Draft QRD veterinary annotated product information template v.9

<table>
<thead>
<tr>
<th>Event</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Draft agreed by CVMP for release for consultation</td>
<td>17 March 2021</td>
</tr>
<tr>
<td>Draft agreed by CMDv for release for consultation</td>
<td>18 March 2021</td>
</tr>
<tr>
<td>Start of public consultation</td>
<td>29 March 2021</td>
</tr>
<tr>
<td>End of consultation (deadline for comments)</td>
<td>14 May 2021</td>
</tr>
</tbody>
</table>

Comments should be provided using this [template](#). The completed comments form should be sent to qrd@ema.europa.eu

**Keywords**

<table>
<thead>
<tr>
<th><strong>QRD product information template</strong></th>
<th></th>
</tr>
</thead>
</table>
ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

[The following are those items of information required by Article 35 of Regulation (EU) 2019/6 and current practice in the centralised, mutual recognition, subsequent recognition, decentralised and national procedures.

Where appropriate, this guidance should also be read in conjunction with all CVMP guidance relevant to the content of product information, as well as relevant Delegated and Implementing Acts arising from Regulation (EU) 2019/6.

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. Where references are made to “Standard terms” published by the Council of Europe, the controlled vocabulary under the Referentials section on the SPOR portal can be used as an additional source for terminology http://spor.ema.europa.eu/rmswi/#/lists/100000108853/terms/

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 list under “Referentials” on the SPOR website http://spor.ema.europa.eu/rmswi/#/lists/100000108853/terms]

[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/subsequent recognition procedures: 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 of the active substance or substances and qualitative composition of excipients and other constituents stating their common name or their chemical description and their quantitative composition, if that information 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}.]

[For novel therapy veterinary medicinal products: Detailed description of cells or tissues and of their specific origin, including the animal species should be provided.]

Active substance(s):

[Full details of the qualitative and quantitative composition in terms of the active substance or 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. A qualitative listing should be provided of all the components of the adjuvant, and/or the registered trade name (where applicable), unless their absence is justified. Quantitative information of adjuvant component(s) responsible for the immune modulatory effect.]

<Excipient(s)>:

[Qualitative composition of excipients and other constituents stated using their common name or their chemical description.] [Each excipient to be listed on a separate line according to the different parts of the product e.g.

Lyophilisate: Sorbitol

Thiomersal 0.1 mg

Solvent: Water for injections]

[Quantitative composition if that information 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 3.5.]

[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.]
3. CLINICAL INFORMATION

3.1 Target species

According to the target species list under “Referentials” on the SPOR website

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

3.2 Indications for use for each target species

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

<Onset of immunity: {x weeks}>
<Duration of immunity: {x years} {has not been established} >

3.3 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 3.13 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).>

3.4 Special warnings [for each target species]

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

<None.>
<Vaccinate healthy animals only.> [For immunologicals, i.e. prophylactic vaccines]

3.5 Special precautions for use

Special precautions for safe use in the target species

[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.

Special precautions for the protection of the environment

[Precautions regarding impact on the environment and risk mitigation measures.]

<Not applicable.>

<Other Precautions>

[Precautions such as chemical reactions of the veterinary medicinal product with furniture or clothes.]

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.’

3.6 Frequency and seriousness of adverse events

[All adverse events should be ranked in “frequency groupings” with the most frequently occurring clinical signs listed first. In each frequency category, it is recommended that the clinical signs should be listed preferably in alphabetical order. Coding of these clinical signs should follow standardised terms (e.g. VeDDRA).]

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;1 animal / 100 treated (common):</td>
<td>{adverse events in alphabetical order}</td>
</tr>
<tr>
<td>1 to 100 animals / 10,000 animals treated (uncommon):</td>
<td>{adverse events in alphabetical order}</td>
</tr>
<tr>
<td>&lt;1 animal / 10,000 animals treated, including isolated reports (very rare):</td>
<td>{adverse events in alphabetical order}</td>
</tr>
</tbody>
</table>

Where necessary: include additional information on particular measures to be taken in case specific adverse events occur (i.e. administration of an antidote, removing of a collar, washing of an application site...). Where relevant, information on the expected severity, duration and outcome of the clinical signs that may result following administration of the veterinary medicinal product can be described (e.g. lameness, 1-3 weeks following booster vaccination, vomiting and/ or diarrhoea, generally lasting 2 days, etc.).

<Reporting adverse events is important. It allows continuous safety monitoring of a product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See also sections 7 and 16 of the package leaflet for respective contact details.>

3.7 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 according 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 3.3 (contraindications), 3.5 (special precautions for use) or 3.6 (adverse events) as appropriate.]

3.8 Interactions 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)}.>

3.9 Administration route(s) and dosage
[Include information on the posology (in units consistent with section 2 on composition) and method of administration. Detailed instructions for use, application and implantation, if necessary, with explanatory drawings and pictures. 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. If appropriate, clear mixing instructions should be provided, in particular for products to be administered into feed or drinking water, taking into account the bodyweight range of animals to be treated, dispensing machines and special dosing equipment, as well as cleaning instructions, as needed. Further practical details for the farmer or owner can be included in the package leaflet or, in its absence, on the combined label-package leaflet.]

[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}.>

<To ensure a correct dosage, body weight should be determined as accurately as possible.>

<The intake of medicated <feed> <water> depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of {active substance} may need to be adjusted accordingly.>

<The use of suitably calibrated measuring equipment is recommended.>

<Based on the recommended dose and the number and weight of animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula [e.g. for administration via drinking water]:

<table>
<thead>
<tr>
<th>mg or ml veterinary medicinal product/ kg body weight day</th>
<th>X average body weight (kg) of animals to be treated</th>
<th>= mg or ml veterinary medicinal product per litre of drinking water</th>
</tr>
</thead>
</table>

| average daily water intake (l/animal) |

[A similar formula could be provided for products administered via feed, if necessary]

[The actual words ‘veterinary medicinal product’ must be used in the table, not converted to the invented name of the product]

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)
['Symptoms’ to be read as ‘clinical signs’]
[Specify quantity e.g.: mg/kg or X-fold overdose.]
3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

[Any restrictions or conditions arising from Articles 106, 107, in particular 107(6), and 110 of Regulation (EU) 2019/6, and from Delegated and Implementing Acts related to these Articles, and from Article 17(3) of Regulation (EU) 2019/4. For antimicrobial and antiparasitic products, any other (discretionary) contraindications, special warnings or precautions originating from product-specific assessment that are not laid out in the aforementioned Articles should continue to be included under the respective sub-section within SPC section 3 ‘Clinical information’. For example, product-related information restricting prophylactic and metaphylactic use linked to Articles 107(3) and 107(4) should appear in SPC section 3.5. Repetition of content across several SPC sections should be avoided].

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

<Any person intending to manufacture, import, possess, distribute, 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.]

<This veterinary medicinal product is intended to be used for the preparation of medicated feed.>

<For use by veterinary surgeons only.>

<Not applicable.>

3.12 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.]

4. <PHARMACOLOGICAL> <IMMUNOLOGICAL> INFORMATION

4.1 ATCvet code: {lowest available level (e.g. subgroup for chemical substance)}

<4.2 Pharmacodynamics> [not applicable for immunologicals.]
4.3 Pharmacokinetics [not applicable for immunologicals.]

Environmental properties [if not applicable delete this section.]

5. PHARMACEUTICAL PARTICULARS

5.1 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.>

5.2 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.>

5.3 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>.>
530 <Protect from light.>
531 <Store in a dry place.>
532 <Protect from direct sunlight.>
533
534 <This veterinary medicinal product does not require any special storage conditions.>
535
536 <This veterinary medicinal product does not require any special temperature storage conditions.>*****
537
538 [* The stability data generated at 25 °C/60 % RH (acc) should be taken into account when deciding
539 whether or not transport under refrigeration is necessary. The statement should only be used in
540 exceptional cases.
541 ** This statement should be used only when critical.
542 *** E.g. for containers to be stored on a farm.
543 **** 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.]
544
545 5.4 Nature and composition of immediate
546 packaging
547 [Include full information about contents of the packaging, such as type(s) of the immediate and outer
548 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.
549
550 All package sizes must be listed. If more than 1 package size applicable, add:]
551
552 <Not all pack sizes may be marketed.>
553
554 5.5 Special precautions for the disposal of unused veterinary medicinal products or waste
555 materials derived from the use of such products
556 [Requirement to use take-back schemes for veterinary medicinal products for the disposal of unused
557 veterinary medicinal products or waste materials derived from the use of such products and, if
558 appropriate, additional precautions regarding hazardous waste disposal of unused veterinary medicinal
559 products or waste materials derived from the use of such products. If appropriate, for used novel therapy
560 products, any special precautions or instructions for handling and disposal, if necessary, with explanatory
drawings and pictures.]
561
562 <Medicines should not be disposed of via wastewater <or household waste>.>
563
564 <The veterinary medicinal product should not enter water courses as {INN/active substance(s)} may be
dangerous for fish and other aquatic organisms.> [if applicable.]
565
566 <Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials
derived thereof in accordance with local requirements. See also section 10 below on national collection
567 systems.> [For MRP/DCP only: additional requirements may apply in some Member States and can be
568 included here.]
569
570 <Not applicable.>
571
572 6. NAME OF THE MARKETING AUTHORISATION HOLDER
573 {Name}
7. MARKETING AUTHORISATION NUMBER(S)

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

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

8. DATE OF FIRST AUTHORISATION

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

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.

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

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


[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.

<Date of the last revision of the SPC:><{MM/YYYY}>,
<Date of the last revision of the SPC:><{DD/MM/YYYY}>,
<Date of the last revision of the SPC:><{DD month YYYY}>,

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

10. NATIONAL COLLECTION SYSTEMS FOR THE DISPOSAL OF WASTE OF VETERINARY MEDICINAL PRODUCTS

[Information on the national collection systems referred to in Article 117 applicable to the veterinary medicinal product concerned.]
11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

[As referred to in Article 34 of Regulation (EU) 2019/6 for each Member State in which it is authorised.]

<Veterinary medicinal product subject to prescription.>

<Veterinary medicinal product not subject to prescription.>

[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 and national procedures.]
ANNEX II [Not applicable for MRP/DCP and national procedures]

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 110(1) of Regulation (EU) 2019/6 competent authorities may, in accordance with the applicable national law, prohibit the manufacture, import, distribution, possession, sale, supply or use of immunological veterinary medicinal products on their territory or in a part of it if at least one of the following conditions is fulfilled:

a) the administration of the veterinary medicinal product to animals may interfere with the implementation of a national programme for the diagnosis, control or eradication of animal disease.

b) the administration of the veterinary medicinal product to animals may cause difficulties in certifying the absence of disease in live animals or contamination of foodstuffs or other products obtained from treated animals.

c) the strains of disease to which the product is intended to confer immunity is largely absent in terms of geographic spread from the territory.>

<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 128 of Regulation (EU) 2019/6]

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 active substance is biological substance. Considered as not requiring an MRL evaluation as per Commission Regulation (EU) No 2018/782.

The excipients listed in the SPC are allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required. 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 the active substance(s) 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 the SPC are allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required. 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 or passive diagnose a state of immunity is not within the scope of Regulation (EC) No 470/2009.

The excipients (including adjuvants) listed in the SPC are allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required. 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, specific adverse reactions monitoring, etc...]

• 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 Member State) should be discussed and reflected in the CVMP AR.]

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 25 of Regulation (EU) 2019/6, the MAH shall conduct, within the stated timeframe, the following measures:

<table>
<thead>
<tr>
<th>Description</th>
<th>Due date</th>
</tr>
</thead>
</table>

<OLIGATION 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:

<table>
<thead>
<tr>
<th>Description</th>
<th>Due date</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Description</th>
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<table>
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<tr>
<th>Description</th>
<th>Due date</th>
</tr>
</thead>
</table>
ANNEX III

LABELLING AND PACKAGE LEAFLET
A. LABELLING

These are all mandatory items as listed in Regulation (EU) 2019/6. 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.). 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.

A Member State may decide that, on the outer packaging of a veterinary medicinal product made available in its territory, an identification code shall be added in the outer package. Such a code may be used to replace the marketing authorisation number in the outer package.

The information mentioned on the immediate and outer packaging shall appear in easily legible and clearly comprehensible characters, or in abbreviations or pictograms, as listed in the Implementing Act providing a list of the abbreviations or pictograms common throughout the Union, as per Article 17(2) of the Regulation.

Standard statements are given in the template or within relevant CVMP guidance, as well as relevant Delegated and Implementing Acts arising from Regulation (EU) 2019/6, 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.

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

According to Article 13 of Regulation (EU) 2019/6, Member States may, within their territory, and on request of the applicant, allow an applicant to include on the immediate or outer packaging additional information which is compatible with the SPC and which is not an advertisement for a veterinary medicinal product.
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

{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. Pharmaceutical form according to the full “Standard terms” published by the Council of Europe.]

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. PACKAGE SIZE

[By weight, by volume, by number of immediate packaging units 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

4. TARGET SPECIES

[As in SPC section 3.1]

[On the printed material, the target species should appear displayed close to the name.]

5. INDICATION(S)

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

[For MRP/DCP and national procedures]:

Draft QRD veterinary annotated product information template v.9
EMA/176485/2021
6. ROUTE(S) OF ADMINISTRATION

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).]

[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.]

7. 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: >

<If withdrawal period is not applicable, the template heading should not be deleted, and the section should be left blank.>

8. EXPIRY DATE

[The expiry date preceded by the abbreviation “EXP” should be taken to mean the last day of that month. Expiry dates should be expressed with the month given as 2 digits and the year as 4 digits. e.g.02/2007]

[For novel therapy veterinary medicinal products, the expiry date may specify the day.]

EXP {mm/yyyy}

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

<Once <broached> <opened> <diluted> <reconstituted> <use by…><use within…> <use immediately.>>

9. SPECIAL STORAGE PRECAUTIONS

[If there are no special storage precautions, 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>

Draft QRD veterinary annotated product information template v.9
EMA/176485/2021
<in order to protect from light and moisture.>

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

[* 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.).]

10. THE WORD “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

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

{Name or company name or logo of the marketing authorisation holder}

14. MARKETING AUTHORISATION NUMBER(S)

[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 and national procedures: Number allocated by the Member State. To be completed in accordance with national requirements after conclusion of the MR phase.]
15. BATCH NUMBER

[The batch number, preceded by the word “Lot”]

Lot {number}
PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{NATURE/TYPE}

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.]

2. STATEMENT OF ACTIVE SUBSTANCES

[Expressed qualitatively and quantitatively 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. TARGET SPECIES

[As in SPC section 3.1.]

[On the printed material, the target species should appear displayed close to the name.]

4. ROUTE(S) OF ADMINISTRATION

[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.

[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.]

5. 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.]

6. EXPIRY DATE
7. SPECIAL STORAGE PRECAUTIONS

[If there are no special storage precautions, 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.>

[* 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.).]}

8. NAME OF THE MARKETING AUTHORISATION HOLDER

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

{Name or company name or logo of the marketing authorisation holder}

9. BATCH NUMBER

[the batch number, preceded by the word “Lot”]

Lot {number}
MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{NATURE/TYP E}

[Blisters or strips, 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 list under “Referentials” on the SPOR website http://spor.ema.europa.eu/rmswi/#/lists/100000108853/terms]

2. QUANTITATIVE PARTICULARS 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. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

[The expiry date preceded by the abbreviation “EXP” should be taken to mean the last day of that month. Expiry dates should be expressed with the month given as 2 digits and the year as 4 digits. e.g.:02-2007]

[For novel therapy veterinary medicinal products, the expiry date may specify the day.]}

EXP {mm/yyyy}

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

<Once <broached> <opened> <diluted> <reconstituted> <use by…> <use within…> < use immediately.>>
B. PACKAGE LEAFLET

The marketing authorisation holder shall make readily available a package leaflet for each veterinary medicinal product. That package leaflet shall contain at least the following information.

The package leaflet should be written and designed to be readable, clear and understandable, in terms that are comprehensible to the general public. Member States may decide that it shall be made available on paper or electronically, or both.

The package leaflet may bear additional information concerning distribution, possession or any necessary precaution in conformity with the marketing authorisation, provided that the information is not promotional. That additional information shall appear in the package leaflet clearly separated from the information in the numbered sections.

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 in SPC section 1]

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

[Name of the veterinary medicinal product followed by strength (if applicable) and pharmaceutical form.]

[Target species: according to the target species list under “Referentials” on the SPOR website

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

{active substance(s)}

2. QUALITATIVE AND QUANTITATIVE COMPOSITION OF THE ACTIVE SUBSTANCE OR SUBSTANCES

[Qualitative and quantitative composition of the active substance or substances and of excipients and other constituents (e.g. adjuvants), 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.]

[For novel therapy veterinary medicinal products: preservative method should be described.]

[For novel therapy veterinary medicinal products: detailed description of cells or tissues and of their specific origin, including the animal species should be provided.]

3. TARGET SPECIES

[According to the target species list under “Referentials” on the SPOR website

[Include main species and any sub-categories.]

[If the text for target species is replaced by a pictogram, 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 1 of the QRD guidance on the use of approved pictograms published on the European Medicines Agency website, or from the Implementing Act providing a list of the abbreviations or pictograms common throughout the Union, as per Article 17(2) of the Regulation.]

4. INDICATIONS FOR USE

[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 3.4 of the SPC, if applicable.]

6. SPECIAL WARNING(S)

[Relevant text from sections 3.4, 3.5, 3.7, 3.8, 3.10, 3.11 and 5.1 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.]

<None.>

<Special warnings [for each target species]:>

<Special precautions for safe use in the target species:>

<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.]

<Special precautions for the protection of the environment:>

<Other precautions:>

<Pregnancy:>

<Lactation:>

<Pregnancy and lactation:>

<Lay:>

<Fertility:>

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

<Symptoms of overdose (and where applicable, emergency procedures, antidotes):>

<Incompatibilities:>

7. ADVERSE EVENTS

[All adverse events should be ranked in “frequency groupings” with the most frequently occurring clinical signs listed first. In each frequency category, it is recommended that the clinical signs should be listed preferably in alphabetical order. Coding of these clinical signs should follow standardised terms (e.g. VeDDRA).]

<Target species>

[Adverse events should be presented in a tabular form for each target species. Information related to several target species may be merged into a single table if it is strictly the same.]

<table>
<thead>
<tr>
<th>Frequency Category</th>
<th>Adverse Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;1 animal/100 treated (common):</td>
<td>{adverse events in alphabetical order}</td>
</tr>
<tr>
<td>1 to 100 animals / 10,000 animals treated (uncommon):</td>
<td>{adverse events in alphabetical order}</td>
</tr>
<tr>
<td>&lt;1 animal/10,000 animals treated, including isolated reports (very rare):</td>
<td>{adverse events in alphabetical order}</td>
</tr>
</tbody>
</table>
Where necessary: include additional information on particular measures to be taken in case specific adverse events occur (i.e. administration of an antidote, removing of a collar, washing of an application site...). Where relevant, information on the expected severity, duration and outcome of the clinical signs that may result following administration of the veterinary medicinal product can be described (e.g. lameness, 1-3 weeks following booster vaccination, vomiting and/or diarrhoea, generally lasting 2 days, etc.).

Where appropriate, warning against certain visible signs of deterioration.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. Alternatively, you can report to the marketing authorisation holder (see also section 16 of the package leaflet for contact details) or via your national reporting system.

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

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

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 EXP> <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 5.2.]

<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 PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

[Include information from sections 5.5 and 10 of the SPC in user-friendly wording]

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

[Special precautions and instructions for handling and disposal of used veterinary medicinal product or waste materials derived from such product if appropriate and, if necessary, with explanatory drawings and pictures.]

Medicines should not be disposed of via wastewater <or household waste>.>

This veterinary medicinal product should not enter water courses as {INN/active substance(s)} may be dangerous for fish and other aquatic organisms.> [if applicable.]

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and, if applicable, national collection systems. Ask your <veterinary surgeon> <or> <pharmacist> how to dispose of medicines no longer required.

These measures should help to protect the environment.

13. NAME OR COMPANY NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

[Name or company name and permanent address or registered place of business of the marketing authorisation holder and of the manufacturer responsible for batch release and, where applicable, of the representative of the marketing authorisation holder – see also section 16.]
14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

[As it appears in section 11 of the SPC.]

15. 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 and national procedures: To be completed in accordance with national requirements after conclusion of the procedure.]

[For veterinary medicinal products authorised via the centralised procedure, the following reference to the European Medicines Agency website should be included:]


16. MARKETING AUTHORISATION HOLDER OR ITS REPRESENTATIVE, AS APPROPRIATE, FOR THE REPORTING OF SUSPECTED ADVERSE EVENTS

<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 and national procedures]. 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 and national procedures].

- 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](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: +31 (0)88 781 6000

---

**België/Belgique/Belgien**

{Nom}/Naam/Name

{Adresse}/Adres/Anschrift

BE-0000 {Localité/Stad/Stadt}>

Tél/Tel: + {N° de téléphone/Telefoonnummer/Telefonnummer}

{E-mail}>

---

**Lietuva**

{pavadinimas}

{adresas}

LT {pašto indeksas} {miestas}>

Tel: +370 {telefono numeris}

{E-mail}>

---

**Республика България**

{Наименование}

{Адрес}

BG {Град} {Пощенски код}>

Тел: +359 {Телефонен номер}

{E-mail}>

---

**Luxembourg/Luxemburg**

{Nom}

{Adresse}

L-0000 {Localité/Stadt}>

Tél/Tel: + {N° de téléphone/Telefoonnummer}>

{E-mail}>

---

**Česká republika**

{Název}

{Adresa}

CZ {město}>

Tel: +{telefonní číslo}

{E-mail}>

---

**Magyarország**

{Név}

{Cím}

HU-0000 {Város}>

Tel.: + {Telefonszám}

{E-mail}>

---

**Danmark**

{Navn}

{Adresse}

DK-0000 {by}>

Tlf: + {Telefonnummer}

{E-mail}>

---

**Malta**

{Isem}

{Indirizz}

MT-0000 {Belt/Rahal}>

Tel: + {Numru tat-telefon}

{E-mail}>

---

**Deutschland**

{Name}

{Anschrift}

DE-000000 {Stadt}>

Tel: + {Telefonnummer}

{E-mail}>

---

**Nederland**

{Naam}

{Adres}

NL-0000 XX {stad}>

Tel: + {Telefoonnummer}

{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>

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

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

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}
{Oraș} {Cod poștal} – RO> Tel: + {Număr de telefon}
</E-mail>

Slovenija
{Ime}
{Adresa}
{Poštanski broj} {grad}>
Tel: + {Telefonski broj}
</E-mail>

Slovenská republika
{Meno}
{Adresa}
SK-000 00 {Mesto}>
Tel: + {Telefónne číslo}
</E-mail>
17. MARKETING AUTHORISATION NUMBER(S)

<18. OTHER INFORMATION>

For MRP/DCP and national procedures: Relevant additional text if necessary.

[Pharmacological or immunological information and environmental properties (if applicable) could be included here.]

All package sizes must be listed here.

For novel therapy veterinary medicinal products: Explanatory illustrations may be included if necessary.

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

The package leaflet may bear additional information concerning distribution, possession or any necessary precaution in conformity with the marketing authorisation, provided that the information is not promotional. That additional information shall appear in the package leaflet clearly separated from the information in the numbered sections above.