**<CONFIDENTIAL**

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

***Name of veterinary medicinal product <strength> pharmaceutical form <target species>***

*[Select using the drop-down menu or alternatively, the prepared headings]*

**<RMS DRAFT LIST OF QUESTIONS DCP Phase II (Day 120)>**

**<COMPILED LIST OF QUESTIONS DCP Phase II (Day 150)>**

**<APPLICANT’S RESPONSES TO THE COMPILED LIST OF QUESTIONS DCP Phase II (Day 170)>**

**<RMS ASSESSMENT OF THE APPLICANT’S RESPONSES TO THE COMPILED LIST OF QUESTIONS DCP Phase II (Day 190)>**

**Applicant:**

**Application according to Art. xx**

**of Regulation (EU) 2019/6**

**Decentralised Procedure (Phase II)**

**Procedure No.: xx/V/xxxx/xxx/DC**

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

*[Information on bracketing convention as follows:*

*[text]: Guidance and explanatory notes.*

*{text}: Information to be filled in. To ensure consistency throughout the document font “Arial”, size 11 should be used.*

*<text>: Text to be selected or deleted as appropriate.]*

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# SUMMARY OF THE DOSSIER

*[The applicant should note that Sections I.I and I.II should remain throughout Phase II of the procedure and the responsibility for updating the various sections is outlined in the explanatory text below].*

## I.I. ADMINISTRATIVE INFORMATION

*[For DCP Phase II Day 120 – filled in by RMS:]*

|  |  |
| --- | --- |
| **Name of the product:** |  |
| **Active substance(s):** |  |
| **Pharmaceutical form:** |  |
| **Target species:** |  |
| **Procedure Number:** | xx/V/xxxx/xxx/DC |
| **Concerned Member States:** |  |
| **Name and address of the applicant:** |  |
| **Person authorised for communication during the procedure on behalf of the applicant (phone and E-mail address)** |  |

## I.II OVERALL CONCLUSIONS ON THE VETERINARY MEDICINAL PRODUCT AT <DAY 120><DAY 190>

*[This section is copied by the RMS from the Day 120 RMS Assessment of the Applicant’s responses to the Compiled LoQI document and is updated by the RMS at Day 190:]*

**Part II: Quality**

**Part III: Safety and residues**

**Part IV: Efficacy**

**Part V: Risk Benefit Assessment**

*[This section is copied by the RMS from the Day 120 - RMS Assessment of the Applicant’s responses to the Compiled LoQI document:]*

The RMS has assessed the applicant’s responses to the compiled List of Questions I. It is the opinion of the RMS that the application currently is

<(i) approvable.>

<(ii) approvable subject to the applicant satisfactorily addressing a number of outstanding issues/proposed changes to the SPC.>

<(iii) not approvable due to a number of major outstanding objections which need to be addressed. The remaining outstanding questions are listed in the separately provided RMS Draft List of Questions II.>

<Following the assessment of the responses to confidential questions on Restricted Part of the ASMF some confidential questions are yet to be satisfactorily addressed by the ASMF holder and these are provided in a separate confidential LOQII document.>

<Some confidential questions have been raised by CMS related to the Reference Product. Major objections/other concerns were identified regarding the <text> of the product.>

[*RMS to indicate the areas where major objections/questions are not resolved and to clearly indicate at the end of their assessment of each question whether or not the issue is resolved or unresolved.]*

*[For DCP Phase II CMS Day 145 conclusions – filled in by applicant:]*

**Conclusions on the veterinary medicinal product from each CMS at Day 145**

**Member States which agree with the overall conclusion of the RMS and are therefore**

**prepared to grant a marketing authorisation for the above mentioned product.**

{Austria, Belgium, Bulgaria, Czech Republic, Croatia, Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom (Northern Ireland)

Iceland, Liechtenstein, Norway}

**Member States which agree with the overall conclusion of the RMS and are therefore**

**prepared to grant a marketing authorisation for the above mentioned product subject to the applicant satisfactorily addressing minor outstanding issues/proposed changes to the SPC.**

{Austria, Belgium, Bulgaria, Czech Republic, Croatia, Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom (Northern Ireland)

Iceland, Liechtenstein, Norway}

**Member States, which have indicated that there are major objections related to the use of this product, and are, at present, not prepared to grant a marketing authorisation. Satisfactory responses to the questions raised are required.**

{Austria, Belgium, Bulgaria, Czech Republic, Croatia, Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom (Northern Ireland)

Iceland, Liechtenstein, Norway}

**No comments were received and the Member States are therefore assumed to agree with the overall conclusion of the RMS. Member States are therefore prepared to grant a marketing authorisation for the above mentioned product.**

{Austria, Belgium, Bulgaria, Czech Republic, Croatia, Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom (Northern Ireland)

Iceland, Liechtenstein, Norway}

*[For DCP Phase II Day 190 – filled in by RMS:]*

<The RMS has assessed the applicant’s responses to the compiled List of Questions II. It is the opinion of the RMS at Day 190 that the application currently is>

<(i) approvable.>

<(ii) approvable subject to the applicant satisfactorily addressing a number of outstanding issues><proposed changes to the SPC>.>

<(iii) not approvable due to a number of major objections which need still to be addressed.>

*[RMS to indicate the areas where major objections/questions are not resolved and to clearly indicate at the end of their assessment of each question whether or not the issue is resolved or unresolved.]*

# II. LIST OF QUESTIONS (DCP Phase II)

*[Information for the RMS:*

*Apart from the headings already introduced in the template, subheading, study number should be identified (as relevant), followed by a clear & concise question that identifies and justifies the concern and clearly outlines what is required by the applicant to address and solve the concern raised. No headings should be deleted by the RMS during preparation of the Day 120 draft LOQII as these headings may be required to house questions raised at a later stage by the CMS.]*

*[Information for the applicant:*

*When compiling the list of questions, the applicant is asked to insert the CMS question(s) into the relevant section of the template (as identified in the CMS Day 145 LOQ document) and under the relevant heading. Where possible, related questions should be listed sequentially. References given by the CMS in the CMS LOQ may be helpful to this regard. The CMS that posed the question should be identified by choosing the respective entry from the drop-down menu provided in the box on the right-hand side of each question. Any heading not required should be deleted..*

*To add CMS questions the following text should be copied and pasted under the relevant section and the question (including possible references) from the CMS Day 145 LOQ should be copied and inserted in place of {Insert Question}. This will ensure the integrity of the automatic numbering system is maintained.]*

|  |  |  |
| --- | --- | --- |
| Question No |  | **{<RMS> / <CMS (Austria, Belgium, ...)>}** |

{Insert Question}

##### Applicant’s response:

##### RMS comments:

## MAJOR OBJECTIONS

## MAJOR OBJECTIONS ON PART 1

<**SUMMARY OF THE DOSSIER>**

### 1.A ADMINISTRATIVE INFORMATION

### 1.C CRITICAL EXPERT REPORTS

1.C.1 Expert Report on Quality

1.C.2 Safety and Residues Expert Report

1.C.3 Efficacy Expert Report

## MAJOR OBJECTIONS ON PART 2

*[For Part 2 use Annex II-format of Regulation (EU) 2019/6 or CTD-format Module 3 (according to Annex I of Directive 2001/83/EC) section and delete other part of the template as appropriate.]*

[**PART 2 SECTION** *(= Annex II to Regulation (EU) 2019/6)*]

<**QUALITY DOCUMENTATION (physico-chemical, biological or microbiological information)** *(Annex II-format)*>

### 2.A. PRODUCT DESCRIPTION

2.A.1. Qualitative and quantitative composition

2.A.2. Product development

*[additionally for biologicals other than immunologicals:]*

2.A.3. Characterisation

2.A.3.1. Elucidation of structure and other characteristics

2.A.3.2. Impurities

### 2.B. DESCRIPTION OF THE MANUFACTURING METHOD

### 2.C. PRODUCTION AND CONTROL OF STARTING MATERIAL(S)

2.C.1. Active substance(s)

2.C.1.1. Active substances listed in pharmacopoeias

2.C.1.2. Active substances not listed in a pharmacopeia

2.C.1.3. Physicochemical characteristics liable to affect bioavailability

2.C.2. Excipients

2.C.3. Packaging (container-closure systems)

2.C.3.1. Active substance

2.C.3.2. Finished product

2.C.4. Substances of biological origin

*[for biologicals other than immunologicals:]*

2.C.1. Starting materials listed in pharmacopoeias

2.C.2. Starting materials not listed in a pharmacopeia

2.C,2.1. Starting materials of biological origin

2.C.2.2. Starting materials of non-biological origin

### 2.D. <CONTROL TESTS CARRIED OUT ON ISOLATED INTERMEDIATES DURING THE MANUFACTURING PROCESS> <CONTROL TESTS DURING THE MANUFACTURING PROCESS *[for biologicals other than immunologicals]*>

### 2.E. CONTROL TESTS ON THE FINISHED PRODUCT

2.E.1. General tests on the finished product

2.E.2. Identification and assay of active substance(s)

2.E.3. Identification and assay of excipient components

2.E.4. Microbiological controls

2.E.5. Batch-to-batch consistency

2.E.6. Other controls

*for biologicals other than immunologicals:]*

2.E.1. Finish product specification

2.E.2. Method descriptions and validation of release tests

2.E.3. Reference standards or materials

### 2.F. <STABILITY TESTS> <BATCH-TO-BATCH CONSISTENCY *[for biologicals other than immunologicals]*>

2.F.1. Active substance(s)

2.F.2. Finished product

### 2.G. <OTHER INFORMATION> < STABILITY TESTS *[for biologicals other than immunologicals]*>

### <2.H. OTHER INFORMATION *[for biologicals other than immunologicals]*>

*[For Part 2 use Annex II-format of Regulation (EU) 2019/6 or CTD-format Module 3 (according to Annex I of Directive 2001/83/EC) and delete other part of the template as appropriate.]*

[**CTD Module 3 SECTION (= Annex I to Directive 2001/83/EC**]

***<QUALITY DOCUMENTATION*** *(CTD-format)****>***

## 3.2.S DRUG SUBSTANCE

3.2.S.1 General Information

3.2.S.2 Manufacture

3.2.S.3 Characterisation

3.2.S.4 Control of Drug Substance

3.2.S.5 Reference Standards or Materials

3.2.S.6 Container Closure System

3.2.S.7 Stability

## 3.2.P DRUG PRODUCT

3.2.P.1 Description and Composition of the Drug Product

3.2.P.2 Pharmaceutical Development

3.2.P.3 Manufacture

3.2.P.4 Control of Excipients

3.2.P.5 Control of the Drug Product

3.2.P.6 Reference Standards or Materials

3.2.P.7 Container Closure System

3.2.P.8 Stability

## MAJOR OBJECTIONS ON PART 3

**<SAFETY DOCUMENTATION (SAFETY AND RESIDUES TESTS)>**

### 3.A SAFETY TESTS

3.A.1 Precise identification of the product and of its active substance(s)

3.A.2 Pharmacology

3.A.2.1 Pharmacodynamics

3.A.2.2. Pharmacokinetics

3.A.3 Toxicology

3.A.4 Other requirements

3.A.4.1. Special studies

3.A.4.2. Observations in humans

3.A.4.3. Development of resistance and related risk in humans

3.A.5 User safety

3.A.6 Environmental risk assessment

### 3.B RESIDUE TESTS

3.B.1 Identification of the product

3.B.2 Depletion of residues

3.B.3 Residue analytical method

## MAJOR OBJECTIONS ON PART 4

**<EFFICACY DOCUMENTATION (PRE-CLINICAL STUDIES AND CLINICAL TRIAL(S))>**

### 4.A PRE-CLINICAL STUDIES

4.A.1 Pharmacology

4.A.1.1. Pharmacodynamics

4.A.1.2. Pharmacokinetics

4.A.2 Development of resistance and related risk in animals

4.A.3 Dose determination and confirmation

4.A.4. Tolerance in the target animal species

### 4.B CLINICAL TRIAL(S)

4.B.1. General principles

4.B.2. Documentation

4.B.2.1. Results of pre-clinical studies

4.B.2.2. Results of clinical trials

## OTHER CONCERNS

## OTHER CONCERNS ON PART 1

<**SUMMARY OF THE DOSSIER>**

### 1.A ADMINISTRATIVE INFORMATION

### 1.C CRITICAL EXPERT REPORTS

1.C.1 Expert Report on Quality

1.C.2 Safety and Residues Expert Report

1.C.3 Efficacy Expert Report

## OTHER CONCERNS ON PART 2

*[For Part 2 use Annex II-format of Regulation (EU) 2019/6 or CTD-format Module 3 (according to Annex I of Directive 2001/83/EC) section and delete other part of the template as appropriate.]*

[**PART 2 SECTION** *(= Annex II to Regulation (EU) 2019/6)*]

<**QUALITY DOCUMENTATION** (physicochemical, biological or microbiological information)*(Annex II-format)*>

### 2.A. PRODUCT DESCRIPTION

2.A.1. Qualitative and quantitative composition

2.A.2. Product development

*[additionally for biologicals other than immunologicals:]*

2.A.3. Characterisation

2.A.3.1. Elucidation of structure and other characteristics

2.A.3.2. Impurities

### 2.B. DESCRIPTION OF THE MANUFACTURING METHOD

### 2.C. PRODUCTION AND CONTROL OF STARTING MATERIAL(S)

2.C.1. Active substance(s)

2.C.1.1. Active substances listed in pharmacopoeias

2.C.1.2. Active substances not listed in a pharmacopeia

2.C.1.3. Physicochemical characteristics liable to affect bioavailability

2.C.2. Excipients

2.C.3. Packaging (container-closure systems)

2.C.3.1. Active substance

2.C.3.2. Finished product

2.C.4. Substances of biological origin

*[for biologicals other than immunologicals:]*

2.C.1. Starting materials listed in pharmacopoeias

2.C.2. Starting materials not listed in a pharmacopeia

2.C,2.1. Starting materials of biological origin

2.C.2.2. Starting materials of non-biological origin

### 2.D. <CONTROL TESTS CARRIED OUT ON ISOLATED INTERMEDIATES DURING THE MANUFACTURING PROCESS> <CONTROL TESTS DURING THE MANUFACTURING PROCESS *[for biologicals other than immunologicals]*>

### 2.E. CONTROL TESTS ON THE FINISHED PRODUCT

2.E.1. General tests on the finished product

2.E.2. Identification and assay of active substance(s)

2.E.3. Identification and assay of excipient components

2.E.4. Microbiological controls

2.E.5. Batch-to-batch consistency

2.E.6. Other controls

*for biologicals other than immunologicals:]*

2.E.1. Finish product specification

2.E.2. Method descriptions and validation of release tests

2.E.3. Reference standards or materials

### 2.F. <STABILITY TESTS> <BATCH-TO-BATCH CONSISTENCY *[for biologicals other than immunologicals]*>

2.F.1. Active substance(s)

2.F.2. Finished product

### 2.G. <OTHER INFORMATION> <STABILITY TESTS *[for biologicals other than immunologicals]*>

### <2.H. OTHER INFORMATION *[for biologicals other than immunologicals]*>

*[For Part 2 use Annex II-format of Regulation (EU) 2019/6 or CTD-format Module 3 (according to Annex I of Directive 2001/83/EC) and delete other part of the template as appropriate.]*

[**CTD Module 3 SECTION (= Annex I to Directive 2001/83/EC**]

***<QUALITY DOCUMENTATION*** *(CTD-format)****>***

### 3.2.S DRUG SUBSTANCE

3.2.S.1 General Information

3.2.S.2 Manufacture

3.2.S.3 Characterisation

3.2.S.4 Control of Drug Substance

3.2.S.5 Reference Standards or Materials

3.2.S.6 Container Closure System

3.2.S.7 Stability

### 3.2.P DRUG PRODUCT

3.2.P.1 Description and Composition of the Drug Product

3.2.P.2 Pharmaceutical Development

3.2.P.3 Manufacture

3.2.P.4 Control of Excipients

3.2.P.5 Control of the Drug Product

3.2.P.6 Reference Standards or Materials

3.2.P.7 Container Closure System

3.2.P.8 Stability

## OTHER CONCERNS ON PART 3

**<SAFETY DOCUMENTATION (SAFETY AND RESIDUES TESTS)>**

### 3.A SAFETY TESTS

3.A.1 Precise identification of the product and of its active substance(s)

3.A.2 Pharmacology

3.A.2.1 Pharmacodynamics

3.A.2.2. Pharmacokinetics

3.A.3 Toxicology

3.A.4 Other requirements

3.A.4.1. Special studies

3.A.4.2. Observations in humans

3.A.4.3. Development of resistance and related risk in humans

3.A.5 User safety

3.A.6 Environmental risk assessment

### 3.B RESIDUE TESTS

3.B.1 Identification of the product

3.B.2 Depletion of residues

3.B.3 Residue analytical method

## OTHER CONCERNS ON PART 4

**<EFFICACY DOCUMENTATION (PRE-CLINICAL STUDIES AND CLINICAL TRIAL(S))>**

### 4.A PRE-CLINICAL STUDIES

4.A.1 Pharmacology

4.A.1.1. Pharmacodynamics

4.A.1.2. Pharmacokinetics

4.A.2 Development of resistance and related risk in animals

4.A.3 Dose determination and confirmation

4.A.4. Tolerance in the target animal species

### 4.B CLINICAL TRIAL(S)

4.B.1. General principles

4.B.2. Documentation

4.B.2.1. Results of pre-clinical studies

4.B.2.2. Results of clinical trials

## COMMENTS ON SPC, LABELLING AND PACKAGE LEAFLET

## PART 1B.1 – SPC

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

3. CLINICAL INFORMATION

3.1 Target species

3.2 Indications for use for each target species

3.3 Contraindications

3.4 Special warnings

3.5 Special precautions for use

i) Special precautions for safe use in the target species

**ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals**

**iii) Special precautions for the protection of the environment**

iv) Other precautions

3.6 Adverse reactions

3.7 Use during pregnancy, lactation or lay

3.8 Interactions with other medicinal products and other forms of interaction

3.9 Administration routes and dosage

3.10 Symptoms of overdose (and where applicable, emergency procedure and antidotes)

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

3.12 Withdrawal periods

**4. PHARMACOLOGICAL INFORMATION**

**4.1 ATCvet code**

4.2 Pharmacodynamics

4.3 Pharmacokinetics

Environmental properties

**5. PHARMACEUTICAL PARTICULARS**

5.1 Major incompatibilities

5.2 Shelf life

5.3 Special precautions for storage

5.4 Nature and composition of immediate packaging

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

**6. NAME OF MARKETING AUTHORISATION HOLDER**

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

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

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

## PART 1B.2 – Labelling

**OUTER PACKAGE**

**IMMEDIATE PACKAGE**

## PART 1B.3 – Package leaflet

## NATIONAL REQUIREMENTS