3 February 2020
EMA/CVMP/36283/2020
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 3-5 December 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 no amendments.

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

The attendance list was completed and competing interests were identified for the December 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 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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Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
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iv. Adoption of the minutes of the previous meeting

The minutes of the November 2019 meeting were adopted with a minor amendment.

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

- There were no items for discussion.

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

- There were no items for discussion.

2.2 Oral explanations and lists of outstanding issues

- The Committee adopted the scientific overview including the list of outstanding issues and agreed comments on the draft product information for a marketing authorisation application for a new generic product (EMEA/V/C/005153/0000) for cattle, pigs and sheep. The Committee noted the comments received from CVMP members.

2.3 Lists of questions

- The Committee adopted the scientific overview including a list of questions and agreed comments on the draft product information for a new vaccine (EMEA/V/C/005190/0000) for chickens. 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

- The Committee endorsed the European public assessment report (EPAR) 'scientific discussion' for **Mirataz** (EMEA/V/C/004733/0000) concerning the granting of the initial marketing authorisation.
- The Committee endorsed the European public assessment report (EPAR) 'scientific discussion' for **Neptra** (EMEA/V/C/004735/0000) concerning the granting of the initial marketing authorisation.

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a type II grouped variation for **Onsior** (EMEA/V/C/000127/II/0024/G) recommending the variation of the marketing authorisation to add a new therapeutic indication for the treatment of pain and inflammation associated with soft tissue surgery in dogs (tablets) and to amend the product information due to new clinical data. 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 (26 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a type II variation for **Nobilis IB 4-91** (EMEA/V/C/000036/II/0026) recommending the variation of the marketing authorisation to amend the product information to include the claim for associated non-mixed use with Innovax-ND-IBD. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a type II grouped variation for **Eravac** (EMEA/C/V/004239/II/0005/G) recommending the variation of the marketing authorisation to extend the duration of immunity from 9 to 12 months. 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 (26 members present of those eligible to vote) the CVMP opinion and the product information, and endorsed the rapporteur's assessment report for a type II variation for **Zulvac SBV** (EMEA/V/C/002781/II/0006) recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a type II variation for **Innovax ILT** (EMEA/V/C/003869/II/0004) recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (26 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 **Simparica** and **MiPet Easecto** (EMEA/V/C/xxxxxx/WS1709) recommending the variation of the marketing authorisations to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (26 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 **Bravecto** and **Bravecto Plus** (EMEA/V/C/xxxxxx/WS1721) recommending the variation of the marketing authorisations to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion and the product information, and endorsed the rapporteur's assessment report for a type

II grouped variation for **Apoquel** (EMEA/V/C/002688/II/0017/G) recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.

- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion and the product information, and endorsed the rapporteur's assessment report for a type II grouped variation for **Circovac** (EMEA/V/C/000114/II/0016/G) recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a type II grouped variation for **Zactran** (EMEA/V/C/000129/II/0042/G) recommending the variation of the marketing authorisation to implement quality-related changes. 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 and agreed comments on the product information for a type II variation for **CLYNAV** (EMEA/V/C/002390/II/0010) to extend the duration of immunity.

3.3 Lists of questions

- The Committee adopted a list of questions for a type II variation (subject to a worksharing procedure) for **Eryseng Parvo**, **Eryseng** and **Rhiniseng** (EMEA/V/C/xxxxx/WS1686) concerning quality-related changes.

3.4 Re-examination of CVMP opinions

- The Committee discussed the report from the ad-hoc expert group meeting held on 19 November 2019 and the rapporteur's assessment report for the re-examination of the negative CVMP opinion for a Type II variation, which was adopted in September 2019, for **Velactis** (EMEA/V/C/003739/II/0004) to demonstrate the safe use of the product, and also heard an oral explanation from the applicant, Ceva Santé Animale. The Committee adopted by consensus (28 members present of those eligible to vote) the final CVMP opinion and the final CVMP assessment report, recommending the refusal of a variation to the terms of the marketing authorisation for Velactis. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of the opinion for publication.

3.5 Other issues

4. REFERRALS AND RELATED PROCEDURES

4.1 Article 33 of Directive 2001/82/EC

- The Committee adopted by consensus (28 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for the referral procedure for **Ketabel 100 mg/ml solution for injection and associated names** (EMEA/V/A/133), concluding that the objections raised by Germany during the decentralised procedure should not prevent the granting of a marketing authorisation. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.

4.2 Article 34 of Directive 2001/82/EC

- The Committee discussed the rapporteur's assessment report including the co-rapporteur's critique for the referral procedure for **Adjusol tmp sulfa liquide and its associated names**

(EMEA/V/A/134) and adopted a list of outstanding issues and the revised timetable for the procedure. The Committee noted two peer review reports and the comments made by CVMP members**.**

4.3 Article 35 of Directive 2001/82/EC

- The Committee adopted by majority (24 members in favour out of the 28 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for the referral procedure for **veterinary medicinal products containing tylosin base (as a single active substance) presented as solutions for injection for intramuscular use in pigs** (EMEA/V/A/131), recommending that the maximum injection volume per site and the withdrawal periods for pig meat and offal should be amended to provide assurance for consumer safety. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. M. Escribano, G. Hahn, N. C. Kyvsgaard and L. Nepejchalová signed a divergent position not supporting the aforementioned recommendation.

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

- The Committee adopted a list of questions and the timetable for a procedure under Article 45 of Regulation (EC) No 726/2004 (EXT/602276/2019) concerning **Suvaxyn PRRS MLV** and noted the marketing authorisation holder's letter to the CVMP Chair. The Committee also endorsed a public statement with recommendations on the use of live attenuated PRRSV vaccines, published in the December 2019 CVMP press release.

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 recommendation for **Ingelvac CircoFLEX** (EMEA/V/C/000126/REC/016).
- The Committee adopted the rapporteur's assessment report on the data submitted concerning a recommendation for **ProtecFlu** (EMEA/V/C/000073/REC/039).
- The Committee adopted the rapporteur's assessment report on the data submitted concerning a recommendation for **ProtecFlu-Te** (EMEA/V/C/000074/REC/043).

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 8 November 2019 and 5 December 2019 for:

Product	Period
Bovilis Blue-8 (EMEA/V/C/004776)	21.11.2018 – 20.11.2019
Broadline (EMEA/V/C/002700)	04.12.2018 – 03.12.2019
Draxxin (EMEA/V/C/000077)	11.11.2018 – 10.11.2019
Easotic (EMEA/V/C/000140)	20.11.2018 – 19.11.2019
Equip WNV (EMEA/V/C/000137)	21.11.2018 – 20.11.2019
Masivet (EMEA/V/C/000128)	17.11.2018 – 16.11.2019
Meloxoral (EMEA/V/C/000151)	19.11.2018 – 18.11.2019
Oxyglobin (EMEA/V/C/000045)	29.11.2018 – 28.11.2019
Porcilis AR-T DF (EMEA/V/C/000055)	16.11.2018 – 15.11.2019
Quadrisol (EMEA/V/C/000032)	04.12.2018 – 03.12.2019
Rabitec (EMEA/V/C/004387)	01.12.2018 – 30.11.2019
Stronghold (EMEA/V/C/000050)	25.11.2018 – 24.11.2019
Vectra 3D (EMEA/V/C/002555)	04.12.2018 – 03.12.2019

5.4 Renewals

- There were no items for discussion.

5.5 Pharmacovigilance – PSURs and SARs

- The Committee endorsed the rapporteur's assessment report including a list of questions for the PSUR for the period 01.05.2016 – 30.04.2019 for **Advocate** (EMEA/V/C/000076).
- The Committee endorsed the following rapporteur's assessment reports on PSURs concluding that no changes to the product literature or other regulatory actions were required for:

Product	Period
Coliprotec F4/F18 (EMEA/V/C/004225)	01.02.2019-31.07.2019
NexGard Spectra (EMEA/V/C/003842)	01.08.1208-31.07.2019
Rheumocam (EMEA/V/C/000121)	01.08.2016-31.07.2019
UBAC (EMEA/V/C/004595)	01.02.2019-31.07.2019
Versican Plus DHPPi (EMEA/V/C/003679)	01.08.2018-31.07.2019
Versican Plus DHPPi L4R (EMEA/V/C/002759)	01.06.2018-31.05.2019
Versican Plus L4 (EMEA/V/C/003680)	01.08.2018-31.07.2019
Versican Plus Pi (EMEA/V/C/003681)	01.08.2018-31.07.2019
Versican Plus Pi L4 (EMEA/V/C/003683)	01.08.2018-31.07.2019
Versican Plus Pi L4R (EMEA/V/C/003682)	01.08.2018-31.07.2019

- 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 adopted the VICH guideline 58 on stability testing of new veterinary drug substances and medicinal products in climatic zones III and IV for implementation in the EU at step 7 of the VICH process, following the sign-off by the VICH Steering Committee.
- The Committee received a verbal report on the 37th VICH Steering Committee and Outreach Forum meetings held from 18 – 21 November 2019 held 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 3 December 2019 and noted the agenda of the meeting.

7.2 Quality Working Party (QWP)

- The Committee received a verbal report from the QWP-V chair on the meetings held on 26-27 September 2019 and on 21-22 November 2019, and noted the agenda and the minutes of the September 2019 meeting, and the agenda of the November 2019 meeting.

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)

7.7 Immunologicals Working Party (IWP)

- There were no items for discussion.

7.8 Pharmacovigilance Working Party (PhVWP-V)

- The Committee received a verbal report from the PhVWP-V chair on the meeting held on 19-20 November 2019 and noted the agenda of the meeting.

7.9 Novel therapy groups and related issues

- There were no items for discussion.

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

The following document was circulated for information:

- Minutes of the SAWP-V meeting held on 5 November 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

8.2 Environmental risk assessment

8.3 Antimicrobial resistance

- The Committee adopted the scientific advice on the AMEG categorisation of antibiotics in the European Union (EMA/CVMP/CHMP/682198/2017) and the overview of comments (EMA/CVMP/CHMP/238275/2019) received following the close of the public consultation. K. Baptiste, N. Kvysgaard, M. Nemes-Terenyi and P. Pasquali expressed a divergent position not supporting the aforementioned scientific advice.

8.4 Pharmacovigilance

Information relating to certain topics discussed under section 8.4 cannot be released at the present time as it is deemed to be commercially confidential.

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.

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.

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.

- The Committee agreed to the transfer of all (co-)rapporteurships and peer reviewer responsibilities from W. Schlumbohm to G. Hahn.

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 noted the draft minutes of the November 2019 meeting and the draft agenda of the meeting held on 5-6 December 2019.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee adopted the CVMP work plan for 2020 (EMA/CVMP/505315/2019).
- The Committee noted the agenda (EMA/635043/2019) on the post-public consultation veterinary stakeholders' workshop relating to 'EMA Regulatory Science to 2025: strategic reflection' to be held on 5-6 December 2019 at the EMA, Amsterdam.

13. LEGISLATION

- The Committee endorsed the open call for data on the use of antimicrobials in animals outside the terms of their marketing authorisation under certain conditions, often referred to as 'cascade use'. This call supports the work of the expert group on the list of antimicrobials reserved for the treatment of certain infections in humans (Article 37(5) of Regulation (EU) 2019/6) (EMA/536558/2019).
- The Committee received verbal reports from the expert group leaders on work progress concerning provision of scientific recommendations to the European Commission on delegated and implementing acts to Regulation 2019/6 on veterinary medicinal products.

14. ANY OTHER BUSINESS

- Upon the completion of the December 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 December 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 Kvysgaard	Full involvement	
EE	Toomas Tiirats	Full involvement	
EL	Angeliki Tsigouri	Full involvement	
ES	Cristina Muñoz Madero	Full involvement	
FI	Tita-Maria Muhonen	Full involvement	
FR	Jean-Claude Rouby	Full involvement	
HR	Frane Božić	Full involvement	
IE	J. Gabriel Beechinor	Full involvement	
IT	Paolo Pasquali	Full involvement	
LT	Snieguolė Trumpickaitė Dzekčiorienė	Full involvement	
LU	Marc Schmit	Full involvement	
LV	Zanda Auce	Full involvement	
MT	Stephen Spiteri	Full involvement	
NL	Peter Hekman	Full involvement	
PL	Anna Wachnik-Święcicka	Involvement only in discussions i.e. no part in final deliberations and voting, and cannot act as rapporteur, other leading /co-ordinating role or formally appointed peer reviewer for:	**3.5** One item **5.5** One item
PT	João Pedro Duarte da Silva	Full involvement	
RO	Lollita Taban	Full involvement	
SE	Frida Hasslung Wikström	Full involvement	
UK	Miguel Escribano	Full involvement	
Co-opted	Keith Baptiste	Full involvement	
Co-opted	Rory Breathnach	Full involvement	
Co-opted	Mary O'Grady	Full involvement	
Co-opted	Ricardo Carapeto GArcía	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	
DK	Merete Blixenkrone-Møller	Full involvement	
FR	Sylvie Louet	Full involvement	
HU	Melinda Nemes-Terenyi	Full involvement	
NL	Jacqueline Poot	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	Els Dewaele *(remotely)*		
BE	Kristine Piccard *(remotely)*		
DE	Andrea Golombiewski		
DE	Anke Finnah		
DE	Christine Schwarz		
DE	Sarah Adler-Flindt *(remotely)*		
DE	Stefan Scheid *(remotely)*		
ES	Hector Duran *(remotely)*		
ES	Jesus Alberto Sanchez Rodriguez *(remotely)*		
ES	Luis Agote Casado (remotely)		
ES	Maria Amparo Haro *(remotely)*		
ES	Maria Dominguez Nicolas *(remotely)*		
FR	Damien Bouchard *(remotely)*		
FR	Florence Pillet *(remotely)*		
FR	Gerard Moulin *(remotely)*		
FR	Meg-Anne Moriceau *(remotely)*		
IT	Antonio Battisti *(remotely)*		
NL	Anita Bottger *(remotely)*		
NL	Engeline van Duijkeren *(remotely)*		
NO	Kari Grave *(remotely)*		
UK	Gillian Diesel *(remotely)*		

CVMP working parties and CMDv	Chair
ADVENT	Jean-Claude Rouby
AWP	Christine Schwarz
CMDv	---
ERAWP	Ricardo Carapeto García
EWP-V	Cristina Muñoz Madero
IWP	Esther Werner
J3Rs WG	---
PhVWP-V	Els Dewaele - *remotely*
QWP	Mary O'Grady *(Vet vice chair)*
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