**<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 ASSESSMENT OF>**

**<APPLICANTS RESPONSE TO>**

**THE COMPILED**

**CMS DAY <30><50><70>**

**LIST OF QUESTIONS**

**Applicant:**

**Application according to Art. xx**

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

**Procedure No.: xx/V/xxxx/xxx/<MR><SR>**

**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.]*

TABLE OF CONTENTS

[I. SUMMARY OF THE DOSSIER 4](#_Toc94683951)

[I.I. ADMINISTRATIVE INFORMATION 4](#_Toc94683952)

[I.II CONCLUSIONS ON THE VETERINARY MEDICINAL PRODUCT FROM EACH CMS AT DAY <30><50><70> 4](#_Toc94683953)

[II. COMPILED LIST OF QUESTIONS (<MRP><SRP>) 6](#_Toc94683954)

[MAJOR OBJECTIONS 6](#_Toc94683955)

[MAJOR OBJECTIONS ON PART 1 6](#_Toc94683956)

[1.A ADMINISTRATIVE INFORMATION 6](#_Toc94683957)

[1.C CRITICAL EXPERT REPORTS 6](#_Toc94683958)

[MAJOR OBJECTIONS ON PART 2 7](#_Toc94683959)

[2.A. PRODUCT DESCRIPTION 7](#_Toc94683960)

[2.B. DESCRIPTION OF THE MANUFACTURING METHOD 7](#_Toc94683961)

[2.C. PRODUCTION AND CONTROL OF STARTING MATERIALS 7](#_Toc94683962)

[2.D. CONTROL TESTS DURING THE MANUFACTURING PROCESS 7](#_Toc94683963)

[2.E. CONTROL TESTS ON THE FINISHED PRODUCT 7](#_Toc94683964)

[2.F. BATCH-TO-BATCH CONSISTENCY 7](#_Toc94683965)

[2.G. STABILITY TESTS 7](#_Toc94683966)

[2.H. OTHER INFORMATION 7](#_Toc94683967)

[MAJOR OBJECTIONS ON PART 3 8](#_Toc94683968)

[3.A General requirements 8](#_Toc94683969)

[3.B Pre-clinical studies 8](#_Toc94683970)

[3.C Clinical trials 8](#_Toc94683971)

[3.D Environmental risk assessment 8](#_Toc94683972)

[3.E Assessment required for veterinary medicinal products containing or consisting of genetically modified organisms 8](#_Toc94683973)

[3.F Residue tests to be included in the pre-clinical studies 8](#_Toc94683974)

[MAJOR OBJECTIONS ON PART 4 8](#_Toc94683975)

[4.A General requirements 9](#_Toc94683976)

[4.B Pre-clinical studies 9](#_Toc94683977)

[4.C CLINICAL TRIALS 9](#_Toc94683978)

[OTHER CONCERNS 10](#_Toc94683979)

[OTHER CONCERNS ON PART 1 10](#_Toc94683980)

[1.A ADMINISTRATIVE INFORMATION 10](#_Toc94683981)

[1.C CRITICAL EXPERT REPORTS 10](#_Toc94683982)

[OTHER CONCERNS ON PART 2 10](#_Toc94683983)

[2.A. PRODUCT DESCRIPTION 10](#_Toc94683984)

[2.B. DESCRIPTION OF THE MANUFACTURING METHOD 10](#_Toc94683985)

[2.C. PRODUCTION AND CONTROL OF STARTING MATERIALS 10](#_Toc94683986)

[2.D. CONTROL TESTS DURING THE MANUFACTURING PROCESS 10](#_Toc94683987)

[2.E. CONTROL TESTS ON THE FINISHED PRODUCT 10](#_Toc94683988)

[2.F. BATCH-TO-BATCH CONSISTENCY 11](#_Toc94683989)

[2.G. STABILITY TESTS 11](#_Toc94683990)

[2.H. OTHER INFORMATION 11](#_Toc94683991)

[OTHER CONCERNS ON PART 3 11](#_Toc94683992)

[3.A General requirements 11](#_Toc94683993)

[3.B Pre-clinical studies 11](#_Toc94683994)

[3.C Clinical trials 11](#_Toc94683995)

[3.D Environmental risk assessment 11](#_Toc94683996)

[3.E Assessment required for veterinary medicinal products containing or consisting of genetically modified organisms 12](#_Toc94683997)

[3.F Residue tests to be included in the pre-clinical studies 12](#_Toc94683998)

[OTHER CONCERNS ON PART 4 12](#_Toc94683999)

[4.A General requirements 12](#_Toc94684000)

[4.B PRE-CLINICAL STUDIES 12](#_Toc94684001)

[4.C CLINICAL TRIALS 12](#_Toc94684002)

[COMMENTS ON SPC, LABELLING AND PACKAGE LEAFLET 13](#_Toc94684003)

[PART 1.B.1 – SPC 13](#_Toc94684004)

[PART 1.B.2 – Labelling 14](#_Toc94684005)

[PART 1.B.3 – Package leaflet 14](#_Toc94684006)

[NATIONAL REQUIREMENTS 14](#_Toc94684007)

# I. SUMMARY OF THE DOSSIER

## I.I. ADMINISTRATIVE INFORMATION

*[For MRP/SRP filled in by the applicant:]*

|  |  |
| --- | --- |
| **Name of the product:** |  |
| **Active substance(s):** |  |
| **Pharmaceutical form:** |  |
| **Target species:** |  |
| **Procedure number:** | xx/V/xxxx/xxx/<MR><SR> |
| **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)** |  |

*[For MRP/SRP CMS Day 30/50/70 conclusions – filled in by applicant:]*

## I.II CONCLUSIONS ON THE VETERINARY MEDICINAL PRODUCT FROM EACH CMS AT DAY <30><50><70>

**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}

# II. COMPILED LIST OF QUESTIONS (<MRP><SRP>)

[*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 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 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*

<**QUALITY DOCUMENTATION (physicochemical, biological or microbiological information)**>

### 2.A. PRODUCT DESCRIPTION

2.A.1. Qualitative and quantitative composition

2.A.2. Product development

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

### 2.C. PRODUCTION AND CONTROL OF STARTING MATERIALS

2.C.1. Starting materials listed in pharmacopoeias

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

2.C.2.1. Starting materials of biological origin

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

### 2.D. CONTROL TESTS DURING THE MANUFACTURING PROCESS

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

2.E.1. General characteristics of the finished product

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

2.E.3. Batch titre or potency

2.E.4. Identification and assay of adjuvants

2.E.5. Identification and assay of excipient components

2.E.6. Sterility and purity test

2.E.7 Residual humidity

2.E.8 Filling volume

### 2.F. BATCH-TO-BATCH CONSISTENCY

### 2.G. STABILITY TESTS

### 2.H. OTHER INFORMATION

## MAJOR OBJECTIONS ON PART 3

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

### 3.A General requirements

### 3.B Pre-clinical studies

3.B.1 Safety of the administration of one dose

3.B.2 Safety of one administration of an overdose

3.B.3 Safety of the repeated administration of one dose

3.B.4 Examination of reproductive performance

3.B.5 Examination of immunological functions

3.B.6 Special requirements for live vaccines

3.B.6.1 Spread of the vaccine strain

3.B.6.2 Dissemination in the vaccinated animal

3.B.6.3 Increase in virulence

3,B.6.4 Biological properties of the vaccine strain

3.B.6.5 Recombination or genomic reassortment of strains

3.B.7 User safety

3.B.8 Interactions

### 3.C Clinical trials

### 3.D Environmental risk assessment

### 3.E Assessment required for veterinary medicinal products containing or consisting of genetically modified organisms

### 3.F Residue tests to be included in the pre-clinical studies

## MAJOR OBJECTIONS ON PART 4

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

### 4.A General requirements

### 4.B Pre-clinical studies

### 4.C 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*

<**QUALITY DOCUMENTATION** **(physicochemical, biological or microbiological information)**>

### 2.A. PRODUCT DESCRIPTION

2.A.1. Qualitative and quantitative composition

2.A.2. Product development

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

### 2.C. PRODUCTION AND CONTROL OF STARTING MATERIALS

2.C.1. Starting materials listed in pharmacopoeias

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

2.C.2.1. Starting materials of biological origin

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

### 2.D. CONTROL TESTS DURING THE MANUFACTURING PROCESS

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

2.E.1. General characteristics of the finished product

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

2.E.3. Batch titre or potency

2.E.4. Identification and assay of adjuvants

2.E.5. Identification and assay of excipient components

2.E.6. Sterility and purity test

2.E.7 Residual humidity

2.E.8 Filling volume

### 2.F. BATCH-TO-BATCH CONSISTENCY

### 2.G. STABILITY TESTS

### 2.H. OTHER INFORMATION

## OTHER CONCERNS ON PART 3

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

### 3.A General requirements

### 3.B Pre-clinical studies

3.B.1 Safety of the administration of one dose

3.B.2 Safety of one administration of an overdose

3.B.3 Safety of the repeated administration of one dose

3.B.4 Examination of reproductive performance

3.B.5 Examination of immunological functions

3.B.6 Special requirements for live vaccines

3.B.6.1 Spread of the vaccine strain

3.B.6.2 Dissemination in the vaccinated animal

3.B.6.3 Increase in virulence

3,B.6.4 Biological properties of the vaccine strain

3.B.6.5 Recombination or genomic reassortment of strains

3.B.7 User safety

3.B.8 Interactions

### 3.C Clinical trials

### 3.D Environmental risk assessment

### 3.E Assessment required for veterinary medicinal products containing or consisting of genetically modified organisms

### 3.F Residue tests to be included in the pre-clinical studies

## OTHER CONCERNS ON PART 4

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

### 4.A General requirements

### 4.B PRE-CLINICAL STUDIES

### 4.C CLINICAL TRIALS

## COMMENTS ON SPC, LABELLING AND PACKAGE LEAFLET

## PART 1.B.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 1.B.2 – Labelling

**OUTER PACKAGE**

**IMMEDIATE PACKAGE**

## PART 1.B.3 – Package leaflet

## NATIONAL REQUIREMENTS