الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Summary of the Product Characteristics (SPC) for Veterinary Immunological 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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INTRODUCTION

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

- **Objective**

This guideline provides guidance on how the SPC should be prepared for veterinary Immunologicals product. The SPC is the basis of technical information for veterinarians on how to use the medicinal product safely and effectively. 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.

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

- **General considerations**

When preparing an SPC, it should be noted that the SPC is intended to provide detailed objective information on the conditions of authorization 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 SFDA.

All statements contained in the SPC must be justified by the contents of the application dossier, which is submitted to the SFDA. 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 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, contraindications, 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. contraindications plus interactions) and in such situations the individual statements may cross refer to other sections when these contain relevant additional information.

A separate SPC should be completed per pharmaceutical form, including all strengths of each pharmaceutical form, if appropriate, and containing all package sizes related to the strength(s) and pharmaceutical form concerned.

- **Related guidelines**

This guideline should be read in conjunction with the “Labeling information and package leaflet for veterinary medicinal products”.

Bracketing convention:

{text}: Information to be filled in.

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

The name of the medicinal product including full information is specifically required in those sections of the SPC. In addition, the name should include both the strength and the pharmaceutical form, even though there is only one strength and/or pharmaceutical form still need to be included. However, strength and pharmaceutical form do not have to be mentioned in the name when referring to the medicinal product throughout the text of the SPC.

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. In addition, for immunological the strength might not be feasible to be include in the name of the product.

When selecting invented names, care should be taken to avoid the use of words or abbreviations, which may give rise to confusion.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

For the active substance(s) and those excipients, where the knowledge is essential for the safe administration of the medicinal product, the qualitative and quantitative composition should be stated. For instance, stating the « E » numbers of preservatives is required whenever it has been mentioned. Nevertheless, other excipients should not be mentioned in this section with stating of the following standard statement 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.

If a diluent is part of the medicinal product, information should be included in the relevant sections, usually sections 3 (pharmaceutical form), 4.9 (Amounts to be administered), 6.1 (List of excipients) and 6.5 (composition of packaging).

2.1 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 pharmacopoeial name.

2.2 Quantitative composition

Active substance<s>:

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).

<Adjuvant(s) :>

E.g. Aluminum gels or salts, mineral or vegetable oil

<Excipient(s):>

Knowledge of which is essential for proper administration of the veterinary medicinal product, e.g. Preservatives and antioxidants

3. PHARMACEUTICAL FORM

The pharmaceutical form should be described by the pharmacopoeial 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 immunization or passive immunization 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.

<Onset of immunity: {x weeks}>

<Duration of immunity: {x years}>

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:
<None >
<Do not use in ….>
<Do not use in cases of hypersensitivity to the active substance(s)<, to the adjuvant(s)> or to any of the excipient(s).>

4.4 Special warnings for each target species

<Vaccinate healthy animals only.>

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

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”

<Vaccinated {species} may excrete the vaccine strain up to {x days/weeks} following vaccination. During this time, the contact of immunodepressed and unvaccinated {species} with vaccinated {species} should be avoided. >

<The vaccine strain can spread to {species}.

Special precautions should be taken to avoid spreading of the vaccine strain to {species}.>

<Appropriate veterinary and husbandry measures should be taken to avoid spread to susceptible species.>

< {Species} and unvaccinated {species} in contact with vaccinated {species} may react to the vaccine strain, presenting clinical signs such as ….>

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.

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, if applicable.

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:
<Not applicable.>

<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>.

<The immunological veterinary medicinal product should not be administered by pregnant women.>
<The <vaccine><immunological veterinary medicinal product> can be pathogenic for humans. Since this <vaccine> <immunological veterinary medicinal product> has been prepared with live, attenuated microorganisms, appropriate measures should be taken to prevent contamination of the handler and other people that collaborate in the process.>

<Vaccinated {species} may excrete the vaccine strain up to {x <days><weeks>} following vaccination.>
<Immunocompromised persons are advised to avoid contact with the <vaccine> <immunological veterinary medicinal product> and vaccinated animals during {period}.>

<The vaccine strain can be found in the environment for up to {x <days> <weeks>}. Personnel involved in attending vaccinated {species} should follow general hygiene principles (changing clothes, wearing gloves, cleaning and disinfection of boots) and take particular care in handling animal waste and bedding materials from recently vaccinated {species}.>

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 veterinarian:

<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-authorization 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, 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:

Adverse reaction	Incidence
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:

<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

<No information is available on the safety and efficacy of this <vaccine><immunological veterinary medicinal product> when used with any other veterinary medicinal product. A decision to use this <vaccine><immunological veterinary medicinal product> before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.>

<Safety> <and> <efficacy> data are available which demonstrate that this <vaccine><immunological veterinary medicinal product> can be administered on the same day but not mixed with {description of tested product(s).}>

<The <veterinary medicinal product><vaccine><immunological veterinary medicinal product> should be given at different sites.>

<Safety> <and> <efficacy> data are available which demonstrate that this <vaccine><immunological veterinary medicinal product> can be administered at least {X} <days><weeks> <before><after> the administration of {description of tested product(s).}>

<No information is available on the safety and efficacy of this <vaccine><immunological veterinary medicinal product> when used with any other veterinary medicinal product except the products mentioned above. A decision to use this <vaccine><immunological veterinary medicinal product> before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.>

<Safety <and> <efficacy> data are available which demonstrate that this <vaccine><immunological veterinary medicinal product> can be mixed and administered with {description of tested product(s).}>

4.9 Amount(s) 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.

<The <vaccine><immunological veterinary medicinal product><veterinary medicinal product> should not be used if {description of the visible signs of deterioration}.>

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)

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.>
- For food producing species where a withdrawal period is necessary:
  <<Meat and offal><Eggs><Milk> <Honey>: {X} <days><hours>.>
  <{X} degree days.>
  <Not authorised for use in 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.> (For food producing species where no MRL exists for milk).

<Not for use in birds producing or intended to produce eggs for human consumption.>

<Do not use within {X} weeks of the start of the laying period.>(For food producing species where no MRL exists for eggs).

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.

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

This section should include:

<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 months: e.g. 6 months/ 18 months/ 30 months/ 3 years. <use immediately.>

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

<Store below <25 °C><30 °C>.> may be applicable for some solvents that may be shipped separately.

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

<Store and transport refrigerated (2 °C - 8 °C).> 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.

<Store in a freezer {temperature range}.>

<Store and transport frozen {temperature range}.> This statement should be used only when critical.

Some vaccines, "live Marek's disease vaccine, must be stored below –100 ºC in order to keep them viable. Such vaccines are therefore stored in liquid nitrogen, which maintains the vaccine at –196 °C. " <Store and transport frozen in liquid nitrogen (-196 °C).>

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

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

<Keep the {container} tightly closed> The actual name of the container should be used (e.g. bottle, blister, etc.).

<Keep the {container} in the outer carton> The actual name of the container should be used (e.g. bottle, blister, etc.).

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 authorized 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.

Standard terms should always be used refer to the following examples:

- "Cardboard box with 1 amber glass vial of 1, 5, 10, 25 or 50 ml with a bromobutyl rubber stopper and aluminium cap".
- "Card envelope containing three translucent plastic unit dose pipettes of 0.50 ml in an aluminium/aluminium blister overwrap".
- "White HDPE bottle containing 30 tablets with cotton coil, desiccant bag, child proof closure and sealing disc".
- "PVC /aluminium heat sealed blisters with 10 tablets/blister. Cardboard box with 2 blisters".

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.

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>

<Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant approved for use by SFDA>

<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 AUTHORIZATION HOLDER

Name, address and contact details of the marketing authorization holder (including electronic mail address, if appropriate) should be included. However, references to web sites on the internet should not be included.

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

8. DATE OF FIRST AUTHORIZATION / RENEWAL OF THE AUTHORIZATION

The date of first authorization and the date of renewal, if applicable, should be indicated.

Date of first authorization <{DD/MM/YYYY}> <{DD month YYYY}>

Date of renewal <{DD/MM/YYYY}> <{DD month YYYY}>

9. DATE OF REVISION OF THE TEXT

Leave blank in case of a first authorization. In case of changes to the product literature affecting the SPC, the date of approval by the SFDA should be indicated.

{MM/YYYY}

<{DD/MM/YYYY}>

<{DD month YYYY}>