9 June 2023
EMA/267672/2023 – draft 3
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 13-15 June 2023

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

Tuesday 13 June 2023, 09:00 – Thursday 15 June 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 13-15 June 2023. See June 2023 CVMP minutes (to be published post July 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)	Fri 09 June 2023	10.00-13.00 CEST

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

No items

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/006000/0000 – chickens and embryonated chicken eggs

Action: For adoption

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

2.3.2. EMEA/V/C/006045/0000 – cattle

Action: For decision

Need for oral explanation

Action: For adoption

CVMP 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/006160/0000 – turkeys

Action: For adoption

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

2.4.2. EMEA/V/C/006222/0000 – cattle

Action: For adoption

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

2.4.3. EMEA/V/C/006043/0000 – chickens

Action: For adoption

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

2.4.4. EMEA/V/C/005989/0000 – 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

No items

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

2.6.1. EMEA/V/C/005132/0000 – dogs

Action: For information

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

3.1.1. Nobilis IB 4-91 – avian infectious bronchitis vaccine – EMEA/V/C/000036/VRA/0029/G – chickens

Variation requiring assessment: to include information on onset of immunity and duration of immunity in the product information and to align the product information with version 9.0 of the QRD template

Rapporteur: C. Miras, Co-rapporteur: P. Pasquali

Action: For adoption

CVMP opinion, CVMP assessment report; product information

3.1.2. Easotic – hydrocortisone aceponate / gentamicin sulfate / miconazole nitrate - EMEA/V/C/000140/VRA/0025 – dogs

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

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

3.4.1. Bravecto – fluralaner – EMA/V/C/002526/VRA/0059 – dogs

Rapporteur: K. Boerkamp, Co-Rapporteur: R. Breathnach

Action: For adoption

List of questions and scientific overview, comments on the product information

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

No items

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)

6.2. Environmental Risk Assessment Working Party (ERAWP)

6.3. Efficacy Working Party (EWP-V)

6.4. Immunologicals Working Party (IWP)

6.4.1. Election of the Chair of the IWP

Action: For decision

Nomination(s) received

E. Werner

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

6.6. Novel Therapies & Technologies Working Party (NTWP)

6.7. Pharmacovigilance Working Party (PhVWP-V)

6.7.2. Revised VeDDRA documents

Action: For adoption

Revised combined VeDDRA list of clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products, list of changes to combined VeDDRA list of clinical terms, guidance notes on the use of VeDDRA terminology for reporting suspected adverse reactions in animals and humans, non-current VeDDRA LLT terms and codes

6.8. Quality Working Party (QWP)

6.9. Scientific Advice Working Party (SAWP-V)

6.10. Safety Working Party (SWP-V)

No items

6.11. Other working party and scientific group issues

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

7.3.1. Draft guideline on the reporting of antimicrobial sales and use in animals at the EU level – denominators and indicators

Action: For adoption

Draft guideline on the reporting of antimicrobial sales and use in animals at the EU level – denominators and indicators

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

7.7.2. Report on Quality Innovation Group Listen and Learn Focus Group (LLFG)

Action: For information

Report from the first Quality Innovation Group Listen and Learn Focus Group (LLFG) (link) held on 13 March 2023

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 confidential.

8.1. VICH

8.1.1. Draft VICH *in vitro* dissolution guideline for immediate release solid oral veterinary dosage forms

Action: For endorsement

Draft *in vitro* dissolution guideline for immediate release solid oral veterinary dosage forms including EU comments

8.2. Codex Alimentarius

No items

8.3. Other EU bodies and international organisations

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 horses

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

9.3. Regulatory matters

No items

10. Organisational and strategic matters

11. CMDv

No items

12. Legislation

12.1. Scientific advice under Article 107(6) of Regulation (EU) 2019/6 for the establishment of a list of antimicrobials which shall not be used in accordance with Articles 112, 113 and 114 of the same Regulation or which shall be used in accordance with these articles subject to certain conditions

Action: For adoption

Scientific advice

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. Opinion under Regulation (EU) 2019/6

Eryseng Parvo – porcine parvovirosis vaccine (inactivated) and swine erysipelas vaccine (inactivated) - EMEA/V/C/002762/WS2446/0014 – pigs

Variation requiring assessment: Quality-related changes

Rapporteur: J. G. Beechinor

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Galliprant – grapiprant - EMEA/V/C/004222/VRA/0020 – dogs

Variation requiring assessment: Quality-related changes

Rapporteur: K. Baptiste

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Simparica Trio – sarolaner/ moxidectin/ pyrantel embonate – EMEA/V/C/004846/VRA/0013 – dogs

Variation requiring assessment: Quality-related changes

Rapporteur: R. Breathnach

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Versican Plus DHPPi – Canine distemper, canine adenovirus, canine parvovirus and canine parainfluenza virus vaccine (live) - EMEA/V/C/003679/VRA/0015 – dogs

Variation requiring assessment: to align the product information with version 9.0 of the QRD template. In addition, translation errors and the name of the Marketing Authorisation Holder were corrected

Rapporteur: E. Werner

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Versican Plus DHPPi/L4 – Canine distemper, canine adenovirus, canine parvovirus and canine parainfluenza virus vaccine (live) and canine leptospirosis vaccine (inactivated) - EMEA/V/C/003678/VRA/0017 – dogs

Variation requiring assessment: to align the product information with version 9.0 of the QRD template. In addition, translation errors and the name of the Marketing Authorisation Holder were corrected

Rapporteur: E. Werner

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Equilis Te – tetanus vaccine - EMEA/V/C/000093/VRA/0011/G - horses

Variation requiring assessment: to align the product information with version 9.0 of the QRD template and to change the product information to implement the outcome signal management activities: to add the adverse event 'hypersensitivity reaction' with a very rare frequency in section 3.6 (SPC) and section 7 (Package Leaflet)

Rapporteur: E. Werner

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Equilis Prequenza – equine influenza vaccine (inactivated) - EMEA/V/C/000094/VRA/0016/G - horses

Variation requiring assessment: to align the product information with version 9.0 of the QRD template and to change the product information to implement the outcome of signal management activities to add the adverse event 'hypersensitivity reaction' with a very rare frequency in section 3.6 (SPC) and section 7 (Package Leaflet)

Rapporteur: E. Werner

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Equilis Prequenza Te – equine influenza (inactivated) and tetanus vaccine - EMEA/V/C/000095/VRA/0019/G - horses

Variation requiring assessment: to align the product information with version 9.0 of the QRD template and to change the product information to implement the outcome of signal management activities to add the adverse event 'hypersensitivity reaction' with a very rare frequency in section 3.6 (SPC) and section 7 (Package Leaflet)

Rapporteur: E. Werner

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

SevoFlo – sevoflurane - EMEA/V/C/000072/VRA/0026 – dogs, cats

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

Mhyosphere PCV ID – *Mycoplasma hyopneumoniae* and porcine circovirus vaccine (inactivated, recombinant) - EMEA/V/C/005272/VRA/0003 – pigs

Variation requiring assessment: Quality-related changes

Rapporteur: E. Werner

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Cytopoint – lokivetmab - EMEA/V/C/003939/VRA/0016 – dogs

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

Rapporteur: R. Breathnach

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Prevexxion RN – EMEA/V/C/005058/VRA/0007 – chickens

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

Rapporteur: F. Klein

Action: For adoption

CVMP opinion, product information

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

Stronghold Plus – selamectin/ sarolaner - EMEA/V/C/004194/VRA/0011 – cats

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

Rapporteur: R. Breathnach

Action: For adoption

List of questions, comments on the product information

Felisecto Plus – selamectin/sarolaner - EMEA/V/C/005093/VRA/0007 – cats

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

Rapporteur: R. Breathnach

Action: For adoption

List of questions, comments on the product information

Zenalpha – medetomidine hydrochloride/ vatinoxan hydrochloride - EMEA/V/C/005465/VRA/0005 – dogs

Variation requiring assessment: Quality-related changes

Rapporteur: R. Breathnach

Action: For adoption

List of questions

ProZinc – insulin human - EMEA/V/C/002634/VRA/0027 – cats, dogs

Variation requiring assessment: Quality-related changes

Rapporteur: R. Breathnach

Action: For adoption

List of questions

Equioxx – firocoxib – EMEA/V/C/00142/VRA/0030 – horses

Variation requiring assessment: Quality-related changes

Rapporteur: J. G. Beechinor

Action: For adoption

List of questions

4. Referrals and related procedures

4.7. Other issues

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

9. Procedural and regulatory matters

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

11. CMDv

Report from the Chair of CMDv

Action: To note

Draft agenda of the CMDv meeting to be held on 15-16 June 2023; minutes of the CMDv meeting held on 17 May 2023; minutes of the CMDv-Interested Parties meeting held on 24 March 2023; draft agenda of the CMDv-Interested Parties meeting to be held on 16 June 2023

Annex to 13-15 June 2023 CVMP Agenda

CVMP Working Parties dates 2023

CVMP WPs dates	CVMP	AWP	ERAWP	EWP	IWP	NTWP	PhVWP	QWP	SAWP	SWP	J3RsWP
June 2023	13-15		21-22	7-8			14	26-28	9	22-23	27-28
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		