[Version 9.1, 11/2024]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

[The information contained in the QRD templates is non-exhaustive. Applicants should refer to all relevant European Union legislation and guidelines when drawing up applications. It is the applicant's responsibility to ensure that the product information complies with all applicable requirements. In particular, applicants should take into account CVMP and CMDv guidance relevant to the content of product information, as well as relevant Delegated and Implementing Acts arising from Regulation (EU) 2019/6. Some examples of guidelines that are commonly applicable to the product information are:

- *CVMP GL for the demonstration of efficacy for VMPs containing anticoccidial substances (EMA/CVMP/EWP/755916/2016);*
- *CVMP GL on the demonstration of palatability of VMPs (EMA/CVMP/EWP/206024/2011);*
- *CVMP GL on the SPC for antiparasitic VMPs (EMEA/CVMP/EWP/170208/2005);*
- *CVMP GL on data requirements for VMPs intended to reduce the risk of transmission of vector-borne pathogens in dogs and cats (EMA/CVMP/EWP/278031/2015);*
- *CVMP Q&A on the information to be included in the SPC section on pharmacodynamics (EMA/CVMP/757903/2016);*
- *CVMP GL on the SPC for VMPs containing antimicrobial substances (EMA/CVMP/383441/2005);*
- *CVMP GL for the demonstration of efficacy for VMPs containing antimicrobial substances (EMA/CVMP/627/2001);*
- *CVMP Revised position paper on indications for veterinary vaccines (EMEA/CVMP/042/97-Rev.1-FINAL);*
- *CVMP GL on the requirements for combined vaccines and associations of immunological VMPs (EMA/CVMP/IWP/594618/2010);*
- *CVMP GL on data requirements for adjuvants in vaccines for veterinary use (EMA/CVMP/IWP/315887/2017);*
- *CVMP GL on user safety for pharmaceutical veterinary medical products (VMPs) (EMA/CVMP/543/03-Rev.1);*
- *CVMP GL on user safety for immunological VMPs (EMEA/CVMP/IWP/54533/2006);*

- *CVMP GL on environmental impact assessment for VMPs in support of the VICH guidelines GL6 and GL38 (EMA/CVMP/ERA/418282/2005-Rev.1- Corr.);*
- *CVMP GL on the assessment of persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances in VMPs (EMA/CVMP/ERA/52740/2012), and supporting Q&A document (EMA/593989/2019);*
- *CVMP GL on declaration of storage conditions: A. in the product information of pharmaceutical veterinary medicinal products, B. for active substance (EMEA/CVMP/422/99/Rev.3);*
- *CVMP GL on quality aspects of pharmaceutical veterinary medicines for administration via drinking water - Annex on compatibility studies between veterinary medicinal products and biocidal products (EMA/CVMP/QWP/592906/2022).*

  Applicants should be aware that many guidelines are under revision and new guidelines are being drafted in relation to the implementation of Regulation (EU) 2019/6. Always check the EMA's website for the current version of existing guidelines and for new guidelines in the different subject areas.]

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

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"):

Standard statements are given in the template which should 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 https://spor.ema.europa.eu/rmswi/#/
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: taking into account the target species list under "Referentials" on the SPOR website https://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.]

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 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>}

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

[For MRP/DCP/SRP: 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.]

[Apart from this section 1 of the SPC, when otherwise referring to the veterinary medicinal product throughout the text, use the words 'veterinary medicinal product' rather than the invented name. The use of pronouns is encouraged where it improves the readability of the text.]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Active substances:
[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.]

<Adjuvants:>
[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.]

<Excipients:>
[The second column of the table can be deleted if it is not applicable i.e. if no information on quantitative composition is required for proper administration.]

<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.]*	**<Quantitative composition if that information is essential for proper administration of the veterinary medicinal product>** *[e.g. preservatives such as formaldehyde, thiomersal or colourants.]*
*[**e.g. Lyophilisate:***	
Sorbitol	
Thiomersal]	*[e.g. 0.1 mg]*
[e.g. Solvent:	
Water for injections]	

[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.]

[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.]

3. CLINICAL INFORMATION

3.1 Target species

Taking into account the target species list under "Referentials" on the SPOR website https://spor.ema.europa.eu/rmswi/#/lists/100000108853/terms]

[Include species and, if appropriate, 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

[Contraindications for target species should be included in this section. 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; in such cases, absolute contraindications for non-target species should be included here. Non-indications (e.g. 'this veterinary medicinal product is not indicated for...') should not be mentioned. Information from 3.12 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 veterinary medicinal 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 veterinary medicinal 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 e.g. treated dogs should not be allowed to enter surface water for 48 hours after treatment to avoid adverse effects on aquatic organisms. Or, e.g. the long-term effects of the VMP 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.]

<Not applicable.>

<Other precautions:>
Where a particular risk has been identified for non-target species that is related to e.g. indirect exposure to the veterinary medicinal product, safety precautions/warnings and appropriate risk mitigation measures should be included here.

[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, should not be included in the SPC:
'For animal treatment only.'
'Keep out of the sight and reach of children.']

3.6 Adverse events

[Adverse events should be coded using VeDDRA standard terms (preferably VeDDRA low level terms (LLTs)) and ranked in "frequency categories" with the most frequently occurring clinical signs listed first. In each frequency category, clinical signs should be grouped in accordance with VeDDRA system organ classes (SOC). NB. Where there may not be an appropriate VeDDRA LLT, a request for a new LLT can be made to the VeDDRA subgroup]

{Target species:}*[The relevant single or multiple target species to be specified]*
[Adverse events should be presented in a tabular form for each target species. Adverse events related to several target species may be merged into a single table if they are strictly the same or when there are a few adverse events which have a different frequency, which can be annotated in a footnote immediately below the table. Tabular rows should be deleted if there are no adverse events in that frequency category. Tables can be omitted from the package leaflet, however the information contained, and structure should be maintained].

Very common (>1 animal / 10 animals treated):	{adverse event/VeDDRA LLT (relevant additional information**, adverse event/VeDDRA LLT (relevant additional information**) etc.}
Common (1 to 10 animals / 100 animals treated):	{adverse event/VeDDRA LLT (relevant additional information**), adverse event/VeDDRA LLT (relevant additional information**) etc.}
Uncommon* (1 to 10 animals / 1 000 animals treated):	{adverse event/VeDDRA LLT (relevant additional information**), adverse event/VeDDRA LLT (relevant additional information**) etc.}
Rare* (1 to 10 animals / 10 000 animals treated):	{adverse event/VeDDRA LLT (relevant additional information**), adverse event/VeDDRA LLT (relevant additional information**) etc.}
Very rare* (<1 animal / 10 000 animals treated, including isolated reports):	{adverse event/VeDDRA LLT (relevant additional information**), adverse event/VeDDRA LLT (relevant additional information**) etc.}

*[*The style of the number separator (space, dot or comma for the thousands or lack thereof) must correspond to the language used in the relevant Member State – please refer to the section on 'Number*

separators' in the Compilation of QRD decisions on stylistic matters in product information EMA/25090/2002.]
*[**Additional information should preferably be detailed in a footnote immediately under the table and should comprise information necessary for supporting adverse event management (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 relevant, information on different frequencies of adverse events reported depending on indication and dosing can be specified (e.g. vomiting is reportedly rare when given at 10 mg/kg dose). If a footnote is not used, then additional information should be briefly stated in parenthesis after the relevant clinical sign(s).]

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder <or its local representative> or the national competent authority via the national reporting system. See the <package leaflet> <immediate packaging> for respective contact details.
[Immediate packaging to be used only in the case of a combined label-leaflet].

3.7 Use during pregnancy, lactation or lay

[The possible impact of the veterinary medicinal product on reproduction parameters should be addressed in this section, taking into account the standard sentences listed below. If relevant for a certain species (e.g. fish or honey bees), other reproductive parameters may be used or existing terms adapted, as needed.]

<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 <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 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 but not mixed:
<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 this case for veterinary medicinal products administered parenterally:*
<The <veterinary medicinal products> <vaccines> <immunological veterinary medicinal products> 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 routes 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, with explanatory drawings and pictures, if necessary. 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 body weight 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, and in accordance with Article 14(4) of Regulation (EU) 2019/6, on the packaging (see combined label-leaflet template).]

[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.>
[Not applicable to immunological veterinary medicinal products]

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

<*[Not applicable to immunological veterinary medicinal products]* 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 (a similar formula could be provided for products administered via feed, if necessary)]*

$$\frac{\begin{matrix}\text{mg or ml veterinary medicinal product/}\\ \text{kg body weight per day}\end{matrix} \; x \; \begin{matrix}\text{average body weight (kg)}\\ \text{of animals to be treated}\end{matrix}}{\text{average daily water intake } (l/animal)} = \begin{matrix}\text{mg or ml veterinary medicinal product}\\ \text{per litre of drinking water}\end{matrix}$$

[The actual words 'veterinary medicinal product' must be used in the formula, not converted to the invented name of the product.]

[With reference to the Commission Delegated Regulation (EU) 2024/1159, for antimicrobial and antiparasitic products, to be administered to a terrestrial food-producing animal species by means of mixing into solid feed or administered on the surface of solid feed immediately prior to feeding, the following statement should be used:]
<The veterinary medicinal product is to be administered only for the treatment of individually fed animals or a small group of animals where the intake by individual animals can be effectively controlled.>

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) of Regulation (EU) 2019/6 should appear in SPC section 3.5. Repetition of content across several SPC sections should be avoided.]

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

<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 administration only by a veterinarian.>

<Official control authority batch release may be required for this product according to national requirements.> *[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]*

<Not applicable.>

3.12 Withdrawal periods

[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.]*

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

<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 'within {X} weeks of the start of the laying period' cannot be determined.]*

4. <PHARMACOLOGICAL> <IMMUNOLOGICAL> INFORMATION

4.1 ATCvet code :

{lowest available level (e.g. subgroup for chemical substance)}

[For biologicals/immunologicals, insert the biological/immunological properties below the ATCvet code and delete sub-sections 4.2 and 4.3 below if not relevant.]

<4.2 Pharmacodynamics> *[not applicable for immunologicals.]*

<4.3 Pharmacokinetics> *[not applicable for immunologicals.]*

<Environmental properties> *[if not applicable delete this section. Information provided here should refer to properties of particular note for the environment (e.g. {active substance} is classified as persistent, bioaccumulative and toxic (PBT)). Any environmental precautions and/or risk mitigation measures should be included under the sub-heading of SPC section 3.5 above, 'Special precautions for protection of the environment'. Information in that section should not be repeated here.]*

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.]

[With reference to the Commission Delegated Regulation (EU) 2024/1159, where data or information on potential interactions or incompatibilities between the veterinary medicinal product and biocidal products, feed additives or other substances used in drinking water is available, the following statement should be used:]
<Data> <and> <information> are available which show that this veterinary medicinal product <can> <cannot> be used simultaneously and/or dissolved in <drinking water> <or> <liquid feed> with {description of tested biocidal product(s), feed additive(s) or other substance(s) used in drinking water.}>

[When these data refer to biocides, statements from the CVMP GL on quality aspects of pharmaceutical veterinary medicines for administration via drinking water - Annex on compatibility studies between veterinary medicinal products and biocidal products, should be included in this section as follows:]
<This veterinary medicinal product must not be administered using drinking water containing {name of biocidal active substance 1, e.g., chlorine} as the active substance {name of active substance} degrades in the presence of <this biocidal active substance > <these biocidal active substances >.>
<This veterinary medicinal product may be administered using drinking water containing {name of biocidal active substance 1, e.g., active chlorine} at a maximum concentration of {XX} ppm.>

[With reference to the Commission Delegated Regulation (EU) 2024/1159, where no data or information on potential interactions or incompatibilities between the veterinary medicinal product and biocidal products, feed additives or other substances used in drinking water is available, the following statement should be used:]
<No information is available on potential interactions or incompatibilities of this veterinary medicinal product administered orally by mixing into <drinking water> <or> <liquid feed> containing <biocidal products>, <feed additives> <or> <other substances used in drinking water.>

<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> <and except those mentioned in section 3.8 above>.>

<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 <dissolution> <dilution> <reconstitution> according to directions:>
<Shelf life after <incorporation> <mixing> 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>.>
<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.]*

5.4 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 appropriate, add:]

<Not all pack sizes may be marketed.>

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

[Requirement to use take-back schemes for veterinary medicinal products for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products and, if appropriate, additional precautions regarding hazardous waste disposal of unused veterinary medicinal products or waste materials derived from the use of such products. If appropriate, for used novel therapy products, any special precautions or instructions for handling and disposal, with explanatory drawings and pictures (if necessary).]

Medicines should not be disposed of via wastewater <or household waste>. *[For MRP/DCP/SRP (after conclusion of the MR/DC/SR phase) and for national procedures, the phrase in brackets <or household waste> may be included or not, in accordance with national requirements. The actual brackets should not be included.]*

<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.]*

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.
[For MRP/DCP/SRP and national procedures only: information on the national collection systems referred to in Article 117 of Regulation (EU) 2019/6, applicable to the veterinary medicinal product concerned, to be completed in accordance with national requirements after conclusion of the MRP/DCP/SRP. Additional requirements may apply in some Member States and can be included here.]

6. NAME OF THE MARKETING AUTHORISATION HOLDER

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

8. DATE OF FIRST AUTHORISATION

[Item to be completed by the marketing authorisation holder once the marketing authorisation has been granted.
For veterinary medicinal products authorised via the centralised procedure 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/target species approvals introduced via subsequent variations.]

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

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

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

[Leave blank in case of first authorisation].
[Item to be completed by the marketing authorisation holder. This date will correspond to the date when the MAH has last reviewed the final text internally during a procedure changing the SPC (variation, Urgent Safety Restriction, or MA transfer), at the latest at the time of communication from EMA, the Reference Member State or the national competent authority about the end of the procedure.
For MRP/DCP and national procedures: the final version submitted to the national competent authority should contain a revision date completed by the marketing authorisation holder.]

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

<**LIMITED MARKETS:**>
<Marketing authorisation granted for a limited market and therefore assessment based on customised requirements for documentation. Only a limited assessment of safety or efficacy has been conducted due to the lack of comprehensive safety or efficacy data.>
[The above standard statement to be included for veterinary medicinal products authorised in accordance with Article 23(2) of Regulation (EU) 2019/6.]

<**EXCEPTIONAL CIRCUMSTANCES:**>
<Marketing authorisation in exceptional circumstances and therefore assessment based on customised requirements for documentation. Only a limited assessment of quality, safety or efficacy has been conducted due to the lack of comprehensive quality, safety or efficacy data.>
[The above standard statement to be included for veterinary medicinal products authorised in accordance with Article 26(2) of Regulation (EU) 2019/6.]

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

[Prescription status, as referred to in Article 34 of Regulation (EU) 2019/6, from the options below, for each Member State in which it is authorised. Any national sub-categories may be included in the separate boxed area at the end of the package leaflet.]
[NB Special conditions for use according to Article 106(4) of Regulation (EU) 2019/6, e.g. 'For administration only by a veterinarian' to be included in SPC section 3.11 above.]

<Veterinary medicinal product subject to prescription.>
<Veterinary medicinal product not subject to prescription.>
<Veterinary medicinal product subject to prescription except for some pack sizes.>

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).

ANNEX II

[Not applicable for MRP/DCP/SRP and national procedures]

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.]

[If there are no other conditions or requirements, use 'None' below and delete the next page.]

<None.>

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION
[If additional risk minimisation activities (e.g. educational material) are proposed beyond those addressed in SPC section 3.11, these should be listed here. Any exception to this rule (e.g. set up of surveillance programmes in only a few Members State) should be discussed and reflected in the CVMP AR.]

<SPECIFIC PHARMACOVIGILANCE REQUIREMENTS:>
[To be included only if different from standard legislative requirements, specific adverse events monitoring, etc…
In addition, for products referred to in Article 42(2)(c) of Regulation (EU) 2019/6, i.e. containing a new active substance, the following sentence should be included. Annually is the default option. If a higher frequency is selected, the CVMP AR should provide the rationale.]
<The MAH shall record in the pharmacovigilance database all results and outcomes of the signal management process, including a conclusion on the benefit-risk balance, according to the following frequency: <annually.> <every X months for the first XX years after authorisation, then annually.>>

<SPECIFIC OBLIGATION TO COMPLETE POST-AUTHORISATION MEASURES FOR THE MARKETING AUTHORISATION IN EXCEPTIONAL CIRCUMSTANCES>
[Conditions in relation to the marketing authorisation in exceptional circumstances status should be distinguished from other conditions. List here all conditions in relation to the marketing authorisation in exceptional circumstances.]

<This being an approval in exceptional circumstances and pursuant to Article 25 of Regulation (EU) 2019/6, 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 in exceptional circumstances. Conditions in relation to the marketing authorisation in 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 Regulation (EU) 2019/6. The information should be presented according to the template below, irrespective of the sequence and position of information on the actual labelling 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 separate template exists for a combined label and package leaflet, in accordance with Article 14(4) of Regulation (EU) 2019/6.

According to Article 11(2) of Regulation (EU) 2019/6, 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 (allocated by the Member State). Such a code may be used to replace the marketing authorisation number in the outer package. Article 17(1) of Regulation (EU) 2019/6 foresees the adoption by the Commission of an Implementing Act establishing uniform rules on identification codes for the packaging of veterinary medicinal products.

The information mentioned on the immediate and outer packaging shall appear in easily legible and clearly comprehensible characters, or in abbreviations or pictograms, as set out in the Annexes to the Commission Implementing Regulation (EU) 2024/875 adopting a list of abbreviations and pictograms common throughout the Union to be used on the packaging of veterinary medicinal products for the purposes of Article 10(2) and Article 11(3) of Regulation (EU) 2019/6.

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: EMA/CMDv/244519/2021 – Rev. 1, 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. Specific CMDv/EMA guidance on practical use of the provisions of Article 13 will be provided in due course.

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.]*

[Article 11(3) provides that abbreviations or pictograms may be used to replace the information in Article 11(1), in accordance with the Commission Implementing Regulation (EU) 2024/875 adopting a list of abbreviations and pictograms common throughout the Union to be used on the packaging of veterinary medicinal products for the purposes of Article 10(2) and Article 11(3) of Regulation (EU) 2019/6].

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

[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. NB According to Article 4(20) of Regulation (EU) 2019/6, 'Common name' means the INN recommended by the WHO for a substance or, if one does not exist, the name generally used.]

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. INDICATIONS

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

[For MRP/DCP/SRP and national procedures:

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 products not subject to veterinary prescription' should be included in this section and grey shaded.]

6. ROUTES 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).]

[Space shall be provided for the prescribed dose to be indicated on the label/outer carton. Routes 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 PERIODS

[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 periods:>
[If withdrawal periods are 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]
[On a case-by-case basis, for novel therapy veterinary medicinal products and for biological veterinary medicinal products (e.g. with a shelf-life of < 2 years), the expiry date may specify the day i.e. dd/mm/yyyy.]

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.>

<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 WORDS "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/SRP and national procedures: To be completed nationally.]

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

14. MARKETING AUTHORISATION NUMBERS

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

15. BATCH NUMBER

[The batch number, preceded by the word "Lot"]

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{NATURE/TYPE}

[Article 10(2) provides that abbreviations or pictograms may be used to replace the information in Article 10(1), in accordance with the Commission Implementing Regulation (EU) 2024/875 adopting a list of abbreviations and pictograms common throughout the Union to be used on the packaging of veterinary medicinal products for the purposes of Article 10(2) and Article 11(3) of Regulation (EU) 2019/6.]

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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

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. NB According to Article 4(20) of Regulation (EU) 2019/6, 'Common name' means the INN recommended by the WHO for a substance or, if one does not exist, the name generally used (INN, if applicable).]

3. TARGET SPECIES

[As in SPC section 3.1.]
[On the printed material, the target species should appear displayed close to the name.]

4. ROUTES 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.

[Routes 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 PERIODS

[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 periods:>
[If withdrawal periods are not applicable, the template heading should not be deleted, and the section should be left blank.]

6. 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]

[On a case-by-case basis, for novel therapy veterinary medicinal products and for biological veterinary medicinal products (e.g. with a shelf-life of < 2 years), the expiry date may specify the day i.e. dd/mm/yyyy.]

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.>>

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/SRP and national procedures: To be completed nationally.]

{Name or company name or logo name 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/TYPE}

[Blisters or strips, ampoules and small single-dose containers other than ampoules. As defined by Article 1(1)(c) of the Commission Implementing Regulation (EU) 2024/878 containers with a nominal volume of up to and including 50 ml shall be considered to be small immediate packaging units. Derogation from this article is provided whereby the Competent Authority/European Medicines Agency may consider multilingual immediate packaging units not exceeding a nominal volume of 100 ml as small immediate packaging units where the conditions of Article 1(2)(a)(b) of the Commission Implementing Regulation (EU) 2024/878 are fulfilled.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

[As defined by Article 4(21) of Regulation (EU) 2019/6 with no qualifiers]

{(Invented) name of veterinary medicinal product}

[It is strongly recommended to include at least a pictogram of the target species e.g. for spot-ons where there is risk of confusion between dog and cat presentations.]

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

[Expressed quantitatively per unit or according to the form of administration for a particular volume or weight, using the common names.]

[For immunological veterinary medicinal products, qualitative description of the active substance(s) may be acceptable instead, if justified (e.g. in case of space limitation).]

[Where there is a prohibitive space limitation, expression of the quantitative particulars of the active substances could be replaced by the unit volume or body weight range. If the primary packaging directly in contact with the veterinary medicinal product (e.g. spot-on pipette/applicator) is contained in an additional layer of packaging (e.g. foil blister/pouch) within the outer packaging, that additional packaging should include the quantitative particulars of the active substances.]

3. BATCH NUMBER

[The batch number, preceded by the word "Lot"]

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]

[On a case-by-case basis, for novel therapy veterinary medicinal products and for biological veterinary medicinal products (e.g. with a shelf-life of < 2 years), the expiry date may specify the day i.e. dd/mm/yyyy.]

Exp. {mm/yyyy}

[Where there is sufficient space, it is strongly recommended to include the in-use shelf-life to ensure the safe and effective use of the veterinary medicinal product.]

[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, unless by the derogation provided by Article 14(4) of Regulation (EU) 2019/6, all the information required is provided on the packaging of the veterinary medicinal product. In all other cases, the 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 it is necessary to deviate from these statements to accommodate product-specific requirements, alternative or additional statements will be considered on a case-by-case basis.

In accordance with Article 2(2) of the Commission Implementing Regulation (EU) 2024/875 adopting a list of abbreviations and pictograms common throughout the Union to be used on the packaging of veterinary medicinal products for the purposes of Article 10(2) and Article 11(3) of Regulation (EU) 2019/6, abbreviations and pictograms used on the labelling of a veterinary medicinal product must be explained in full text in the relevant sections of the package leaflet.

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

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

[As in SPC section 1]
{(Invented) name of veterinary medicinal product <strength> pharmaceutical form <target species>}

2. Composition

[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 i.e. those listed quantitatively in section 2 of the SPC should be stated here.]

[Include a description of the visual appearance of the pharmaceutical form, as marketed e.g. shape, texture, colour, imprint. Also, include a description of the appearance of the product before reconstitution/dilution, if applicable.]

3. Target species

[As in SPC section 3]

4. Indications for use

[Indication(s) in each target species should be stated here, using understandable language.
A short section clearly describing 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 from section 3.3 of the SPC, if applicable.]

6. Special warnings

[Relevant text from sections 3.4, 3.5, 3.7, 3.8, 3.10, 3.11 and 5.1 of 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. Where the statement "Not applicable" appears in the SPC the relevant sub-heading should not be included in the package leaflet.]

[For warning on accidental self-administration, etc. include statement as it appears in the SPC section 3.5.]

<None.>

<Special warnings: *[for each target species, as per SPC section 3.4]*>

<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:>

[In accordance with SPC section 3.5, special precautions regarding impact on the environment and risk mitigation measures e.g. treated dogs should not be allowed to enter surface water for 48 hours after treatment to avoid adverse effects on aquatic organisms.]

<Other precautions:>*[In accordance with SPC section 3.5, particular risk regarding non-target species, chemical reactions of the VMP with furniture or clothes.]*

<Pregnancy:>

<Lactation:>

<Pregnancy and lactation:>

<Laying birds:>

<Fertility:>

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

<Overdose:>
[Symptoms of overdose and, where applicable, emergency procedures, antidotes]

<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.]
[Information from SPC section 3.11 appropriate to the package leaflet.]

<Major incompatibilities:>

7. Adverse events

[Adverse events should be coded using VeDDRA standard terms (preferably VeDDRA low level terms (LLTs) and ranked in "frequency groupings" with the most frequently occurring clinical signs listed first. In each frequency category, clinical signs should be grouped in accordance with VeDDRA system organ classes (SOC).]

{Target species:}*[The relevant single or multiple target species to be specified]*
[Adverse events may be presented as in the SPC, a singular column tabular format for each target species or only text in sections maintaining the headings and structure used in the SPC and described as follows.

Adverse events related to several target species may be merged if they are strictly the same or when there are a few adverse events which have a different frequency, which can be annotated in a footnote immediately below the table or section. Tabular rows or sections should be deleted if there are no adverse events in that frequency category].

[Example single column table below]

Very common (> 1 animal / 10 animals treated):
*{adverse event/VeDDRA LLT (relevant additional information**), adverse event/VeDDRA LLT (relevant additional information**) etc.}*
Common (1 to 10 animals / 100 animals treated):
*{adverse event/VeDDRA LLT (relevant additional information**), adverse event/VeDDRA LLT (relevant additional information**) etc.}*
Uncommon (1 to 10 animals / 1 000 animals treated):*
*{adverse event/VeDDRA LLT (relevant additional information**), adverse event/VeDDRA LLT (relevant additional information**) etc.}*
Rare (1 to 10 animals / 10 000 animals treated):*
*{adverse event/VeDDRA LLT (relevant additional information**), adverse event/VeDDRA LLT (relevant additional information**) etc.}*
Very rare (<1 animal / 10 000 animals treated, including isolated reports):*
*{adverse event/VeDDRA LLT (relevant additional information**), adverse event/VeDDRA LLT (relevant additional information**) etc.}*

*[*The style of the number separator (space, dot or comma for the thousands or lack thereof) must correspond to the language used in the relevant Member State – please refer to the section on 'Number separators' in the Compilation of QRD decisions on stylistic matters in product information EMA/25090/2002.]*

*[**Additional information should preferably be detailed in a footnote immediately under the table or section and should comprise information necessary for supporting adverse event management (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 relevant, information on different frequencies of adverse events reported depending on indication and dosing can be specified (e.g. vomiting is reportedly rare when given at 10 mg/kg dose). If a footnote is not used, then additional information should be briefly stated in parenthesis after the relevant clinical sign(s).]

[Close this section with:]
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. You can also report any adverse events to the marketing authorisation holder <or its local representative> using the contact details at the end of this leaflet, or via your national reporting system: {national system details}*[listed in Appendix I*]*.

*[***For the printed materials:** Where national system details are included in the printed material (in accordance with national requirements), the actual details of the national reporting system of the concerned Member State(s) (as listed in Appendix I) should be displayed on the printed version. No reference to Appendix I should be included in the printed materials.*
The examples below are not exhaustive; the design and layout chosen for the package leaflet should drive the display of the details. Linguistic adjustments may also be necessary depending on the grammatical rules of the languages used.

- *In case the details of the national reporting system are short, e.g. website only, you may wish to integrate the details within the text as per the example below:*
  "You can also report any adverse events to <the marketing authorisation holder> <the local

representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system: www.xxx.xx.xx".

- *In case the details of the national reporting system are long and/or leaflet addressed to more than one Member States, you may wish to follow the example below:*
  "You can also report any adverse events to <the marketing authorisation holder> <the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system:

  Ireland
  {Name}
  <{Address}
  {Town} {Postal code} - IE
  Tel: + {Telephone number}>
  website
  <{E-mail}>

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

8. Dosage for each species, routes and method of administration

9. Advice on correct administration

[Directions for proper use of the veterinary medicinal product by healthcare professionals, farmer or animal owner; including practical details such as mixing instructions e.g. "Shake well before use". Relevant text from section 3.9 of the SPC should be included as appropriate in user-friendly wording. Detailed instructions for use, application and implantation, if necessary, with explanatory drawings and pictures. If the medicine contains or requires the use of devices for administration or implantation a description of those devices should be provided.]

[A description of appearance after reconstitution, if applicable. Where appropriate, warning against certain visible signs of deterioration:]
<Do not use {(Invented) name of veterinary medicinal product} if you notice {description of visible signs of deterioration}.>

10. Withdrawal periods

[As it appears in section 3.12 of the SPC.]

11. Special storage precautions

[As it appears in section 5.3 of the SPC.]

Keep out of the sight and reach of children.

<Do not store above <25 °C> <30 °C>.>
<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 immediate packaging: …..>
<Shelf life after <dissolution> <dilution> <reconstitution> according to directions: …..>
<Shelf life after <incorporation> <mixing> into meal or pelleted feed: ….>

12. Special precautions for disposal

[Special precautions for the disposal of unused product or waste materials, if any. Include the information from section 5.5 of the SPC in user-friendly wording.]
[For MRP/DCP/SRP and national procedures: information on the national collection systems referred to in Article 117 of Regulation (EU) 2019/6, applicable to this veterinary medicinal product, to be completed in accordance with national requirements after conclusion of the MRP/DCP/SRP. 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, with explanatory drawings and pictures (if necessary).]

Medicines should not be disposed of via wastewater <or household waste>. *[For MRP/DCP/SRP (after conclusion of the MR/DC/SR phase) and for national procedures, the phrase <or household waste> may be included or not, in accordance with national requirements. The actual brackets should not be included.]*

<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 with any applicable national collection systems. These measures should help to protect the environment.
[The next sentence below should be included unless the veterinary medicinal product is for administration only by a veterinarian. For MRP/DCP/SRP (after conclusion of the MR/DC/SR phase) and for national procedures, the options to include <veterinary surgeon> or <pharmacist> should be included or not, in accordance with national requirements. The actual brackets should not be included.]
<Ask your <veterinary surgeon> <or> <pharmacist> how to dispose of medicines no longer required.>

13. Classification of veterinary medicinal products

[As it appears in section 10 of the SPC, but only the information on classification, not the statement on availability of further information in the UPD because that statement already appears in section 15 of the template for the package leaflet.]

14. Marketing authorisation numbers and pack sizes

[MA numbers may be presented as a range e.g. EU/2/XX/XXX/001-005.]

[All pack sizes must be detailed here, as per section 5.4 of the SPC and indicating any devices supplied. E.g. Cardboard box with 1 x 15 ml bottle and an oral syringe, or cardboard box with 1 or 5 vial(s) of 50 ml or 100 ml.]

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

15. Date on which the package leaflet was last revised

[Leave blank in case of first authorisation].
[Item to be completed by the marketing authorisation holder. This date will correspond to the date when the MAH has last reviewed the final text internally during a procedure changing the package leaflet (variation, Urgent Safety Restriction, or MA transfer), at the latest at the time of communication from EMA, the Reference Member State or the national competent authority about the end of the procedure. For MRP/DCP and national procedures: the final version submitted to the national competent authority should contain a revision date completed by the marketing authorisation holder.]

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

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).

16. Contact details

[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, if different. Local representatives to be included, where applicable.]

[In cases where more than one manufacturer responsible for batch release is authorised, list all of them in this product information document, but the printed package leaflet must only state the name and address of the manufacturer responsible for the release of the concerned batch.]

[Including town, postal code (if available) and country name in the language of the text (telephone numbers, E-mail addresses may be included but no websites or E-mails linking to websites allowed). Where the marketing authorisation holder is also the contact to report suspected adverse events, a telephone number must be included and, optionally, an E-mail address.]

[For MRP/DCP/SRP and national procedures: To be completed nationally. There may be national differences in the designated contact point for the reporting of suspected adverse events (MAH or local representative) which can be reflected accordingly in each national translation.]

Marketing authorisation holder <,> <and> <manufacturer responsible for batch release> <and contact details to report suspected adverse events>:
[If there are no local representatives and the marketing authorisation holder is the contact point for the reporting of adverse events according to Article 14(1)(l) of Regulation (EU) 2019/6, then all necessary contact details, (including a mandatory telephone number and, optionally, an E-mail address) must be included here and the following must be included in the subheading: < and contact details to report suspected adverse events*>.]*

[If there are national contact details for the MAH (not local representatives) that are used for the reporting of suspected adverse events, then these should be listed here per country with a mandatory telephone number and, optionally, an E-mail address, but the address is not necessary. In this case the sub-heading must be as follows: Marketing authorisation holder <and manufacturer responsible for batch release> and contact details to report suspected adverse events>:*]*

Manufacturer responsible for batch release:

<Local representatives< and contact details to report suspected adverse events>:>
[If the local representative is the contact point for the reporting of adverse events according to Article 14(1)(l) of Regulation (EU) 2019/6, then all necessary contact details (including a mandatory telephone number and, optionally, an E-mail address) must be included here and it must be included in the subheading: < and contact details to report suspected adverse events*>.]*

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.>
[The statement should only be used if the local representative is also providing other information e.g. technical services.]

- *[Listing of local representatives is not a requirement, but where used they must be provided 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/SRP and national procedures for which the local representative can be stated separately for each Member State during the national phase when translations of the product information are provided). 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/SRP 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: https://publications.europa.eu/code/en/en-370100.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 should be indicated by name/company name, permanent address/registered place of business, telephone number (mandatory) and E-mail address (optional). 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}>

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

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

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

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}
{Town} {Postal code} - IE
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}
{Oraş} {Cod poştal} – RO
Tel: + {Număr de telefon}
<{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}>

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}>

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}>

<17. Other information>

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

[For novel therapy veterinary medicinal products and other veterinary medicinal products on a case-by-case basis: Explanatory illustrations may be included if necessary.]

[In accordance with Article 14(2) of Regulation (EU) 2019/6, 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 sections above.]

Any additional, national distribution categories should be completed here in accordance with national requirements after conclusion of the MR/DC/SR phase of the procedure (with reference to the RMS list 'Legal Status for the Supply: https://spor.ema.europa.eu/rmswi/#/lists/100000072051/terms). In case of multi-lingual leaflets, distribution categories should be clearly indicated per country using the country codes i.e. AT, BE, DE etc.