[Version 8.2, 01/2021]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

[The following are those items of information required by Article 14 of Directive 2001/82/EC, the Guideline on Summary of the Product Characteristics, SPC - Pharmaceuticals, and the Guideline on Summary of the Product Characteristics, SPC - Immunologicals and current practice in the centralised procedure, mutual recognition procedure and decentralised procedure.

Where appropriate, this guidance should also be read in conjunction with the Revised Guideline on the SPC for antimicrobial products and the Guideline on the Summary of Product Characteristics for anthelmintics.

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. This guidance should also be read in conjunction with the relevant guidelines that can be found on the European Medicines Agency website (see e.g. "Quality Review of Documents (QRD) convention to be followed for the EMA-QRD templates"): http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500005091.pdf

Standard statements are given in the template which must be used whenever they are applicable. If the applicant can justify the need to deviate from these statements to accommodate product-specific requirements, alternative or additional statements will be considered on a case by case basis.]

Bracketing convention:
[text]: Guidance and explanatory notes.
{text}:Information to be filled in.
<text>:Text to be selected or deleted as appropriate.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

*[Name of the veterinary medicinal product **followed** by the strength (if applicable) and the pharmaceutical form:*
*- **(invented) name** (no ® ™ symbols attached here or throughout the text),*
*- **strength** (consistent with section 2 of the SPC),*
*- **pharmaceutical form** (according to the full "Standard terms" published by the Council of Europe;." tablets" and "capsules" in the plural),*
*- **if necessary, target species,** in order to avoid any confusion over different presentations of the veterinary medicinal product (e.g. same active substance and invented name) in different formulations for different target species. Indicate species in singular or plural as per official language.*
Target species: according to the target species control term list (CTL) on the EUTCT website http://eutct.ema.europa.eu/eutct/displayWelcome.do]

[For immunologicals: the strength might not be feasible to be included after the invented name of the veterinary medicinal product.]

[In those sections of the SPC, labelling and package leaflet, in which full information on the invented name of the veterinary medicinal product is specifically required, the invented name should be followed by the strength, the pharmaceutical form and if necessary, the target species, even if there is only one strength, pharmaceutical form and target species. However, when otherwise referring to the veterinary medicinal product throughout the text, strength, pharmaceutical form and target species do not have to be mentioned following the invented name. The INN should be used when referring to properties of the active substance(s) rather than those of the veterinary medicinal product. The use of pronouns is encouraged where it improves the readability of the text.

The strength following the invented name of the veterinary medicinal product is the quantity of the active substance which is relevant for the correct identification and use of the veterinary medicinal product. Different strengths of fixed-combination products should be presented separated by a slash" / ". However, when the units of the strength are stated with a slash "/" it may be more appropriate to separate the strengths using the "+" sign.

E.g. {(Invented) name} 0.5 mg/ml + 10 mg/ml oral suspension for dogs

The names of the active substances should be presented separated by a slash" / " and in the same order relating to the strength.

The use of "%", ppm or ppb as a strength should be avoided.

Thus, whenever the full information on the invented name of the veterinary medicinal product is specifically required to be provided in the SPC, labelling or package leaflet, it should be written in the following order:

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

[Strength and target species can only be omitted when relevant, as explained above].

[For MRP/DCP only: During the evaluation process, if the invented name is different in some Member States, all invented names should be mentioned here (with the corresponding Member State in brackets). Elsewhere in the document reference should only be made to the invented name in the Reference Member State.]

E.g. *{(Invented) name} 10 mg tablets for dogs*
{(Invented) name} 20 mg/ml solution for injection for dogs
{(Invented) name} 10 mg/ml concentrate for oral solution for use in drinking water or milk replacer

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

[Qualitative and quantitative composition in terms of the active substances and constituents of the excipient, knowledge of which is essential for proper administration of the veterinary medicinal product. ***Expressed per dosage unit*** *or according to the form of administration for a given volume or weight. E.g. for vaccines: "Each 2 ml dose contains {x} units {active substance}.The usual common name or chemical description shall be used.*
For further details refer to the SPC guidelines for pharmaceuticals and immunologicals.]

Active substance<s>:

[Full details of the qualitative and quantitative composition in terms of active substances should be provided using their INN or common names (in the language of the text).

For salt/ester: {quantity of active moiety} as {salt/ester}
or
{quantity of active moiety} equivalent to {quantity of salt/ester}

E.g.: 5 mg {X} as {Y}
8 mg {X} equivalent to 10 mg {Y}]

[In case the veterinary medicinal product is to be reconstituted prior to administration, the quantity per ml after reconstitution should also be stated.]

<Adjuvant<s>:>
[E.g. Aluminium 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 such as formaldehyde, thiomersal or colourants.]

[Any warnings necessary for excipients or residues from the manufacturing process should be mentioned in section 4.5.]

[For immunologicals, traces of antibiotics and traces of other substances used in production of vaccines not present in sufficient quantities to have a pharmacological effect should not be included in the SPC.]

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

[According to the full "Standard terms" published by the Council of Europe.]

[Include here a description of the visual appearance of the veterinary medicinal product's pharmaceutical form as marketed e.g. shape, texture, colour, imprint, including information on pH and osmolarity as required. In case of veterinary medicinal products intended for reconstitution, the appearance of the veterinary medicinal product before reconstitution should be stated here.]

4. CLINICAL PARTICULARS

4.1 Target species

[According to the target species CTL on the EUTCT website
http://eutct.ema.europa.eu/eutct/displayWelcome.do]

[Include any sub-category; indicate species in singular or plural as per official language use.]

4.2 Indications for use, specifying the target species

[For immunologicals, the onset and duration of immunity should be specified.]

<Onset of immunity: {x weeks}>

<Duration of immunity: {x years}>

[For immunologicals see also CVMP "Position Paper on Indications for Veterinary Medicinal Products" ref.: CVMP/IWP/042/97- Rev.1 final.]

4.3 Contraindications

[It is not necessary to contraindicate species that are not included in the target species, unless studies indicate a particular risk with off-label use in a non-target species. Non-indications (e.g. 'this veterinary medicinal product is not indicated for...') should not be mentioned. Information from 4.11 should not be repeated here.]

<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

[Warnings to ensure the effective use of the veterinary medicinal product.]

<None.>

<Vaccinate healthy animals only.> *[For immunologicals]*

4.5 Special precautions for use

Special precautions for use in animals
[Relative contraindications to ensure the safe use of the veterinary medicinal product, i.e. precaution(s) relating to particular sub-groups such as animals with renal, hepatic or cardiac failure, or use in young or old animals, or certain specific breeds.]

[For immunologicals, actions necessary to avoid pathogenic agents spreading from the vaccinated animal to either non-target categories of the same species or non-target species.]

<Not applicable.>

<Vaccinated {species} may excrete the vaccine strain up to {x <days> <weeks>} following vaccination. During this time, the contact of immunosuppressed 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 of the vaccine strain to susceptible species.>

<{Species} and unvaccinated {species} in contact with vaccinated {species} may react to the vaccine strain, presenting clinical signs such as ….>
[Any warnings necessary for excipients or residues from the manufacturing process.]

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

[For the operator safety warnings. If necessary, information should also be given for persons in close contact to the treated animal (e.g. owner, children, immunocompromised persons, pregnant women, etc…).]

<Not applicable.>

<In case of accidental <self-administration><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 {INN} should <avoid contact with the veterinary medicinal product.><administer the veterinary medicinal product with caution.> >

<Personal protective equipment consisting of {specify} should be worn when handling the veterinary medicinal product.>

<The 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}.>

[If the veterinary medicinal product contains mineral oil:]
<To the user:
This veterinary medicinal 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 veterinary medicinal 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.>

[Other precautions regarding impact on the environment, or chemical reactions of the veterinary medicinal product with furniture or clothes.]
<The long-term effects of the veterinary medicinal product 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.>

[For environmental risk mitigation measures see Reflection paper on risk mitigation measures related to the environmental risk assessment of veterinary medicinal products (EMA/CVMP/ERAWP/409328/2010)]

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

4.6 Adverse reactions (frequency and seriousness)
[For MRP/DCP only: To be completed in accordance with national requirements, if any (e.g. for DE: address of the national authority to which adverse reactions should be reported).]

[All adverse reactions should be ranked in "frequency groupings" with the most frequently occurring reactions listed first. The adverse reaction should appear at the start of the statement. The origin of the data source (i.e. studies, spontaneous reports or other sources (source to be specified) should be put at the end of the statement. Statements relating to different data sources should be presented in separate sub-sections.

E.g.

Application site reactions occurred rarely in studies.

Vomiting and diarrhoea have been reported very commonly in spontaneous reports.

Adverse reactions should only be listed once, based on the highest frequency classification.

For further guidance, a Q&A is available on how to express the frequency of adverse reactions within the product information (EMA/CVMP/150343/2016)]

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

<The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).>

4.7 Use during pregnancy, lactation or lay

<The safety of the veterinary medicinal product has not been established during <pregnancy> <lactation> <lay>.>

<Pregnancy:> <and lactation:>

<Can be used during pregnancy.>
<The use is not recommended (during the whole or part of the pregnancy).>
<Do not use (during the whole or part of the pregnancy).>
<The use is not recommended during <pregnancy> <lactation>.>
<Use only accordingly to the benefit/risk assessment by the responsible veterinarian.>
<Laboratory studies in {species} have not produced any evidence of a <teratogenic>,< foetotoxic>, <maternotoxic> effects.>
<Laboratory studies in {species} have shown evidence of <teratogenic>, <foetotoxic>, <maternotoxic> effects.>

<Lactation:>
<Not applicable>

<Laying birds:>
<Do not use in <birds in lay> <breeding birds> <and within 4 weeks before the start of the laying period>.>

<Fertility:>
<Do not use in breeding animals.>

[Information regarding fertility in both males and females can also be given in sections 4.3 (contraindications), 4.5 (special precautions for use) or 4.6 (adverse reactions) as appropriate.]

4.8 Interaction with other medicinal products and other forms of interaction

<None known.>

<No data available.> *[If appropriate for pharmaceuticals]*

<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.> *[For vaccines and other immunological veterinary medicinal products.]*

[Where safety and efficacy data are available for use of the veterinary medicinal products with others the following statements are applicable:

When the vaccines or other immunological veterinary medicinal products can be used on the same day:
<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).}>

In case of veterinary medicinal products administered parenterally:
<The <veterinary medicinal product><vaccine><immunological veterinary medicinal product> should be given at different sites.>

When the vaccines or other immunological veterinary medicinal products are not used on the same day:
<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).}>
[The X number of days/weeks and the references to before or after are based on the data presented by the applicant in the marketing authorisation file. They correspond to the minimum time between administrations for which compatibility data have been submitted.].]

[In addition to the above statements, to reflect the absence of information on the safety and efficacy of the association with any other vaccines or other immunological veterinary medicinal products, the following wording should also be included:]
<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.>

[If applicant has demonstrated that mixing of veterinary medicinal products (simultaneous administration) is possible and if it is accepted by national competent authorities, the following statement should be used:]
<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 Amounts to be administered and administration route

[Include information on the posology and method of administration. Posology: target groups to be specified, e.g. cattle less than 1 year of age. Method of administration: directions for proper use by healthcare professionals or by the farmer or owner and mixing instructions, if appropriate. Further practical details for the farmer or owner can be included in the package leaflet or, in its absence, on the label.]

[In case of veterinary medicinal products intended for reconstitution, a visual description of the reconstituted product should be included here.]

<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

[Specify quantity e.g.: mg/kg or X-fold overdose.]

4.11 Withdrawal period(s)

[For the various foodstuffs, including those for which the withdrawal period is zero. Listed by species and/or food components.]

<Not applicable> *[for non-food producing animals only.]*
<Zero days.> *[when none, for food producing animals.]*
<<Meat and offal> <Eggs> <Milk> <Honey> {X} <days><hours>.>
<{X}degree days.> *[for fish meat.]*

<Not authorised for use in animals producing milk for human consumption.> *[for milk producing animals]*
<Do not use in pregnant animals which are intended to produce milk for human consumption within {X} months of expected parturition.> *[for milk producing animals, where no MRL exists for milk.]*

<Not for use in birds producing or intended to produce eggs for human consumption.> *[for laying birds and for future laying birds, where no MRL exists for eggs and when a period of {X} weeks of start of the laying period cannot be determined.]*

<Do not use within {X} weeks of the start of the laying period.> *[for laying birds, where no MRL exists for eggs.]*

5. <PHARMACOLOGICAL> <IMMUNOLOGICAL> PROPERTIES

Pharmacotherapeutic group: {group*[appropriate therapeutic subgroup level.]*},
ATCvet code: {lowest available level (e.g. subgroup for chemical substance)}

<5.1 Pharmacodynamic properties> *[not applicable for immunologicals.]*

<5.2 Pharmacokinetic particulars> *[not applicable for immunologicals.]*

<Environmental properties> *[if not applicable delete this section.]*

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

[For immunologicals, traces of antibiotics and traces of other substances used in production of vaccines should not be included in the SPC.]

[Each excipient to be listed on a separate line according to the different parts of the product]
[A qualitative list (not quantitative) should be provided]
[Name of the excipient(s) in the language of the text]

e.g.
Powder:
Sucrose

Solvent:
Water for injections

6.2 Major incompatibilities

[Information should be given about major physical or chemical incompatibilities of the veterinary medicinal product with other products with which it is likely to be diluted or mixed. Major incompatibilities observed from compatibility studies should be included here.]

<Not applicable.> *[If incompatibility is not a concern due to the pharmaceutical form of the product, e.g. for solid oral pharmaceutical forms.]*

<In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.> *[e.g. for parenterals, premixes for medicated feeding stuffs.]*

[It is not permitted to mix immunological products with other products, except other components or the recommended solvent , unless compatibility data have been provided. In the absence of this data the following statement should be used.]
<Do not mix with any other veterinary medicinal product<, except <solvent or other component> <recommended> <supplied> <for use with the veterinary medicinal product.> >

<None known.>

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> <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.><use immediately.>

6.4 Special precautions for storage

<Do not store above <25 °C><30 °C>.> or
<Store below <25 °C><30 °C>.>
<Store in a refrigerator (2 °C – 8 °C).>
<Store and transport refrigerated (2 °C – 8 °C).>*
<Store in a freezer {temperature range}.>
<Store and transport frozen {temperature range}.>**
<Do not <refrigerate> <or> <freeze>.>
<Protect from frost.>***

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

<Keep the {container}**** tightly closed>
<Keep the {container}**** in the outer carton>

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

<Protect from light.>
<Store in a dry place.>
<Protect from direct sunlight.>

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

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

[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.*
*** This statement should be used only when critical.*
**** E.g. for containers to be stored on a farm.*
***** The actual name of the container should be used (e.g. bottle, blister, etc.).*
******Depending on the pharmaceutical form and the properties of the product, there may be a risk of deterioration due to physical changes if subjected to low temperatures. Low temperatures may also have an effect on the packaging in certain cases. An additional statement may be necessary to take account of this possibility.]*

6.5 Nature and composition of immediate packaging

[Include full information about contents of the packaging, such as type(s) of the immediate and outer container (e.g. one glass vial in a cardboard box), material (e.g. glass type, type of plastic) in contact with the veterinary medicinal product, package size(s) for the particular pharmaceutical form and strength(s). Also, indicate devices supplied and, if applicable, number of immediate containers in outer package (e.g. two glass vials in a cardboard box). Include the fill-volume/weight of the container, if appropriate.

All package sizes must be listed. If more than 1 package size applicable, add:]

<Not all pack sizes may be marketed.>

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

[For MRP/DCP only: additional requirements may apply in some Member States and can be included here.]

<Not applicable.>
<Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.>

<{Invented name} should not enter water courses as this may be dangerous for fish and other aquatic organisms.> *[if applicable.]*

7. MARKETING AUTHORISATION HOLDER

{Name
Address

Country}*[Country name in the language of the text.]*
<{Tel}>
<{Fax}>
<{E-mail}> *[no website addresses or E-mails linking to websites are allowed.]*

8. MARKETING AUTHORISATION NUMBER(S)

[Item to be completed by the marketing authorisation holder once the marketing authorisation has been granted.]

[For MRP/DCP only: Number allocated by the Member State. To be completed in accordance with national requirements after conclusion of the DC/MR phase.]

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

[Item to be completed by the marketing authorisation holder once the marketing authorisation has been granted or renewed.
The date should correspond to the Commission Decision of the initial authorisation of the veterinary medicinal product concerned. It should not reflect individual strength/presentation approvals introduced via subsequent variations and/or extensions.
Both the date of first authorisation and, if the authorisation has been renewed, the date of the Commission Decision of the (last) renewal should be stated.]

<Date of first authorisation:> <{DD/MM/YYYY}><{DD month YYYY}>.
<Date of last renewal:> <{DD/MM/YYYY}><{DD month YYYY}>.

[For MRP/DCP only: To be completed in accordance with national requirements after conclusion of the DC/MR phase.]

10. DATE OF REVISION OF THE TEXT

[Leave blank in case of first authorisation.
Item to be completed by the marketing authorisation holder at time of printing the SPC. Date of approval of latest variation or transfer changing the SPC, e.g. the latest Commission Decision amending the marketing authorisation, implementation date of the Urgent Safety Restriction or date of EMA notification amending the annexes to the marketing Authorisation.]

[For MRP/DCP only: To be completed in accordance with national requirements after conclusion of the DC/MR phase.]

<{MM/YYYY}>
<{DD/MM/YYYY}>
<{DD month YYYY}>

[For veterinary medicinal products authorised via the centralised procedure, the following reference to the European Medicines Agency website should be included:]
Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu/ . *[Not applicable for MRP/DCP.]*

PROHIBITION OF SALE, SUPPLY AND/OR USE

[For MRP/DCP only: To be completed in accordance with national requirements after conclusion of the DC/MR phase.]

<Not applicable.>

<Any person intending to manufacture, import, possess, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.> *[for immunologicals, if applicable.]*

<Consideration should be given to official guidance on the incorporation of medicated premixes in final feeds.> *[for premixes for medicated feed.]*

ANNEX II *[Not applicable for MRP/DCP]*

A. <MANUFACTURER<S> OF THE BIOLOGICAL ACTIVE SUBSTANCE<S> AND> MANUFACTURER<S> RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

<D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION>

[Annex II will be completed in English by the European Medicines Agency at the time of adoption of the opinion, therefore, applicants are not to provide the Annex II in the English version of the Annexes as part of a new marketing authorisation application.

Translations of the adopted Annex II in all languages are, however, to be included in the full set of translated Annexes as provided by the applicant after opinion, reflecting the adopted English Annex II.]

A. <MANUFACTURER<S> OF THE BIOLOGICAL ACTIVE SUBSTANCE<S> AND> MANUFACTURER<S> RESPONSIBLE FOR BATCH RELEASE

<Name and address of the manufacturer<s> of the biological active substance<s>

{Name and address}>

Name and address of the manufacturer<s> responsible for batch release

{Name and address}

[In cases where more than one manufacturer responsible for batch release is designated: list all and add the following statement:]
<The printed package leaflet of the medicinal product must state the name and address of the manufacturer responsible for the release of the concerned batch.>

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

<Veterinary medicinal product subject to prescription.>
<Veterinary medicinal product not subject to prescription.>

<According to Article 71 of Directive 2001/82/EC of the European Parliament and of the Council as amended, a Member State may, in accordance with its national legislation, prohibit the manufacture, import, possession, sale, supply and/or use of immunological veterinary medicinal products on the whole or part of its territory if it is established that:

a) the administration of the product to animals will interfere with the implementation of a national programme for the diagnosis, control or eradication of animal diseases, or will cause difficulties in certifying the absence of contamination in live animals or in foodstuffs or other products obtained from treated animals.

b) the disease to which the product is intended to confer immunity is largely absent from the territory in question.>

<Official control authority batch release is required for this product.> *[only for those immunological veterinary medicinal products which are listed for Official Control Authority Batch Release (OCABR) in accordance with Article 82 of Directive 2001/82/EC as amended.]*

C. STATEMENT OF THE MRLs

<Not applicable.>

[For pharmaceutical products.]
The active substance<s> in {name of the product} <is> <are> <an> allowed substance<s> as described in table 1 of the annex to Commission Regulation (EU) No 37/2010:

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification

<The excipients listed in section 6.1 of the SPC are <either> <allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required> <or> <considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product>.>

[In case of MRLs not been published yet.]
The Committee for Medicinal Products for Veterinary Use has recommended the inclusion of {name of the active substance(s)} in {name of the product} in table 1 (Allowed substances) of the annex to Commission Regulation (EU) No 37/2010 as follows:

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification

<The excipients, listed in section 6.1 of the SPC are <either> <allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required> <or> <considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product.>>

[For immunological products.]
The active substance being a principle of biological origin intended to <produce> <active> <passive> <diagnose a state of > immunity is not within the scope of Regulation (EC) No 470/2009.

<The excipients (including adjuvants) listed in section 6.1 of the SPC are <either> <allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required> <or> <considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product>.>

<D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

<Specific pharmacovigilance requirements:> [*Specify only, if different from standard legislative requirements, e.g. PSUR cycle, specific adverse reactions monitoring,…etc.]*

<The periodic safety update report (PSUR) cycle should be re-started for submission of 6- monthly reports (covering all authorised presentations of the product) for the next two years, followed by yearly reports for the subsequent two years and thereafter at 3 yearly intervals. *>[Only applicable, if justified after authorisation.]*

· CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

[If additional risk minimisation activities (e.g. educational material, restriction of use to veterinary surgeons) are proposed beyond those addressed in the product information, these should be listed here. Any exception to this rule (e.g. set up of surveillance programmes in only a few MS) should be discussed and reflected in the CVMP AR. These restrictions should also be copied into the separate Annex <ANNEX RELATED TO ARTICLE 95b CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT TO BE IMPLEMENTED BY THE MEMBER STATES>]

<Not applicable.>
<For use by veterinary surgeons only.>

· <SPECIFIC OBLIGATION TO COMPLETE POST-AUTHORISATION MEASURES FOR THE MARKETING AUTHORISATION UNDER EXCEPTIONAL CIRCUMSTANCES>

[Conditions in relation to the marketing authorisation under exceptional circumstances status should be distinguished from other conditions. List here all conditions in relation to the marketing

authorisation under exceptional circumstances i.e. specific obligations subject to annual re-assessment.]

<This being an approval under exceptional circumstances and pursuant to Article 39(7) of Regulation (EC) No 726/2004, the MAH shall conduct, within the stated timeframe, the following measures:

Description	**Due date**

>

· **<OBLIGATION TO CONDUCT POST-AUTHORISATION MEASURES>**

[List here all conditions to the marketing authorisation that are NOT related to the marketing authorisation under exceptional circumstances. Conditions in relation to the marketing authorisation under exceptional circumstances status should be distinguished from other conditions and should not be listed here.]

<The MAH shall complete, within the stated timeframe, the following measures:

Description	**Due date**

> >

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

[These are all mandatory items as listed in Directive 2001/82/EC. The data should be presented according to the template below, irrespectively of their sequence on the actual labelling and their position and possible repetition on the individual sides/flaps of the packaging (e.g. top flap, front, back etc.). Blue-boxes and their contents should not be included here.
A separate text for the labelling of the outer and immediate packaging should be provided unless the particulars to appear on the outer and immediate packaging are the same. Separate labelling documents should be prepared for each strength and pharmaceutical form. However, different package sizes of the same strength can be presented in one document. Where the same text for outer and immediate packaging is used, this should be clearly indicated in the heading and in {nature/type}.

For solvent labelling the CMDv conclusions and recommendations should be taken into consideration: http://www.hma.eu/uploads/media/CMD_v__GUI-016_Diluents_-__EMEA-CMDv-352379-2009_ed._01.pdf, as well as the CVMP Q&A on mentioning solvents in the product information of veterinary medicinal products authorised via the centralised procedure: EMA/CVMP/550607/2015)

On the printed outer packaging material, an empty space should be provided for the prescribed dose; however, this should not appear in the Labelling template text (Annex IIIA).

Standard statements are given in the template, which must be used whenever they are applicable. If the applicant needs to deviate from these statements to accommodate product-specific requirements, alternative or additional statements will be considered on a case by case basis.

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

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

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

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

PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> <AND> <THE IMMEDIATE PACKAGE>

{NATURE/TYPE}

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

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

[Expressed qualitatively and quantitatively per dosage unit or according to the form of administration for a given volume or weight, using the common names. Where the active substance is present as a salt, this should be clearly indicated e.g.: "mg X" or "mg Y-hydrochloride (equivalent to mg Y)".]

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

3. PHARMACEUTICAL FORM

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

Pharmaceutical form according to the full "Standard terms" published by the Council of Europe. If the pharmaceutical form is already mentioned following the name of the product, it should be repeated here in grey shading (i.e. it will appear in the template text but NOT on the mock-ups and on the final printed materials) e.g. Oral solution.]

4. PACKAGE SIZE

[By weight, by volume or by number of doses of the veterinary medicinal product (i.e. package size, including a reference to any ancillary items included in the pack such as needles, swabs; content of bottle etc.).]
[A short statement should be used to describe the package size:
e.g.
"10 ml"(not "10 ml vial")
"10 x 50 ml" (not "10 vials with 50 ml of solution for injection")]

[In case of a combined labelling text covering different package sizes of the same strength, further package size(s) should be included in grey shading.

e.g.
28 tablets
56 tablets
100 tablets]

5. TARGET SPECIES

[As in SPC section 4.1.]
[On the printed material, the target species should appear displayed close to the name.]
[In addition to the wording, a pictogram can be used. Please refer to the QRD guidance on the use of approved pictograms published on the European Medicines Agency website]

6. INDICATION(S)

*[Indication to be included **only** for medicinal products **not** subject to medical prescription.]*

[For MRP/DCP only]:
[For medicinal products not subject to medical prescription the inclusion of the indication may not be mandatory. In cases where the prescription status differs between Member States the heading For OTC products should be included in this section and grey shaded.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

[Method of administration: directions for proper use of the veterinary medicinal product; e.g. "Shake well before use". In all cases, and especially if full details cannot be included on the outer packaging itself, a reference to the package leaflet must be included. If the route of administration is already mentioned in the name of the veterinary medicinal product, it should be repeated here in grey shading (i.e. it will appear in the template text but NOT on the mock-ups and on the final printed materials, e.g Oral solution).]

Read the package leaflet before use.

[Space shall be provided for the prescribed dose to be indicated on the label/outer carton. Route(s) of administration should be mentioned according to "Standard terms" published by the Council of Europe. If the information exceeds the size of the label, reduced text is acceptable.]

8. WITHDRAWAL PERIOD (S)

[Withdrawal period for veterinary medicinal products to be administered to food-producing species, for all the species concerned and for the various foodstuffs concerned (meat and offal, eggs, milk, honey), including those for which the withdrawal period is zero.]

[Not applicable for non-food producing animals. Present by species and/or food components.]

<Withdrawal period(s): >
[If withdrawal period is not applicable, the template heading should not be deleted and the section should be left blank.]

9. SPECIAL WARNING(S), IF NECESSARY

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

<Read the package leaflet before use.> *[Unless already included under section 7 or in case of space limitation.]*

[For certain veterinary medicinal products e.g. injectables containing mineral oil or live vaccines, the following statement should be included:]
<Accidental injection is dangerous.>
<Accidental administration> <Contact with the mucosa> is dangerous. >

10. EXPIRY DATE

[For terms on Batch number and Expiry date see Appendix IV on the European Medicines Agency website http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2014/08/WC500170559.pdf]

[The expiry date should be taken to mean the last day of that month. Expiry dates should be expressed with the month given as 2 digits or 3 characters and the year as 4 digits. e.g.:02-2007, Feb 2007]

<EXP {month/year}>
<Once <broached> <opened> <diluted> <reconstituted> <use by…><use within…> <use immediately.>>

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

11. SPECIAL STORAGE CONDITIONS

[If there are no special storage conditions, this section should be left blank.]

<Do not store above <25 °C> <30 °C>.>
<Store below <25 °C> <30 °C>.>
<Store in a refrigerator.>
<Store and transport refrigerated.>*
<Store in a freezer.>
<Store and transport frozen.>**
<Do not <refrigerate> <or> <freeze>.>
<Protect from frost.>***
<Store in the original <container><package>>
<Keep the {container}**** tightly closed>
<Keep the {container}**** in the outer carton>

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

<Protect from light.>
<Store in a dry place.>
<Protect from direct sunlight.>
<Not applicable.>

[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.*
*** This statement should be used only when critical.*
**** E.g. for containers to be stored on a farm.*
***** The actual name of the container should be used (e.g. bottle, blister, etc.)].*

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

[Not requested on the immediate label.]

[As it appears in SPC under section 6.6. In case of space limitation a shorter statement is preferred if consistently used in all Member States languages.]

<Dispose of waste material in accordance with local requirements.>
<Disposal: read package leaflet.>

[For veterinary medicinal products authorised via the centralised procedure, a reference to any appropriate collection system in place (e.g. the Grüne Punkt recycling symbol if applicable) should be included in the Blue Box on the outer packaging.]

[For MRP/DCP only: additional requirements may apply in some Member States and can be included here.]

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. <To be supplied only on veterinary prescription.>

<The import, possession, sale, supply and/or use of this veterinary medicinal product may be prohibited in a Member State on the whole or part of its territory, see package leaflet for further information.> *[immunologicals, outer packaging only.]*

<Consideration should be given to official guidance on the incorporation of medicated premixes in final feeds.> *[For premixes for medicated feeding stuff.]*

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

[Not required on the immediate label.]

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Local representatives of the MAH, may be included in the Blue Box on the outer packaging.]

[For MRP/DCP: To be completed nationally.]

{Name
Address *[Including town, postal code (if available)]*
Country}*[Country name in the language of the text.]*
<{Tel}>
<{Fax}>
<{E-mail}> *[no website addresses or e-mails linking to websites are allowed.]*

16. MARKETING AUTHORISATION NUMBER(S)

[Recommended, but not required on the immediate label.]
[Item to be completed by the marketing authorisation holder once the marketing authorisation has been granted.]
[In case of a combined labelling text covering different package sizes of the same strength, the respective package size should be included in grey shading after the corresponding EU Sub-Number and listed on a separate line.
e.g.
EU/0/00/000/001 28 tablets
EU/0/00/000/002 56 tablets
EU/0/00/000/003 100 tablets]

EU/0/00/000/000

[For MRP/DCP only: Number allocated by the Member State. To be completed in accordance with national requirements after conclusion of the MR phase.]

17. MANUFACTURER'S BATCH NUMBER

[For terms on Batch number and Expiry date see Appendix IV on the European Medicines Agency website
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2014/08/WC500170559.pdf]

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

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{NATURE/TYPE}

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

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

{(Invented) name of veterinary medicinal product <strength> pharmaceutical form <target species>}
{active substance(s)}
[Pharmaceutical form: short terms according to "Standard terms" published by the Council of Europe may be used in case of space limitation, if consistently used in all language versions.
Target species: according to the target species CTL on the EUTCT website
http://eutct.ema.europa.eu/eutct/displayWelcome.do
Target species: on small immediate packaging units, the target species may be replaced with a pictogram from Annex 1of the QRD guidance on the use of approved pictograms published on the European Medicines Agency website]

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

4. ROUTE(S) OF ADMINISTRATION

[According to "Standard terms" published by the Council of Europe. See also QRD reference document "Tables of non-standard abbreviations".]

5. WITHDRAWAL PERIOD(S)

[Not applicable for non-food producing animals.
Present by species and/or food components.]

<Withdrawal period(s):>
[If withdrawal period is not applicable, the template heading should not be deleted and the section should be left blank.]

6. BATCH NUMBER

[For terms on Batch number and Expiry date see Appendix IV on the European Medicines Agency website

http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2014/08/WC500170559.pdf]

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

7. EXPIRY DATE

[For terms on Batch number and Expiry date see Appendix IV on the European Medicines Agency website
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2014/08/WC500170559.pdf]

[Month: 2 digits or 3 characters; year: 4 digits. Expiry date refers to the last day of the month.]

<EXP {month/year}>
<Once <broached> <opened> <diluted> <reconstituted> <use by…> <use within…> < use immediately.>>

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

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{NATURE/TYPE}

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

{(Invented) name of veterinary medicinal product <strength> pharmaceutical form <target species>}
{active substance(s)}
[Pharmaceutical form short terms according to "Standard terms" published by the Council of Europe may be used in case of space limitation, if consistently used in all language versions.
Target species : according to the target species CTL on the EUTCT website
http://eutct.ema.europa.eu/eutct/displayWelcome.do
Target species: on blisters or strips, the target species may be replaced with a pictogram from Annex 1of the QRD guidance on the use of approved pictograms published on the European Medicines Agency website]

2. NAME OF THE MARKETING AUTHORISATION HOLDER

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

[For MRP/DCP only: An abbreviated name can be proposed if common to all Member States. Otherwise, this is to be filled in nationally.]

3. EXPIRY DATE

[For terms on Batch number and Expiry date see Appendix IV on the European Medicines Agency website
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2014/08/WC500170559.pdf]

[Month: 2 digits or 3 characters; year: 4 digits. Expiry date refers to the last day of the month.]

<EXP {month/year}>

4. BATCH NUMBER

[For terms on Batch number and Expiry date see Appendix IV on the European Medicines Agency website
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2014/08/WC500170559.pdf]

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

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

[The inclusion of a package leaflet in the packaging of veterinary medicinal products shall be obligatory unless all the information required can be conveyed on the container and the outer package. The package leaflet must contain, but is not limited to, the following items.

The package leaflet should be written in a language understandable by the general public and should reflect the terminology the reader is likely to be familiar with.

Standard statements are given in the template which must be used whenever they are applicable. If the applicant needs to deviate from these statements to accommodate product-specific requirements, alternative or additional statements will be considered on a case by case basis.

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

PACKAGE LEAFLET:
{(Invented) name of veterinary medicinal product <strength> pharmaceutical form <target species>} *[as this information appears in the SPC under section 1.]*

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE , IF DIFFERENT

[Name or corporate name and permanent address or registered place of business of the marketing authorisation holder and of the manufacturer responsible for batch release and, where appropriate, of the representative of the marketing authorisation holder – see also section 15.]

[Including town, postal code (if available) and country name in the language of the text (Telephone Fax numbers, E-mail addresses may be included (no websites or E-mails linking to websites allowed).]

[For MRP/DCP: To be completed nationally.]

<Marketing authorisation holder <and manufacturer responsible for batch release>:

<Manufacturer responsible for batch release:>

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

[Name of the veterinary medicinal product followed by strength (if applicable) and pharmaceutical form. The common name shall appear if the product contains only one active substance and its name is an invented name.]
[Target species: according to the target species CTL on the EUTCT website http://eutct.ema.europa.eu/eutct/displayWelcome.do]

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

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

[Qualitative and quantitative composition in terms of the active substances and constituents of the excipient, knowledge of which is essential for proper administration of the veterinary medicinal product.
Include information on the description of the pharmaceutical form. Also, include information on the appearance of the product before reconstitution/dilution, if applicable.]

4. INDICATION(S)

[Indication(s) in the target species should be stated here, using understandable language.
A short section describing clearly the benefits of the veterinary medicinal product and the purpose of the treatment should be stated here, using understandable language, in order to provide a good balance between information on the benefits of the product and its risks.]

5. CONTRAINDICATIONS

[Include information under section 4.3 of the SPC, if applicable.]

6. ADVERSE REACTIONS

[All adverse reactions displayed during the course of one treatment should be ranked in "frequency groupings" with the most frequently occurring reactions listed first.]

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

< The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)>

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

[For MRP/DCP only:
The following statement may also be added <Alternatively you can report via your national reporting system {national system details}.>*]*

7. TARGET SPECIES

[According to the target species CTL on the EUTCT website http://eutct.ema.europa.eu/eutct/displayWelcome.do]

[Include any sub-categories.]

If the text for target species is replaced by a pictogram on small immediate packaging units/blisters, this pictogram should be reproduced here and on the printed leaflet to reinforce and clarify its meaning (N.B. in this case only approved pictograms may be used from Annex 1of the QRD guidance on the use of approved pictograms published on the European Medicines Agency website.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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

9. ADVICE ON CORRECT ADMINISTRATION

[Directions for proper use by healthcare professionals, farmer or animal owner; including practical details such as mixing instructions. A description of appearance after reconstitution, if applicable.]

[Where appropriate, warning against certain visible signs of deterioration.]
<Do not use {name} if you notice {description of the visible signs of deterioration}.>

10. WITHDRAWAL PERIOD(S)

[As it appears in the SPC.]

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

<Do not store above <25 °C> <30 °C>.> or
<Store below <25 °C> <30 °C>.>
<Store in a refrigerator (2 °C – 8 °C).>
<Store and transport refrigerated (2 °C – 8 °C).>*
<Store in a freezer {temperature range}.>
<Store and transport frozen {temperature range}.>**
<Do not <refrigerate> <or> <freeze>.>
<Protect from frost.>***

<Store in the original <container><package>>
<Keep the {container}**** in the outer carton>
<Keep the {container}**** tightly closed>

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

<Protect from light.>
<Store in a dry place>
<Protect from direct sunlight.>

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

[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.*
*** This statement should be used only when critical.*
**** E.g. for containers to be stored on a farm.*
***** The actual name of the container should be used (e.g. bottle, blister, etc.).*
******Depending on the pharmaceutical form and the properties of the product, there may be a risk of deterioration due to physical changes if subjected to low temperatures. Low temperatures may also have an effect on the packaging in certain cases. An additional statement may be necessary to take account of this possibility.]*

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

[Where applicable, shelf life after reconstitution, dilution or after first opening the container, as in SPC section 6.3.]
<Shelf life after first opening the container: …..>
<Shelf life after <dilution> <reconstitution> according to directions: …..>
<Shelf life after incorporation into meal or pelleted feed: ….>

12. SPECIAL WARNING(S)

[Warnings from relevant sections 4.4, 4.5, 4.7, 4.8, 4.10 and 6.2 from the SPC should be included as appropriate in user-friendly wording.]
[Sub-headings should be used in this section to list warnings and precautions. For certain veterinary medicinal product not all sub-headings may be relevant, in this case the heading should not be included.]

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

[For prohibition on manufacture, import, possession, sale, supply and/or use include statement as it appears in the SPC.]

<None.>

<Special warnings for each target species:>

<Special precautions for use in animals:>

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

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

<Pregnancy:>

<Lactation:>

<Pregnancy and lactation:>

<Lay:>

<Fertility:>

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

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

<Incompatibilities:>

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

[Include information from section 6.6 of the SPC in user-friendly wording.]
[For MRP/DCP only: additional national requirements may apply in some Member States and can be included here.]

<Medicines should not be disposed of via wastewater <or household waste>.>
<Ask your <veterinary surgeon> <or> <pharmacist> how to dispose of medicines no longer required. These measures should help to protect the environment.>

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

[Leave blank in case of first authorisation. Item to be completed by the marketing authorisation holder at time of printing the package leaflet. Date of approval of latest variation or transfer changing the package leaflet, e.g. the latest Commission Decision amending the marketing authorisation, implementation date of Urgent Safety Restriction or date of EMA notification amending the annexes to the marketing authorisation.]
[The date must be stated only in figures <DD/MM/YYYY>.]

[For MRP/DCP: To be completed in accordance with national requirements after conclusion of the MR phase.]

[For veterinary medicinal products authorised via the centralised procedure, the following reference to the European Medicines Agency website should be included:]
Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu/.*[Not applicable for MRP/ DCP.]*

<15. OTHER INFORMATION>

[For MRP/DCP: Relevant additional text if necessary.]

[Information about pharmacological or immunological properties could be included here.]

[All package sizes must be listed here.]

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

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

- *Listing of local representatives is not a requirement, but where used they must be stated for all Member States. If included in the product information annexes, the full list for all Member States must be stated [not applicable for MRP/DCP]. However, a representative may be designated for more than one country and may also be the MAH where no other local representative is indicated. In cases where the same representative is designated for more than one country, the representative's details may be listed only once below the names of the countries concerned.*
- *In the **printed** package leaflet, only the concerned local representative can be mentioned provided the whole list has been included in the product information annexes [not applicable for MRP/DCP].*
- *Where a local representative is located outside the country concerned and where an address is given, the country name must be included in the address of the local representative and must be given in the language(s) of the country for which the local representative is designated.*
- *ISO country codes* may be used to replace the full name of the country heading. ISO codes together with the respective names of EU/EEA countries can be found at the following web site: http://publications.eu.int/code/en/en-370101.htm.*
- *In order to save space in the printed package leaflet, local representatives may be presented sequentially rather than in a tabulated format. In case of multi-lingual leaflets, the list of local representatives can be printed only once at the end of the printed leaflet.*
- *The local representative may be indicated by name, telephone number and E-mail address (optional) only. Postal address may be added space permitting. Website addresses or E-mails linking to websites are not allowed.*
- *For Belgium and Finland addresses may appear in two languages, respectively Dutch/French and Finnish/Swedish.*
- *For Greece and Cyprus, the address must appear in Greek.'*

Telephone numbers: international dialling code followed by the area code and telephone number, e.g. EMA Tel: + 44-(0)20 7418 8400.]

**[except for the United Kingdom, for which UK is recommended (instead of the ISO code GB)]*

België/Belgique/Belgien
{Nom/Naam/Name}
<{Adresse/Adres/Anschrift }
BE-0000 {Localité/Stad/Stadt}>
Tél/Tel: + {N° de téléphone/Telefoonnummer/ Telefonnummer}
<{E-mail}>

Република България
{Наименование}
<{Адрес}
BG {Град} {Пощенски код}>
Тел: + 359 {Телефонен номер}
<{E-mail}>

Lietuva
{pavadinimas}
<{adresas}
LT {pašto indeksas} {miestas}>
Tel: +370{telefono numeris}
<{E-mail}>

Luxembourg/Luxemburg
{Nom}
<{Adresse}
L-0000 {Localité/Stadt}>
Tél/Tel: + {N° de téléphone/Telefonnummer}
<{E-mail}>

Česká republika
{Název}
<{Adresa}
CZ {město}>
Tel: +{telefonní číslo}
<{E-mail}>

Danmark
{Navn}
<{Adresse}
DK-0000 {by}>
Tlf: + {Telefonnummer}
<{E-mail}>

Deutschland
{Name}
<{Anschrift}
DE-00000 {Stadt}>
Tel: + {Telefonnummer}
<{E-mail}>

Eesti
(Nimi)
<(Aadress)
EE - (Postiindeks) (Linn)>
Tel: +(Telefoninumber)
<{E-mail}>

Ελλάδα
{Όνομα}
<{Διεύθυνση}
EL-000 00 {πόλη}>
Τηλ: + {Αριθμός τηλεφώνου}
<{E-mail}>

España
{Nombre}
<{Dirección}
ES-00000 {Ciudad}>
Tel: + {Teléfono}
<{E-mail}>

France
{Nom}
<{Adresse}
FR-00000 {Localité}>
Tél: + {Numéro de téléphone}
<{E-mail}>

Hrvatska
{Ime}
<{Adresa}
{Poštanski broj} {grad}>
Tel: + {Telefonski broj}
<{e-mail}>

Magyarország
{Név}
<{Cím}
HU-0000 {Város}>
Tel.: + {Telefonszám}
<{E-mail}>

Malta
{Isem}
<{Indirizz}
MT-0000 {Belt/Raħal}>
Tel: + {Numru tat-telefon}
<{E-mail}>

Nederland
{Naam}
<{Adres}
NL-0000 XX {stad}>
Tel: + {Telefoonnummer}
<{E-mail}>

Norge
{Navn}
<{Adresse}
N-0000 {poststed}>
Tlf: + {Telefonnummer}
<{E-mail}>

Österreich
{Name}
<{Anschrift}
A-00000 {Stadt}>
Tel: + {Telefonnummer}
<{E-mail}>

Polska
{Nazwa/ Nazwisko:}
<{Adres:}
PL – 00 000{Miasto:}>
Tel.: + {Numer telefonu:}
<{E-mail}>

Portugal
{Nome}
<{Morada}
PT-0000–000 {Cidade}>
Tel: + {Número de telefone}
<{E-mail}>

România
{Nume}
<{Adresă}
{Oraş} {Cod poştal} – RO>
Tel: + {Număr de telefon}
<{E-mail}>

Ireland
{Name}
<{Address}
IE - {Town} {Code for Dublin}>
Tel: + {Telephone number}
<{E-mail}>

Ísland
{Nafn}
<{Heimilisfang}
IS-000 {Borg/Bær}>
Sími: + {Símanúmer}
<{Netfang}>

Italia
{Nome}
<{Indirizzo}
IT-00000 {Località}>
Tel: + {Numero di telefono}>
<{E-mail}>

Κύπρος
{Όνομα}
<{Διεύθυνση}
CY-000 00 {πόλη}>
Τηλ: + {Αριθμός τηλεφώνου}
<{E-mail}>

Latvija
{Nosaukums}
<{Adrese}
{Pilsēta}, LV{Pasta indekss }>
Tel: + {Telefona numurs}
<{E-mail}>

Slovenija
{Ime}
<{Naslov}
SI-0000 {Mesto}>
Tel: + {telefonska številka}
<{E-mail}>

Slovenská republika
{Meno}
<{Adresa}
SK-000 00 {Mesto}>
Tel: + {Telefónne číslo}
<{E-mail}>

Suomi/Finland
{Nimi/Namn}
<{Osoite/Adress}
FI-00000 {Postitoimipaikka/Stad}>
Puh/Tel: + {Puhelinnumero/Telefonnummer}
<{E-mail}>

Sverige
{Namn}
<{Adress}
SE-000 00 {Stad}>
Tel: + {Telefonnummer}
<{E-mail}>

United Kingdom (Northern Ireland)
{Name}
<{Address}
{Town} {Postal code} – UK>
Tel: + {Telephone number}
<{E-mail}>