7 July 2023
EMA/317476/2023 – draft 3
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 11-13 July 2023

Chair: G. J. Schefferlie – Vice-chair: F. Hasslung Wikström

Tuesday 11 July 2023, 09:00 – Thursday 13 July 2023, 13:00 - Room 2C and virtual

Health & Safety Information

In accordance with the Agency's Health and Safety policy, delegates are to be briefed on health and safety and emergency information and procedures prior to the start of this meeting.

Disclaimer

Some of the information contained in this agenda is considered commercially confidential or sensitive and therefore not disclosed. With regard to intended therapeutic indications or procedure scopes listed against products, it must be noted that these may not reflect the full wording proposed by applicants and may also vary during the course of the review. Additional details on some of these procedures will be published in the CVMP meeting highlights once the procedures are finalised and start of referrals will also be available.

Of note, this agenda is a working document primarily designed for CVMP members and the work the Committee undertakes.

Declaration of interests

In accordance with the Agency's policy and procedure on the handling of competing interests, participants in this meeting are 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 will take 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 meeting.

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).

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i. Adoption of the agenda

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 to be held 11-13 July 2023. See July 2023 CVMP minutes (to be published post September 2023 CVMP meeting)

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

iv. Adoption of the minutes of the previous meeting

v. Topics and experts' participation in discussions, rapporteur's meetings and breakout sessions held in advance or in the margins of the present CVMP meeting

Scientific Advice Working Party (virtual)	Mon, 10 July 2023	Written procedure

1. Maximum residue limits

1.1. Opinions

No items

1.2. Oral explanations

No items

1.3. List of outstanding issues

No items

1.4. List of questions

No items

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

No items

1.6. Other issues

No items

2. Marketing authorisations and extensions

2.1. Opinions under Regulation (EU) 2019/6

2.1.1. EMEA/V/C/005992/0000 – rabbits

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

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

No items

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

No items

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

No items

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

2.3.1. EMEA/V/C/005628/0000 – dogs

Action: For adoption

Scientific overview and list of outstanding issues, comments on the product information

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

No items

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

2.4.1. EMEA/V/C/006249/0000 – dogs, cats

Action: For adoption

Scientific overview and list of questions, comments on the product information

2.4.2. EMEA/V/C/006147/0000 – horses

Action: For adoption

CVMP scientific overview and list of questions, comments on the product information

2.4.3. EMEA/V/C/006288/0000 – chickens

Action: For adoption

CVMP scientific overview and list of questions, comments on the product information

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

No items

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

No items

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

No items

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

2.6.1 EMEA/V/C/006118/0000 – chickens

Action: For adoption

Request from the applicant for an extension of the clock-stop

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

No items

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

3.1.1. Tessie – tasipimidine - EMEA/V/C/005427/VRA/0001 – dogs

Variation requiring assessment: to amend the product information with regard to the interactions with other medicinal products

Rapporteur: K. Boerkamp

Action: For adoption

CVMP opinion, CVMP assessment report, product information

3.1.2. Ypozane – osaterone acetate – EMEA/V/C/000112/VRA/0006 – dogs

Variation requiring assessment: to align the product information with version 9.0 of the QRD template

Rapporteur: J. G. Beechinor

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

3.1.3. Palladia – toceranib - EMEA/V/C/000150/VRA/0019 – dogs

Variation requiring assessment: to align the product information with version 9.0 of the QRD template.

Rapporteur: H. Bremer

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

3.1.4. NexGard Combo – esafoxolaner/eprinomectin/praziquantel - EMEA/V/C/005094/VRA/0007/G – cats

Variation requiring assessment: to add two new therapeutic indications and to align the product information with version 9.0 of the QRD template

Rapporteur: A. Golombiewski, Co-Rapporteur: N. C. Kyvsgaard

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

3.1.5. Cimalgex – cimicoxib - EMEA/V/C/000162/VRA/0009 – dogs

Variation requiring assessment: to implement the outcome of the MAH's signal management process

Rapporteur: H. Bremer

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

3.5. Re-examinations of CVMP opinions on variations under Regulation (EC) No 726/2004

No items

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

No items

3.6. Other issues under Commission Regulation (EC) No 1234/2008

No items

4. Referrals and related procedures

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

4.1.1. Veterinary medicinal products containing procaine benzylpenicillin as a single active substance presented as suspensions for injection – EMEA/V/A/145

Scope: dose rate and duration, risk of antimicrobial resistance development

Rapporteur: A. Golombiewski, Co-Rapporteur: K. Baptiste

Action: For discussion

Revised rapporteur's assessment report including co-rapporteur's critique

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

5. Post-authorisation issues for marketing authorisations

Information relating to GMP, pharmacovigilance inspections, supervision and sanctions will not be published as it would undermine the purpose of such inspections.

5.1. Pharmacovigilance under Regulation (EU) 2019/6

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

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)

6.1.1. Concept paper for the development of a reflection paper on the availability and characteristics of diagnostic tests to improve the responsible use of antibiotics in animals

Action: For adoption

6.2. Environmental Risk Assessment Working Party (ERAWP)

6.2.1. Verbal report on ERAWP meeting held on 21–22 June 2023

Action: For information

6.3. Efficacy Working Party (EWP-V)

6.3.1. Concept paper on the revision of the guideline for the demonstration of efficacy of ectoparasiticides

Action: For adoption

6.4. Immunologicals Working Party (IWP)

6.4.1. Guideline on requirements for the quality (production and control), safety and efficacy of allergen products for use in horses, dogs and cats (EMA/CVMP/IWP/170689/2016)

Action: For adoption

6.5. Joint CVMP/CHMP Working Party on the application of the 3Rs (J3RsWP)

No items

6.6. Novel Therapies & Technologies Working Party (NTWP)

6.6.1. Verbal report on NTWP meeting held on 15-16 June 2023

Action: For information

6.7. Pharmacovigilance Working Party (PhVWP-V)

6.7.1. Verbal report on PhVWP-V meetings held on 14 June 2023 and 4-5 July 2023

Action: For information

6.7.2. Focus group meeting for veterinarians or other healthcare professionals on facilitating pharmacovigilance reporting of medicinal products used in poultry to be held on 11 October 2023

Action: For information

6.8. Quality Working Party (QWP)

6.8.1. Election of the veterinary vice-chair of QWP

Action: For decision

6.8.2. Verbal report on QWP meeting held on 26-28 June 2023

Action: For information

6.8.3. Guideline on excipients in the dossier for application for marketing authorisation for veterinary medicinal products

Action: For adoption

6.8.4. Q&A on stability of tablet fractions

Action: For adoption

6.9. Scientific Advice Working Party (SAWP-V)

6.10. Safety Working Party (SWP-V)

6.10.1. Verbal report on SWP-V meeting held on 22-23 June 2023

Action: For information

6.11. Other working party and scientific group issues

6.11.1. Appointment of the CVMP Co-chair of the ESUAvet WG

Action: For decision

6.11.2. Verbal report on the ESUAvet WG meeting held on 19 June 2023 and adoption of the 2023/2024 Workplan for the ESUAvet WG

Action: For adoption

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

No items

7.2. Environmental risk assessment

No items

7.3. Antimicrobial resistance

7.4. Pharmacovigilance

No items

7.5. Vaccine antigen master file (VAMF) certification

Information on this section cannot be released at the present time as it is deemed to be commercially confidential.

No items

7.6. Platform technology master file (PTMF) certification

Information on this section cannot be released at the present time as it is deemed to be commercially confidential.

No items

7.7. Other issues

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

8.1.1. VICH GL49 on validation of analytical methods used in residue depletion studies

Action: For endorsement

VICH GL49 containing proposed updates for circulation to VICH Expert Working Group; annex 3 to GL including proposed amendments and SWP comments; supplementary material, i.e. appendix to annex 3

8.2. Codex Alimentarius

No items

8.3. Other EU bodies and international organisations

8.3.1. World Organisation for Animal Health – call for experts to join WOAH's Specialist Commissions

Action: For information

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

9.1.1. Request for classification

Action: For classification

CVMP recommendation for a veterinary medicinal product for dogs

9.1.2. Request for classification

Action: For classification

CVMP recommendation for a veterinary medicinal product for honeybees

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

9.3. Regulatory matters

10. Organisational and strategic matters

10.1. Verbal report on Veterinary Domain meeting held on 29 June 2023

Action: For information

10.2. CVMP/CMDv Informal meeting under the Spanish Presidency, Málaga, 21 – 22 September 2023

Action: For adoption

Draft agenda of the CVMP informal meeting under the Spanish Presidency

11. CMDv

11.1. Verbal report from CMDv Chair on meetings held on 16-17 May 2023 and 15-16 June 2023

Action: For information

12. Legislation

12.3. Guideline on efficacy and target animal safety data requirements for applications for non-immunological veterinary medicinal products intended for limited markets but not eligible for authorisation under Article 23 of Regulation (EU) 2019/6

Action: For adoption

12.4. Guideline on quality data requirements for applications for veterinary medicinal products other than biologicals intended for limited markets

Action: For adoption

12.5. Guideline on safety and residue data requirements for applications for non-immunological veterinary medicinal products intended for limited markets but not eligible for authorisation under Article 23 of Regulation (EU) 2019/6

Action: For discussion

12.6. Guideline on quality data requirements for applications for biological veterinary medicinal products intended for limited markets

Action: For discussion

12.7. Guideline on safety and efficacy data requirements for applications for immunological veterinary medicinal products intended for limited markets but not eligible for authorisation under Article 23 of Regulation (EU) 2019/6

Action: For discussion

13. Any other business

13.1. AOB

No items

13.2. Meeting highlights

Action: For comments

Meeting highlights

14. Annex

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

Apoquel – oclacitinib maleate – EMEA/V/C/002688/VRA/0026 – dogs

Variation requiring assessment: Quality-related changes

Rapporteur: R. Breathnach

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Felpreva – tigolaner / emodepside / praziquantel - EMEA/V/C/005464/VRA/0003 – cats

Variation requiring assessment: Quality-related changes

Rapporteur: A. Golombiewski

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Kexxtone – monensin – EMEA/V/C/002235/VRA/0017 – cattle

Variation requiring assessment: Quality-related changes

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Zactran – gamithromycin - EMEA/V/C/000129/VRA/0048 – cattle, sheep, pigs

Variation requiring assessment: to align the product information with version 9.0 of the QRD template

Rapporteur: N. C. Kyvsgaard

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Porcilis PCV – Porcine circovirus vaccine (inactivated) - EMEA/V/C/000135/VRA/0015 – pigs

Variation requiring assessment: to align the product information with version 9.0 of the QRD template

Rapporteur: A. Battisti

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Tulaven – tulathromycin - EMEA/V/C/005153/VRA/0007/G – cattle, pigs, sheep

Variation requiring assessment: Quality-related changes

Rapporteur: A. Golombiewski

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Dexdomitor – dexmedetomidine - EMEA/V/C/000070/VRA/0045 – dogs, cats

Variation requiring assessment: to align the product information with version 9.0 of the QRD template

Rapporteur: H. Bremer

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

CircoMax Myco - EMEA/V/C/005184/VRA/0004/G – porcine circovirus vaccine (inactivated) and *Mycoplasma hyopneumoniae* vaccine (inactivated) - pigs

Variation requiring assessment: Quality-related changes

Rapporteur: N. C. Kyvsgaard

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Enteroporc Coli AC – EMEA/V/C/005149/VRA/0005/G – pigs

Variation requiring assessment: Quality-related changes

Rapporteur: N. C. Kyvsgaard

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Zuprevo – tildipirosin - EMEA/V/C/002009/VRA/0017/G – cattle, pigs

Variation requiring assessment: to align the product information with version 9.0 of the QRD template and to implement the outcome of a signal management procedure

Rapporteur: A. Golombiewski

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

RenuTend - tenogenic primed equine allogeneic peripheral blood-derived mesenchymal stem cells - EMEA/V/C/005428/VRA/0001 - horses

Variation requiring assessment: to align the product information with version 9.0 of the QRD template

Rapporteur: F. Hasslung Wikström

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Panacur AquaSol – fenbendazole – EMEA/V/C/002008/VRA/0023 – pigs, chickens

Variation requiring assessment: to align the product information with version 9.0 of the QRD template

Rapporteur: J. Poot

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

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

Innovax-ND-ILT – Marek's disease vaccine, Newcastle disease vaccine and infectious laryngotracheitis vaccine (live recombinant) - EMEA/V/C/005190/VRA/0004 – chickens

Variation requiring assessment: to align the product information with version 9.0 of the QRD template

Rapporteur: J. Poot

Action: For adoption

List of questions, comments on the product information

Suvaxyn CSF Marker – classical swine fever vaccine (live, recombinant) - EMEA/V/C/002757/VRA/0011 – pigs

Variation requiring assessment: to align the product information with version 9.0 of the QRD template

Rapporteur: M. Blixenkrone-Møller

Action: For adoption

List of questions, comments on the product information

Tulinovet – tulathromycin – EMA/V/C/005076/VRA/0006 – dogs

Variation requiring assessment: to align the product information with version 9.0 of the QRD template

Rapporteur: L. Nepejchalová

Action: For adoption

List of questions, comments on the product information

Porcilis PCV M Hyo – Porcine circovirus and porcine enzootic pneumonia vaccine (inactivated) – EMA/V/C/002526/ VRA/0019/G – pigs

Variation requiring assessment: Quality-related changes

Rapporteur: E. Werner

Action: For adoption

List of questions

Fortekor Plus – pimobendan / benazepril hydrochloride - EMEA/V/C/002804/VRA/0023/G – dogs

Variation requiring assessment: Quality-related changes

Rapporteur: N. C. Kyvsgaard

Action: For adoption

List of questions

EMEA/V/C/005819/WS2493 – Evanovo, Gumbohatch - Coccidiosis vaccine live for chickens, avian infectious bursal disease vaccine (live) – chickens

Variation requiring assessment: Quality-related changes

Rapporteur: J. G. Beechinor

Action: For adoption

List of questions

Leucofeligen FeLV/RCP – Feline calicivirosis vaccine, feline viral rhinotracheitis, feline infectious enteritis (feline panleucopenia) vaccine (live), feline leukaemia vaccine (recombinant protein) - EMEA/V/C/000143/VRA/0015 – cats

Variation requiring assessment: to align the product information with version 9.0 of the QRD template

Rapporteur: E. Werner

Action: For adoption

List of questions, comments on the product information

Previcox – firocoxib - EMEA/V/C/000082/VRA/0051 – dogs

Variation requiring assessment: to align the product information with version 9.0 of the QRD template

Rapporteur: J. G. Beechinor

Action: For adoption

List of questions, comments on the product information

4. Referrals and related procedures

4.7. Other issues

5.2. Post-authorisation measures under Regulation (EC) No 2019/6

Neoleish – EMEA/V/C/005538/REC/001 & EMEA/V/C/005538/REC/002

Rapporteur: C. Miras

Action: For endorsement

Rapporteur's assessment report

5. Post-authorisation issues for marketing authorisations

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

6. Working parties

6.5 Joint CVMP/CHMP Working Party on the application of the 3Rs (3RsWP)

7. Other scientific matters

7.7. Other issues

8. Co-operation with other EU or International bodies

8.1. VICH

8.3. Other EU bodies and international organisations

Pain in animals workshop 2023 (PAW2023)

Action: For information

9. Procedural and regulatory matters

9.3. Regulatory matters

Invented names

10. Organisational and strategic matters

10.1. CVMP/CMDv Informal meeting under the Swedish Presidency, Uppsala, 30 – 31 May 2023

Action: For adoption

Minutes of the CVMP/CMDv Informal meeting under the Swedish Presidency

Annex to 11-13 July 2023 CVMP Agenda

CVMP Working Parties dates 2023

CVMP WPs dates	CVMP	AWP	ERAWP	EWP	IWP	NTWP	PhVWP	QWP	SAWP	SWP	J3RsWP
July 2023	11-13						4-5		10		
Sept 2023	5-7	19-20					26-27	18-20	4		19-20
Oct 2023	3-5		11-12	10-11			25		29		
Nov 2023	7-9	21-22					28-29	13-15	6	16-17	14-15
Dec 2023	5-7						19		4		