10 May 2022
EMA/CVMP/260411/2022
Committee for Veterinary Medicinal Products (CVMP)

# Committee for Veterinary Medicinal Products

## Minutes of the 11-13 April 2022 meeting

Chair: D. Murphy – Vice-chair: G. J. Schefferlie

**Note on access to documents**

Some documents mentioned in the agenda/minutes cannot be released at present within the framework of Regulation (EC) No 1049/2001 on access to documents because they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/729522/2016).

### i. Adoption of the Agenda

The Committee adopted the agenda with no modifications.

### ii. Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the CVMP plenary session 11-13 April 2022

The attendance list was completed and competing interests were identified for the April 2022 meeting. In accordance with the Agency's policy and procedure on the handling of competing interests, participants in this meeting were asked to declare any interests on the matters for discussion (in particular any changes, omissions or errors to the already declared interests). Discussions, deliberations and voting took place in full respect of the restricted involvement of CVMP members and, where relevant, experts attending the plenary meeting, as announced by the CVMP secretariat at the start of the meeting (see Annex I). All decisions taken at this meeting were made in presence of a quorum of members, i.e. 17 or more members of the 32 members eligible to vote were present. Furthermore, absolute majority requires that 17 members vote in favour of the proposed decision.

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### iii. Declaration of contacts between members and companies with regard to points on the agenda

*Information relating to declared contacts between members and companies with regard to points on the agenda cannot be released at the present time as it is deemed to be commercially confidential.*

No contacts were declared.

### iv. Adoption of the minutes of the previous meeting

The minutes of the March 2022 meeting were adopted with no amendments.

### v. Topics for rapporteur's meetings, break-out sessions held in advance or in the margins of the present CVMP meeting

*Information relating to briefing meetings taking place with applicants/marketing authorisation holders cannot be released at the present time as it is deemed to be commercially confidential.*

## 1. Maximum residue limits

### 1.1. Opinions

- There were no items for discussion.

### 1.2. Oral explanations

- The Committee heard an oral explanation from the applicant and discussed the rapporteur's assessment of the responses to the list of outstanding issues and rapporteur's EPMAR for the extension of MRLs to chickens for a substance, (EMEA/V/MRL/003652/EXTN/0004). The Committee noted the comments received from CVMP members. The adoption of the opinion is foreseen for the May 2022 meeting of the Committee.

### 1.3. Lists of outstanding issues

- There were no items for discussion.

### 1.4. List of questions

- There were no items for discussion.

### 1.5. Re-examination of CVMP opinions on maximum residue limits

- There were no items for discussion.

### 1.6. Other issues

- There were no items for discussion.

## 2. Marketing authorisations and extensions

### 2.1. Opinions under Regulation (EU) 2019/6

- There were no items for discussion.

### 2.1. Opinions under Regulation (EC) No 726/2004

- There were no items for discussion.

### 2.2. Oral explanations under Regulation (EU) 2019/6

- There were no items for discussion.

### 2.2. Oral explanations under Regulation (EC) No 726/2004

- There were no items for discussion.

### 2.3. List of outstanding issues under Regulation (EU) 2019/6

- There were no items for discussion.

### 2.3. List of outstanding issues under Regulation (EC) No 726/2004

- The Committee adopted the scientific overview including the list of outstanding issues and agreed comments on the draft product information for a marketing authorisation application for a new product (EMEA/V/C/005816/0000), for dogs. The Committee noted a peer review report and the comments received from CVMP members.
- The Committee adopted the scientific overview including the list of outstanding issues and agreed comments on the draft product information for a marketing authorisation application for a new vaccine (EMEA/V/C/005829/0000), for chickens. The Committee noted peer review reports and the comments received from CVMP members.

### 2.4. List of questions under Regulation (EU) 2019/6

- There were no items for discussion.

### 2.4. List of questions under Regulation (EC) No 726/2004

- The Committee adopted a list of questions and agreed comments on the draft product information for a new product (EMEA/V/C/005948/0000), for cats. The Committee noted a peer review report and the comments received from CVMP members.

### 2.5. Re-examination of CVMP opinions under Regulation (EU) 2019/6

- There were no items for discussion.

### 2.5. Re-examination of CVMP opinions under Regulation (EC) No 726/2004

- There were no items for discussion.

### 2.6. Other issues under Regulation (EU) 2019/6

- There were no items for discussion.

### 2.6. Other issues under Regulation (EC) No 726/2004

- There were no items for discussion.

## 3. Variations to marketing authorisations

### 3.1. Opinions under Regulation (EU) 2019/6

- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report, for an application for a variation requiring assessment (subject to a worksharing procedure) for **Purevax RC, Purevax RCP FeLV, Purevax RCPCh FeLV, Purevax RCPCh, Purevax RCP** (EMEA/V/C/xxxx/WS2036), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.

### 3.1. Opinions under Commission Regulation (EC) No 1234/2008

- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information, for a grouped type II variation application for **Gumbohatch** (EMEA/V/C/004967/II/0005/G), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report, for a type II variation application for **NexGard Spectra** (EMEA/V/C/003842/II/0031), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion, and the product information and endorsed the rapporteur's assessment report, for a grouped type II variation application for **Bonqat** (EMEA/V/C/005489/II/0002/G), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report, for a type II variation application for **Suprelorin** (EMEA/V/C/000109/II/0033), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report, for a grouped type II variation application for **Rabitec** (EMEA/V/C/004387/II/0007/G), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.

### 3.2. Oral explanations under Regulation (EU) 2019/6

- There were no items for discussion.

### 3.2. Oral explanations under Commission Regulation (EC) No 1234/2008

- The Committee heard an oral explanation from the marketing authorisation holder Virbac S.A. concerning a grouped type II variation application for **Suprelorin** (EMEA/V/C/000109/II/0032/G), to add a new therapeutic indication and to add a non-food producing target species. The Committee also noted the rapporteurs' initial assessment of the responses to the list of outstanding issues, and the comments on the product information. The adoption of the opinion is foreseen for the May 2022 CVMP meeting.

### 3.3. List of outstanding issues under Regulation (EU) 2019/6

- There were no items for discussion.

### 3.3. List of outstanding issues under Commission Regulation (EC) No 1234/2008

- There were no items for discussion.

### 3.4. List of questions under Regulation (EU) 2019/6

- The Committee adopted a list of questions for an application for a variation requiring assessment for **Prevomax** (EMEA/V/C/004331/VRA/0012), concerning quality-related changes.

- The Committee adopted a list of questions and agreed comments on the draft product information for an application for a grouped variation requiring assessment for **Librela** (EMEA/V/C/005180/VRA/0004/G), concerning quality-related changes.
- The Committee adopted the rapporteur's assessment report including a list of questions and agreed comments on the draft product information for an application for a variation requiring assessment for **Felpreva** (EMEA/V/C/005464/VRA/0001), concerning quality-related changes.

### 3.4. List of questions under Commission Regulation (EC) No 1234/2008

- The Committee adopted a list of questions and agreed comments on the draft product information for a type II variation application for **Sileo** (EMEA/V/C/003764/II/0022), to modify the approved indication.
- The Committee adopted a list of questions and agreed comments on the draft product information for a grouped type II variation application for **Simparica Trio** (EMEA/V/C/004846/II/0007/G) to add a new therapeutic indication and to update SPC section 5.1.
- The Committee adopted a list of questions and agreed comments on the draft product information for a type II variation application (subject to a worksharing procedure) for **Simparica** and **MiPet Easecto** (EMEA/V/C/xxxx/WS2217) to add a new therapeutic indication.

### 3.5. Re-examination of CVMP opinions on variations requiring assessment under Regulation (EU) 2019/6

- There were no items for discussion.

### 3.5. Re-examination of CVMP opinions on variations under Regulation (EU) 726/2004

- There were no items for discussion.

### 3.6. Other issues under Regulation (EU) 2019/6

- There were no items for discussion.

### 3.6. Other issues under Commission Regulation (EC) 1234/2008

- There were no items for discussion.

## 4. Referrals and related procedures

### 4.1. Union interest referral under Article 82 of Regulation (EU) 2019/6

- There were no items for discussion.

### 4.2. Union interest referral under Article 82 based on Article 129(3) of Regulation (EU) 2019/6

- There were no items for discussion.

### 4.3. Procedure under Article 70(11) of Regulation (EU) 2019/6 due to lack of consensus between Member States in the SPC harmonisation procedure

- There were no items for discussion.

### 4.4. Request for clarification from the European Commission under Article 54(8) of Regulation (EU) 2019/6 on a CMDv review procedure

- There were no items for discussion.

### 4.5. Request from the European Commission under Article 130(4) of Regulation (EU) 2019/6 on suspending, revoking or varying the terms of centrally authorised products

- There were no items for discussion.

### 4.6. Request for a scientific opinion under Article 141(1)(c) or 141(1)(e) of Regulation (EU) 2019/6

- There were no items for discussion.

### 4.7. Other issues

*Information on certain topics discussed under section 4.7 cannot be released at the present time as it is deemed to be confidential.*

#### 4.7.1. Referrals under Regulation (EU) 2019/6

- There were no items for discussion.

#### 4.7.2. Referrals under Article 35 of Directive 2001/82/EC

- There were no items for discussion.

## 5. Post-authorisation issues for marketing authorisations

### 5.1. Pharmacovigilance under Regulation (EU) 2019/6

- There were no items for discussion.

### 5.1. Pharmacovigilance – PSURs and SARs under Regulation (EC) No 726/2004

- The Committee considered the marketing authorisation holder's appeal request on the January 2022 CVMP PSUR outcome and adopted the revised CVMP assessment report on the 3rd PSUR for the period 01.02.2021 – 31.07.2021 for **Stelfonta** (EMEA/V/C/005018), confirming its previous recommendation for changes to the summary of product characteristics.
- The Committee adopted a recommendation for changes to the summary of product characteristics as an outcome of signal detection activities for **BTVPUR** (EMEA/V/C/002231).
- The Committee endorsed the following rapporteur's assessment reports on PSURs concluding that no changes to the product information or other regulatory actions were required for:

| Product | Period |
|---|---|
| **Gumbohatch** (EMEA/V/C/004967) | 01.06.2021 – 30.11.2021 |
| **HorStem** (EMEA/V/C/004265) | 01.07.2021 – 31.12.2021 |
| **SevoFlo** (EMEA/V/C/000072) | 01.12.2020 – 30.11.2021 |
| **Virbagen Omega** (EMEA/V/C/000061) | 01.12.2018 – 30.11.2021 |

### 5.2. Post-authorisation measures under Regulation (EU) 2019/6

- There were no items for discussion.

### 5.2. Post-authorisation measures under Regulation (EC) No 726/2004

- The Committee endorsed the rapporteur's assessment report on the data submitted in response to the Committee's post-authorisation recommendation for **Nobivac DP Plus** (EMEA/V/C/005251/REC/005) which is now considered fulfilled.

### 5.3. Inspections and controls under Regulation (EU) 2019/6

*Information relating to GMP and pharmacovigilance inspections will not be published as it would be undermining the purpose of such inspections*

### 5.3. Supervision and sanctions under Regulation (EC) No 726/2004

*Information relating to supervision and sanctions will not be published as it would be undermining the purpose of such inspections.*

### 5.4. Re-examination of limited markets and exceptional circumstances authorisations under Regulation (EU) 2019/6

- There were no items for discussion.

## 6. Working parties

*Information relating to certain topics discussed under section 6 cannot be released at the present time as it is deemed to be commercially confidential.*

### 6.1. Antimicrobials Working Party (AWP)

- The Committee received a verbal report from the AWP chair on the meeting held on 22- 23 March 2022, and noted the minutes of the meeting held on 23-24 November 2021.

### 6.2. Environmental Risk Assessment Working Party (ERAWP)

### 6.3. Efficacy Working Party (EWP-V)

- The Committee confirmed the appointment of Dr Andres Garcia-Campos as a new member of the Efficacy Working Party.

### 6.4. Immunologicals Working Party (IWP)

- There were no items for discussion.

### 6.5. Joint CVMP/CHMP Working Group on the application of the 3Rs (J3RsWG)

- The Committee endorsed the recommendations of the transitional domain governance for membership in the Joint CVMP/CHMP 3Rs Working Party.

### 6.6. Novel therapies & Technologies Working Party (NTWP)

- There were no items for discussion.

### 6.7. Pharmacovigilance Working Party (PhVWP-V)

- The Committee received a verbal report from the PhVWP-V chair on the meeting held on 29- 30 March 2022, and noted the agenda of the meeting.

### 6.8. Quality Working Party (QWP)

- The Committee adopted the work plan for 2022 for the Joint CHMP/CVMP QWP.

### 6.9. Scientific Advice Working Party (SAWP-V)

- The Committee received a verbal report from the SAWP-V chair on the meeting held on 8 April 2022, and noted the agenda of the meeting, together with the final minutes of the SAWP- V meeting held on 14 March 2022.

### 6.10. Safety Working Party (SWP-V)

- The Committee received a verbal report from the SWP-V chair on the meeting held on 31 March – 1 April 2022, and noted the agenda of the meeting, together with the minutes from the meeting held on 18-19 November 2022.

### 6.11. Other working party and scientific group issues

- There were no items for discussion.

## 7. Other scientific matters

*Information on scientific matters or other critical issues cannot be released at the present time as it is deemed to be confidential.*

### 7.1. MRL issues

- There were no items for discussion.

### 7.2. Environmental risk assessment

- There were no items for discussion.

### 7.3. Antimicrobial resistance

### 7.4. Pharmacovigilance

- There were no items for discussion.

### 7.5. Vaccine antigen master file (VAMF) certification

- There were no items for discussion.

### 7.6. Platform technology master file (PTMF) certification

- There were no items for discussion.

### 7.7. Other issues

- The Committee adopted the procedural advice for veterinary vaccine antigen master file (VAMF) certification (EMA/CVMP/127488/2021), together with the overview of comments received during public consultation (EMA/CVMP/45571/2022).

## 8. Co-operation with other EU or International bodies

*Information on certain topics discussed under section 8 cannot be released at the present time as it is deemed to be commercially confidential.*

### 8.1. VICH

- The Committee endorsed the EU comments on the revised VICH GL49 on Validation of Analytical Methods used in Residue Depletion Studies, the EU proposal for annex 3, and supplementary material to Annex 3.

- The Committee endorsed the following revised VICH guidelines, for sign-off by the VICH Steering Committee at step 3 of the VICH process:

  - VICH GL07(R) - Anthelmintics - General requirements
  - VICH GL12(R) - Anthelmintics – Bovines
  - VICH GL13(R) - Anthelmintics – Ovines
  - VICH GL14(R) – Anthelmintics – Caprines
  - VICH GL15(R) - Anthelmintics – Equines
  - VICH GL16(R) - Anthelmintics – Porcines
  - VICH GL19(R) - Anthelmintics – Canines
  - VICH GL20(R) - Anthelmintics – Felines
  - VICH GL21(R) - Anthelmintics – Chickens

### 8.2. Codex Alimentarius

- There were no items for discussion.

### 8.3. Other EU bodies and international organisations

- The committee adopted a draft report on the development of a harmonised approach on exposure assessment methodologies for residues from VMPs, feed additives and pesticides in food of animal origin. A 2-month period of public consultation on this report will be launched after its endorsement by the EFSA Scientific Committee and subsequent review by the European Commission. The Committee noted the minutes from the enlarged expert group's 9th meeting held on 2 March 2022.

***The following document was circulated for information:***

- Status of active VICH guidelines and action plan of CVMP and working parties.

## 9. Procedural and regulatory matters

*Information relating to limited markets classifications, new applications and eligibility requests for Union marketing authorisations and certain regulatory matters cannot be released at the present time as it is deemed to be commercially confidential.*

### 9.1. Limited markets classifications according to Article 4(29) and confirmation of eligibility for authorisation according to Article 23 of Regulation (EU) 2019/6

### 9.2. Eligibility for centralised procedures, appointment of rapporteurs, co-rapporteurs and peer reviewers

### 9.3. Regulatory matters

## 10. Organisational and strategic matters

- The Committee adopted the revision of the procedure for nomination and appointment of co-opted members.

- The Committee was informed of the an EMA Veterinary Info Day to be held on 12-13 May 2022, and noted the draft programme.
- The Committee endorsed agenda of the upcoming CVMP/CMDv Informal meeting under the French Presidency, due to be held in Saint Malo, France on 31 May – 1 June 2022.

# 11. CMDv

- The Committee received a verbal report from the chair of CMDv on the meetings held on 17- 18 February 2022 and 17-18 March 2022, and noted the draft minutes of the meeting held on 17-18 March 2022 as well as the draft agenda of the meeting to be held on 12-13 April 2022.

# 12. Legislation

- The Committee adopted the procedural advice on the accelerated assessment of marketing authorisation applications pursuant to Article 44 (3) of Regulation (EU) No 2019/6 (EMA/CVMP/32995/2006 – Rev. 1).
- The Committee received a verbal update on work progress of the expert group concerning provision of scientific recommendations on implementing act to Regulation (EU) 2019/6 on the list of antimicrobials, which shall not be used in accordance with Articles 112-114 or which may be used in accordance with these articles subject to certain conditions (Article 107(6)).

# 13. Any other business

## 13.1. AOB

- There were no items for discussion.

## 13.2. Meeting highlights

- Upon the completion of the April 2022 CVMP meeting, the draft news highlights was circulated for members to provide comments within 24 hours.

# ANNEX I

**List of participants** including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the April 2022 meeting

| Country | CVMP Member | Outcome restriction following evaluation of e-DoI for the meeting | Topics on current agenda for which restriction applies |
|---|---|---|---|
| **CHAIR** | **David Murphy** | **Full involvement** | |
| AT | Petra Falb | Full involvement | |
| BE | Bruno Urbain | Full involvement | |
| CZ | Leona Nepejchalová | Full involvement | |
| DE | Esther Werner | Full involvement | |
| DK | Niels Christian Kyvsgaard | Full involvement | |
| EE | Toomas Tiirats | Full involvement | |
| EL | Spyridon Farlopoulos | Full involvement | |
| ES | Cristina Muñoz Madero | Full involvement | |
| FI | Minna Leppänen | Full involvement | |
| FR | Sylvie Louet | Full involvement | |
| HR | Frane Božić | Full involvement | |
| HU | Gábor Kulcsár | Full involvement | |
| IE | J. Gabriel Beechinor | Full involvement | |
| IT | Paolo Pasquali | Full involvement | |
| LU | Marc Schmit | Full involvement | |
| LV | Zanda Auce | Full involvement | |
| NL | Jacqueline Poot | Full involvement | |
| PL | Anna Wachnik-Święcicka | Full involvement | |
| PT | João Pedro Duarte da Silva | Full involvement | |
| RO | Gabriela Tuchila | Full involvement | |
| SE | Frida Hasslung Wikström | Full involvement | |
| Co-opted | Keith Baptiste | Full involvement | |
| Co-opted | Rory Breathnach | Full involvement | |
| Co-opted | G. Johan Schefferlie<br>**VICE CHAIR** | Full involvement | |
| Co-opted | Mary O'Grady | Full involvement | |
| Co-opted | Ricardo Carapeto García | Full involvement | |
| NO | Hanne Bergendahl | Full involvement | |

| Country | CVMP Alternate | Outcome restriction following evaluation of e-DoI for the meeting | Topics on current agenda for which restriction applies |
|---|---|---|---|
| AT | Manuela Leitner | Full involvement | |
| BE | Frédéric Klein | Full involvement | |
| DE | Andrea Golombiewski | Full involvement | |
| DK | Merete Blixenkrone-Møller | Full involvement | |

| Country | CVMP Alternate | Outcome restriction following evaluation of e-DoI for the meeting | Topics on current agenda for which restriction applies |
|---|---|---|---|
| FR | Christine Miras | Full involvement | |
| IE | Paul McNeill | Full involvement | |
| NL | Kim Boerkamp | Full involvement | |
| SE | Carina Bergman | Full involvement | |
| SI | Boris Kolar | Full involvement | |
| SK | Eva Chobotová | Full involvement | |
| NO | Annelin Aksdal Bjelland | Full involvement | |

| Country | CVMP Expert* | Outcome restriction following evaluation of the e-DoI for the meeting | Topics on current agenda for which restriction applies |
|---|---|---|---|
| * Experts were only evaluated against the topics they have been invited to talk about. | | | |
| ES | Patricia Vera Luque | Full involvement | |
| ES | María Domínguez Nicolás | Full involvement | |
| ES | Belén Gutiérrez Soriano | Full involvement | |
| ES | Luis Agote Casado | Full involvement | |
| ES | Carlos Ballesteros | Full involvement | |
| ES | Verónica Devesa García | Full involvement | |
| DK | Kathrine Just Andersen | Full involvement | |
| DK | Henrik Duelund Pedersen | Full involvement | |
| DE | Kathrin Schmidt | Full involvement | |
| SE | Malin Öhlund | Full involvement | |
| SE | Hanna Bremer | Full involvement | |
| ES | Irene de la Casa | Full involvement | |
| FR | Gérard Moulin | Full involvement | |
| DE | Nikola Lange | Full involvement | |
| FR | Anne-Marie Jacques | Full involvement | |
| DE | Anke Finnah | Full involvement | |
| DE | Sandra Bertulat | Full involvement | |
| DE | Wiebke Weiher | Full involvement | |
| CZ | Eva Pomezná | Full involvement | |
| CZ | Jakub Stejkora | Full involvement | |
| CZ | Josef Suchý | Full involvement | |
| CZ | Zdenka Mašková | Full involvement | |
| CZ | Dana Halová | Full involvement | |
| IE | Sarah Buckley | Full involvement | |
| IE | Alice Stack | Full involvement | |
| IE | Sarah Hanley | Full involvement | |
| BE | Sandy Vermout | Full involvement | |
| ES | Rocio Fernández Granda | Full involvement | |
| ES | Susana Casado | Full involvement | |

| CVMP working parties and CMDv | Chair |
|---|---|
| NTWP | Jacqueline Poot |
| AWP | Christine Schwarz |
| CMDv | Laetitia Le Letty |
| ERAWP | Ricardo Carapeto García |
| EWP-V | Cristina Muñoz Madero |
| IWP | Esther Werner |
| J3Rs WG | --- |
| PhVWP-V | Els Dewaele |
| SAWP-V | Frida Hasslung Wikström |
| SWP-V | Carina Bergman |

| Observers from Swissmedic | |
|---|---|
| Present | |

| *European Medicines Agency support* |
|---|
| Meeting run with relevant support from the EMA staff |