Veterinary Medicines Directorate

Marketing Authorisation Applications

PRODUCT INFORMATION TEMPLATE GUIDANCE

V3 – updated 29/04/2024

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.

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.

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

SUMMARY OF PRODUCT CHARACTERISTICS

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 European Directorate for the Quality of Medicines & HealthCare, Council of Europe (EDQM)),*
*- **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.]*
[Target species: according to 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

[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 the 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 substance<s>:
[Full details of the qualitative and quantitative composition in terms of active substance(s) should be provided using their INN or common names.

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>:>
[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.]

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 3.12 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 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 user safety warnings. If necessary, information should also be given for people in close contact with the treated animal (e.g., owner, children, immunocompromised people, 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 veterinary medicinal product on the population dynamics of dung beetles have not been investigated; therefore, it is advisable not to treat animals on the same pasture every season.]

<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, 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].

[The use of 'undetermined' frequency should be restricted only to those exceptional cases where it is impossible to determine a frequency for a specific adverse event, i.e., the potential causal association cannot be determined based on findings from data submitted with the initial marketing authorisation application or/and through analysis of pharmacovigilance data and taking into account current scientific knowledge. As soon as it becomes possible to define a frequency, the adverse event should be moved to the appropriate frequency category.]

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.}

*[*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 parentheses 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 for respective contact details.

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 accordingly 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 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 the national competent authority, 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, 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)]*

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

[The actual words 'veterinary medicinal product' must be used in the formula, 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

[For antimicrobial and antiparasitic products, any (discretionary) contraindications, special warnings or precautions originating from product-specific assessment should continue to be included under the respective subsection within SPC section 3 ‘Clinical information’. For example, product-related information restricting prophylactic and metaphylactic use should appear in SPC section 3.5. Repetition of content across several SPC sections should be avoided.]

<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. Reference to Member State is not relevant to the UK, including NI, however where shared labelling with an EU country is desired, the text in chevrons may be included.]*

<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 is required for this product.> *[only for those immunological veterinary medicinal products where shared labelling with an EU country is desired and whom use Official Control Authority Batch Release (OCABR)]*

<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 no withdrawal period is required 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 species, where there may be an MRL for milk established, but no residues data in milk are provided, and there is no relevant restriction noted in the 'other provisions' column of the MRL list.]*

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

<Not permitted for use in animals producing <milk><eggs> for human consumption.> *[for milk/egg producing species where there is a restriction to use in such animals in the 'other provisions' column of the MRL list.]*

<Not authorised for use in birds producing eggs for human consumption.>

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

<Not <authorised> for use in birds producing or intended to produce eggs for human consumption.> *[for laying birds and for future laying birds (pullets), where no MRL exists for eggs and when a period of 'within {X} weeks before 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 subheading of SPC section 3.5 above, 'Special precautions for the 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.]

<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/doses 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 product 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>.
[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.

<Not applicable.>

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.]

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 initial authorisation of the veterinary medicinal product concerned. It should not reflect individual strength/presentation approvals introduced via subsequent variations.]

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

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. Date of latest procedure changing the SPC.]

<{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.>

<**EXCEPTIONAL CIRCUMSTANCES:**>
<Marketing authorisation in exceptional circumstances and therefore assessment based on customised requirements for documentation.>

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

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

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

LABELLING

[The items below are required in accordance with Veterinary Medicines Regulations 2013, as amended. The information 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.).

A separate text for the labelling of the outer and immediate packaging should be provided unless the particulars to appear on the outer and immediate packaging are the same. Where the same text for outer and immediate packaging is used, this should be clearly indicated in the heading and in {nature/type}.

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.

The information mentioned on the immediate and outer packaging shall appear in easily legible and clearly comprehensible characters, or abbreviations or pictograms. Pictograms available at QRD guidance on the use of approved pictograms on the packaging of veterinary medicinal products authorised via the centralised (CP), mutual recognition (MRP) and decentralised procedures (DCP) (europa.eu) can be applied.

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.

For solvent labelling the CMDv conclusions and recommendations should be taken into consideration: Rec diluents (hma.eu), and is included in this template.

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.

Grey shading must not be used to indicate additional information agreed as part of a separate EU procedure. Should you wish to achieve a shared label between GB and another country you should liaise with the respective member state to ensure the below labelling requirements can be accommodated on a shared label.]

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {NATURE/TYPE}

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

*Headings are provided to help applicants when completing the template; they should remain in the document. 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}

[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 European Directorate for the Quality of Medicines & HealthCare, Council of Europe (EDQM).]

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.]

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 is not required for prescription medicines. For non-prescription medicines the inclusion of the indication may not be mandatory.]

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. Route(s) of administration should be mentioned according to "Standard terms" published by EDQM. If the information exceeds the size of the label, reduced text is acceptable.]

7. WITHDRAWAL PERIODS

[Withdrawal period for veterinary medicinal product 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.]

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

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

[Local representatives of the MAH may also be included in the Blue Box of the Outer Packaging.]

14. MARKETING AUTHORISATION NUMBERS

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

Vm <number>

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}

[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.

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.

[Route(s) of administration should be mentioned according to "Standard terms" published by EDQM. 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 period is 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

{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, 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 VMD.]

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

{(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 given 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 is 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.>>

PARTICULARS TO APPEAR ON THE IMMEDIATE LABEL OF THE DILUENT/SOLVENT
(normal sized bottles)

1. NAME OF THE DILUENT/SOLVENT

[The 'trade' name with a brief description or a more descript way of naming (Solvent /diluent for type of vaccine it can be used with or properties of the diluent).]

2. TARGET SPECIES

3. ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

4. EXPIRY DATE

Exp. {month/year}

5. SPECIAL STORAGE PRECAUTIONS

[For example: Store below 25 °C.]

6. NAME OF THE MARKETING AUTHORISATION HOLDER

[Company logo or name of company]

7. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

[The marketing authorisation holder shall make readily available a package leaflet for each veterinary medicinal product unless all the information required is provided on the packaging of the veterinary medicinal product. In all other cases, the package leaflet shall contain, but is not limited to, 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. Only a package leaflet approved in the marketing authorisation may be published or included with the veterinary medicinal product. The VMD may require the information provided below to be made available in written form 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

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 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 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 3.3 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, in this case the heading should not be included.]

[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:>*[E.g., chemical reactions of the veterinary medicinal product 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 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.}*

*[*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 diarrhea, 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 10mg/kg dose). If a footnote is not used, then additional information should be briefly stated in parenthesis after the relevant clinical sign(s).]
[The package leaflet should be written in terms that are understandable to the general public, i.e. plain language or 'layman's terms'. The VeDDRA LLT from the SPC may be included in the package leaflet followed by the layman's term equivalent in parentheses: e.g. 'Ataxia (Incoordination).]

[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 the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

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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.]

[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>.

[The phrase in brackets <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. 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.]

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm <number>

[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. PID link (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

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]

[Including town, postal code (if available) and country (telephone numbers, E-mail addresses may be included (no websites or E-mails linking to websites allowed).]

[Where the marketing authorisation holder is also the contact to report suspected adverse reactions, a telephone number must be included and, optionally, an E-mail address.]

Marketing authorisation holder <and manufacturer responsible for batch release> <and contact details to report suspected adverse reactions>:

[If there is no local representative and the marketing authorisation holder is the contact point for the reporting of adverse reactions, 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 reactions>.]

Manufacturer responsible for batch release:

<Local representatives< and contact details to report suspected adverse reactions>:>

[If there is no local representative and the marketing authorisation holder is the contact point for the reporting of adverse reactions, 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 reactions>.]

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

17. Other information

[Distribution category]

POM-VPS
POM-V
AVM-GSL
NFA-VPS

[Pharmacological or immunological information and environmental properties (if applicable) could be included here, i.e., pharmacodynamics, pharmacokinetics and environmental properties.]

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

[For veterinary medicines authorised under the Centralised Procedure in the EU and where an, identical GB marketing authorisation/application has been issued/received, the VMD will not enforce a requirement for inclusion of the name and address of the GB marketing authorisation holder/distributor (if different to the EU marketing authorisation holder information), and the GB Vm number on the accompanying package leaflet. Instead, if the name and address of the GB marketing authorisation holder/distributor (if different to the EU marketing authorisation holder information), and the GB Vm number are not included on the package leaflet, information specific to GB are to appear in the 'Blue Box' on the outer packaging (or immediate packaging if no outer packaging). This same principle applies for the inclusion of 'Find more product information by searching for the 'Product Information Database' on www.gov.uk.' if this cannot be accommodated on the centralised package leaflet. The text is to still appear in the correct location in this template and agreement will be reached when mock-ups are submitted.]

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING WHERE THERE IS NO PACKAGE LEAFLET, i.e. Combined label and package leaflet {NATURE/TYPE}

*[This template can only be used when **all** printed information is **directly visible** on the immediate container and cannot be used if a fold-out or concertina[1] format is proposed.]*

[All information shall be clearly displayed on the printed label. Information given in sections 1, 3 and 4 must be displayed on the main panel and in the same field of vision as these are important items for correct and safe identification and avoidance of mix-ups of the veterinary medicinal product]

[Guidance given in the preamble of the labelling text and package leaflet templates should also be applied on the combined label-leaflet when applicable.]

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

[As in SPC section 1]

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

[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 EDQM. 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.]

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. 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")

[1] For concertina labels, the immediate label template heading requirements must begin and end the proposal. The leaflet requirements should go in-between. The immediate label must be stuck to the container and be replicated on the outer facing part of the concertina label.

"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]

5. INDICATIONS FOR USE

Indications for use

[Indication(s) in each 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.]

6. CONTRAINDICATIONS

Contraindications

[Include information from section 3.3 of the SPC, if applicable.]

7. SPECIAL WARNINGS

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, in this case the heading should not be included.]

[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:> *[E.g. chemical reactions of the VMP with furniture or clothes.]*

<Pregnancy:>

<Lactation:>

<Pregnancy and lactation:>

<Laying birds:>

<Fertility:>

<Interactions 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:>

8. ADVERSE EVENTS

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.}*

*[*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 10mg/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 on this label, 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 the local representative of the marketing authorisation holder> using the contact details on this label, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration
[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 EDQM]

10. ADVICE ON CORRECT ADMINISTRATION

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}.>

11. WITHDRAWAL PERIODS

Withdrawal periods

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

12. SPECIAL STORAGE PRECAUTIONS

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>.> 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.>

13. SPECIAL PRECAUTIONS FOR DISPOSAL

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.]
[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>.>

[The phrase in brackets <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.]

<Ask your <veterinary surgeon> <or> <pharmacist> how to dispose of medicines no longer required.>

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products

[As it appears in section 10 of the SPC]

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

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

Vm <number>

Pack sizes

[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 the product only has one package size and it is stated in section 5, it can be repeated here in grey shading.]

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

16. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

17. CONTACT DETAILS

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.]

[Including town, postal code (if available) and country (telephone numbers, E-mail addresses may be included (no websites or E-mails linking to websites allowed).]

<Marketing authorisation holder <and manufacturer responsible for batch release> <and contact details to report suspected adverse reactions>:>

[If there are no local representatives and the marketing authorisation holder is the contact point for the reporting of adverse reactions, then all necessary contact details must be included here and the following must be included in the subheading: <and contact details to report suspected adverse reactions>*.]*

<Manufacturer responsible for batch release:>

<Local representatives <and contact details to report suspected adverse reactions>:>

[If the local representative is the contact point for the reporting of adverse reactions, then all necessary contact details must be included here and it must be included in the subheading: <and contact details to report suspected adverse reactions>*.]*

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

18. OTHER INFORMATION

<Other information>

[Pharmacological or immunological information and environmental properties (if applicable) could be included here, i.e., pharmacodynamic properties, pharmacokinetic particulars and environmental properties.]

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

[Distribution category]

POM-VPS

POM-V
AVM-GSL
NFA-VPS

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. 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.>>

<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: ….>

21. BATCH NUMBER

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