8 July 2022
EMA/636044/2022
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 12-14 July 2022

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

12 July 2022, 09:00 – 14 July 2022, 13:00 - Room 1C 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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iii. Declaration of contacts between members and companies with regard to points on the agenda.

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Scientific Advice Working Party (virtual)	Friday 8 July 2022	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

2.1. EMEA/V/C/006030/0000 – cats and dogs

Action: For adoption

CVMP opinion

CVMP assessment report, product information

Action: For endorsement

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

No items

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

2.3.1. EMEA/V/C/005860/0000 – chickens

Action: For decision

Need for oral explanation

Action: For adoption

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

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

2.4.1. EMEA/V/C/005993/0000 – dogs

Action: For adoption

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/005902/0000 – dogs

Action: For decision

Request for an extension of clock stop

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

3.1.1. Purevax RCPCh – feline calicivirosis vaccine (inactivated), feline viral rhinotracheitis, feline infectious enteritis (feline panleucopenia), feline chlamydiosis vaccine (live) - EMEA/V/C/000088/VRA/0036 – cats

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

Rapporteur: B. Urbain

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

3.1.2. Purevax RCPCh FeLV – feline calicivirosis vaccine (inactivated), feline viral rhinotracheitis, feline infectious enteritis (feline panleucopenia), feline chlamydiosis vaccine (live), feline leukaemia vaccine (live recombinant) - EMEA/V/C/000085/VRA/0036 – cats

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

Rapporteur: B. Urbain

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

3.3.1. CircoMax – porcine circovirus vaccine (inactivated recombinant) - EMEA/V/C/005185/VRA/0001/G - pigs

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

Rapporteur: N. C. Kyvsgaard

Action: For decision

Need for oral explanation

Action: For adoption

List of outstanding issues, comments on the product information

3.3.2. CircoMax Myco - porcine circovirus vaccine (inactivated, recombinant) and mycoplasma hyopneumonia vaccine (inactivated) - EMEA/V/C/005184/VRA/0002/G - pigs

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

Rapporteur: N. C. Kyvsgaard

Action: For decision

Need for oral explanation

Action: For adoption

List of outstanding issues, comments on the product information

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

3.3.1. EMEA/V/C/xxxx/WS2184

Versican Plus Pi/L4R and Versican Plus DHPPi/L4R – dogs

Variation: Quality-related changes

Rapporteur: E. Werner

Action: For adoption

List of outstanding issues, comments on the product information

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

3.4.1. Equip WNV – West Nile fever vaccine (inactivated) – EMEA/V/C/000137/VRA/0028 – horses

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

Rapporteur: C. Miras

Action: For adoption

List of questions, comments on the product information

3.4.2. Zeleris – florfenicol/meloxicam - EMEA/V/C/004099/VRA/0005/G – cattle

Variation requiring assessment: to add a new therapeutic indication and to align the product information with version 9.0 of the QRD template.

Rapporteur: A. Golombiewski, Co-Rapporteur: F. Božić

Action: For adoption

List of questions, 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 Commission Regulation (EU) 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 N-methyl pyrrolidone as an excipient – EMEA/V/A/146

Scope: User/target animal safety

Rapporteur: A. Golombiewski, Co-Rapporteur: C. Bergman

Action: For decision

Need for list of questions

Action: For discussion

Rapporteurs' assessment report

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

4.7.1. Referrals under Regulation (EU) 2019/6

No items

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

Veterinary medicinal products containing toltrazuril to be administered orally to chickens – EMEA/V/A/144

Scope: Consumer safety

Rapporteur: J. Poot, Co-Rapporteur: S. Louet

Action: For adoption

CVMP opinion, CVMP assessment report

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

5.1.1. BTVPUR – inactivated bluetongue virus multistrain: 1-2 strains out of a set of 4 - EMEA/V/C/002231

Recommendation for changes to the product information as an outcome of signal detection activities

Rapporteur: C. Muñoz Madero

Action: For endorsement

Veterinary signal assessment report

5.1.2. Hiprabovis IBR Marker Live – Infectious bovine rhinotracheitis vaccine (live) - EMEA/V/C/000158

Recommendation for regulatory actions as an outcome of signal detection activities

Rapporteur: B. Urbain

Action: For discussion and decision

Veterinary signal assessment report and P-SMEG expert opinion

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)

No items

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

No items

6.6. Novel Therapies & Technologies Working Party (NTWP)

No items

6.7. Pharmacovigilance Working Party (PhVWP-V)

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

No items

7.4. Pharmacovigilance

7.5. Vaccine antigen master file (VAMF) certification

No items

7.6. Platform technology master file (PTMF) certification

No items

7.7. Other issues

No items

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. EU comments on draft guideline on good manufacturing practice guide for active pharmaceutical ingredients used in veterinary medicinal products

Action: For endorsement

8.1.2. EU comments on draft guideline on pharmaceutical development

Action: For endorsement

8.1.3. EU comments on draft revised guideline on stability testing for medicated premixes

Action: For endorsement

8.2. Codex Alimentarius

No items

8.3. Other EU bodies and international organisations

No items

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

10.1. Veterinary Domain verbal report

Verbal report from the chair of the Veterinary Domain on the meeting held on 7 July 2022

Action: For information

Agenda of the meeting held on 7 July 2022 and minutes of the meeting held on 5 May 2022

10.2 Appointment of a 5th CVMP co-opted member (Toxicology and residues)

Action: For decision

Nominations received for:

- Carina Bergman

- Nikola Lange

10.3. Recommendations from Presidency CVMP and Joint CVMP/CMDv meetings held under the French Presidency of the EU, Saint Malo, France 31 May – 1 June 2022

Presenter: S. Louet

Action: For endorsement

Recommendations from the Presidency CVMP and Joint CVMP/CMDv meetings held under the French Presidency of the EU

11. CMDv

No items

12. Legislation

12.1 Article 34 of Regulation (EU) 2019/6

Action: For adoption

Draft guideline on the application of Article 34 of Regulation (EU) 2019/6

12.2. Article 37(2)(j)

Action: For discussion

Revised draft reflection paper on Article 37(2)(j) of Regulation (EU) 2019/6, overview of comments

12.3. Guideline on quality data requirements for applications for non-biological products intended for limited markets (applicable to applications submitted under either Article 8 or Article 23 of Regulation (EU) 2019/6)

Action: For discussion

Guideline on quality data requirements for applications for non-biological products intended for limited markets (applicable to applications submitted under either Article 8 or Article 23 of Regulation (EU) 2019/6)

12.4. Guideline on safety and residues data requirements for applications for non-IVMPs intended for limited markets but not deemed eligible for authorisation under Article 23 of Regulation (EU) 2019/6

Action: For discussion

Guideline on safety and residues data requirements for applications for non-IVMPs intended for limited markets but not deemed eligible for authorisation under Article 23 of Regulation (EU) 2019/6

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

Action: For discussion

Guideline on efficacy and target animal safety data requirements for applications for non-IVMPs intended for limited markets but not deemed eligible for authorisation under Article 23 of Regulation (EU) 2019/6

12.6. Guideline on quality data requirements for applications for biological products (including IVMPs) intended for limited markets (applicable to applications submitted under either Article 8 or Article 23 of Regulation (EU) 2019/6)

Action: For discussion

Guideline on quality data requirements for applications for biological products (including IVMPs) intended for limited markets (applicable to applications submitted under either Article 8 or Article 23 of Regulation (EU) 2019/6)

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

Action: For discussion

Guideline on safety and efficacy data requirements for applications for IVMPs intended for limited markets but not deemed eligible for authorisation under Article 23 of Regulation (EU) 2019/6

12.8 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))

Action: For information

Verbal feedback

13. Any other business

13.1. AOB

No items

13.2. Meeting highlights

Action: For comments

Meeting highlights

14. Annex

Documents for silent adoption and information

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

Letifend – canine leishmaniasis vaccine – EMEA/V/C/003865/VRA/0028 – dogs

Variation requiring assessment: Quality-related changes

Rapporteur: C. Muñoz Madero

Action: For adoption

CVMP opinion

Nexgard – afoxolaner - EMEA/V/C/002729/VRA/0036 – dogs

Variation requiring assessment: Quality-related changes

Rapporteur: K. Boerkamp

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Prevomax – maropitant - EMEA/V/C/004331/VRA/0012 – cats and dogs

Variation requiring assessment: Quality-related changes

Rapporteur: S. Louet

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

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

ProZinc – insulin human - EMEA/V/C/002634/II/0025 – cats and dogs

Variation: Quality-related changes

Rapporteur: R. Breathnach

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

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

EMEA/V/C/xxxxx/WS2257

Poulvac E. coli – avian colibacillosis vaccine (live) – chicken, turkey

Variation requiring assessment: Quality-related changes

Rapporteur: E. Werner

Action: For adoption

Rapporteur's assessment report including list of questions

Zenalpha – medetomidine hydrochloride/vatinoxan hydrochloride - EMEA/V/C/005465/VRA/0003 – dogs

Variation requiring assessment: Quality-related changes

Rapporteur: R. Breathnach

Action: For adoption

List of questions

Lydaxx – tulathromycin - EMEA/V/C/005199/VRA/0003– Cattle/Pig/Sheep

Variation requiring assessment: Quality-related changes

Rapporteur: S. Louet

Action: For adoption

List of questions

Clynav – salmon pancreas disease vaccine (recombinant DNA plasmid) - EMEA/V/C/002390/VRA/0013 – Atlantic salmon

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

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

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

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

7. Other scientific matters

7.1. MRL issues

Inclusion of graft copolymer PC-PA-PEG in the list of substances considered as not falling within the scope of Regulation (EC) No. 470/2009

Action: For adoption

List of substances considered as not falling within the scope of Regulation (EC) No. 470/2009 - *Rev.53*

7.7. Other issues

8. Co-operation with other EU or International bodies

8.1. VICH

8.3. Other EU bodies and international organisations

Development of a common approach on exposure assessment methodologies for residues from VMPs, feed additives and pesticides residues in food of animal origin

Action: For information

Further to adoption by CVMP, endorsement by EFSA Scientific Committee and review by European Commission, the draft report has been published for consultation (link to news announcement; link to public consultation)

9. Procedural and regulatory matters

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

9.3. Regulatory matters

11. CMDv

Report from the Chair of CMDv

Action: To note

Draft agenda of the CMDv meeting to be held on 14-15 July 2022, minutes of the CMDv meeting held on 16-17 June 2022

Annex to 12-14 July 2022 CVMP Agenda

CVMP Working Parties dates 2022

CVMP WPs dates	CVMP	AWP	ERAWP	EWP	IWP	NTWP	PhVWP	QWP	SAWP	SWP	J3RsWP
July 2022	12-14								8		
Sept 2022	6-8	20-21				15-16		19-21	5		
Oct 2022	4-6		19-20	12-13					3		
Nov 2022	8-10	22-23			23-24	14		21-23	7	17-18	
Dec 2022									5		