility :>

<Interaction with other medicinal products and other forms of interaction :>

<Overdose (symptoms, emergency procedures, antidotes) :>

<Incompatibilities :>

12. Special precautions for the disposal of unused product or waste materials, if any

Include information from section 6.6 of the SPC in user-friendly wording.

<Medicines should not be disposed of via wastewater < or household waste.>

<Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment>

13. Name and address of the marketing authorization holder

Name, address and contact details of the marketing authorization holder (Including town, postal code (if available) and country name (Telephone, fax numbers, email addresses may be included (no websites or e-mails linking to websites allowed).

<Marketing authorisation holder <and manufacturer>:

{Name and address}

<{tel}>

<{fax}>

<{e-mail}>

14. Date on which the package leaflet was last approved

Leave blank in case of a first authorization. In case of changes to the package leaflet, the date of approval by the SFDA should be indicated.

The date must be stated only in figures <DD/MM/YYYY>

15. < Other information>

Information about pharmacological or immunological properties could be included here.

All package sizes must be listed here.

If applicable, add: <Not all pack sizes may be marketed.>

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.>

- To report any side effect(s):

- The National Pharmacovigilance Centre (NPC):
  - SFDA Call Center: 19999
  - E-mail: npc.drug@sfda.gov.sa
  - Website: https://ade.sfda.gov.sa/

IV. APPENDIX 1: Information that are required to be translated into Arabic language (For labeling part):

A. Information on the outer package*:*

1. Name of the veterinary medicinal product and strength
2. Pharmaceutical form.
3. Pack size.
4. Special storage condition.
5. Marketing authorization holder
6. Only for veterinary use, (this phrase should be in red color).

B. Information on the outer package of small containers:

1. Name of the veterinary medicinal product and strength
2. Special storage condition.
3. Marketing authorization holder.
4. Only for veterinary use, (this phrase should be in red color).

C. Blister information:

1. Name of the veterinary medicinal product and strength.
2. Marketing authorization holder.
3. Only for veterinary use, (this phrase should be in red color).

V. APPENDIX 2: Readability of the label and package leaflet

A. Introduction

The main purpose of this part is to provide guidance on how to ensure that the information on the labelling and package leaflet is accessible to and can be understood by users.

This document is written to assist applicants and marketing authorizations holders when drawing up the labeling and package leaflet and preparing the mock-ups or specimens of the sales presentations.

B. Recommendations for the package leaflet

1.1. General considerations

The package leaflet is intended for the user. If the package leaflet is well designed and clearly worded, this maximizes the number of people who can use the information. Companies are encouraged to seek advice from specialists in information design when devising their house style for the package leaflet to ensure that the design facilitates navigation and access to information.

The following guidance sets out recommendations on various aspects related to the preparation of package leaflets. It is aimed at helping applicants/marketing authorization holders to fully comply with the legal requirements and is based on experience where it has been shown that using these techniques optimizes the usability of the package leaflet.

1.2. Type size and font

Choose a font which is easy to read. Stylized fonts which are difficult to read should not be used. It is important to choose a font in which similar letters/numbers, such as “i”, “l” and “1” can be easily distinguished from each other. The type size should be as large as possible to aid readers. A type size of 9 points, as measured in font ‘Times New Roman’, not narrowed, with a space between lines of at least 3 mm, should be considered as a minimum.

Consideration should be given to using different text sizes to enable key information to stand out and to facilitate navigation in the text (e.g., for headings).

The widespread use of capitals should not be used. The brain recognizes words in written

documents by the word shape, so choose lower case text for large blocks of text. However, capitals may be useful for emphasis.

Do not use italics and underlining as they make it more difficult for the reader to recognize the word-shape. Italics, however, may be considered when using Latin terms.

1.3. Design and layout of the information

The use of "justified" text (that is text aligned to both left hand and right hand margins) should in principle not be used.

Line spaces should be kept clear. The space between lines is an important factor influencing the clarity of the text. As a general rule the space between one line and the next should be at least 1.5 times the space between words on a line, where practical.

Contrast between the text and the background is important. Factors like paperweight, color of the paper, size and weight of the type, color of the type and the paper itself should be considered. Too little contrast between the text and the background adversely affects the accessibility of the information. Therefore, background images should in principle not be placed behind the text since they may interfere with the clarity of the information making it harder to read.

A column format for the text can help the reader navigate the information. The margin between the columns should be large enough to adequately separate the text. If space is limited, a vertical line to separate the text may be used. Related information should be kept together so the text flows easily from one column to the next. Consideration should be given to using a landscape layout, which can be helpful to users. Where a multi-lingual package leaflet is proposed there should be a clear demarcation between the different languages used; all the information provided in each language should be assembled.

1.4. Headings

Headings are important and can help users navigate the text if used well. Therefore, bold typeface for the heading or a different color, may help make this information stand out. The spacing above and below the headings should be consistently applied throughout the leaflet. Same level headings should appear consistently (numbering, bulleting, color, indentation, font and size) to aid the reader.

The use of multiple levels of headings should be considered carefully, as more than two levels may make it difficult for readers to find their way around the leaflet. However, where complex information has to be communicated multiple levels of headings may be needed.

Using lines to separate the different sections within the text can also be helpful as a navigational tool.

1.5. Print color

Accessibility is not only determined by print size. Characters may be printed in one or several colors allowing them to be clearly distinguished from the background. A different type size or color is one way of making headings or other important information clearly recognizable.

The relationship between the colors used is as important as the colors themselves. As a general rule dark text should be printed on a light background. But there may be occasions when reverse type (light text on a dark background) could be considered to highlight for instance particular warnings. In such circumstances, the quality of the print will need careful consideration and may require the use of a larger type size or bold text. Similar colors should not be used for the text and background as legibility is impaired.

1.6. Syntax

Some people may have poor reading skills, and some may have poor health literacy. Aim to use simple words of few syllables.

Long sentences should not be used. It is better to use a couple of sentences rather than one longer sentence, especially for new information.

Long paragraphs can confuse readers, particularly where lists of side effects are included. The use of bullet points for such lists is considered more appropriate. Where possible, no more than five

or six bullet points in a list are recommended.

When setting out the side effects it is particularly important to consider the order in which they are given so the users may maximize the use of the information. In general, setting out the side effects by frequency of occurrence, starting with the highest frequency, is recommended to help communicate the level of risk to individuals. Frequency terms should be explained in way users can understand – for example “very common” (more than 1 in 10 animals). However, where a serious side effect exists which would require the user to take urgent action this should be afforded greater prominence and appear at the start of the section. Setting side effects by organ/system/class is not recommended since users are in general not familiar with these classifications.

1.7. Style

When writing, an active voice should be used, instead of passive voice. For example:

-'take 2 tablets' instead of '2 tablet should be taken','

-'you must....' is better than 'it is necessary ...'

When telling users what action to take, reasons should be provided. Instructions should come first, followed by the reasoning.

“This medicine,…etc.” should be used rather than repeating the name of the product, as long as the context makes clear what is being referred to.

Abbreviations and acronyms should not usually be used unless these are appropriate. When first used in the text, the meaning should be spelled out in full. Similarly scientific symbols (e.g. > or <) are not well understood and should not be used.

Medical terms should be translated into language, which users can understand. Consistency should be assured in how translations are explained by giving the lay term with a description first and the detailed medical term immediately after. On a case by case basis the most appropriate term (lay or medical) may then be used thereafter throughout the package leaflet in order to achieve a readable text. Make sure that the language used alerts the reader to all relevant information, and gives sufficient detail on how to recognize possible side effects and understand any action, which may be necessary.

1.8. Paper

The paperweight chosen should be such that the paper is sufficiently thick to reduce transparency, which makes reading difficult, particularly where the text size is small. Glossy paper reflects light making the information difficult to read, so the use of uncoated paper should be considered.

Make sure that when the package leaflet is folded the creases do not interfere with the readability of the information.

1.9. Use of symbols and pictograms

The images, pictograms and other graphics can be used to aid comprehension of the information, but these exclude any element of a promotional nature. Symbols and pictograms can be useful provided the meaning of the symbol is clear and the size of the graphic makes it easily legible. They should only be used to aid navigation, clarify or highlight certain aspects of the text and should not replace the actual text. Evidence may be required to ensure that their meaning is generally understood and not misleading or confusing. If there is any doubt about the meaning of a particular pictogram, it will be considered inappropriate.

C. Recommendations for the labeling

1.1. General considerations

Labeling covers both outer packaging and inner packaging. Although inner packaging may include a lesser set of particulars, many of the principles outlined in relation to outer packaging will apply equally to the labeling of blister packs or other small package units.

Labeling ensures that the critical information necessary for the safe use of the medicine is legible, easily accessible and that users of medicines are assisted in assimilating this information so that confusion and error are minimized.

Those involved in the design of labeling should consider the following sections prior to submission to the SFDA. The recommendations given in relation to the package leaflet (section A) may be applicable to labeling and should be borne in mind in designing and laying out the required information on labels. The particulars appearing on the label of all medicinal products should be printed in characters of at least 7 points (or of a size where the lower case "x" is at least 1.4 mm in

height), leaving a space between lines of at least 3 mm.

In particular, the information presented on small packs will need careful consideration so that the text is presented in as large a type size as possible to reduce the likelihood of medication error.

1.2. Name of the medicine

The full name of the medicinal product, with its strength and its pharmaceutical form, and the target species should appear on the outer packaging and on the immediate packaging to aid accurate identification of the medicinal product.

Where the medicinal product contains up to three active ingredients, the international non-proprietary name (INN)/common name(s) of these active ingredient(s) should be stated after the full name on the outer packaging and the immediate packaging, unless the INN/common name(s) is part of the name. The INN should be afforded due prominence for safety reasons.

1.3. Strength and total content

Different strengths of the same medicinal product should be expressed in the same manner: for example, 250 mg, 500 mg, 750 mg, 1000 mg and NOT 1 g. Trailing zeros should not appear (2.5 mg and NOT 2.50 mg). The use of decimal points (or comma) should be avoided where these can be removed (i.e. 250 mg is acceptable whereas 0.25 g is not). For safety reasons it is important that micrograms is spelt out in full and not abbreviated. However, in certain instances where this poses a practical problem which cannot be solved by using a smaller type size then abbreviated forms may be used, if justified and if there are no safety concerns.

1.4. Route(s) of administration

This should be as stated in the summary of product characteristics (SPC). Negative statements should not be used: for example “Not for intravenous use”. In principle, only standard abbreviations may be acceptable (i.v., i.m., s.c.).

Other nonstandard routes of administration should be spelled out in full. Some routes of administration will be unfamiliar to users and may need to be explained within the package leaflet.

1.5. Design and layout

Applicants and marketing authorization holders should make best use of the space available to ensure that the important information is clearly mentioned on prime spaces on the outer and immediate packaging, presented in a sufficiently large type size. Company logos and pictograms may be presented, where space permits, on the outer packaging and on immediate packaging, provided they do not interfere with the legibility of the mandatory information.

Use of a large type size will be appropriate, although other factors may also be important in making the information legible. Consideration should be given to the line-spacing and use of white space to enhance the legibility of the information provided. For some small packs, it may not be possible to present all the critical information in the same field of view. The use of any innovative technique in packaging design to aid in the identification and selection of the medicinal product is encouraged. It is also encouraged where space is at a premium.

Colors should be chosen to ensure a good contrast between the text and the background to assure maximum legibility and accessibility of the information. Highly glossy, metallic or reflective packaging should be avoided, as this affects the legibility of the information. Different colors in the name of the product are discouraged since they may negatively impact on the correct identification of the product name. The use of different colors to distinguish different strengths is strongly recommended.

Similarity in packaging, which contributes to medication error, can be reduced by the judicious use of color on the pack. The number of colors used on packs will need careful consideration as too many colors could confuse. Where color is used on the outer pack, it is recommended that it be carried onto primary packaging to aid identification of the medicine.

Where a multi-lingual outer and/or immediate packaging is proposed there should be a clear demarcation between different languages where space permits.

1.6. Blister pack presentations

For blister pack presentations, it is important that the particulars remain available to the user up to the point at which the last dose is removed. Often it will not be possible to apply all the information over each blister pocket, consequently where a random display of the information is proposed it should frequently appear across the pack. In all cases, it will be acceptable to apply the batch number, manufacturing and expiry dates to the end of the blister strip. If technically possible, applying this information to both ends of each strip should be considered.

In addition, blister foils should be printed to ensure maximum legibility of the information using a sufficiently large font.

Color for the text and the font style, should be chosen carefully as the legibility of the text on the foil is already impaired due to the nature of the material. Where possible, non-reflective material or colored foils should be considered to enhance the readability of the information presented and the correct identification of the medicine.

1.7. Small containers

Where the labeling particulars cannot be applied in full to the labeling of small containers, the minimum particulars could be considered. Other factors may need to be taken into account such as the amount of information, which has to be included, and the font size necessary to ensure the legibility of the information. The criteria for small container status would normally apply to containers of nominal capacity of 100 ml or less.

Innovative pack design is encouraged where space is at a premium (e.g. the use of wrap-around or concertina labels). Paper labels are recommended to increase the legibility of the information applied to, for example, ampoules.