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NOTICE TO APPLICANTS
VETERINARY MEDICINAL PRODUCTS

VOLUME 6C

Summary of the Product Characteristics

SPC - Immunologicals

June 2007

GUIDELINE ON THE SUMMARY OF PRODUCT CHARACTERISTICS FOR IMMUNOLOGICAL VETERINARY MEDICINAL PRODUCTS

TABLE OF CONTENTS

EXECUTIVE SUMMARY **3**

I. INTRODUCTION **3**

II. SCOPE **4**

III. LEGAL BASIS **4**

IV. GENERAL CONSIDERATIONS FOR THE PREPARATION OF THE SPC **4**

REFERENCES (SCIENTIFIC AND / OR LEGAL) **16**

EXECUTIVE SUMMARY

In accordance with Article 14 of Directive 2001/82/EC[1] of the European Parliament and of the Council on the Community Code relating to veterinary medicinal products, as amended by Directive 2004/28/EC[2] and Article 31 of Regulation (EC) No. 726/2004 of the European Parliament and of the Council[3], any application for a marketing authorisation must be accompanied by the Summary of Product Characteristics (SPC) which is proposed by the applicant and approved by the competent authority.

This guideline provides guidance on how the SPC should be prepared.

I. INTRODUCTION

The SPC contains the information on the condition of use of a veterinary medicinal product as developed during the course of the assessment process. It is the common basis of communication between the competent authorities of all the Member States. As such the content cannot be changed by the authorisation holder except with the approval of the competent authorities.

The purpose of the summary of product characteristics is to provide a clear and unambiguous description of the approved conditions of use of a veterinary medicinal product in the European Community or Member State(s) concerned, presented in accordance with a single standardised layout.

The labelling, package leaflet and any data sheet must comply with the approved conditions of use set out in the SPC. The content of the package leaflet must be consistent with the SPC in a wording that can be easily understood by non-professionals as appropriate. The SPC is the basis of technical information for veterinarians on how to use the medicinal product safely and effectively. The SPC also provides an instrument for the control by the competent authorities, of promotional material provided by the authorisation holder.

At the Community level, the SPC provides a basis for comparing the approved conditions of use of a particular veterinary medicinal product in the different Member States. When using the Community mutual recognition, decentralised or centralised procedures, applicants must propose an identical SPC for all Member States. In the case of the mutual recognition procedure this SPC must also be identical with that approved by the Member State on whose authorisation the application is based. In the case of centralised procedures, the Committee for Medicinal Products for Veterinary Use (CVMP) agrees on the SPC for the product, as part of its opinion. The SPC is annexed to the Commission decision granting marketing authorisation and will apply throughout the Community.

The SPC is also used as a means of providing information to third countries about the conditions of use of a veterinary medicinal product within the Member States of the Community. In accordance with Article 93 of Directive 2001/82/EC as amended, the competent authorities of a Member State will, upon request, provide the authorities of a third country with a copy of the SPC for the product concerned.

Separate SPCs are required for each pharmaceutical form. The European Commission and certain Member States may require separate SPCs for each strength. For the purposes of advertising or of giving information to prescribers, the text contained in the SPC of different pharmaceutical forms and strengths may be combined for appropriate products within the same range.

[1] http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-5/dir_2001_82/dir_2001_82_en.pdf
[2] http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-5/dir_2004_28/dir_2004_28_en.pdf
[3] http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-1/reg_2004_726/reg_2004_726_en.pdf

II. SCOPE

The order of presentation of the SPC is specified in Article 14 of the Directive, and should always be followed. This guideline provides guidance on the information required in the different sections of the SPC for immunological veterinary medicinal products.

III. LEGAL BASIS

In accordance with Article 14 of Directive 2001/82/EC and Article 31 of Regulation (EC) No. 726/2004 any application for a marketing authorisation must be accompanied by the Summary of Product Characteristics (SPC) which is proposed by the applicant. Furthermore, Article 14 of Directive 2001/82/EC requires that the content must be approved by the competent authority. Thus the SPC forms an intrinsic and integral part of the marketing authorisation. The SPC is a publicly available document, which must be provided upon request.

IV. GENERAL CONSIDERATIONS FOR THE PREPARATION OF THE SPC

When preparing an SPC, it should be noted that the SPC is intended to provide detailed objective information on the conditions of authorisation of a veterinary medicinal product. The SPC is not a promotional document, nor is it intended to constitute a summary of the evaluation of the medicinal product by the competent authorities.

It follows that all the statements contained in the SPC must be justified by the contents of the application dossier which is submitted to the competent authority. Statements of a promotional nature such as "*x is the treatment of choice for y*" are not acceptable. Moreover, additional information not found in the dossier s should not be included in the SPC unless necessary to enable the practitioner to assess the benefits and risks of the use of the product in a particular case.

Particular care should be taken to ensure that clear and unambiguous language is used throughout the SPC. Attention should be given to the clear definition of the scope of the indications, contra-indications, precautions for use and warning statements to ensure that these clearly identify the groups or sub-groups of animals concerned.

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 of the SPC (e.g. contra-indications plus interactions). In such situations, the individual statements may cross-refer to other sections when these contain relevant additional information.

For centralised, decentralised and mutual recognition procedures the SPC, in English should always be included in the dossier and will form the basis of product discussion. For national applications and at the time of approval of European (MRP, DCP, centralised..) applications, the SPC must always be presented in the national language or languages of the Member State(s) concerned by the application. Where the SPC has been translated from another language, particular care should be taken to ensure the accuracy of the translation and to ensure that appropriate terminology has been used in the different languages concerned.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

In those sections of the SPC in which full information on the name of the medicinal product is specifically required, where relevant the name should include the pharmaceutical form, even if there is only one strength and/or pharmaceutical form. However, when otherwise referring to the medicinal product throughout the text of the SPC, pharmaceutical form does not have to be mentioned in the name. The use of pronouns is encouraged where it improves the readability of the text. For vaccines and other biological, biotechnological medicinal products where the expression of the pharmaceutical form is not straightforward, it may be acceptable not to include the pharmaceutical form. To avoid confusion qualifiers such as strain contained in the vaccine, target species, number of doses in the vial, etc may be added.

The pharmaceutical form should be described by the European Pharmacopoeia full standard term. If an appropriate standard term does not exist, a new term may be constructed from a combination of standard terms.

When selecting invented names, care should be taken to avoid the use of words or abbreviations, which may give rise to confusion. A guideline on the acceptability of invented names for veterinary medicinal products processed in the centralised procedure has been published by the EMEA.

It may in certain circumstances be acceptable to have different names in different Member States.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

The qualitative and quantitative composition should be stated for the active substance(s) and those excipients, where the knowledge is essential for the proper administration of the medicinal product. The usual common name or chemical description shall be used. Other excipients should not be mentioned here. A standard statement should be included at the end of the section: “For full list of excipients, see section 6.1”.

The qualitative and quantitative composition of the adjuvant(s) should be stated, where knowledge of this is essential for the safe administration of the medicinal product. Adjuvants must always be mentioned at least by name.

Traces of antibiotics and/or other substances used in production of vaccines, but not present in sufficient quantities to have a pharmacological effect should not be included in the SPC.

Qualitative composition

Where the active substance is of a particular quality standard, for example selected mutants or marker virus, this should be indicated.

Excipients should be referred to by their recommended INN if one exists or by their European Pharmacopoeia name.

Quantitative composition

The biological activity, the titre or the potency of the active substance should be described in international or other Units and expressed per dose. In inactivated vaccines the titre before inactivation is not acceptable.

The composition should be given in terms of minimum quantities per dose and, if appropriate with maximum quantities per dose and an indication of the nature of a single dose (e.g. volume).

3. PHARMACEUTICAL FORM

The pharmaceutical form should be described by the European Pharmacopoeia full standard term. If an appropriate standard term does not exist, a new term may be constructed from a combination of standard terms. The term used in this section should be the same as the term used in section 1.

No reference should be made to the route of administration or to the container unless these elements are part of the standard term.

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 emulsion for injection”

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 and should be substantiated by data in the dossier.

The indications may be considered as the general claims for the immunological veterinary medicinal products. It gives the intention of the use of the immunological veterinary medicinal product.
One or more of the following standard text and wording should be used, as appropriate.

For active immunisation or passive immunisation of target species to:

- Prevent mortality, clinical signs and/or lesions of the disease;
- Prevent infection;
- Reduce mortality, clinical signs and/or lesions of the disease;
- Reduce infection.

In addition to the indications, the onset and duration of immunity of the immunological veterinary medicinal product should be specified, if appropriate.

Where appropriate, further information on the protection that can be expected from the use of the immunological veterinary medicinal product may be included.

4.3 Contraindications

Situations which arise from a set of circumstances where the veterinary medicinal product must not be used for target animal safety reasons, i.e. absolute contraindications, are the subject of this section. Contraindications may be linked with a target species or a sub-group of the target species, the administration of the product by a particular route or administration in conjunction with other products. Furthermore, particular clinical diagnoses, concomitant diseases, age or sex may constitute contraindications. Other veterinary medicines or classes of medicine which should be specifically avoided (i.e. contraindicated) for concomitant or consecutive use should only be stated here, if such use has serious consequences (e.g. fatalities). Otherwise, this information should be mentioned under section 4.8 (Interactions).

Absolute contraindications must be unambiguously, comprehensively and clearly worded. It is not necessary to contraindicate species, which are not included in the target species, unless data indicate a particular risk with off-label use in a non-target species. Cross reference to other sections may be made, if necessary e.g. to sections 4.7 (Use during pregnancy, lactation or lay) and 4.8. Interactions.

Non-indications (e.g. '*this veterinary medicinal product is not indicated for*...') should not be mentioned. Relative contraindications should be listed in section 4.5. (Special precautions for use).

Contraindications arising from hypersensitivity reactions in the target species to any of the excipients, residues from the manufacturing process or the presence of certain excipients should be included. Possible hypersensitivity reactions in the user should not be addressed here, but in section 4.6 (Adverse Reactions).

Additionally, all information relating to consumer safety should only be given in 4.11.

The standard phrase to be used in listing of contraindications is: '*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.

Additionally it is to warn prescribers of possibilities of modifications of the efficacy profile of the product, which may arise in particular situations such as very old or very young animals.

Description should be made under which conditions the veterinary medicinal product may be recommended for use in such groups provided the special precautions are followed. Situations in which use of the medicinal product is absolutely contraindicated should be mentioned under section 4.3. only and is not to be repeated in this section.

Descriptions of warning and precautions regarding pregnancy, lactation or lay and other aspects of interactions should be dealt with in sections 4.7 and 4.8 respectively.

4.5 Special precautions for use, including special precautions to be taken by the person administering the medicinal product to animals

i) 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 target animals. The section should include information on relative contraindications. It should also contain information on particular animal groups likely to experience adverse reactions (ADRs) to the product or similar products occurring under normal conditions of use e.g. specified breeds, age groups or animals with certain diseases/conditions should be mentioned here.

Any measures which can be taken to identify animals at risk and prevent the occurrence, or detect early the onset or worsening of conditions. If there is a need for awareness of clinical signs representing early warning of a serious ADR, a statement should be included. Any need for specific clinical or laboratory monitoring should be stated.

Actions necessary to avoid pathogenic agents spreading from the vaccinate to either non-target categories of the same species or non-target species.

Situations in which use of the product is absolutely contraindicated should be mentioned under section 4.3 (Contraindications) only. Relative contraindications should be mentioned first.

Descriptions on general information for instance on handling and directions for proper use concerning the mode of administration should be dealt with in section 4.9 (Amounts to be administered) with cross reference to section 4.4 (Special warnings) e.g. “Do not use chlorinated water”

ii) 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.

If applicable, information should also be given for persons in close contact to the treated animal e.g. animal owner, children, immuno-compromised persons, and pregnant women.

Where necessary, recommendations to minimise exposure of the product user during administration and, where relevant, during preparation of the product for administration should also be given in this section.

Guidance on remedial action to be taken following accidental contact should also be given, where necessary. It might be helpful to describe the expected outcome of a self-injection.

This is particularly important in respect of oil-adjuvants and live zoonotic agents. In some cases recommendations for appropriate action will be linked with particular characteristics of the user, such as a susceptibility to allergies or risk for compromise of the immune system.

The following statements, which do not cover all possible cases, should be used:

In the case of accidental self-injection / ingestion / spillage onto skin, seek medical advice immediately and show the package leaflet or the label to the physician.

People with known hypersensitivity to XXX *should <avoid contact with the product>*
Personal protective equipment consisting of XXX *should be worn when handling the product.*

For products containing mineral oil the following statements are recommended:

"To the user:

This product contains mineral oil. Accidental injection/self injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given.

If you are accidentally injected with this product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you.

If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:

This product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon."

For the immediate packaging and for the outer carton the following wording is suggested:

"Accidental injection of humans is dangerous – see package leaflet before use"

The following statements, which are relevant for the product label and package leaflet, should not be included in the SPC:
'For animal treatment only'
'Keep out of reach of children.'

iii) 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.

4.6 Adverse reactions (frequency and seriousness)

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. The main adverse reactions in the target species should be included in the SPC, if they are at least possibly causally related, based for example on their comparative incidence in clinical trials, or on findings from epidemiological studies and/or on an evaluation of causality from individual reports. Adverse events, without at least a suspected causal relationship, should not be listed in the SPC. Data can be derived either from data submitted in an application dossier or from post-authorisation pharmacovigilance reports.

This section 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 there is a need for awareness of clinical signs representing early warning of a serious adverse reaction, a statement should be included. Any need for specific clinical or laboratory monitoring should be stated.

Claims regarding the absence of specific adverse reactions, statements on lack of proof of causal association or comparative frequency statements other than those described below should not be included in this section.

In order to provide clear and readily accessed information, the section should be structured according to the following recommendations:

a) Description of the adverse reaction(s)
The information in this section must be consistent with the figures presented and should not contain general statements such as "*well tolerated*" etc.

The following information should be provided for each adverse reaction: a brief description of the nature of the reaction, the duration, reversibility and intensity of the reactions, the frequency of the reaction experienced in treated animals and any effect on the general state of health of the animal. In addition, it should be indicated whether certain species or breeds or types of individual are more susceptible to the undesirable effect concerned, or whether it is more frequent under certain types of husbandry conditions.

All adverse reactions should be ranked in “frequency groupings” with the most frequently occurring reactions listed first, using the following convention:

Very common *(more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)*
Common *(more than 1 but less than 10 animals in 100 animals*)
Uncommon *(more than 1 but less than 10 animals in 1,000 animals*)
Rare *(more than 1 but less than 10 animals in 10,000 animals*)
Very rare (*less than 1 animal in 10,000 animals*), including isolated reports.

More precise figures on the frequency of adverse reactions from clinical trials, e.g. XX% animals, are generally of limited value under conditions of market use and should only be included when it is of particular relevance to the animal owner or user of the product and/or prescriber to be informed of certain risks. In these cases it is preferable that the data should be based on pooled study results and/or large studies performed under actual market conditions and should refer to adverse reactions, not to unrelated adverse events.

This information can be presented in tabular format. Examples of acceptable statements are given below:

Examples:
- *“Commonly reported adverse reactions are gastrointestinal signs such as diarrhoea.”*
- *“Adverse reactions are rare (<1/1,000). At the beginning of therapy, colic, diarrhoea, or tremors may occur”*

b) Measures to be taken to avoid specific adverse reactions should be mentioned under 4.4 (Special Warnings) and cross-referenced here.
Any adverse reactions resulting directly from an interaction should be mentioned here and cross-referenced to Section 4.8 (Interactions).

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. Information about use of the product during pregnancy or lactation may have been provided in the sections dealing with contra-indications or special precautions for use. In such cases, a cross-reference to the relevant section will be sufficient. Information on the reasons for the relevant recommendation should be given. In the absence of data, the use of this vaccine is not recommended.

<Pregnancy>

The following standard phrases should be used when applicable:

- If the safety on pregnant animals has been shown in the target species: *<Can be used during pregnancy>*
- If adverse reactions have been shown during pregnancy with the recommended dose in the target species, a case by case evaluation is needed and depending on the type of reaction*: <The use is not recommended* (during the whole or part of the pregnancy*)>* or *<Do not use* (during the whole or part of the pregnancy)>

<Lactation>

The following standard phrase should be used when appropriate:
- *<Not applicable>*

<Laying birds>

For chicken/avian products when the product is not suitable for laying birds the following statement should be used:
<Do not use in birds in lay (breeding birds and/or within 4 weeks before the onset of the laying period.)>

If the product is not for use in laying birds the prohibition of use is given in section 4.4. Information about the consequences of residues for the use of eggs for human consumption should be given in section 4.11. Withdrawal period.

<Fertility>

The following standard phrase should be used when applicable:
<Do not use in breeding animals>

Information regarding fertility in both males and females should be given in sections 4.3, 4.6 or 4.4 as appropriate.

4.8 Interaction with other medicinal products and other forms of interaction

- When no adequate information has been provided on the safety and efficacy of the association or when the applicant has no specific claim under this point the following wording should be used :

- "No information is available on the compatibility of this vaccine with any other. Therefore the safety and efficacy of this product when used with any other (either when used on the same day or at different times) has not been demonstrated".

- If the applicant has demonstrated that mixing of products (simultaneous administration) is possible and if it is accepted by national competent authorities, the following wording should be used :

- "Safety and/or efficacy data are available which demonstrate that this vaccine can be mixed with <description of tested product(s)>".

- If the applicant has demonstrated that concurrent administration is possible, the following wording should be used :

  * When the vaccines are used the same day:

"Safety and/or efficacy data are available which demonstrate that this vaccine can be administered the same day but not mixed with <description of tested product(s)>".

or

* When the vaccines are not used the same day:
"Safety and/or efficacy data are available which demonstrate that this vaccine can be administered at least <X number of> days/weeks before/after the administration of <description of tested product(s)>".

The <X number of> days/weeks are based on the data presented by the applicant in the marketing authorization file. They correspond to the minimum time between administrations for which compatibility data have been submitted.

The recommendation that no other vaccines should be administered within 14 days before or after vaccination with the product must be omitted in the SPC as there is no scientific justification for this period.

4.9 Amounts to be administered and administration route

Where necessary, the target group of animals should be specified, e.g. *cattle less than 1 year of age*.

The method, including route and site of administration including directions for proper use by the veterinarian, farmer or owner should be given. Any special equipment needed for administration of the product should be mentioned. Where the product is to be administered via the feed, water or aerosol, any dosage adjustment for animals reluctant to eat and/or drink should be specified as well as the conditions of correct delivery in case of mass vaccination.

The dosage should be expressed in terms of a veterinary medicinal product (e.g. by unit doses or by a volume of solution administered to the animal). Whenever a titre is expressed in terms of infectious dose the wording should be cell culture infectious dose (CCID 50%) and egg infectious dose.
Other terms can be added in order to guide for proper use of the product**.** SI units should be used.
The frequency/interval and duration of administration should be specified in hours, days, weeks or months.

The impact of maternally derived antibodies on vaccination should be stated, where applicable.

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

The purpose of overdose studies is to detect signs of possible adverse reactions and to identify the dose at which they occur, in order to establish a safety margin.

Signs observed at higher dose levels than the recommended one should be mentioned. If no clinical signs were observed this should be mentioned as well. The following information should be provided, if available:

- Clinical signs, nature, evolution, seriousness, duration. It should also be indicated at what doses the overdosage signs were observed.
- Available symptomatic treatments
- Emergency procedures
- Antidote

4.11 Withdrawal period(s)

In Community legislation, the withdrawal period is defined as the period between the last administration of the veterinary medicinal product to animals and the production of foodstuffs from such animals. For a majority of immunological products the concern is in respect of live zoonotic organisms, adjuvants and preservatives. It is not anticipated that animals will be likely to be slaughtered for human consumption within a few days of being vaccinated, however this possibility should be addressed if relevant. Withdrawal periods should be indicated in days, using Arabic numerals. A zero withdrawal period should be expressed as '*Zero hours/days'*.

However, for fish meat, the withdrawal period should be stated in degree days. The number of degree days is divided by the average water temperature, in °C, to give the withdrawal period in days.

Where all foodstuffs may be used for human consumption during the treatment period and immediately after the last administration of a veterinary medicinal product no withdrawal period is necessary.

The following statements, which do not cover all possible cases, should be used:

For non-food producing species: *'Not applicable'*

For food producing species where no withdrawal period is necessary*: 'Zero days'*

5. IMMUNOLOGICAL PROPERTIES

This section should include a brief description of the immunological properties and characteristics of the active substance(s) and the ATC vet code. For example:

1) To stimulate active immunity against (active substance(s))
2) To stimulate active immunity in order to provide passive immunity to the progeny against active substance(s).
3) To provide passive immunity against (named infection)
4) *In vivo* diagnostic substance to diagnostic the state of immunity against (named infection)
5) To affect the physiological function of <target species> through immunological mechanism(s)
6) To modulate the function of the immune system of <target species>

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

A list should be given of the excipients, expressed qualitatively only.

At the top of the list, those excipients that should also be named on the product literature should appear. Unless specified in section 2, it is not necessary to give the quantitative details of these excipients on the product literature. Excipients include preservatives and colorants.

For clarity, it is recommended that each excipient be listed on a separate line.

Abbreviations for excipients should not be used. However, where justified for space considerations, abbreviations for excipient names may appear on the labelling, on condition that these abbreviations are also included in this section together with the full name.

6.2 Incompatibilities

In this section information should be given about physical or chemical incompatibilities of the product with other products with which it is likely to be diluted, mixed or co-administered.

Major incompatibilities observed from compatibility studies should be included here.

It is not permitted to mix immunological products with other products, except other components or the recommended diluent, unless compatibility data have been provided. In the absence of this data the following phrase should be used: '*do not mix with any other medicinal product* [except diluent or other component recommended/supplied for use with the product]'

If incompatibility is not a concern due to the pharmaceutical form of the product 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 (where relevant)
- Shelf-life after dilution or reconstitution according to directions (where relevant)
-
- ***Shelf-life after incorporation into meal or pelleted feed***

The shelf-life should be expressed in Arabic numerals as a number of years or months:
e.g. 6 months/ 1 year/ 18 months/ 2 years/ 30 months/ 3 years

The shelf life which has to be mentioned concerns only the finished product once it is released and not the active ingredient.

In the case of multi-dose preparations presented in sealed containers, the shelf-life of the broached or opened container should also be stated.
No storage conditions should be included here. They should be given in SPC point 6.4.

6.4 Special precautions for storage

This section contains the information necessary for the correct storage of the product: temperature, light and humidity. If no storage warning is required, state <*No special precautions for storage*>.

6.5 Nature and composition of immediate packaging

A short but complete description of the immediate packaging used for (and the contents of) the final sales presentation should be provided, including:

- Fill-volume/weight of the container, where appropriate
- Type of the container
- Material of the primary container
- Devices supplied - only if authorised during the procedure and included in the package

- Package size(s). All pack sizes should be listed. Pack sizes mentioned should include the number of units, number of doses for multi-dose vaccines, total weight or volume of the immediate container, as appropriate, and the number of containers present in any outer carton. If appropriate, a standard statement, 'Not all pack sizes may be marketed', should be included, in order to alert veterinarians to the fact that not all listed pack sizes may be available for prescribing or dispensing. Additionally, this information on all pack sizes is not necessary for the package leaflet.

Multiple unit packs for distribution purposes only do not constitute new pack sizes for marketing of the product and should therefore not be included in this section.

The Ph- Eur. standard terms should always be used. An example is:

- "Cardboard box with 1 amber glass vial of 1, 5, 10, 25 or 50ml with a rubber stopper and aluminium cap".

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. Where the requirements for disposal differ between Member States, the disposal advice on the package leaflet and labelling must conform to the requirements in the particular Member State where the veterinary medicinal product is to be authorised.

The following standard phrases may be used:

<*Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with the local requirements*> [inactivated immunologicals]
<*Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant approved for use by the competent authorities*>
< *Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.*>

7. MARKETING AUTHORISATION HOLDER

Name and permanent address or registered place of business of the marketing authorisation holder (including electronic mail address, if appropriate). References to web-sites on the Internet should not be included.

8. MARKETING AUTHORISATION NUMBER(S)

Item to be completed by the competent authority or by the marketing authorisation holder once the marketing authorisation has been granted. For veterinary medicinal products for which the European Commission is the competent authority, the number to be included in this section is the number in the Community Register.

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

Item to be completed by the competent authority or by the marketing authorisation holder once the marketing authorisation has been granted or renewed. The date of first authorisation and the date of renewal if applicable, should be indicated.

10. DATE OF REVISION OF THE TEXT

Leave blank in case of a first authorisation.

In case of changes to the product literature affecting the SPC, the year and month of approval by the Competent Authority should be indicated.

For veterinary medicinal products for which the European Commission is the competent authority: date of the latest Commission Decision or date of EMEA approval, if applicable.

For products for which Member States are the competent authorities: date of approval of latest variation or implementation date of the urgent safety restriction in the EU procedure resulting in a revision of the SPC.

Item to be completed by the competent authority or by the marketing authorisation holder.

PROHIBITION OF SALE, SUPPLY AND/OR USE

The import, sale, supply and/or use of <product name> is/or may be prohibited in certain Member States on the whole or part of their territory pursuant to National animal health policy. Any person intending to import, sell, supply and/or use <product name> has to consult the relevant Member States Competent Authorities on the current vaccination policies prior to the import, sale, supply and/or use.

The import, sale, supply and/or use of <product name> is only allowed under the particular conditions established by European Community legislation on the control of <community legislation number>. Any person intending to import, sell, supply and/or use the veterinary medicinal product must be authorized by the competent authority of the Member State.

Not applicable

REFERENCES (scientific and / or legal)

Directive 2001/82/EC, as amended by Directive 2004/28/EC

Regulation (EC) No. 726/2004

Guideline on the “Acceptability of invented names for veterinary medicinal products processed in the centralised procedure”

Note for guidance on Declaration of Storage Conditions for Veterinary Medicinal Products

Directive on Dangerous Substances Directive 67/548/EEC as amended