Veterinary Medicines Directorate

Marketing Authorisation Applications

NATIONAL SPC/QRD TEMPLATE GUIDANCE

V~~1~~2 – updated ~~16/06/22~~13/06/23

Please note: The guidance contained is national specific and should be implemented according to the Product Literature Standard available on www.gov.uk.

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

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

*[- **(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 ~~as per official language~~.]*
[Target species: according to the target species list under "Referentials" on the SPOR web-site http://spor.ema.europa.eu/rmswi/#/lists/100000108853/terms~~: according to the target species "Standard terms"~~]

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

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:

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

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

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

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

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

[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 in terms of the active substance(s), ~~and constituents of the~~ excipient(s) and other constituents (e.g., adjuvants), knowledge of which

is essential for proper administration of the veterinary medicinal product. ***Expressed per dosage unit*** *or according to the form of administration for a given volume or weight. E.g., for vaccines: "Each 2 ml dose contains {x} units {active substance}. The usual common name or chemical description shall be used.*

<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 ~~(in the language of the text)~~.
For salt/ester: {quantity of active moiety} as {salt/ester}
or
{quantity of active moiety} equivalent to {quantity of salt/ester}
E.g.: 5 mg {X} as {Y}
8 mg {X} equivalent to 10 mg {Y}]
[In case the veterinary medicinal product is to be reconstituted prior to administration, the quantity per ml after reconstitution should also be stated.]

<Adjuvant<s>:>

[E.g., Aluminium gels or salts, mineral or vegetable oil]

<Excipient<s>:>

[Knowledge of which is essential for proper administration of the veterinary medicinal product, e.g., preservatives such as formaldehyde, thiomersal or colourants.]
[Any warnings necessary for excipients or residues from the manufacturing process should be mentioned in section 4.5.]
[For immunologicals, traces of antibiotics and traces of other substances used in production of vaccines not present in sufficient quantities to have a pharmacological effect should not be included in the SPC.]
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1 Target species

[According to the target species list under "Referentials" on the SPOR website http://spor.ema.europa.eu/rmswi/#/lists/100000108853/terms ~~"Standard terms"~~]
[Include any sub-category if appropriate; indicate species in singular or plural ~~as per official language use~~.]

4.2 Indications for use, specifying the target species

[For immunologicals, the onset and duration of immunity should be specified.]
<Onset of immunity: {x <days><weeks>}>
<Duration of immunity: {x <days><weeks><months><years>} {has not been established}. >

4.3 Contraindications

[It is not necessary to contraindicate species that are not included in the target species, unless studies indicate a particular risk with off-label use in a non-target species. Non-indications (e.g., 'this veterinary medicinal product is not indicated for...') should not be mentioned. Information from 4.11 should not be repeated here.]
<None.>

<Do not use in ...>
<Do not use in cases of hypersensitivity to the active substance(s)<, to the adjuvant(s)> or to any of the excipient(s).>

4.4 Special warnings for each target species

[Warnings to ensure the effective use of the veterinary medicinal product.]
<None.>
<Vaccinate healthy animals only.> *[For immunologicals]*

4.5 Special precautions for use

~~i)~~ Special precautions for use in animals

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.]

~~ii)~~ 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 with the treated animal (e.g. owner, children, immunocompromised persons, pregnant women, etc…).]
[User warnings should be in accordance with the current guidance (e.g., user safety and topical product guidelines).]

<Not applicable.>
<In case of accidental <self-administration><self-injection><ingestion><skin contact><spillage onto skin>, seek medical advice <immediately> and show the package leaflet or the label to the physician.>
<People with known hypersensitivity to {INN} should <avoid contact with the veterinary medicinal product.><administer the veterinary medicinal product with caution.> >
<Personal protective equipment consisting of {specify} should be worn when handling the veterinary medicinal product.>
<The veterinary medicinal product should not be administered by pregnant women.>
<The <vaccine><immunological veterinary medicinal product> can be pathogenic for humans. Since this <vaccine> <immunological veterinary medicinal product> has been prepared with live, attenuated microorganisms, appropriate measures should be taken to prevent contamination of the handler and other people that collaborate in the process.>
<Vaccinated {species} may excrete the vaccine strain up to {x <days><weeks>} following vaccination.>

<Immunocompromised persons are advised to avoid contact with the <vaccine> <immunological veterinary medicinal product> and vaccinated animals during {period}.>
<The vaccine strain can be found in the environment for up to {x <days> <weeks>}. Personnel involved in attending vaccinated {species} should follow general hygiene principles (changing clothes, wearing gloves, cleaning and disinfection of boots) and take particular care in handling animal waste and bedding materials from recently vaccinated {species}.>
[If the veterinary medicinal product contains mineral oil:]
<To the user:
This veterinary medicinal product contains mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given. If you are accidentally injected with this product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.
To the physician:
This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.>

Special precautions for the protection of the environment:

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

~~iii)~~ Other precautions

[Precautions such as chemical reactions of the veterinary medicinal product with furniture or clothes.]
<Not applicable.>
[The following statements, which are relevant only for the veterinary medicinal product label and package leaflet, should not be included in the SPC:
'For animal treatment only.'
'Keep out of the sight and reach of children.']

4.6 Adverse reactions (frequency and seriousness)

[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 the '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 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 also ~~the last~~ section 16 of the package leaflet for contact details.>

4.7 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 a <teratogenic>,< foetotoxic>, <maternotoxic> effects.>
<Laboratory studies in {species} have shown evidence of <teratogenic>, <foetotoxic>, <maternotoxic> effects.>
<Lactation:>
<Not applicable>
<Laying birds:>
<Do not use in <birds in lay> <breeding birds> <and within 4 weeks before the start of the laying period>.>
<Fertility:>
<Do not use in breeding animals.>
[Information regarding fertility in both males and females can also be given in sections 4.3 (contraindications), 4.5 (special precautions for use) or 4.6 (adverse reactions) as appropriate.]

4.8 Interaction with other medicinal products and other forms of interaction

<None known.>
<No data available.> *[If appropriate for pharmaceuticals]*
<No information is available on the safety and efficacy of this <vaccine><immunological veterinary medicinal product> when used with any other veterinary medicinal product.
A decision to use this <vaccine><immunological veterinary medicinal product> before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.> *[For vaccines and other immunological veterinary medicinal products.]*
[Where safety and efficacy data are available for use of the veterinary medicinal products with others the following statements are applicable:
When the vaccines or other immunological veterinary medicinal products can be used on the same day:
<Safety> <and> <efficacy> data are available which demonstrate that this <vaccine><immunological veterinary medicinal product> can be administered on the same day but not mixed with {description of tested product(s).}>
In case of veterinary medicinal products administered parenterally:
<The <veterinary medicinal product><vaccine><immunological veterinary medicinal product> should be given at different sites.>
When the vaccines or other immunological veterinary medicinal products are not used on the same day:
<Safety> <and> <efficacy> data are available which demonstrate that this <vaccine><immunological veterinary medicinal product> can be administered at least {X} <days> <weeks> <before> <after> the administration of {description of tested product(s).}>
[The X number of days/weeks and the references to before or after are based on the data presented by the applicant in the marketing authorisation file. They correspond to the minimum time between administrations for which compatibility data have been submitted.].]
[In addition to the above statements, to reflect the absence of information on the safety and efficacy of the association with any other vaccines or other immunological veterinary medicinal products, the following wording should also be included:]
<No information is available on the safety and efficacy of this <vaccine><immunological veterinary medicinal product> when used with any other veterinary medicinal product except the products mentioned above. A decision to use this <vaccine><immunological veterinary

medicinal product> before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.>
[If applicant has demonstrated that mixing of veterinary medicinal products (simultaneous administration) is possible and if it is accepted by the national competent authorit~~ies~~y, the following statement should be used:]
<Safety <and> <efficacy> data are available which demonstrate that this <vaccine> <immunological veterinary medicinal product> can be mixed and administered with {description of tested product(s).}>

4.9 Amount(s) to be administered and administration route

[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.]

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

['Symptoms' to be read as 'clinical signs'.]
[Specify quantity e.g.: mg/kg or X-fold overdose.]

4.11 Withdrawal period(s)

[For the various foodstuffs, including those for which the withdrawal period is zero. Listed by species and/or food components.]
<Not applicable> *[for non-food producing animals only.]*

<Zero days.> <Zero hours> *[when no withdrawal period is requiredne, for food producing animals.]*
<<Meat and offal> <Eggs> <Milk> <Honey> {X} <days><hours>.>
<{X} degree days.> *[for fish meat.]*
<Not authorised for use in animals producing milk for human consumption.> *[for milk producing animals]*
<Do not use in pregnant animals which are intended to produce milk for human consumption within {X} months of expected parturition.> *[for milk producing animals, where no MRL exists for milk.]*
<Not for use in birds producing ≤or intended to produce≥ eggs for human consumption.> *[for laying birds and for future laying birds, where no MRL exists for eggs and when a period of {X} weeks of start of the laying period cannot be determined.]*
<Not authorised for use in birds producing eggs for human consumption>

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

5. <PHARMACOLOGICAL> <IMMUNOLOGICAL> PROPERTIES

Pharmacotherapeutic group: {group*[appropriate therapeutic subgroup level.]*},

ATCvet cCode: {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 5.1 and 5.2 below if not relevant.]

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

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

<5.3 Environmental properties> [if not applicable delete this section.]

[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 4.5 above, 'Special precautions for protection of the environment'. Information in that section should not be repeated here.]

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

[For immunologicals, traces of antibiotics and traces of other substances used in production of vaccines should not be included in the SPC.]
[Each excipient to be listed on a separate line according to the different parts of the product]
[A qualitative list (not quantitative) should be provided]
[Name of the excipient(s) in the language of the text]
e.g.
Powder:

Sucrose
Solvent:
Water for injections

6.2 Major incompatibilities

[Information should be given about major physical or chemical incompatibilities of the veterinary medicinal product with other products with which it is likely to be diluted or mixed. Major incompatibilities observed from compatibility studies should be included here.]
<Not applicable.> *[If incompatibility is not a concern due to the pharmaceutical form of the product, e.g., for solid oral pharmaceutical forms.]*
<In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.> *[e.g., for parenterals, premixes for medicated feeding stuffs.]*
[It is not permitted to mix immunological products with other products, except other components or the recommended solvent, unless compatibility data have been provided. In the absence of this data the following statement should be used.]
<Do not mix with any other veterinary medicinal product <, except <solvent or other component>> <recommended> <supplied> <for use with the veterinary medicinal product.> >
<None known.>

6.3 Shelf life

<Shelf life of the veterinary medicinal product as packaged for sale:>
<Shelf life after first opening the immediate packaging: >
<Shelf life after <dilution> <reconstitution> according to directions: >
<Shelf life after <incorporation into meal or pelleted feed: >
<6 months.> <...><1 year.><18 months.><2 years.><30 months.><3 years.><use immediately.>

6.4 Special precautions for storage

<Store below <25 °C><30 °C>.>
<Store in a refrigerator (2 °C – 8 °C).>
<Store and transport refrigerated (2 °C – 8 °C).>*
<Store in a freezer {temperature range}.>
<Store and transport frozen {temperature range}.>**
<Do not <refrigerate> <or> <freeze>.>
<Protect from frost.>***
<Store in the original <container><package>>
<Keep the {container}**** tightly closed>
<Keep the {container}**** in the outer carton>
<in order to protect from <light> <and> <moisture>.>
<Protect from light.>
<Store in a dry place.>
<Protect from direct sunlight.>
<This veterinary medicinal product does not require any special storage conditions.>
<This veterinary medicinal product does not require any special temperature storage conditions.>*****
[The stability data generated at 25°C/60 % RH (acc) should be taken into account when deciding whether or not transport under refrigeration is necessary. The statement should only be used in exceptional cases.*
*** This statement should be used only when critical.*
**** E.g., for containers to be stored on a farm.*
***** The actual name of the container should be used (e.g., bottle, blister, etc.).*

*****Depending on the pharmaceutical form and the properties of the product, there may be a risk of deterioration due to physical changes if subjected to low temperatures. Low temperatures may also have an effect on the packaging in certain cases. An additional statement may be necessary to take account of this possibility.]*

6.5 Nature and composition of immediate packaging

[Include full information about contents of the packaging, such as type(s) of the immediate and outer container (e.g. one glass vial in a cardboard box), material (e.g. glass type, type of plastic) in contact with the veterinary medicinal product, package size(s) for the particular pharmaceutical form and strength(s). Also, indicate devices supplied and, if applicable, number of immediate containers in outer package (e.g. two glass vials in a cardboard box). Include the fill-volume/weight/doses of the container, if appropriate.
All package sizes must be listed. If appropriate, add:]
<Not all pack sizes may be marketed.>

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

<Not applicable.>
<Medicines should not be disposed of via wastewater.>
[The majority of medicines may be disposed of via household waste.]
<Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.>
<The veterinary medicinal product~~{Invented name}~~ should not enter water courses as {INN/active substance(s)} this may be dangerous for fish and other aquatic organisms.> *[if applicable.]*

7 MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER~~(S)~~

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

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

[Item to be completed by the marketing authorisation holder once the marketing authorisation has been granted or renewed, if applicable.]
<Date of first authorisation:> <{DD/MM/YYYY}><{DD month YYYY}>.
<Date of last renewal:> <{DD/MM/YYYY}><{DD month YYYY}>.

10. DATE OF REVISION OF THE TEXT

[Leave blank in case of first authorisation.

Item to be completed by the marketing authorisation holder at time of printing the SPC. Date of approval of latest variation or transfer changing the SPC.]
<{MM/YYYY}>
<{DD/MM/YYYY}>
<{DD month YYYY}>

PROHIBITION OF SALE, SUPPLY AND/OR USE

<Not applicable.>
<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~~ country 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.>
<Consideration should be given to official guidance on the incorporation of medicated premixes in final feeds.> *[for premixes for medicated feed.]*

For antimicrobial and antiparasitic products, any other (discretionary) contraindications, special warnings or precautions originating from product-specific assessment should continue to be included under the respective sub-section within SPC section 4 'Clinical information'. For example, product-related information restricting prophylactic and metaphylactic use ~~linked to Articles 107(3) and 107(4)~~ should appear in SPC section 4.5. Repetition of content across several SPC sections should be avoided.]

<**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.>

[Exceptional MAs are subject to normal labelling requirements, but are also required to include the following information on the packaging:

- *A clear statement that the product does not have a full Marketing Authorisation and to highlight areas of 'weakness'. For example: "This is a Limited Marketing Authorisation. A full set of supporting safety and efficacy data is not available for the product"*
- *The statement "All suspected adverse reactions and any suspected lack of efficacy should be reported to [company pharmacovigilance phone number and address]"*
- *The statement "Further information on this product and its supporting data can be found on the Product Information Database"]*

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT~~S~~

<Veterinary medicinal product subject to prescription.>
<Veterinary medicinal product not subject to prescription.>
<Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.>

[The items below are required in accordance with Veterinary Medicines Regulations 2013. The data should be presented according to the template below, irrespectively of their sequence on the actual labelling and their position and possible repetition on the individual sides/flaps of the packaging (e.g., top flap, front, back etc.).]

A separate text for the labelling of the outer and immediate packaging should be provided unless the particulars to appear on the outer and immediate packaging are the same. Separate labelling documents should be prepared for each strength and pharmaceutical form. However, different package sizes of the same strength can be presented in one document. Where the same text for outer and immediate packaging is used, this should be clearly indicated in the heading and in {nature/type}.

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.

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. Inclusion of additional GB information contained within this template should not impede shared labelling. Section 4, Article 13 of the Regulation (EU) 2019/6 allows 'an applicant to include on the immediate packaging or outer packaging of a veterinary medicinal product additional useful information which is compatible with the summary of the product characteristics and which is not an advertisement for a veterinary medicinal product.'.

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 opinion/decision annexes. However, they are **not** to appear in the final printed packaging materials (mock-ups/specimens).*

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

[Qualitative and quantitative composition in terms of the active substance(s) and ~~constituents of the~~ excipient(s),and other constituents (e.g., adjuvants) knowledge of which is essential for safe and proper administration of the veterinary medicinal product. Expressed qualitatively and quantitatively per dosage unit or according to the form of administration for a given volume or weight, using the common names. Where the active substance is present as a salt, this should be clearly indicated e.g.: "mg X" or "mg Y-hydrochloride (equivalent to mg Y)".]

3. PACKAGE SIZE

By weight, by volume, or by number of doses of the veterinary medicinal product, followed by number of immediate packaging units, if applicable ~~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 4.1.]
[On the printed material, the target species should appear displayed close to the name.]

[This may be included in grey shading if referenced under section 1 due to different presentations.]

5. INDICATION~~(S)~~

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

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". If the information exceeds the size of the label, reduced text is acceptable.]

7. WITHDRAWAL PERIODS

[Withdrawal period for veterinary medicinal product~~s~~ 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. Should reflect section 4.11 of the SPC]~~]~~
<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

~~Keep the {container}**** in the outer carton. *[This is a national requirement and ensures all packaging elements are kept together]*~~

<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 ~~AND ADDRESS~~ OF THE MARKETING AUTHORISATION HOLDER

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

{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

Vm <number>

15. BATCH NUMBER

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

["Lot" is the preferred term to achieve shared labelling with other countries.]

16. SPECIAL WARNING(S), IF NECESSARY

[Indicate any particulars essential for safety or health protection, including any special precautions relating to use and any other warnings.]
For example: <{INN/active substance(s)} may occasionally cause severe allergic reactions. See package leaflet for user warnings.>
<Pregnant or breast feeding women should not handle this product. See package leaflet for user warnings.>

[For certain veterinary medicinal products e.g., injectables containing mineral oil ~~or live vaccines~~, the following statement should be included:]

~~<Accidental injection is dangerous.>~~
<Accidental administration> <Contact with the mucosa> is dangerous. >

~~<User Warnings>~~

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

~~<Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.>~~

~~<Dispose of waste material in accordance with local requirements>~~

<Disposal: Read package leaflet>

[Indicate any particulars essential for the protection of the environment.]

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE *[Distribution category]*

POM-VPS (‘~~To be supplied only on veterinary~~Veterinary medicinal product subject to prescription’)
POM-V (‘Veterinary medicinal product subject to~~To be supplied only on veterinary~~ prescription’)
AVM-GSL
NFA-VPS

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}

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

[Qualitative and quantitative composition in terms of the active substance(s) and ~~constituents of the~~ excipient(s) and other constituents (e.g., adjuvants), knowledge of which is essential for safe and proper administration of the veterinary medicinal product. Expressed qualitatively and quantitatively per dosage unit or according to the form of administration for a given volume or weight, using the common names. Where the active substance is present as a salt, this should be clearly indicated e.g.: "mg X" or "mg Y-hydrochloride (equivalent to mg Y)".]

3. TARGET SPECIES

[As in SPC section 4.1.]
[On the printed material, the target species should appear displayed close to the name.]

[A pictogram of the target species may be included in addition to this text].

[This may be included in grey shading if referenced under section 1 owing to different presentations.]

4. ROUTES OF ADMINISTRATION

<Read the package leaflet before use.> (if relevant)

[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).]

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. Should reflect section 4.11 of the SPC.]
<Withdrawal period(s): >
[If withdrawal period is not applicable, the template heading should not be deleted, and the section should be left blank.]

6. EXPIRY DATE

[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

Keep the {container}**** in the outer carton. *[This is a national requirement and ensures all packaging elements are kept together]*

<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 ~~AND ADDRESS~~ OF THE MARKETING AUTHORISATION HOLDER

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

9. BATCH NUMBER

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

["Lot" is the preferred term to achieve shared labelling with other countries.]

~~10. PACKAGE SIZE~~

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

~~11. INDICATION(S)~~

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

10~~2~~. SPECIAL WARNING(S), IF NECESSARY

[Indicate any particulars essential for safety or health protection, including any special precautions relating to use and any other warnings.]
[For certain veterinary medicinal products e.g. injectables containing mineral oil ~~or live vaccines,~~ the following statement should be included:]
~~<Accidental injection is dangerous.>~~
<Accidental administration> <Contact with the mucosa> is dangerous. >

~~<User Warnings>~~

11~~3~~. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT~~S~~ OR WASTE MATERIALS, IF ANY

~~<Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.>~~

~~<Dispose of waste material in accordance with local requirements>~~

<Disposal: Read package leaflet>

[Indicate any particulars essential for protection of the environment.]

12~~4~~. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

For animal treatment only.

POM-VPS (‘Veterinary medicinal product subject to ~~To be supplied only on veterinary~~ prescription’)
POM-V (‘Veterinary medicinal product subject to~~To be supplied only on veterinary~~ prescription’)
AVM-GSL
NFA-VPS

~~**15. MARKETING AUTHORISATION NUMBER(S)**~~

~~**Vm <number>**~~

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {NATURE/TYPE}

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

[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.]

~~*[Target species: on small immediate packaging units, the target species may be replaced with an approved pictogram]*~~

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE~~(S)~~

[Expressed qualitatively and quantitatively per dosage unit or according to the form of administration for a given volume or weight, using the common names. If the strength is already mentioned following the name of the veterinary medicinal product in section 1, it should be repeated here in grey shading (i.e. it will appear in the template text but NOT on the mock-ups and the final printed materials e.g. 20 mg/ml).]

[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).]

3. BATCH NUMBER

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

["Lot" is the preferred term to achieve shared labelling with other countries.]

4. EXPIRY DATE

<EXP {~~month~~mm/~~year~~yyyy}>
<Once <broached> <opened> <diluted> <reconstituted> <use by…> <use within…> < use immediately.>>
[Where applicable, shelf life after reconstitution, dilution or after first opening the container.]

~~**5. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**~~

~~6~~5. ROUTE(S) OF ADMINISTRATION

[According to "Standard terms".]

~~**7. WITHDRAWAL PERIOD**~~

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

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

6~~8~~. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

[While it is not mandatory to include the distribution category on the small immediate packaging, we strongly encourage you to do so.]

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

[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.]

~~*Target species: on small immediate packaging units, including blisters or strips, the target species may be replaced with an approved pictogram.*~~

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE~~(~~S~~)~~

[Expressed qualitatively and quantitatively per dosage unit or according to the form of administration for a given volume or weight, using the common names. If the strength is already mentioned following the name of the veterinary medicinal product in section 1, it should be repeated here in grey shading (i.e. it will appear in the template text but NOT on the mock-ups and the final printed materials e.g. 20 mg/ml).]

3. BATCH NUMBER

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

["Lot" is the preferred term to achieve shared labelling with other countries.]

4. EXPIRY DATE

[Month: 2 digits or 3 characters; year: 4 digits. Expiry date refers to the last day of the month.]
<EXP {mm/yyyy~~month/year~~}>

~~**5. NAME OF THE MARKETING AUTHORISATION HOLDER**~~

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

~~6~~5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE IMMEDIATE LABEL OF THE DILUENT/SOLVENT ~~LABEL~~

1. NAME OF THE DILUENT/SOLVENT

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

2. CONTENT BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

3. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

4. STORAGE CONDITIONS

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

5. BATCH NUMBER

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

6. EXPIRY DATE

<EXP {month/year}>

7. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

[While it is not mandatory, we strongly encourage you to include the Marketing Authorisation number on the diluent label.]

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

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

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.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

[As in SPC section 1]

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 safe and 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 4.1]

~~*[Include any sub-categories.]*~~

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 4.3 of the SPC, if applicable.]

6. SPECIAL WARNING~~(~~S~~)~~

[Warnings from relevant sections 4.4, 4.5, 4.7, 4.8, 4.10 and 6.2 from the SPC should be included as appropriate in user-friendly wording.]

[Sub-headings should be used in this section to list warnings and precautions. For certain veterinary medicinal product not all sub-headings may be relevant, in this case the heading should not be
included.]
[For warning on accidental self-administration, etc. include statement as it appears in the SPC]
<None.>
<Special warnings: *[for each target species, as per SPC section 4.4]*>
<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, t~~The warnings in the SPC should be repeated here.]

<Special precautions for the protection of the environment:>
[In accordance with SPC section 4.5, 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~~VMP~~ with furniture or clothes.]*
<Pregnancy:>
<Lactation:>
<Pregnancy and lactation:>
<Laying birds:>
<Fertility:>
<Interaction~~s~~ 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 10 appropriate to the package leaflet.]~~
<Major incompatibilities:>

[Information from SPC section 6.2]

~~For Animal Treatment Only~~

~~Keep out of sight and reach of children.~~

~~**[Immunologicals ONLY** - *For injectables containing mineral oil, the following statement should be included:]*~~

~~<To the user:~~

~~This product contains mineral oil. Accidental injection/self injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given.~~

~~If you are accidentally injected with this product, seek prompt medical advice even if only a very small amount is injected and take the package insert with you.~~

~~If pain persists for more than 12 hours after medical examination, seek medical advice again.~~

~~To the physician:~~

~~This product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.>~~

7. ADVERSE EVENTS

[Information from SPC section 4.6. Tables can be omitted from the package leaflet, however the information contained, and structure should be maintained. The~~, including the~~ following statement should be included:]

<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><the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system <{national system details}.>

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

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

9. ADVICE ON CORRECT ADMINISTRATION

[Directions for proper use 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 4.9 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 PERIOD~~(~~S~~)~~

[As it appears in the SPC 4.11.]

11. SPECIAL STORAGE PRECAUTIONS

[As it appears in 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 {abbreviation used for expiry date}>. *[Where a specific abbreviation for Expiry date is used on the labelling, it should be mentioned here.]* <The expiry date refers to the last day of that month.>
[Where applicable, shelf life after reconstitution, dilution or after first opening the container, as in SPC section 6.3.]
<Shelf life after first opening the container: …..>
<Shelf life after <dilution> <reconstitution> according to directions: …..>
<Shelf life after incorporation into meal or pelleted feed: ….>

~~**[Pharmaceuticals ONLY** - *The following statement should be included if there is an in-use shelf life (example: solution for injection)]*~~

<~~When the container is broached/opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided.{}<><broached>>~~

12. SPECIAL PRECAUTIONS FOR DISPOSAL

[Include information from section 6.6 of the SPC ~~in user-friendly wording~~.]

<Medicines should not be disposed of via wastewater.>

[The majority of medicines may be disposed of via household waste]

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

<Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.>
<These measures should help to protect the environment.>

<Ask your <veterinary surgeon> <or> <pharmacist> how to dispose of medicines no longer required. ~~These measures should help to protect the environment.~~> *[for products that are not solely used in the veterinary surgery]*

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

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

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

All pack sizes must be detailed here, as per section 6.5 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.>

Vm <number>

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 at time of printing the package leaflet. Date of approval of latest variation or transfer changing the package leaflet]

[~~It is recommended that the following reference to the VMD Website is included~~ The following statement must be included where reference to the Union Product Database is included on the product information developed as part of a separate EU procedure and a shared label is intended. This statement is applicable for both UK(GB) and UK(NI) and may only be omitted where reference to the UPD is also not present:]

<Find more product information by searching for the 'Product Information Database' or 'PID' 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 ~~name in the language of the text~~ (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>:>

<Manufacturer responsible for batch release: < and contact details to report suspected adverse reactions>:>>

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

17. OTHER INFORMATION

[Distribution category]

POM-VPS ('Veterinary medicinal product subject to~~To be supplied only on veterinary~~ prescription')
POM-V ('Veterinary medicinal product subject to ~~To be supplied only on veterinary~~ prescription')
AVM-GSL
NFA-VPS

<For animal treatment only.>

[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.]

For veterinary medicines authorised under the Centralised Procedure in the EU and where a parallel, identical GB marketing authorisation/application has been issued or 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). The text should still appear in the correct location in this template and agreement will be reached when mock-ups are submitted.

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

[This template should 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]~~.~~ ~~F~~ format is proposed. It should be populated using the guidance provided above for the package leaflet]

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

2. COMPOSITION

3. PACKAGE SIZE

4. TARGET SPECIES

5. INDICATIONS FOR USE

6. CONTRAINDICATIONS

7. SPECIAL WARNINGS

8. ADVERSE REACTIONS

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

10. ADVICE ON CORRECT ADMINISTRATION

[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.

11. WITHDRAWAL PERIODS

12. SPECIAL STORAGE PRECAUTIONS

Keep the container in the outer carton.

~~**[Pharmaceuticals ONLY** – *The following statement should be included if there is an in-use shelf life (example: solution for injection)]*~~

~~<[]<><broached>When the container is broached/opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided.~~>

13. SPECIAL PRECAUTIONS FOR DISPOSAL

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

[As it appears in section 11 from the SPC in addition to the distribution category]

POM-VPS ('Veterinary medicinal product subject to~~To be supplied only on veterinary~~ prescription')
POM-V ('Veterinary medicinal product subject to~~To be supplied only on veterinary~~ prescription')
AVM-GSL
NFA-VPS

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm <number>

16. DATE ON WHICH THE LABEL WAS LAST REVISED

[The following statement is ~~It is~~ mandatory for Exceptional Marketing Authorisations and where reference to the Union Product Database is included on the product information developed as part of a separate EU procedure and a shared label is intended~~and recommended for others that the following reference to the VMD Website is included~~::]

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

17. CONTACT DETAILS

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

<Manufacturer responsible for batch release:>

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

18. OTHER INFORMATION

19. THE WORDS “FOR ANIMAL TREATMENT ONLY”

20. EXPIRY DATE

21. BATCH NUMBER

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