TEMPLATE FOR THE SUMMARY OF PRODUCT CHARACTERISTICS AND PACKAGING FOR IMMUNOLOGICAL VETERINARY PRODUCTS

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1. B. 1

SUMMARY OF PRODUCT CHARACTERISTICS

1.B.1 SUMMARY OF PRODUCT CHARACTERISTICS

Template for the Summary of Product Characteristics (SPC) for an Immunological Veterinary Product

1. NAME OF THE IMMUNOLOGICAL VETERINARY PRODUCT
State the name under which the product will be marketed.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Provide the qualitative and quantitative composition per unit dosage form in terms of the immunogenic substance(s) and excipients in a format as indicated below:

Each dose of (product name) contains:
Active substance(s):
Adjuvant(s) (if any):
Excipient(s):

3. IMMUNOLOGICAL DOSAGE FORM
State clearly the immunological dosage form of the product. Any descriptive terms to give an indication of the exact type of dosage form should also be included. The visual and physical characteristics of the product also should be stated.

4. CLINICAL PARTICULARS

4.1 Target species
State target species, including any sub-category where appropriate.

4.2 Indications for use
Provide information on indications of the product in the target species, state whether for active or passive immunity. Give information on onset and duration of immunity. *See also CVMP "Position Paper on Indications and Specific Claims for Immunological Veterinary Medicinal Products" ref.: CVMP/IWP/042/97- Rev.1, 2003, and SPC Guideline.*

4.3 Contraindications
State the contraindications for this immunological product e.g. not for use in pregnant animals, very young and old animals.

4.4 Special warnings
State any specific warnings associated with this product.

4.5 Special precautions for use
State precautions to be taken by person administering the immunological veterinary medicinal product (if any).
State precautions that should be taken for use in animals.

4.6 Adverse effects following immunization (frequency and seriousness
State the side effects and adverse reactions of the product. Within each frequency grouping, undesirable effects should be presented in order of decreasing seriousness. **Use during pregnancy, lactation or lay**
Provide information on the use of the product in pregnant, lactating animals or laying birds and the reasons for any relevant recommendation. 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 under special warnings section.
Information about the consequences of residues for the use of eggs for human consumption should be given under withdrawal period section

4.7 Interaction with pharmaceutical or other immunological and other forms of interaction

State briefly the interactions of the product with other types of medicinal products, or state whether compatible with other immunological products likely to be used at the same time.

4.8 Amount to be administered and administration route

State the dose, dosage schedule and route of administration. A distinction should be made between the primary vaccination course and any booster doses.

4.9 Overdose (symptoms, emergency procedures, if necessary)

Describe symptoms observed at higher dose levels. Give the recommended management and emergency procedures.

4.10 Withdrawal period

State the withdrawal periods (if applicable)

5. IMMUNOLOGICAL PROPERTIES

State the immunological properties of the product e.g. to induce a ctive immunity, or to provide passive immunity.

6. IMMUNOLOGICAL VETERINARY PRODUCT PARTICULARS

6.1 Incompatibilities:

Provide information on incompatibilities of the product with medicinal and other immunological products.

6.2 Shelf life

6.2.1 Shelf life (in months) of the immunological veterinary product.

6.2.2 State the immunological veterinary product shelf life after reconstitution (where applicable).

6.2.3 For multi-dose packages state the in use shelf life after first opening (where applicable).

6.3 Special precautions for storage

State the recommended storage conditions (e.g. temperature, light) as established by stability studies. The storage temperature must be stated in figures.

6.4 Nature and composition of packaging

State briefly the type(s) of packing and pack size(s) being applied for registration. The pack sizes declared here should correspond with the samples submitted.

6.5 Special precautions for the disposal of unused products or waste material derived from the use of such products.

Provide practical instructions for the safe disposal of the medicinal product and waste materials derived from the used/unused vaccines (if applicable).

7. MARKETING AUTHORISATION HOLDER/LICENCE HOLDER

State the name and physical address of registrant including telephone, fax number and e-mail. In addition provide the name and physical address of the manufacturer including telephone, fax number and e-mail if different from the Marketing Authorization Holder.

8. DATE OF REVISION OF THE TEXT

To be stated at the time of approval of change to the SPC.

1.B.2 LABELLING

The Labels and Secondary Packaging should be sufficiently robust to withstand the storage conditions

Labelling should be presented in the official language(s) of the country(s) where the product is intended to be marketed.

<PARTICULARS TO APPEAR ON THE PRIMARY PACKAGE>

1. NAME OF THE IMMUNOLOGICAL VETERINARY PRODUCT

2. NAME AND QUANTITY OF ACTIVE SUBSTANCE(S)

3. TARGET SPECIES

4. INDICATION(S)

5. DOSAGE AND ADMINISTRATION

6. CONTRAINDICATIONS

See package leaflet

7. CONTENT BY VOLUME OR NUMBER OF DOSES

8. STORAGE CONDITIONS

9. DATE OF MANUFACTURE, EXPIRY AND BATCH NUMBER IN AN UNCODED FORM

10. NAME AND PHYSICAL ADDRESS OF MANUFACTURER

11. MA NUMBER (ONLY IF REQUIRED BY REGULATORY AUTHORITY)

For small volume containers (below 20 ml) the logo will suffice and other details must be in the secondary pack and in the insert (Sections 1, 2, 3, 5, 7 & 8 are mandatory for the primary pack)

<PARTICULARS TO APPEAR ON THE SECONDARY PACKAGE>

1. NAME OF THE IMMUNOLOGICAL VETERINARY PRODUCT

2. NAME AND QUANTITY OF ACTIVE SUBSTANCE(S) AND EXIPIENTS

3. TARGET SPECIES

4. INDICATION(S)

5. DOSAGE AND ADMINISTRATION

6. CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS,

"FOR ANIMAL TREATMENT ONLY" "KEEP OUT OF REACH OF CHILDREN" are mandatory.

7. CONTENT BY VOLUME OR NUMBER OF DOSES

8. STORAGE CONDITIONS

9. DATE OF MANUFACTURE, EXPIRY AND BATCH NUMBER IN AN UNCODED FORM

10. NAME AND PHYSICAL ADDRESS OF MANUFACTURER

11. MA NUMBER (ONLY IF REQUIRED BY REGULATORY AUTHORITY)

BLISTERS PACKS

Blister packs 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.

1.B.3 PACKAGE LEAFLET

<PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET>

1. NAME OF THE IMMUNOLOGICAL VETERINARY PRODUCT

2. NAME AND QUANTITY OF ACTIVE SUBSTANCE(S) AND EXCIPIENTS

3. INDICATION(S)

4. CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS

5. ADVERSE EFFECTS FOLLOWING IMMUNIZATION (FREQUENCY AND SERIOUSNESS)

6. TARGET SPECIES

7. AMOUNT TO BE ADMINISTERED AND ADMINISTRATION ROUTE FOR EACH SPECIES

8. WITHDRAWAL
PERIOD (Where applicable) (Normally "ZERO DAYS")

9. SPECIAL STORAGE PRECAUTIONS

- Do not use after the expiry date stated on the <label><carton><bottle>
- <Shelf-life after first opening the container.>
- <Shelf-life after dilution or reconstitution according to directions.>
- <Do not use the product if you notice {description of the visible signs of deterioration}.>

10. SPECIAL WARNING(S)

11. CONTENT OF PACK(S) BY VOLUME OR NUMBER OF DOSES

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

(Dispose according to local regulations)

13. NAME AND PHYSICAL ADDRESS OF THE MANUFACTURER AND MARKETING AUTHORISATION HOLDER, IF DIFFERENT FROM THE MANUFACTURER

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED