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SCIENCE MEDICINES HEALTH

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Veterinary Medicines Division

## **Committee for Veterinary Medicinal Products (CVMP)**

### **CVMP assessment report for Elmaro (EMA/V/C/006389/0000)**

INN: Maropitant citrate monohydrate

**Assessment report as adopted by the CVMP with all information of a commercially confidential nature deleted.**



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## Introduction

The applicant Elanco GmbH submitted on 4 December 2023 an application for a marketing authorisation to the European Medicines Agency (The Agency) for Elmaro, through the centralised procedure under Article 42(4) of Regulation (EU) 2019/6 (optional scope).

The eligibility to the centralised procedure was agreed upon by the CVMP on 13 July 2023 as no other marketing authorisation has been granted for the veterinary medicinal product within the Union.

At the time of submission, the applicant applied for the following indications:

### Dogs

- For the treatment and prevention of nausea induced by chemotherapy.
- For the prevention of vomiting except that induced by motion sickness.
- For the treatment of vomiting, in combination with other supportive measures.
- For the prevention of perioperative nausea and vomiting and improvement in recovery from general anaesthesia after use of the  $\mu$ -opiate receptor agonist morphine.

### Cats

- For the prevention of vomiting and the reduction of nausea, except that induced by motion sickness.
- For the treatment of vomiting, in combination with other supportive measures.

The active substance of Elmaro is maropitant citrate monohydrate, a neurokinin 1 (NK1) receptor antagonist, which acts as an antiemetic by inhibiting the binding of substance P, a neuropeptide of the tachykinin family. The target species are dogs and cats.

Elmaro solution for injection contains 10 mg/ml maropitant (as maropitant citrate monohydrate) and is presented in packs containing one 20 ml vial containing 20 ml of product.

The rapporteur appointed is Sylvie Louet and the co-rapporteur is Anna Wachnik-Święcicka.

The dossier has been submitted in line with the requirements for submissions under Article 18 of Regulation (EU) 2019/6 – a generic application.

On 12 February 2025, the CVMP adopted an opinion and CVMP assessment report.

On 28 March 2025, the European Commission adopted a Commission Decision granting the marketing authorisation for Elmaro.

## Part 1 - Administrative particulars

### ***Summary of the Pharmacovigilance System Master File***

The applicant has provided a summary of the pharmacovigilance system master file which fulfils the requirements of Article 23 of Commission Implementing Regulation (EU) 2021/1281. Based on the information provided the applicant has in place a pharmacovigilance system master file (PSMF), has the services of a qualified person responsible for pharmacovigilance, and has the necessary means

to fulfil the tasks and responsibilities required by Regulation (EU) 2019/6.

## ***Manufacturing authorisations and inspection status***

### **Active substance**

Manufacture, quality control, primary packaging, secondary packaging, storage and/or distribution of the active substance maropitant citrate monohydrate take place outside the EEA. A GMP declaration for the active substance manufacturing site was provided from the Qualified Person (QP) at the EU batch release site manufacturer of dosage form on behalf of all QPs involved. The declaration was based on an on-site audit by a third party following inspection.

### **Finished product**

Batch release of the finished product takes place at Fareva, Amboise, France. The site has a manufacturing authorisation issued on 9 October 1979 by the Competent Authority in France. GMP certification, which confirms the date of the last inspection as 23 July 2021 and shows that the site is authorised for activities indicated above, is available in EudraGMDP.

## ***Overall conclusions on administrative particulars***

The summary of the pharmacovigilance system master file was considered to be in line with legal requirements.

The GMP status of the active substance and finished product manufacturing sites has been satisfactorily established and is in line with legal requirements.

## **Part 2 - Quality**

### ***Composition***

The finished product is presented as an injectable solution containing 10 mg of maropitant as active substance per ml. The product contains the active substance maropitant in the form of citrate monohydrate.

Other ingredients are benzyl alcohol, sulfobutylbetadex sodium and water for injections.

The pack sizes are consistent with the dosage regimen and duration of use.

### ***Containers and closure system***

The finished product is presented in a Type I amber glass vial of 20 ml with bromobutyl rubber stopper (coated) sealed with a 20 mm aluminium cap with flip-off seal. The secondary packaging is a cardboard box containing only one 20 ml vial.

The primary packaging is described as stated in the SPC (5.4). The material complies with the relevant European Pharmacopoeia (Ph. Eur.) and EU requirements. The choice of the container closure system has been validated by stability data and is adequate for the intended use of the product.

## ***Product development***

A substantial pharmaceutical development section has been presented in which the studies focused on development of a product which contains the same concentration of the active substance and comparable excipients in similar amounts as the reference product (Cerenia 10 mg/ml solution for injection for dogs and cats). The preservative used in the reference product (metacresol) is different to that in the test product (benzyl alcohol). Different preservatives were studied taking into account their compatibility with the active substance and compliance with Ph. Eur. (5.1.3) for efficacy of antimicrobial preservation. Benzyl alcohol was chosen for the final formulation. Comparative batch data between the reference and test products have been provided comparing relevant physico-chemical characteristics (appearance, density, pH), identification and assay of the active substance, and impurity profile. All excipients are well-known pharmaceutical ingredients, and their quality is compliant with Ph. Eur. standards.

There are no novel excipients used in the finished product formulation. The list of excipients is included in section 2 of the SPC.

The development report also details studies in which the manufacturing process was developed and optimised. The sterilisation method chosen is in accordance with the Guideline on the sterilisation of the medicinal product, active substance, excipient and primary container EMA/CHMP/CVMP/QWP/850374/2015. The sterilisation conditions have been well justified and are considered appropriate.

The primary packaging, a 20 ml amber type I glass vial, was selected based on forced degradation studies which showed that the solution is sensitive to light. Results for fragmentation and self-sealing testing for the closure system selected, coated bromobutyl rubber stoppers, have been provided. The compatibility of the container closure system with the product is investigated and accepted with ongoing stability studies with vials in inverted position.

The studies carried out during development are appropriate for a generic product.

## ***Description of the manufacturing method***

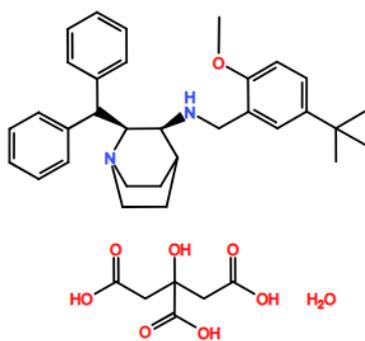
The manufacturing process consists of a series of dissolution and filtration steps with the product being terminally sterilised. The order of introduction of components has been demonstrated to be important. The process is considered to be a standard manufacturing process. The process is well described and details of in-process control (IPC) tests have been provided and are adequate for this pharmaceutical form. Critical steps and holding times applied for commercial batches are stated in the manufacturing process.

Major steps of the manufacturing process have been validated by a number of studies. Testing results from commercial scale batches have been provided to verify the homogeneity of the drug product and ensure that the drug product complied with the proposed specifications and quality attributes. Bioburden testing is performed in line with Ph. Eur. requirements and its suitability is confirmed by validation data. It has been demonstrated that the manufacturing process is capable of producing the finished product of intended quality in a reproducible manner. An acceptable process validation for three pilot scale batches was provided. The process validation data on the first 3 commercial scale batches should be available at the manufacturing site for inspection.

## Control of starting materials

### Active substance

The chemical IUPAC name of the active substance (maropitant citrate monohydrate) in Elmaro is (2S,3S)-2-benzhydryl-N-[(5-tert-butyl-2-methoxyphenyl)methyl]-2-(diphenylmethyl)-1-azabicyclo[2.2.2]octan-3-amine;2-hydroxypropane-1,2,3-tricarboxylic acid hydrate and has the following structure:



The maropitant citrate monohydrate is a white to pale yellow powder with two chiral centres and exhibits polymorphism being polymorph A the one used in Elmaro. Enantiomeric purity is routinely controlled.

The information on the active substance is provided according to the Active Substance Master File (ASMF) procedure and the active substance is not described in a pharmacopoeia.

Maropitant citrate monohydrate is synthesised in four main steps using commercially available well-defined starting materials with acceptable specifications. According to the results obtained from three validation batches, maropitant citrate monohydrate is slightly hygroscopic.

Adequate in-process controls are applied during the synthesis. The specifications and control methods for intermediate products, starting materials and reagents have been presented.

Potential and actual impurities were well discussed with regards to their origin and characterization.

Detailed information on the manufacturing process of the active substance has been provided in the restricted part of the ASMF and it was considered satisfactory.

The active substance specification includes tests for appearance, identity, citrate identification, water content, sulfated ash, enantiomer, assay, impurities, residual solvents, optical rotation, genotoxic impurities and elemental impurities.

The control tests were carried out to comply with the specifications. All chromatographic methods have been adequately validated and described according to VICH GL1 and 2. Other methods are compendial and described in the Ph. Eur..

Satisfactory information regarding the reference standards used for assay and impurities testing has been presented.

Validation batch analysis data of the active substance have been provided. The results are within the specifications and consistent from batch to batch.

Stability data for the active substance from the proposed manufacturer under long term conditions at 25°C/60% RH and for up to 6 months under accelerated conditions at 40°C/75% RH according to

the VICH guidelines was provided.

The parameters tested are the same as in the active substance specification. The analytical methods used were the same as for the active substance specification; methods are stability indicating. Moreover, microbiological quality is controlled during stability studies.

All tested parameters were within the specification.

The stability results indicate that the active substance manufactured by the proposed supplier is sufficiently stable. The stability results justify the proposed retest period in the proposed container. The storage precaution is "*Preserve in tightly closed containers. Store below 30°C*".

#### Applicant's dossier

The finished product manufacturer uses specifications and respective methods from the active substance manufacturer and it is acceptable. Additional tests are proposed given that the active substance is to be used in a sterile product: bacterial endotoxins and microbiological quality with limits in accordance with Ph. Eur. requirements. The Ph. Eur. methods 2.6.12, 2.6.13 and 2.6.14 to control the microbiological quality are satisfactorily verified by the finished product manufacturer. The method for assay of residual solvents is satisfactorily validated according to VICH guidelines. Specifications and reference standards are discussed. Analytical certificates of two batches of maropitant citrate monohydrate used for registration are provided.

## **Excipients**

All excipients are well-known pharmaceutical ingredients and their quality is compliant with Ph. Eur..

## ***Specific measures concerning the prevention of the transmission of animal spongiform encephalopathies***

None of the starting materials used for the active substance or the finished product are risk materials as defined in the current version of the Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (EMA/410/01 rev 3).

Valid TSE declarations from the manufacturers of the active substance, excipients and finished product confirming compliance with the Ph. Eur. monograph and the Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (EMA/410/01 rev 3) have been provided.

## ***Control tests on the finished product***

The finished product specification includes tests for appearance, degree of coloration, extractable volume, visible particles, density, pH, clarity, active substance identification, assay, degradation products, benzyl alcohol identification and assay and sterility.

The potential presence of elemental impurities in the finished product has been assessed on a risk-based approach in line with the CVMP guidance on risk management requirements for elemental impurities in veterinary medicinal products. The risk assessment demonstrated that each relevant elemental impurity was not detected above 30% of the respective acceptable limit.

The analytical methods used have been adequately described and appropriately validated in accordance with the VICH guidelines. Satisfactory information regarding the reference standards

used for assay and impurities testing has been presented.

Batch analysis results are provided for 3 batches confirming the consistency of the manufacturing process and its ability to manufacture to the intended product specification.

## ***Stability***

Stability data of industrial batches of finished product stored under long term conditions for 18 months at 30°C/65% RH and for up to 6 months under accelerated conditions at 40°C/75% RH according to the VICH GL3 were provided. The batches of maropitant injectable solution 10 mg/ml are representative of those proposed for marketing and were packed in the primary packaging proposed for marketing.

The specifications proposed at the end of shelf-life are appropriate to control the quality of the finished product. The parameters tested and limits are the same as those proposed at release except for the limit for 'any unspecified impurity' which is widened at shelf-life and is considered acceptable. The analytical procedures used are stability indicating.

No significant changes have been observed.

Based on the in-use stability data provided, an in-use shelf-life of 60 days is acceptable.

In addition, one batch was exposed to light as defined in the VICH GL5 on photostability testing of new veterinary drug substances and medicinal products.

Based on the available stability data, the proposed shelf-life of 24 months without storage conditions is acceptable.

## ***Overall conclusions on quality***

The solution for injection is manufactured in a straightforward process involving sequential addition and dissolution of the product constituents in the formulation. The order of introduction of components has been demonstrated to be important. The proposed method of sterilisation of the solution is a standard terminal one. The process is well described and details of IPC tests have been provided. Process validation has been carried out on three industrial scale batches and is found satisfactory.

Information on the control of the starting materials has been provided. The active substance maropitant citrate monohydrate is not monographed in Ph. Eur. and supporting data for the active substance has been provided in an ASMF. Fate and purge of different impurities are correctly discussed. Specifications proposed for the active substance are acceptable. Excipients are compendial and well controlled. The product is packaged into amber glass vials sealed with sterilised rubber stoppers. The data presented to support the finished product container closure system are satisfactory.

The finished product specification controls appropriate parameters for the dosage form and includes control of an unidentified impurity. Finished product batch data in line with the proposed release specification are provided. Finished product analytical test methods for active substance assay, related substances, enantiomer and the preservative are clearly described and are supported by satisfactory validation data. Stability data for 18 months from batches under VICH long term conditions, accompanied by 6 months data under accelerated conditions have been provided. The SPC specifies a shelf life of 2 years for the finished product as packaged for sale with no proposed

storage precautions, that is acceptable. An in-use stability study has also been provided and 60 days is acceptable. Data on freeze-thaw and photostability have been also presented in the dossier.

## **Part 3 – Safety documentation (Safety tests)**

The product is a solution for (intravenous and subcutaneous) injection intended for use in dogs and cats with maropitant (as maropitant citrate monohydrate) as active ingredient. Maropitant has been developed as an anti-emetic for dogs and cats and has been used in veterinary medicine for more than 10 years. The dossier has been submitted in line with the requirements for submissions under Article 18 of Regulation (EU) 2019/6 - a generic application. The reference product is Cerenia 10 mg/ml solution for injection for dogs and cats (EU/2/06/062/005), which was first granted a marketing authorisation following a centralised procedure on 29 September 2006.

### ***Safety tests***

A safety file in accordance with Article 18 of Regulation (EU) 2019/6 has been provided. As bioequivalence is established between the reference product and the candidate product, results of pharmacological, toxicological and tolerance tests are not required, since a generic application may rely on the results of the appropriate safety and efficacy studies of the reference product.

The applicant has provided a User Safety Assessment and a Phase I Environmental Risk Assessment in accordance with to the relevant guidelines (see below).

## **Pharmacology**

### ***Pharmacodynamics and pharmacokinetics***

See part 4.

## **Toxicology**

As this is a generic application submitted according to Article 18 of Regulation (EU) 2019/6 and considering that bioequivalence with the reference product is accepted (pharmaceutical equivalent composition, see also pharmacology part thereafter), results of toxicological tests are not required.

### ***Tolerance in the target species***

See part 4.

## **Other requirements**

### ***Special studies***

Given the legal basis of this application and that bioequivalence between candidate and reference products is demonstrated, the omission of special studies is considered acceptable.

## **Observations in humans**

Maropitant is not used in human medicinal products.

## **Excipients**

The pharmaceutical product is not identical to the reference product since one different excipient is used (the preservative benzyl alcohol is added instead of metacresol, the preservative used in the reference product Cerenia). Benzyl alcohol is well-known and widely used in pharmaceutical products intended for human and veterinary use. This excipient has been sufficiently described and assessed. According to the Q&A on benzyl alcohol use as an excipient in medicinal products for human use (EMA/CHMP/508188/2013), benzyl alcohol may cause allergic reactions (by any route of administration) and mild local irritation (in case of topical use). This has been adequately addressed in the product information (see below).

## **User safety**

In accordance with the legal basis of this application, this generic veterinary medicinal product may rely on the results of the reference product since the conditions in Article 18 of Regulation (EU) 2019/6 are fulfilled. The risks for the user handling this veterinary medicinal product are expected to be the same as those of the reference product and the warnings in the product information for the reference product can be considered adequate as regards the potential risks. However, the applicant has presented a user safety assessment in accordance with the CVMP guideline on user safety for pharmaceutical veterinary medicinal products (EMA/CVMP/543/03-Rev.1).

Information has been provided on the acute toxicity on laboratory animals, the repeated dose toxicity, the reproduction toxicity, the mutagenicity and the eye and dermal irritation. The excipient benzyl alcohol used in the candidate product and not present in the reference product is well-known and widely used in other pharmaceutical products. This excipient does not represent an additional particular risk, except for people with hypersensitivity to benzyl alcohol.

Dermal, ocular and accidental self-injection exposures are identified as possible routes of user exposure. The levels of the different exposures allow calculating a quantitative risk which is identical to that of the reference product.

Maropitant is considered as a sensitizer according to the results of the local lymph node assay in mice. Therefore, a risk may exist to people with hypersensitivity to the active substance. Based on this assessment, the fact that this is an application based on Article 18 of Regulation (EU) 2019/6 and that bioequivalence with the reference product has been established, it is considered acceptable to keep the same mitigation measures as those present in the SPC of the reference product but with the addition of the risk of hypersensitivity to benzyl alcohol.

## **Environmental risk assessment**

The Environmental Risk Assessment (ERA) of the pharmaceutical product was performed according to the relevant guidelines (VICH guidelines GL6 and GL38 and CVMP guideline on the Environmental Impact Assessment for Veterinary Medicinal Products in support of the VICH guidelines GL6 and GL38 (EMA/CVMP/ERA/418282/2005-Rev.1)).

The conclusion is that the ERA can stop at phase I and no phase II is required because the veterinary medicinal product will only be used in non-food animals. The product is not expected to

pose a risk for the environment when used according to the SPC.

### ***Overall conclusions on the safety documentation: safety tests***

As this is a generic application submitted in accordance with to Article 18 of Regulation (EU) 2019/6 – generic application, and as bioequivalence with the reference product is established (pharmaceutical equivalent composition, see also pharmacology part thereafter), results of pharmacological or toxicological tests are not required.

A user risk assessment and an environmental risk assessment have been provided. The new excipient benzyl alcohol used in the formulation is well-known and widely used in pharmaceutical products intended for human and veterinary use. It is sufficiently assessed to conclude that it does not represent a risk for the user, except for people with hypersensitivity to benzyl alcohol. Based on the user safety assessment and the type of application it is acceptable to keep the same mitigation measures, as those present in the SPC of the reference product, with the addition of the risk of hypersensitivity to benzyl alcohol.

The environmental risk assessment can stop at phase I. The product is not expected to pose a risk for the environment when used according to the SPC.

## **Part 4 – Efficacy**

### ***Pre-clinical studies***

Elmaro is a clear, colourless to light yellow solution for injection containing 10 mg/ml maropitant (as maropitant citrate monohydrate) as active ingredient, an antiemetic substance. Elmaro is intended for use in dogs and cats for the treatment and/or the prevention of vomiting. The proposed dose is 1 mg maropitant/kg for up to five consecutive days, by intravenous or subcutaneous route.

The active substance, maropitant citrate monohydrate, is a neurokinin 1 (NK1) receptor antagonist, which acts as an antiemetic by inhibiting the binding of substance P, a neuropeptide of the tachykinin family. Substance P is found in significant concentrations in the nuclei comprising the emetic centre and is considered the key neurotransmitter involved in vomiting. By inhibiting the binding of substance P within the emetic centre, maropitant is effective against neural and humoral (central and peripheral) causes of vomiting. Signs of nausea in dogs including excessive salivation and lethargy might remain after treatment.

The application has been submitted in accordance with Article 18 of Regulation (EU) 2019/6 - generic application. The cited reference product is Cerenia 10 mg/ml solution for injection for dogs and cats registered in the European Union since 29 September 2006.

## **Pharmacology**

### ***Pharmacodynamics and pharmacokinetics***

No pharmacodynamic or pharmacokinetic studies were presented. As bioequivalence between Elmaro and the reference product is accepted, the omission of pharmacodynamic and pharmacokinetic data is acceptable given the legal basis of the application.

The pharmacodynamic properties of the active substance are detailed in section 4.2 of the SPC and are identical to those approved for the reference product.

### ***Bioequivalence studies***

No *in vivo* bioequivalence studies were provided. Both Elmaro and the reference product are intended for intravenous and subcutaneous use.

For intravenous route, the waiver of a bioequivalence study in dogs and in cats can be accepted according to the current bioequivalence guideline (EMA/CVMP/016/2000-Rev.4, exemption 7.1.a), given that the new product is an aqueous intravenous solution containing the same concentration of the active substance as the reference product.

For the subcutaneous route, the waiver of a bioequivalence study in dogs and in cats can be accepted according to the current bioequivalence guideline (EMA/CVMP/016/2000-Rev.4, exemption 7.1.b), given that the new product is of the same type of solution, contains the same concentration of the active substance and comparable excipients in similar amounts as the reference product, and that the differences in excipients and/or their concentration are not expected to affect the rate and/or extent of absorption of the active substance.

### **Dose determination and confirmation**

No dose determination and confirmation studies were provided. Considering the legal basis of the application (Article 18 of Regulation (EU) 2019/6 – generic application) and as bioequivalence with the reference product is established, the omission of dose determination and confirmation studies is acceptable.

### **Tolerance in the target animal species**

As this is a generic application submitted according to Article 18 of Regulation (EU) 2019/6 and given that bioequivalence with the reference product is satisfactorily demonstrated, results of tolerance tests are not required. The special precautions for safe use in the target species present in the SPC are identical to the ones of the reference product.

### ***Clinical trial(s)***

Considering the legal basis of the application (generic application submitted in accordance with Article 18 of Regulation (EU) 2019/6) and as bioequivalence with the reference product is established, no clinical trials are required.

### ***Overall conclusions on efficacy***

This application has been submitted in accordance with Article 18 of Regulation (EU) 2019/6 (a generic veterinary medicinal product).

#### **Bioequivalence:**

Elmaro is considered bioequivalent with the reference product, Cerenia, for both the intravenous and subcutaneous routes, according to the exemptions 7.1.a) and 7.1.b) of the Guideline on the conduct of bioequivalence studies (CVMP/016/2000/Rev.4), respectively.

Thus, it is expected that both Elmaro and the reference product will have a similar safety and efficacy profile and the same indications and posology apply.

As bioequivalence between the proposed generic product and the reference product has been demonstrated, the omission of dose determination, tolerance and clinical data is acceptable.

## **Part 5 – Benefit-risk assessment**

### ***Introduction***

Elmaro is a solution for injection containing 10 mg/ml maropitant (as maropitant citrate monohydrate) and is presented in packs containing 20 ml vial containing 20 ml of product. The active substance, maropitant citrate monohydrate, is a neurokinin 1 (NK1) receptor antagonist, which acts as an antiemetic by inhibiting the binding of substance P, a neuropeptide of the tachykinin family. The product is intended for the following indications:

Dogs

- For the treatment and prevention of nausea induced by chemotherapy.
- For the prevention of vomiting except that induced by motion sickness.
- For the treatment of vomiting, in combination with other supportive measures.
- For the prevention of perioperative nausea and vomiting and improvement in recovery from general anaesthesia after use of the  $\mu$ -opiate receptor agonist morphine.

Cats

- For the prevention of vomiting and the reduction of nausea, except that induced by motion sickness.
- For the treatment of vomiting, in combination with other supportive measures.

The product should be injected subcutaneously or intravenously, once daily, at a dose of 1 mg maropitant/kg bodyweight (1 ml/10 kg bodyweight). Treatment may be repeated for up to five consecutive days.

The application has been submitted in accordance with Article 18 of Regulation (EU) 2019/6 - generic application. The reference product is Cerenia 10 mg/ml solution for injection for dogs and cats.

### ***Benefit assessment***

#### **Direct benefit**

The benefit of Elmaro is its efficacy for the treatment and prevention of nausea and vomiting, in dogs and cats. Based on the bioequivalence to the reference product, Cerenia, the evidence for the benefit is considered established when the veterinary medicinal product is administered using the intravenous route and the subcutaneous route, at the same dose and dosing interval as recommended in the marketing authorisation for the reference product.

## **Additional benefits**

None identified.

## **Risk assessment**

### Quality

Information on development, manufacture and control of the active substance and finished product has been presented generally in a satisfactory manner. The results of tests carried out indicate consistency and uniformity of important product quality characteristics, and these in turn lead to the conclusion that the product should have a satisfactory and uniform performance in clinical use.

### Safety

The risks associated with the use of Elmaro are expected to be the same as those associated with the reference product Cerenia. On this basis, it is concluded that Elmaro is not expected to present an unacceptable risk to the target animal or the environment when used in accordance with the SPC.

Based on the demonstration of bioequivalence and the user safety assessment provided, the user safety for this product is acceptable, with the addition of the risk to users with hypersensitivity to benzyl alcohol.

## ***Risk management or mitigation measures***

Given that bioequivalence between the reference and candidate products is accepted, it is considered appropriate that the warnings and risk mitigation measures proposed for inclusion in the candidate product SPC reflect those approved for the reference product, with an additional warning for users with hypersensitivity to benzyl alcohol.

### Conditions or restrictions as regards the supply or safe and effective use of the VMP concerned, including the classification (prescription status)

The veterinary medicinal product is subject to prescription.

## ***Evaluation of the benefit-risk balance***

Based on the data presented, the overall benefit-risk balance is considered positive. The product information has been reviewed and is considered to be satisfactory and in line with the assessment.

## **Conclusion**

Based on the original and complementary data presented on quality, safety and efficacy the Committee for Veterinary Medicinal Products (CVMP) considers that the application for Elmaro is approvable since these data satisfy the requirements for an authorisation set out in the legislation (Regulation (EU) 2019/6).

The CVMP considers that the benefit-risk balance is positive and, therefore, recommends the granting of the marketing authorisation for the above mentioned medicinal product.