<NCA logo>

**<CONFIDENTIAL**

**(NOT TO BE SENT TO THE APPLICANT)>**

**<Concerned Member State> Day**

 **List of Questions**

**Date:** {dd.mm.yyyy}

|  |  |
| --- | --- |
| Name of the product in the RMS  |  |
| Name of the product in the CMS (if different) |  |
| Name of the active substance(s) |  |
| Procedure number | xx/V/xxxx/xxx/<DC><MR><SR> |

### <Separate confidential document(s) provided to RMS:>

<Questions (< major objections><and><other concerns> to the restricted part of the ASMF>

<and>

<Questions (< major objections><and><other concerns> related to the Reference Product in regard to <safety><and><efficacy>

**Overall conclusion on the medicinal product:**

*[CMS should choose the most appropriate statement to outline their position.]*

*[For DCP Phase I]*

<The <name of the Agency> has additional questions concerning the veterinary medicinal product. A satisfactory response to the questions as listed below is required.>

*[For DCP Phase II]*

*[No Major objections from RMS / CMS:]*

<The <name of the Agency> agrees with the overall conclusion of the RMS and is therefore prepared to grant a marketing authorisation for this product <once satisfactory answers to all the questions raised have been provided and/or a favourable evaluation of the final SPC and label/package leaflet has been made>.>

*[Major objections from RMS <and additional major objections from CMS>:]*

<The <name of the Agency> agrees with the overall conclusion of the RMS and is, at present, not prepared to grant a marketing authorisation for this product. A satisfactory response to the questions raised by the RMS <and the following additional queries/questions as listed below >is required.>

*[No Major objections from RMS; CMS has major objections:]*

<The <name of the Agency> has major objections related to the use of this product (see below) and is, at present, not prepared to grant a marketing authorisation. Satisfactory responses to allthe questions raised are required.>

*[For MRP/SRP]*

*[No <concerns><major objections> from CMS:]*

<The <name of the Agency> agrees with the overall conclusion of the RMS and is therefore prepared to grant a marketing authorisation for this product <once satisfactory answers to the questions raised have been provided and/or a favourable evaluation of the final SPC and label/package leaflet has been made>.>

*[CMS has major objections:]*

<The <name of the Agency> has major objections related to the use of this product (see below) and is, at present, not prepared to grant a marketing authorisation. Satisfactory responses to the questions raised are required.>

**List of Questions**

*[Information to CMS:*

*The question should clearly identify and justify the concern and outline what is required by the applicant to address and solve the concern raised.*

*The questions should be introduced under relevant heading/subheading (see headings in RMS assessment report/RMS DCP LOQ). Further identification/reference could be given if relevant (e.g. study number).*

*Where appropriate, reference/cross-reference to other questions raised could be given as an introduction to a question. The question referred to should be identified* ***by question number*** *in own, RMS or Compiled LOQ,* ***by question type*** *(major objection/other concern) and* ***by specified dossier section*** *(e.g. part, heading, subheading) as applicable.*

*e.g.(ad Q x, other concern, section 2.F stability)*

*or (ad Q x in CLOQ(Day xxx), major objections, section 4.A.3)*

*The CMS may also use optional free text in their reference/cross reference as long as identification is ensured.*

*To add questions, the following text should be copied and pasted under the relevant section. This will ensure the integrity of the automatic numbering system is maintained.]*

|  |  |  |
| --- | --- | --- |
| Question No  |  |  |

{Insert Question}

### <Major objections *[DCP Phase II/ MRP/SRP]*> <Concerns *[DCP Phase I]*>

**<Part I - Administrative>**

**<Part II - Quality>**

**<Part III A - Safety>**

**<Part IIIA - ERA>**

**<Part III B - Residues>**

**<Part IV - Efficacy>**

**--------------------------------------------------------------------------------------------------------------------**

*[For DCP Phase I, CMS questions should not be differentiated into major objections and other concerns. As such, the section « other concerns » below may be deleted for DCP Phase I.]*

<**Other concerns>** *[for DCP Phase II, MRP/SRP]*

**<Part I - Administrative>**

**<Part II - Quality>**

**<Part III A - Safety>**

**<Part IIIA - ERA>**

**<Part III B - Residues>**

**<Part IV - Efficacy>**

**Comments on SPC, labelling and package leaflet**

**<Part 1B.1 - SPC>**

*[The question should be introduced under the appropriate SPC point/heading, cross reference to major objections/<other> concerns should be given when applicable.]*

|  |  |
| --- | --- |
| **Question No**  |  |

{Insert Question}

**<Part 1B.2-Labelling>**

<In addition to any changes following from changes to the SPC, the following change/ changes to the /labelling/ package leaflet is/are <required><included for your consideration>:

**<Part 1B.3-Package leaflet>**

**<National requirements>**

*[National requirements should not be included in DCP Phase I comments.]*

**<Practical information to the applicant:>**

*[i.e. National specific comments/issues, general email address, post address]*

**<Contact points: >**

*[if relevant to the CMS]*