1 September 2023
EMA/397508/2023 – draft 3
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 5-7 September 2023

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

Tuesday 5 September 2023, 09:00 – Thursday 7 September 2023, 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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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 05-07.07.2023. See September 2023 CVMP minutes (to be published post October 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 1 Sept 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

1.3.1. Substance – EMEA/V/MRL/003420/EXTN/0004 – chickens

Action: For adoption

Scientific overview and list of outstanding issues

Action: For decision

Need for oral explanation

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/006099/0000 – dogs

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

2.1.2. EMEA/V/C/006000/0000 – chickens

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

2.1.1. EMEA/V/C/0005132/0000 – dogs

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

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

2.2.1. EMEA/V/C/005972/0000 – cats

Action: Oral explanation to be held on 6 September 2023

Rapporteurs' assessment of responses to list of outstanding issues, comments on the product information, presentation from the applicant

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/006146/0000 – chickens

Action: For decision

Need for oral explanation

Action: For adoption

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

2.3. 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/006247/0000 – sea bream

Action: For adoption

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

2.4.2. EMEA/V/C/005345/0000 – dogs

Action: For adoption

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

2.4.3. EMEA/V/C/006230/0000 – cats

Action: For adoption

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

2.4.4. EMEA/V/C/006260/0000 - cattle

Action: For adoption

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

2.4.5. EMEA/V/C/006235/0000 – dogs

Action: For adoption

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

2.4.6. EMEA/V/C/006234/0000 – cattle, pigs, dogs, cats

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

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. 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

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

3.1.2. 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

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

3.1.3. Solensia – frunevetmab – EMEA/V/C/005179/VRA/0006 – cats

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

Rapporteur: R. Breathnach

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. NexGard Spectra – afoxolaner / milbemycin oxime - EMEA/V/C/003842/VRA/0035/G – dogs

Variation requiring assessment: to lower the minimum bodyweight of target animals and 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

3.4.2. Suvaxyn Circo+MH RTU – porcine circovirus and porcine enzootic pneumonia vaccine (inactivated) - EMEA/V/C/003924/VRA/0021 – pigs

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

Rapporteur: B. Urbain

Action: For adoption

List of questions, comments on the product information

3.4.3. Suvaxyn Circo – porcine circovirus vaccine (inactivated recombinant - EMEA/V/C/004242/VRA/0011 – pigs

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

Rapporteur: F. Klein

Action: For adoption

List of questions, comments on the product information

3.4.4. Eryseng – swine erysipelas vaccine (inactivated) - EMEA/V/C/002761/VRA/0010 – pigs

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

3.4.5. Eryseng Parvo – porcine parvovirosis vaccine (inactivated) and swine erysipelas vaccine (inactivated) - EMEA/V/C/002762/VRA/0015 – pigs

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

3.4.6. Nasym – bovine respiratory syncytial virus vaccine (live, attenuated) – EMEA/V/C/004897/VRA/0005 – cattle

Variation requiring assessment: to align the product information with version 9 of the QRD template

Rapporteur: J. G. Beechinor

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 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 adoption

CVMP opinion, CVMP 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.

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

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

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)

No items

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)

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)

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

7.4. 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

8.2. 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

9.1.1. Request for classification

Action: For classification

CVMP recommendation for a veterinary medicinal product for ornamental birds, pet rabbits, rats, mice and reptiles

9.1.2. 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

9.2.1. Summary of eligibility requests and table of offers from rapporteurs

Action: For decision

9.3. Regulatory matters

10. Organisational and strategic matters

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

Presenter: C. Muñoz Madero

Action: For information

Agenda

11. CMDv

No items

12. Legislation

12.1. 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 adoption

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

Action: For adoption

12.3. 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 adoption

13. Any other business

13.2. Meeting highlights

Action: For comments

Meeting highlights

14. Annex

3. Variations to marketing authorisations

3.1 Opinions under Regulation (EU) 2019/6

Felpreva – tigolaner, emodepside, praziquantel – EMEA/V/C/005464/VRA/0005 – cats

Variation requiring assessment: Quality-related changes

Rapporteur: A. Golombiewski

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Felpreva – tigolaner, emodepside, praziquantel – EMEA/V/C/005464/VRA/0006 – cats

Variation requiring assessment: Quality-related changes

Rapporteur: A. Golombiewski

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Stelfonta – tigilanol tiglate - EMEA/V/C/005018/VRA/0008/G – dogs

Variation requiring assessment: Quality-related changes

Rapporteur: K. Boerkamp

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

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

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

EMEA/V/C/WS2508/G – Simparica, MiPet Easecto – sarolaner – dogs

Variation requiring assessment: Quality-related changes

Rapporteur: J. G. Beechinor

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Nobivac DP Plus – EMEA/V/C/005251/VRA/0004 – dogs

Variation requiring assessment: Quality-related changes

Rapporteur: E. Werner

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Porcilis PCV M Hyo - EMEA/V/C/003796/VRA/0019/G – pigs

Variation requiring assessment: Quality-related changes

Rapporteur: E. Werner

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

EMEA/V/C/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

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Clynav – EMEA/V/C/002390/VRA/0016 – atlantic salmon

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, comments on the product information

Action: For endorsement

Rapporteur's assessment report

NexGard Spectra – afoxolaner / milbemycin oxime - EMEA/V/C/003842/VRA/0036 – dogs

Variation requiring assessment: Quality-related changes

Rapporteur: J. G. Beechinor

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report, product information

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

Variation requiring assessment: Quality-related changes

Rapporteur: R. Breathnach

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

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

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

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

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Prevexxion RN+HVT+IBD – Infectious bursal disease and Marek's disease vaccine (live recombinant) - EMEA/V/C/005057/VRA/0008 - chickens

Variation requiring assessment: Quality-related changes

Rapporteur: F. Klein

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report, 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

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

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

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

Variation requiring assessment: Quality-related changes

Rapporteur: J. G. Beechinor

Action: For adoption

List of outstanding issues

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

Felpreva – tigolaner/emodepside/praziquantel – EMEA/V/C/005464/VRA/0004/G – cats

Variation requiring assessment: Quality-related changes

Rapporteur: A. Golombiewski

Action: For endorsement

Rapporteur's assessment report including list of questions

Contacera – meloxicam—EMEA/V/C/002612/VRA/0016 – horses, cattle and pigs

Variation requiring assessment: Quality-related changes

Rapporteur: S. Louet

Action: For endorsement

Rapporteur's assessment report including list of questions

EMEA/V/C/WS2478 - Nobivac LeuFel, Leucogen – feline leukaemia vaccines (inactivated) - cats

Variation requiring assessment: to align the product information with version 9 of the QRD template. In addition minor corrections have been applied to both PIs.

Rapporteur: E. Werner

Action: For adoption

List of questions, comments on the product information for Nobivac Leufel and Leucogen

Startvac – *Staphylococcus aureus* and coagulase-negative staphylococci and *Escherichia coli* J5 vaccine (inactivated) – EMEA/V/C/000130/VRA/0009 – cattle

Variation requiring assessment: to align the product information with version 9 of the QRD template

Rapporteur: E. Werner

Action: For adoption

List of questions, comments on the product information

Vepured – *E. coli* verotoxoid vaccine (inactivated recombinant) – EMEA/V/C/004364/VRA/0006 – pigs

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

Rapporteur: N. C. Kyvsgaard

Action: For adoption

List of questions, comments on the product information

Mhyosphere PCV ID – EMEA/V/C/005272/VRA/0004 – pigs

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

Ubac – *Streptococcus uberis* vaccine (inactivated) - EMEA/V/C/004595/VRA/0007 – cattle

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

Tulinovet – tulathromycin – EMEA/V/C/005076/VRA/0005/G – cattle, pigs, sheep

Variation requiring assessment: Quality-related changes

Rapporteur: L. Nepejchalová

Action: For adoption

List of questions, comments on the product information

Rhiniseng – porcine progressive atrophic rhinitis vaccine (inactivated) - EMEA/V/C/000160/VRA/0013 – 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

Hiprabovis IBR Marker Live – infectious bovine rhinotracheitis vaccine (live) – EMEA/V/C/000158/VRA/0013 – cattle

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

Rapporteur: B. Urbain

Action: For adoption

List of questions, comments on the product information

Nobivac Myxo-RHD Plus – Myxomatosis and rabbit haemorrhagic viral disease vaccine (live recombinant) - EMEA/V/C/004989/VRA/0002 – rabbits

Variation requiring assessment: to align the product information with version 9 of the QRD template

Rapporteur: E. Werner

Action: For adoption

List of questions, comments on the product information

Eravac – rabbit haemorrhagic disease vaccine (inactivated) - EMEA/V/C/004239/VRA/0008 – rabbits

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

Rapporteur: C. Muñoz Madero

Action: For adoption

List of questions, comments on the product information

Evalon – coccidiosis vaccine (live) - EMEA/V/C/004013/VRA/0004 – chickens

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

Evant – coccidiosis vaccine live – EMEA/V/C/004902/VRA/0003 - chickens

Variation requiring assessment: to align the product information with version 9 of the QRD template

Rapporteur: J. G. Beechinor

Action: For adoption

List of questions, comments on the product information

Meloxoral – meloxicam- EMEA/V/C/000151/VRA/0017 – dogs, cats

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

Action: For adoption

List of questions, comments on the product information

Credelio plus – lotilaner/milbemycin oxime - EMEA/V/C/00151/VRA/0006 - dogs

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

4. Referrals and related procedures

4.7. Other issues

5. Post-authorisation issues for marketing authorisations

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

Reconcile – EMEA/V/C/000133/REC/021

Rapporteur: S. Louet

Action: For endorsement

Rapporteur's assessment report

Circomax – EMEA/V/C/005185/REC/001

Rapporteur: N. C. Kyvsgaard

Action: For endorsement

Rapporteur's assessment report

Mometamax Ultra – EMEA/V/C/004987/REC/001

Rapporteur: K. Baptiste

Action: For endorsement

Rapporteur's assessment report

5.3 Inspections controls under Regulation (EU) 2019/6

6. Working parties

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

7. Other scientific matters

7.7. Other issues

8. Co-operation with other EU or International bodies

8.1. VICH

VICH status of guidelines

Action: For information

VICH status of guidelines

8.3. Other EU bodies and international organisations

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

EMA tracking table of the requests for Limited markets classification (Article 4(29)) and confirmation of eligibility (Article 23)

Action: For information

EMA tracking table of the requests for Limited markets classification (Article 4(29)) and confirmation of eligibility (Article 23)

9.3. Regulatory matters

Invented names

10. Organisational Matters

Veterinary Stakeholder Meeting held in Uppsala on 10 May 2023

Action: For information

Minutes of the Veterinary Stakeholder meeting held on 10 May 2023

11. CMDv

Report from the Chair of CMDv

Action: To note

Draft agenda of the CMDv meeting to be held on 7-8 September 2023; minutes of the CMDv meeting held on 13-14 July 2023

Annex to 5-7 September 2023 CVMP Agenda

CVMP Working Parties dates 2023

CVMP WPs dates	CVMP	AWP	ERAWP	EWP	IWP	NTWP	PhVWP	QWP	SAWP	SWP	J3RsWP
Sept 2023	5-7	19-20					26-27	18-20	1		19-20
Oct 2023	3-5		11-12	10-11			25		2		
Nov 2023	7-9	21-22					28-29	13-15	6	16-17	14-15
Dec 2023	5-7						19		1 or 4		
Jan 2024	16-18										