5 November 2019
EMA/CVMP/597241/2019
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 8-10 October 2019 meeting

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

Note on access to documents

Some documents mentioned in the agenda/minutes cannot be released at present within the framework of Regulation (EC) No 1049/2001 on access to documents because they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).

i. Adoption of the Agenda

The Committee adopted the agenda with the addition of a new item under point 12.

ii. CVMP delegates' list of intended participation and identified interests

The attendance list was completed and competing interests were identified for the October 2019 meeting. In accordance with the Agency's policy and procedure on the handling of competing interests, participants in this meeting were asked to declare any interests on the matters for discussion (in particular any changes, omissions or errors to the already declared interests). Discussions, deliberations and voting took place in full respect of the restricted involvement of CVMP members and, where relevant, experts attending the plenary meeting, as announced by the CVMP secretariat at the start of the meeting (see Annex I). All decisions taken at this meeting were made in presence of a quorum of members, i.e. 22 or more members of the 33 members eligible to vote were present in the room. It was noted that 17 members were needed for an absolute majority.

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

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

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iv. Adoption of the minutes of the previous meeting

The minutes of the September 2019 meeting were adopted with no amendments.

v. Topics for rapporteur's meetings, break-out sessions and oral explanations

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

1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion including the EPMAR and the CVMP assessment report, recommending that the current maximum residue limits for **dicyclanil** (EMEA/V/MRL/003131/MODF/0003) in sheep remain unchanged. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of the opinion for publication.

1.2 Oral explanations and lists of outstanding issues

- There were no items for discussion.

1.3 Lists of questions

- There were no items for discussion.

1.4 Re-examination of CVMP opinions

- There were no items for discussion.

1.5 Other issues

- There were no items for discussion.

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

- The Committee adopted by consensus (29 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Neptra** (EMEA/V/C/004735/0000), recommending the granting of a marketing authorisation. Neptra is a new product for the treatment of canine otitis externa caused by susceptible strains of bacteria sensitive to florfenicol (*Staphylococcus pseudintermedius*) and fungi sensitive to terbinafine (*Malassezia pachydermatis*). The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of the opinion for publication.
- The Committee adopted by consensus (30 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Mirataz** (EMEA/V/C/004733/0000), recommending the granting of a marketing authorisation. Mirataz is a new product for bodyweight gain in cats experiencing poor appetite and weight loss resulting from chronic medical conditions. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of the opinion for publication.

2.2 Oral explanations and lists of outstanding issues

- The Committee heard an oral explanation from the applicant concerning an application for a new product (EMEA/V/C/005018/0000) for dogs. The Committee also discussed the draft product information and the rapporteurs' assessment of the responses to the list of outstanding issues. The adoption of the opinion is foreseen for the November 2019 CVMP meeting.

- The Committee heard an oral explanation from the applicant concerning an application for a new product (EMEA/V/C/004991/0000) for horses. The Committee also discussed the draft product information and the rapporteurs' assessment of the responses to the list of outstanding issues. The adoption of the opinion is foreseen for the November 2019 CVMP meeting.

2.3 Lists of questions

- The Committee adopted the scientific overview including the list of questions and agreed comments on the draft product information for a new product (EMEA/V/C/005094/0000) for cats. The Committee noted a peer review report and the comments received from CVMP members.
- The Committee adopted the scientific overview including the list of questions and agreed comments on the draft product information for a new product (EMEA/V/C/005219/0000) for pigs. The Committee noted two peer review reports and the comments received from CVMP members.
- The Committee adopted the scientific overview including the list of questions and agreed comments on the draft product information for a new vaccine (EMEA/V/C/005148/0000) for pigs. The Committee noted two peer review reports and the comments received from CVMP members.

2.4 Re-examination of CVMP opinions

- There were no items for discussion.

2.5 Other issues

- There were no items for discussion.

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a type II variation for **Exzolt** (EMEA/V/C/004344/II/0006), recommending the variation of the marketing authorisation to implement quality changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report for a type II variation (subject to a worksharing procedure) for **Suvaxyn Circo** and **Suvaxyn Circo+MH RTU** (EMEA/V/C/00XXXX/WS1668), recommending the variation of the marketing authorisation to implement quality changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a type IB variation (subject to a worksharing procedure) for **Meloxidolor**, **Novaquin**, **Sedadex** and **Prevomax** (EMEA/V/C/00XXXX/WS1666), recommending the variation of the marketing authorisation to introduce a new pharmacovigilance system. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.

3.2 Oral explanations and lists of outstanding issues

- The Committee adopted a list of outstanding issues for a type II variation for **Panacur AquaSol** (EMEA/V/C/002008/II/0017), concerning quality changes.

3.3 Lists of questions

- There were no items for discussion.

3.4 Re-examination of CVMP opinions

- The Committee agreed to the request from the applicant for a re-examination, in accordance with Article 62(1) of Regulation (EC) No 726/2004, of the CVMP opinion adopted in September 2019 for a type II variation for **Velactis** (EMEA/V/C/003739/II/0004) and appointed a rapporteur and a co-rapporteur. The Committee agreed to the applicant's request for the involvement of an *ad hoc* expert group (AHEG). The adoption of the opinion is foreseen for the December 2019 meeting of the Committee.

3.5 Other issues

- There were no items for discussion.

4. REFERRALS AND RELATED PROCEDURES

4.1 Article 33 of Directive 2001/82/EC

- There were no items for discussion.

4.2 Article 34 of Directive 2001/82/EC

- There were no items for discussion.

4.3 Article 35 of Directive 2001/82/EC

- The Committee considered the notification from Germany for a referral for **Stresnil 40 mg/ml solution for injection for pigs and associated names, and generic products thereof**. The referral concerns the withdrawal period (meat and offal) in pigs. The Committee agreed to start a referral procedure (EMEA/V/A/138) under Article 35 and appointed G. Hahn as rapporteur and L. Nepejchalová as co-rapporteur for the procedure. The Committee adopted a list of questions and the timetable of the procedure.

4.4 Article 78 of Directive 2001/82/EC

- There were no items for discussion.

4.5 Article 13 of Regulation (EC) No 1234/2008

- There were no items for discussion.

4.6 Article 30(3) of Regulation (EC) No 726/2004

- There were no items for discussion.

4.7 Other issues

- There were no items for discussion.

The following documents were circulated for information:

- Referrals tracking table;
- Veterinary medicinal products containing paromomycin to be administered parenterally to pigs – Article 35 referral (EMEA/V/A/129) - Questions and answers for publication;
- Veterinary medicinal products containing tylosin presented as solution for injection to be administered to sheep – (EMEA/V/A/130) - Questions and answers for publication.

5. POST-AUTHORISATION ISSUES FOR COMMUNITY MARKETING AUTHORISATIONS (EXCLUDING VARIATIONS)

5.1 General issues

- There were no items for discussion.

5.2 Post-authorisation measures and annual reassessments

- The Committee adopted the rapporteur's assessment report on the data submitted concerning a condition for **HorStem** (EMEA/V/C/004265/ANX/001).
- The Committee adopted the rapporteur's assessment report on the data submitted concerning a condition for **ZULVAC BTV** (EMEA/V/C/004185/ANX/001).

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 13.09.2019 – 10 October 2019:

Product	Period
Cerenia (EMEA/V/C/000106)	29.09.2018 – 28.09.2019
COXEVAC (EMEA/V/C/000155)	30.09.2018 – 29.09.2019
ERAVAC (EMEA/V/C/004239)	22.09.2018 – 21.09.2019
Palladia (EMEA/V/C/000150)	23.09.2018 – 22.09.2019
Previcox (EMEA/V/C/000082)	13.09.2018 – 12.09.2019
Recocam (EMEA/V/C/002247)	13.09.2018 – 12.09.2019
RHINISENG (EMEA/V/C/000160)	16.09.2018 – 15.09.2019

5.4 Renewals

- The Committee adopted a list of outstanding issues for the renewal of the marketing authorisation for **Coliprotec F4** (EMEA/V/C/003797/R/0005).
- The Committee adopted a list of outstanding issues for the renewal of the marketing authorisation for **ZULVAC SBV** (EMEA/V/C/002781/R/0007).
- The secretariat informed the Committee that the need for MAHs to comply with the frequency convention for adverse events in QRD template v8.1 will now be included in the reminder letter for renewals.

5.5 Pharmacovigilance – PSURs and SARs

- The Committee endorsed the following rapporteurs' assessment reports on PSURs concluding that no changes to the product literature or other regulatory actions were required for:

Product	Period
Easotic (EMEA/V/C/000140)	01.06.2016-31.05.2019
EQUIP WNV (EMEA/V/C/000137)	01.06.2018-31.05.2019
Halocur (EMEA/V/C/000040)	01.05.2016-30.04.2019

MS-H vaccine (EMEA/V/C/000161)	15.06.2016-14.06.2019
Naxcel (EMEA/V/C/000079)	01.06.2016-31.05.2019
Nobivac Myxo RHD (EMEA/V/C/002004)	01.05.2016-30.04.2019
Porcilis PCV M Hyo (EMEA/V/C/003796)	01.06.2018-31.05.2019
Zeleris (EMEA/V/C/004099)	01.12.2018-31.05.2019

- The Committee endorsed the list of products and calendar for signal detection analysis.

5.6 Supervision and sanctions

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

The following document was circulated for information:

- Status report on PSURs for centrally authorised veterinary medicinal products

6. CO-OPERATION WITH OTHER EU OR INTERNATIONAL BODIES

6.1 VICH

- The Committee noted the draft agenda for the VICH Steering Committee meeting scheduled to take place on 18–21 November 2019 in Tokyo, Japan.

6.2 Codex Alimentarius

- There were no items for discussion.

6.3 Other EU bodies and international organisations

The following document was circulated for information:

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

7. WORKING PARTIES AND SCIENTIFIC ADVISORY GROUPS

Information relating to certain topics discussed under section 7 cannot be released at the present time as it is deemed to be commercially confidential.

7.1 Scientific Advice Working Party (SAWP-V)

- The Committee received a verbal report from the SAWP-V chair on the meeting held on 8 October 2019 and noted the agenda of the meeting.

7.2 Quality Working Party (QWP)

- There were no items for discussion.

7.3 Safety Working Party (SWP-V)

- There were no items for discussion.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- There were no items for discussion.

7.5 Efficacy Working Party (EWP-V)

- There were no items for discussion.

7.6 Antimicrobials Working Party (AWP)

- There were no items for discussion.

7.7 Immunologicals Working Party (IWP)

7.8 Pharmacovigilance Working Party (PhVWP-V)

- The Committee received a verbal report from the PhVWP-V chair on the meeting held on 24-25 September 2019 and noted the agenda of the meeting.

7.9 Novel therapy groups and related issues

7.10 Joint CVMP/CHMP Working Group on the application of the 3Rs (J3RsWG)

- There were no items for discussion.

7.11 Other working party and scientific group issues

- There were no items for discussion.

The following documents were circulated for information:

- Minutes of the SAWP-V meeting held on 10 September 2019;
- Minutes of the ADVENT meeting held on 29 January 2019 and draft minutes of the ADVENT meeting held on 12 September 2019.

8. OTHER SCIENTIFIC MATTERS

8.1 MRLs issues

Information on certain MRL related issues cannot be released at the present time as it is deemed to be commercially confidential

- The Committee agreed to include **ethoxylated nonylphenol with an average of 9–10 ethylene oxide moieties** and **ethoxylated octylphenol with an average of 7–9 ethylene oxide moieties** as new entries in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 under the heading of excipients (EMA/CVMP/473132/2019), and adopted a revised list of substances (EMA/CVMP/519714/2009 – Rev.41).

8.2 Environmental risk assessment

- There were no items for discussion.

8.3 Antimicrobial resistance

- The Committee adopted the draft CVMP reflection paper on 'Promoting the authorisation of alternatives to antimicrobials in the EU' (EMA/CVMP/461776/2017) for release for a 6-month period of public consultation. - *see also agenda point 9.*

8.4 Pharmacovigilance

- A petition by concerned citizens regarding the safety of Bravecto was presented to the CVMP, which considered it along with a video and list of questions that were received with the petition. A response to the questions posed will be drafted for endorsement at an upcoming meeting of the Committee.

8.5 Other issues

Information on other critical issues related to centralised procedures cannot be released at the present time as it is deemed to be commercially confidential.

The following document was circulated for information:

- HealthforAnimals - Roadmap to reducing the need for antibiotics (link).

9. AVAILABILITY OF MEDICINES AND MUMS CLASSIFICATION

Information relating to availability of medicines cannot be released at the present time as it is deemed to be commercially confidential.

- The Committee adopted the draft CVMP reflection paper on 'Promoting the authorisation of alternatives to antimicrobials in the EU' (EMA/CVMP/461776/2017) for release for a 6-month period of public consultation – *see also agenda point 8.3.*

10. PROCEDURAL AND REGULATORY MATTERS

10.1 Eligibility and appointment of rapporteurs, co-rapporteurs and peer reviewers

Information relating to notification of intent for new MRL applications and notification of intent and eligibility requests for Community marketing authorisations cannot be released at the present time as it is deemed to be commercially confidential.

10.2 Regulatory matters

Information relating to certain regulatory issues cannot be released at the present time as it is deemed to be commercially confidential.

11. CO-ORDINATION GROUP FOR MUTUAL RECOGNITION AND DECENTRALISED PROCEDURES

- The Committee received a verbal report from the chair of CMDv on the meetings held on 18-19 July and 12-13 September 2019, and noted the draft minutes of the meeting held on 12-13 September 2019 as well as the draft agenda of the meeting held on 10-11 October 2019.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee received a verbal report from the chair of the Strategic Planning Group on the meeting held on 9 October 2019, and noted the agenda of the meeting and the minutes of the meeting held on 11 September 2019.
- The Committee received a verbal report from T.-M. Muhonen on the initial conclusions from the informal presidency CVMP/CMDv meeting held during the Finnish presidency on 25-27 September 2019 in Porvoo, Finland. It was agreed that the recommendations and draft minutes of the meeting will be presented for endorsement at the November 2019 CVMP meeting.
- The Committee noted the announcement on the upcoming informal presidency CVMP/CMDv meeting to be held (during the Croatian presidency) on 4-5 June 2020 in Maisons–Alfort, France.

13. LEGISLATION

- The Committee endorsed the draft report on the criteria for the designation of antimicrobials to be reserved for treatment of certain infections in humans (EMA/CVMP/158366/2019), following the comments received by various CVMP members. The report will be sent to the European Commission by 31 October 2019 and it will be published on the Commission and the EMA websites.
- The Committee received verbal reports from the expert group leaders on work progress concerning the provision of scientific recommendations on delegated and implementing acts to Regulation 2019/6 on veterinary medicinal products.

14. ANY OTHER BUSINESS

- Upon the completion of the October 2019 CVMP meeting, the draft press release was circulated for members to provide any comments within 24 hours.

ANNEX I - List of participants including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the October 2019 meeting

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
CHAIR	**David Murphy**	**Full involvement**	
AT	Petra Falb	Full involvement	
BG	Emil Kozhuharov	Full involvement	
DE	Gesine Hahn	Full involvement	
DK	Niels Christian Kyvsgaard	Full involvement	
EE	Toomas Tiirats	Full involvement	
EL	Angeliki Tsigouri	Full involvement	
ES	Cristina Muñoz Madero	Full involvement	
FI	Tita-Maria Muhonen	Full involvement	**10.2** – One item
FR	Jean-Claude Rouby	Full involvement	
HR	Frane Božić	Full involvement	
HU	Gábor Kulcsár	Full involvement	
IE	J. Gabriel Beechinor	Full involvement	
LT	Snieguolė Trumpickaitė Dzekčiorienė	Full involvement	
LV	Zanda Auce	Full involvement	
NL	Peter Hekman	Full involvement	
PL	Anna Wachnik-Święcicka	Involvement in discussions only and cannot act as rapporteur or peer reviewer for:	**02.1** – Neptra **10.1** – One item
PT	João Pedro Duarte da Silva	Full involvement	
RO	Lollita Taban	Full involvement	
SE	Frida Hasslung Wikström	Full involvement	
SI	Katarina Straus	Full involvement	
SK	Judita Hederová	Full involvement	
UK	Helen Jukes	Full involvement	
Co-opted	Keith Baptiste	Full involvement	
Co-opted	Rory Breathnach	Full involvement	
Co-opted	G. Johan Schefferlie	Full involvement	
Co-opted	Wilhelm Schlumbohm	Full involvement	
Co-opted	Ricardo Carapeto	Full involvement	
NO	Hanne Bergendahl	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
BE	Frédéric Klein	Full involvement	
CZ	Leona Nepejchalová	Full involvement	
DE	Esther Werner	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
FR	Sylvie Louet	Full involvement	
IT	Antonio Battisti	Full involvement	
NL	Jacqueline Poot	Full involvement	
PL	Ewa Augustynowicz	Full involvement	
NO	Tonje Høy	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
* Experts were only evaluated against the topics they have been invited to talk about			
BE	Hilde Nellis	Full involvement	
DE	Andrea Golombiewski	Full involvement	
DE	Anna Schöppner – *remotely*	Full involvement	
DE	Kathrin Dietze – *remotely*	Full involvement	
DK	Anja Silke Christensen – *remotely*	Full involvement	
DK	Bettina Nielsen – *remotely*	Full involvement	
DK	Anne Malene Nissen - *remotely*	Full involvement	
DK	Mette Madsen – *remotely*	Full involvement	
ES	Luis Agote Casado – *remotely*	Full involvement	
ES	Rocío Fernández Granda – *remotely*	Full involvement	
FI	Katariina Kivilahti-Mäntylä – *remotely*	Full involvement	
FI	Ulla Nevalainen – *remotely*	Full involvement	
FI	Tiina Hakonen – *remotely*	Full involvement	
FR	Anne Sagnier – *remotely*	Full involvement	
FR	Benoit Courty – *remotely*	Full involvement	
FR	Florence Pillet – *remotely*	Full involvement	
FR	Gerard Moulin – *remotely*	Full involvement	
FR	Hicham Ait Lbacha – *remotely*	Full involvement	
FR	Mathilde Harvey – *remotely*	Full involvement	
FR	Meg-Anne Moriceau - *remotely*	Full involvement	
IT	Paolo Pasquali – *remotely*	Full involvement	
NO	Annelin Bjelland – *remotely*	Full involvement	
NO	Hans Kristian Østensen – remotely	Full involvement	
NO	Øyvind Holte – *remotely*	Full involvement	
PL	Marcin Glanda – *remotely*	Full involvement	
UK	Claire Stratford – *remotely*	Full involvement	
UK	Jean-Paul Schmidt – *remotely*	Full involvement	
UK	John Mitchell – *remotely*	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
UK	Miguel Escribano	Full involvement	
UK	Paul McNeill – *remotely*	Full involvement	
UK	Sharon Reynolds	Full involvement	

CVMP working parties and CMDv	Chair
ADVENT	Jean-Claude Rouby
AWP	---
CMDv	Laetitia Le Letty
ERAWP	Ricardo Carapeto García
EWP-V	Cristina Muñoz Madero
IWP	Esther Werner
J3Rs WG	---
PhVWP-V	Els Dewaele - *remotely*
QWP	---
SAWP-V	Frida Hasslung Wikström
SWP-V	Stefan Scheid - *remotely*

Observer from the European Commission	
Present	

Observers from Swissmedic	
Remotely	

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