TEMPLATES FOR THE SUMMARY OF PRODUCT CHARACTERISTICS AND PACKAGING FOR VETERINARY PHARMACEUTICAL PRODUCTS

Document No.	Effective Date:	Review Due Date:
Revision No.	Revision Date:	

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY PHARMACEUTICAL PRODUCT

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance<s>:

<Excipient(s):>

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

The description of pharmaceutical form should include visual of the appearance of the product (colour, markings, etc.)

4. CLINICAL PARTICULARS

4.1 Target species

4.2 Indications for use, specifying the target species

4.3 Contraindications

4.4 Special warnings <for each target species>

4.5 Special precautions for use

i) Special precautions for use in animals

ii) Special precautions to be taken by the person administering the veterinary pharmaceutical medicinal product to animals

4.6 Adverse reactions (frequency and seriousness)

4.7 Use during pregnancy, lactation or lay

4.8 Interaction with other medicinal products and other forms of interaction

4.9 Amounts to be administered and administration route

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

4.11 Withdrawal period(s)

<Meat and offal> <Milk><Eggs>: {X} <hours><days>

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: {group}, ATC code: {lowest available level (e.g. subgroup for chemical substance)}

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

6.2 Incompatibilities

<In the absence of compatibility studies, this veterinary Pharmaceutical product must not be mixed with other veterinary Pharmaceutical products.>

6.3 Shelf life

Shelf-life of the veterinary Pharmaceutical product as packaged for sale

Shelf-life after first opening the immediate packaging

Shelf-life after dilution or reconstitution according to directions where applicable

Shelf life after incorporation into meal or pelleted feed where applicable

6.4. Special precautions for storage

<Do not store above <25 °C><30 °C>>

<Store below <25 °C><30 °C>>

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

<Store and transport refrigerated (2 °C – 8 °C)>*

<Protect from light>

6.5 Nature and composition of immediate packaging

<Not all pack sizes may be marketed.>

6.6 Special precautions for the disposal of unused veterinary Pharmaceutical product or waste materials derived from the use of such products

<Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.>

7. MARKETING AUTHORISATION HOLDER

{Name and address}
Tel:
Fax:
E-mail:

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<{DD/MM/YYYY}> <{DD month YYYY}>…

10 DATE OF REVISION OF THE TEXT

{MM/YYYY} or <month YYYY>

CONTAINER LABELLING

Primary packaging and where applicable secondary packaging label

Every immediate and outer container of any Pharmaceutical product shall be labelled in legible and indelible letters. The labelling shall be in English and another language if required by another Partner State.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

2. NAME AND QUANTITY OF ACTIVE SUBSTANCE(S)

3. TARGET SPECIES

4. INDICATION(S) with recommended dosage per target species

5. METHOD OF ADMINISTRATION and any warnings or precautions that may be necessary

6. CONTRAINDICATIONS See package leaflet For Animal Use Only

7. WITHDRAWAL PERIOD

8. BATCH NUMBER, MANUFACTURING DATE AND EXPIRY DATE INCLUDING IN-USE SHELF LIFE WHERE APPROPRIATE

9. PACK SIZE

10. STORAGE CONDITIONS and any handling precautions that may be necessary

11. THE NAME AND ADDRESS OF THE MANUFACTURER.

12. THE NAME AND ADDRESS OF THE COMPANY OR PERSON RESPONSIBLE FOR PLACING THE PODUCT ON THE MARKET IF DIFFERENT FROM THE MANUFACTURER

13. THE MARKETING AURTHORISATION NUMBER IF REQUIRED BY THE NATIONAL REGULATORY AUTHORITY (to be included after approval)

Blisters and strips

Blisters and strips should include, as a minimum, the following information printed direct on blister or/and strip:

(a) Name, strength and pharmaceutical form of the VMP.
(b) Name of the manufacturer.
(c) The batch number assigned by the manufacturer.
(d) The manufacturing and expiry dates.

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

2. Qualitative and quantitative composition

Active substance(s):

Excipient(s):

The qualitative and quantitative composition should be stated for the active substance(s) and those excipients, where the knowledge is essential for the safe administration of the medicinal product. For example, preservatives should always be mentioned with their « E » numbers. Other excipients should not be mentioned here.

3.1 Qualitative composition

The international non-proprietary name (INN) should be used, accompanied by its salt, derivative or hydrate form if relevant. If no INN exists, the Pharmacopoeia name should be used. If the substance is not in the Pharmacopoeia, the usual common name should be used. In the absence of a common name, the exact scientific designation should be given. Substances without an INN or an exact scientific designation should be described by a statement of how and from what they were prepared. References to a pharmacopoeial quality should not be included.

Where the active substance is present in the form of the parent molecule, the standard terminology should be used (e.g. dexamethasone, levamisole).

Where the active substance is present as a salt, derivative or hydrate, this should be clearly stated e.g.: dexamethasone acetate, levamisole hydrochloride.

3.2 Quantitative composition

The quantity of the active substance must be expressed per dosage, per unit volume, or per unit of weight.

It is recommended that a visual description of the appearance of the product (e.g. colour, markings, clarity, and shape) or other parameters such as pH should be given.

Examples:

- Tablet – "White, circular flat bevelled-edge tablets marked '100' on one side".
- Solution for injection – "Pale yellow, clear solution for injection, pH 7.0"

If the product is not presented in the final pharmaceutical form intended for administration to animals, the final pharmaceutical form should also be stated, e.g. "powder and solvent for solution for injection".

In case of tablets, designed with a score line, a statement should be given whether or not reproducible halving of the tablets has been shown.

Examples:
- "The tablets can be divided into equal halves".
- "The score line is intended to facilitate ease of swallowing and not to divide into equal doses".

4. Clinical particulars

4.1 Target species

The target species, and sub-category, when appropriate, should be indicated.

4.2 Indications for use, specifying the target species

The indications should be clearly defined for the target species. It should be clearly stated whether the treatment is for prophylactic, therapeutic or diagnostic purposes.

4.3 Contraindications

<None>
<Do not use in...>

4.4 Special warnings for each target species

The purpose of this section is to provide clear information on how to ensure the effective use of the product in target animals. Information could include recommendations on the handling of animals, the proper use of the product or any other impact on the efficacy of the product.

4.5 Special precautions for use

4.5.1 Special precautions for use in animals

The purpose of this section is to provide clear information on how to ensure the safe use of the product in animals. The section should include information on relative contraindications.

4.5.2 Special precautions to be taken by the person administering the medicinal product to animals

Risks resulting from the nature of the product, its preparation and use and of any risks resulting from the particular characteristics of the user should be stated here.
Possible hypersensitivity reactions in the user to any of the excipients or residues from the manufacturing process should be included.

4.5.3 Other precautions

Information should be included here regarding possible reactions of the product with its surrounding, e.g. impact on the environment or chemical reactions of the product with furniture or cloth.

Examples:
The solvent in this product may stain certain materials including leather, fabrics, plastics and finished surfaces. Allow the application site to dry before permitting contact with such materials.

This product is highly flammable. Keep away from heat, sparks, open flame or other sources of ignition.

The product should not be allowed to enter surface waters as it has harmful effects on aquatic organisms.

Do not allow treated animals to swim in water courses until at least …hours/days after administration.

"The long-term effects of <the molecule>on the population dynamics of dung beetles have not been investigated. Therefore, it is advisable not to treat animals on the same pasture every season"

4.6 Adverse reactions

Adverse reactions which have been described for the active ingredient(s) or their pharmacological class and which are very rare or occur with delayed onset of clinical signs. These reactions may not have been observed in relation to the product, but are generally accepted as being attributable to the pharmacological class. The fact that this is a class attribution should be mentioned

4.7 Use during pregnancy, lactation or lay

In order to ensure the safe use of the product, the user must be informed of the recommendations regarding the use of the product in pregnant/lactating animals or laying birds.

4.8 Interaction with other medicinal products and other forms of interaction

<None known.>
<No data available.>

4.9 Amount(s) to be administered and administration route

< Dosage to be given per each specified species and rout of administration should be stated }.>

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

- “Signs as <description> may occur in <target specie> when the dose is exceeded.

“Do not exceed the recommended dose”. (Effects which do not occur under normal treatment). And provide corrective measure if available

4.11 Withdrawal period(s)

<Not applicable.>
<Zero days.>
<Meat and offal><Milk><Eggs>: {X} <hours><days>
<{Degree days}>

<Not authorised for use in lactating animals producing milk for human consumption.>
<Do not use in pregnant animals which are intended to produce milk for human consumption within {X} months of expected parturition.>
<Not authorised for use in laying birds producing eggs for human consumption.>
<Do not use within {X} weeks of onset of the laying.>

5. Pharmacological properties

The section should begin by stating the therapeutic group, according to the ATCvet classification system and the group of substances to which it belongs (ATCvet code).

5.1 Pharmacodynamic properties

The pharmacodynamic activity of the active substance(s) should be specified, together with the mechanism of the action, on the basis of the information contained in the application dossier. Also, information on resistance should be included in this section, if appropriate.

5.2 Pharmacokinetic particulars

Information, relevant for the proposed use of the product should be provided on the absorption, distribution, biotransformation and excretion of the active substance in each of the target species.

5.3. Environmental properties

For products, which might enter the environment directly e.g. medicines for fish or via manure, general information on environmental effects should be provided. The impact of the active substance or relevant metabolites excreted into the environment should be addressed. Information on degradation and factors influencing this (e.g. light, pH, temperature) and other ways of deactivation (e.g. binding to organic matter) should be given. Possible accumulation in the environment should be addressed.

6. Pharmaceutical particulars

6.1 List of excipients

A list should be given of the excipients, expressed qualitatively only. All excipients, which are present in the product, even those present in small amounts, should be included.

In the case of premixes for medicated feeding-stuffs, the main carriers in brackets should be indicated.

6.2 Incompatibilities

Where incompatibility studies have not been carried out, and if appropriate for the product, a warning should be included <not to mix the product with other medicinal products> (e.g. for parenterals or premixes for medicated feeding stuffs).

In other cases, the standard term <None known> is used.
If incompatibility is not a concern due to pharmaceutical form of the product, e.g. solid oral pharmaceutical forms, the term used is <Not applicable>.

6.3 Shelf-life

<Shelf-life of the veterinary medicinal product as packaged for sale>
<Shelf-life after first opening the immediate packaging >
<Shelf-life after dilution or reconstitution according to directions >
<Shelf life after incorporation into meal or pelleted feed>

<6 months><...><1 year><18 months><2 years><30 months><3 years>

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

This section should include information necessary for the safe disposal of unused product, and the equipment used for the administration of the product to animals. In addition, reference should be made to any restrictions on the disposal of waste products from treated animals.

7. Marketing Authorisation Holder

State the name and address of registration holder including telephone, fax number and e-mail.

8. Date of revision of the text

To be stated at the time of printing once a change to the prescribing information has been approved