18 February 2020
EMA/CVMP/86082/2020
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 21-23 January 2020 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 two new items under points 1.5 and 8.5.

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

The attendance list was completed and competing interests were identified for the January 2020 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 the 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.

iv. Adoption of the minutes of the previous meeting

The minutes of the December 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

- There were no items for discussion.

1.2 Oral explanations and lists of outstanding issues

- The Committee heard an oral explanation from the applicant and discussed the rapporteur's assessment of the responses to the list of outstanding issues and the rapporteur's EPMAR for the establishment of MRLs in porcine for a substance (EMEA/V/MRL/005009/FULL/0001). The adoption of the opinion is foreseen for the February 2020 meeting of the Committee.

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

- The Committee agreed to the request from the applicant for an extension to the clock-stop for the establishment of MRLs in horses for a substance (EMEA/V/MRL/005302/FULL/0001).
- The Committee discussed the need to convene an ad hoc expert group for the establishment of MRLs in *Salmonidae* for a substance (EMEA/V/MRL/004481/FULL/0002).

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 vaccine (EMEA/V/C/005057/0000) for chickens. The Committee noted the comments received from CVMP members.
- 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 vaccine (EMEA/V/C/005058/0000) for chickens. The Committee noted the comments received from CVMP members.
- 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/005199/0000) in cattle, pigs and sheep. The Committee noted a peer review report and 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/005184/0000) for pigs. The Committee noted a peer review report and the comments received from CVMP members.
- 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/005301/0000) for rabbits. The Committee noted three peer review reports and the comments received from CVMP members.
- The Committee adopted the scientific overview including a list of questions and agreed comments on the draft product information for a new product (EMEA/V/C/005180/0000) for dogs. The Committee noted four 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 **Stelfonta** (EMEA/V/C/005018/0000) concerning the granting of the initial marketing authorisation.
- The Committee endorsed the European public assessment report (EPAR) 'scientific discussion' for **Aservo EquiHaler** (EMEA/V/C/004991/0000) concerning the granting of the initial marketing authorisation.

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- 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 a type II variation for **Innovax-ND-IBD** (EMEA/V/C/004422/II/0003) recommending the variation of the marketing authorisation to add a new indication for mixed use with Nobilis Rismavac for the subcutaneous route of administration. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- 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 a type II variation for **Rabitec** (EMEA/V/C/004387/II/0002) recommending the variation of the marketing authorisation to extend the duration of immunity from 6 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 (30 members present of those eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a type II variation for **Bravecto** (EMEA/V/C/002526/II/0039) 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 (29 members present of those eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a type II grouped variation for **Clevor** (EMEA/V/C/004417/II/0005/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

3.3 Lists of questions

- The Committee adopted a list of questions for a type II grouped variation for **UpCard** (EMEA/V/C/003836/II/0005/G) concerning quality-related changes.

3.4 Re-examination of CVMP opinions

- There were no items for discussion.

3.5 Other issues

- The Committee was informed of the formal notification from the marketing authorisation holder, Boehringer Ingelheim, of their decision to withdraw the application for a type II variation for **Afoxolaner Merial** (EMEA/V/C/005126/II/0003) to change the legal status.

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

- The Committee agreed to the request from Virbac for an extension of the clock-stop for the referral procedure for **Adjusol tmp sulfa liquide and its associated names** (EMEA/V/A/134) and adopted a revised timetable for the procedure.

4.3 Article 35 of Directive 2001/82/EC

- The Committee discussed the rapporteur's assessment report and the co-rapporteur's assessment report for the referral procedure for **Dinolytic 12.5 mg/ml and 5 mg/ml solutions for injection and associated names, and generic products thereof** (EMEA/V/A/136). The Committee adopted a list of outstanding issues for the marketing authorisation holders to address in writing, and the revised timetable for the procedure. The Committee noted two peer review reports and the comments made by CVMP members**.**

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 document was circulated for information:

- Referrals tracking table.

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

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 06.12.2019 and 23.01.2020:

Product	Period
Acticam (EMEA/V/C/000138)	09/12/2018 – 08/12/2019
Activyl Tick Plus (EMEA/V/C/002234)	09/01/2019 – 08/01/2020
Bovela (EMEA/V/C/003703)	22/12/2018 – 21/12/2019
BTVPUR (EMEA/V/C/002231)	17/12/2018 – 16/12/2019
Cepedex (EMEA/V/C/004376)	13/12/2018 – 12/12/2019
Coliprotec F4/F18 (EMEA/V/C/004225)	09/01/2019 – 08/01/2020
Contacera (EMEA/V/C/002612)	06/12/2018 – 05/12/2019
Cortavance (EMEA/V/C/000110)	09/01/2019 – 08/01/2020
Galliprant (EMEA/V/C/004222)	09/01/2019 – 08/01/2020
Halagon (EMEA/V/C/004201)	13/12/2018 – 12/12/2019
Imrestor (EMEA/V/C/002763)	09/12/2018 – 08/12/2019
Inflacam (EMEA/V/C/002497)	09/12/2018 – 08/12/2019
Isemid (EMEA/V/C/004345)	09/01/2019 – 08/01/2020
Meloxidyl (EMEA/V/C/000115)	15/01/2019 – 14/01/2020
Metacam (EMEA/V/C/000033)	07/01/2019 – 06/01/2020
NexGard Spectra (EMEA/V/C/003842)	15/01/2019 – 14/01/2020
Onsior (EMEA/V/C/000127)	16/12/2018 – 15/12/2019
Panacur AquaSol (EMEA/V/C/002008)	09/12/2018 – 08/12/2019
Porcilis PCV (EMEA/V/C/000135)	12/01/2019 – 11/01/2020
Prac-tic (EMEA/V/C/000103)	18/12/2018 – 17/12/2019
Respiporc FLU3 (EMEA/V/C/000153)	14/01/2019 – 13/01/2020
Rheumocam (EMEA/V/C/000121)	10/01/2019 – 09/01/2020

Product	Period
SevoFlo (EMEA/V/C/000072)	11/12/2018 – 10/12/2019
Syvazul BTV (EMEA/V/C/004611)	09/01/2019 – 08/01/2020
Velactis (EMEA/V/C/003739)	09/12/2018 – 08/12/2019
Ypozane (EMEA/V/C/000112)	11/01/2019 – 10/01/2020
Zulvac 8 Bovis (EMEA/V/C/000145)	15/01/2019 – 14/01/2020
Zulvac 8 Ovis (EMEA/V/C/000147)	15/01/2019 – 14/01/2020

5.4 Renewals

- The Committee adopted a list of outstanding issues for the renewal of the marketing authorisation for **Sileo** (EMEA/V/C/003764/R/0014).
- The Committee adopted a list of outstanding issues for the renewal of the marketing authorisation for **Innovax ILT** (EMEA/V/C/003869/R/0005).
- The Committee adopted a list of outstanding issues for the renewal of the marketing authorisation for **Canigen L4** (EMEA/V/C/004079/R/0007).

5.5 Pharmacovigilance – PSURs and SARs

- The Committee adopted the CVMP assessment report of the PSUR for the period 01.05.2016-30.04.2019 for **Advocate** (EMEA/V/C/000076) with a recommendation to amend the product information.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.02.2019-31.07.2019 for **Credelio** (EMEA/V/C/004247) with a recommendation to amend the product information.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.05.2016-30.04.2019 for **Metacam** (EMEA/V/C/000033) and **Novem** (EMEA/V/C/000086) with a recommendation to amend the product information.
- 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
Activyl (EMEA/V/C/000163)	01.09.2016-31.08.2019
Clomicalm (EMEA/V/C/000039)	01.08.2016-31.07.2019
Evant (EMEA/V/C/004902)	05.02.2019-31.08.2019
Loxicom (EMEA/V/C/000141)	11.08.2016-10.08.2019
Neocolipor (EMEA/V/C/000035)	01.09.2016-31.08.2019
Oxybee (EMEA/V/C/004296)	01.03.2019-31.08.2019
Semintra (EMEA/V/C/002436)	01.03.2019-31.08.2019
Startvac (EMEA/V/C/000130)	01.09.2016-31.08.2019

Suvaxyn Circo (EMEA/V/C/004242)	01.03.2019-31.08.2019
Syvazul BTV (EMEA/V/C/004611)	09.01.2019-31.07.2019
Vepured (EMEA/V/C/004364)	01.03.2019-31.08.2019
Versican Plus DHPPI L4 (EMEA/V/C/003678)	01.06.2018-31.05.2019
Zulvac SBV (EMEA/V/C/002781)	01.09.2018-31.08.2019

- 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 indicated its support for a concept paper proposing that VICH should adopt ICH Q7: Good manufacturing practice for active pharmaceutical ingredients but highlighted that there are aspects of the ICH guideline that may not apply for active pharmaceutical ingredients for use in veterinary medicinal products and that, consequently, a stand-alone VICH guideline based on the ICH guideline will probably be necessary.

6.2 Codex Alimentarius

- The Committee noted the mission report on the Codex Alimentarius Task Force on Antimicrobial Resistance 7 session, held on 9-13 December 2019 in PyeongChang, South Korea.

6.3 Other EU bodies and international organisations

- The Committee endorsed the call to appoint an expert on poultry diseases in support of the work for the OIE Antimicrobial Working Group – *see also point 8.3*
- The Committee noted the summary and conclusions of the 88th meeting of the Joint FAO/WHO Expert Committee on Food Additives and agreed that members of the SWP-V should be asked to draft EU comments on the JECFA recommendations.

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 21 January 2020 and noted the agenda of the meeting.

7.2 Quality Working Party (QWP)

- The Committee adopted a reflection paper on risk management requirements for elemental impurities in veterinary medicinal products (EMA/CVMP/QWP/153641/2018) and the overview of comments received (EMA/CVMP/QWP/434956/2019). The Committee also adopted a revised version of the document addressing the implementation of risk assessment requirements to control elemental impurities in veterinary medicinal products (EMA/CVMP/QWP/631010/2017-Rev.2).

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)

- The Committee endorsed a corrigendum of the guideline on the conduct of bioequivalence studies for veterinary medicinal products (EMA/CVMP/EWP/16/2000-Rev.3-corr), which was amended to correct a typographical error (p.17, line 1; adding "absence of" before the word "bioequivalence").

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)

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

- There were no items for discussion.

The following documents were circulated for information:

- Minutes of the SAWP-V meeting held on 3 December 2019;
- Minutes of the PhVWP-V meeting held on 19-20 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

- The Committee agreed to include **steel shot** as a new entry in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 under the heading of substances that act by purely physical mechanisms (EMA/CVMP/519714/2009-Rev.42).

8.2 Environmental risk assessment

- The Committee adopted questions and answers in support of the guideline on the assessment of persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances in veterinary medicinal products (EMA/CVMP/ERA/52740/2012).

8.3 Antimicrobial resistance

- The Committee endorsed the call to appoint an expert on poultry diseases in support of the work for the OIE Antimicrobial Working Group – *see also point 6.3*

8.4 Pharmacovigilance

- There were no items for discussion.

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 M. Turk to B. Kolar.
- The Committee agreed to the transfer of all (co-)rapporteurships and peer reviewer responsibilities from J. Bureš to L. Nepejchalová.

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 CMDv chair on the meetings held on 10-11 October, 7-8 November and 5-6 December 2019, and noted the draft minutes of the December 2019 meeting as well as the draft agenda of the meeting held on 23-24 January 2020.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee received a verbal report on the next steps of the EMA 'Regulatory science to 2025' veterinary stakeholders' workshop held on 5-6 December 2019.

13. LEGISLATION

- 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 January 2020 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 January 2020 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	
BE	Bruno Urbain	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	Involvement only in discussions in relation to any medicinal product from **Orion oyj**:	**3.1** Clevor **5.4** Sileo **10.1** One item **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	
IT	Paolo Pasquali	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:	**5.5** Advocate **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	
UK	Miguel Escribano	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 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	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
CZ	Leona Nepejchalová	Full involvement	
DE	Esther Werner	Full involvement	
DK	Merete Blixenkrone-Møller	Full involvement	
FR	Sylvie Louet	Full involvement	
NL	Jacqueline Poot	Full involvement	
SK	Eva Chobotová	Full involvement	
UK	Rory Cooney	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.			
AT	Manuela Leitner - *remotely*	Full involvement	
BE	Koen Brusselmans		
CZ	Dana Studená - *remotely*		
CZ	Dana Halová - *remotely*		
CZ	Eva Pomezná - *remotely*		
CZ	Vilma Dosedlová - *remotely*		
DE	Andrea Golombiewski		
DE	Anke Finnah		
DE	Babett Kobe - *remotely*		
DE	Dagmar Sommer – *remotely*		
DE	Kathrin Schmidt – *remotely*		
DE	Nikola Lange – *remotely*		
DE	Rolf Beckmann – *remotely*		
DE	Sarah Adler-Flindt – *remotely*		
DE	Thilo Nölke - *remotely*		
DE	Uta Herbst		
DK	Anja Silke Christensen – *remotely*		
DK	Nanna Aaby Kruse		
DK	Susanne Havn Aamand		
ES	Alberto de Prado – *remotely*		
ES	Gema Cortés – *remotely*		
ES	Maria Jose Ferrer – *remotely*		
ES	Rosario Bullido – *remotely*		
ES	Teresa Gomez – *remotely*		
FI	Pertti Pellinen – *remotely*		
FR	Gerard Moulin – *remotely*		
FR	Martine Redureau – *remotely*		

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
FR	Mathilde Harvey		
NL	Anita Bottger – *remotely*		
NO	Kari Grave – *remotely*		
SE	Carina Bergman – *remotely*		
SE	Fabienne Gaugazová – *remotely*		
SE	Hanna Bremer		
SE	Jennie Sandberg - *remotely*		
SE	Malin Öhlund – *remotely*		
SE	Mats Jernberg – *remotely*		
SE	Stefan Nilsson – *remotely*		
SE	Wilmar Igl – *remotely*		

CVMP working parties and CMDv	Chair
ADVENT	Jean-Claude Rouby
AWP	Christine Schwarz - *remotely*
CMDv	Laetitia Le Letty
ERAWP	Ricardo Carapeto García
EWP-V	---
IWP	---
J3Rs WG	---
PhVWP-V	Els Dewaele
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