21 May 2019
EMA/CVMP/281537/2019
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 15-16 April 2019 meeting

Chair: D. Murphy – Vice-chair: H. Jukes

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 modifications.

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

The attendance list was completed. No competing interests were identified for the April 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 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 March 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 (31 members present of those eligible to vote) the CVMP opinion including the EPMAR and the CVMP assessment report recommending the establishment of MRLs for **bambermycin** (EMA/V/MRL/004828/FULL/0001) in rabbits. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication.

1.2 Oral explanations and lists of outstanding issues

- There were no items for discussion.

1.3 Lists of questions

- The Committee adopted the scientific overview and list of questions for the modification of MRLs in ovine for a substance (EMEA/V/MRL/003131/MODF/0003), following discussion of the rapporteur's assessment report including the critique from the co-rapporteur. The Committee noted two peer review reports and the comments received from CVMP members.

1.4 Re-examination of CVMP opinions

- There were no items for discussion.

1.5 Other issues

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 product (EMEA/V/C/004733/0000). The Committee agreed to invite the applicant for an oral explanation. The adoption of the opinion is foreseen for the September 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 vaccine (EMEA/V/C/005077/0000) for chickens. 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 vaccine (EMEA/V/C/005057/0000) for chickens. 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/005058/0000) 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 adopted the EPAR module scientific discussion for **Forceris** (EMEA/V/C/004329/0000) concerning the granting of the initial marketing authorisation.
- The Committee adopted the EPAR module scientific discussion for **Afoxolaner MERIAL** (EMEA/V/C/005126/0000) concerning the granting of the initial marketing authorisation.
- The Committee adopted the EPAR module scientific discussion for **ReproCyc ParvoFLEX** (EMEA/V/C/004858/0000) concerning the granting of the initial marketing authorisation.
- The Committee adopted the EPAR module scientific discussion for **Innovax-ND-IBD** (EMEA/V/C/004422/X/0001) concerning an extension to the marketing authorization.
- The Committee adopted the EPAR module scientific discussion for **Arti-Cell Forte** (EMEA/V/C/004727/0000) concerning the granting of the initial marketing authorisation.
- The Committee adopted the EPAR module scientific discussion for **HorStem** (EMEA/V/C/004265/0000) concerning the granting of the initial marketing authorisation.

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- The Committee adopted by consensus (31 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 **Suvaxyn PRRS MLV** (EMEA/V/C/004276/II/0004/G), recommending the variation of the marketing authorisation to reduce the onset of immunity, to extend the duration of immunity and to implement other changes to the product information. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion.
- The Committee adopted by consensus (31 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a type II variation (subject to a worksharing procedure) for **Porcilis PCV M Hyo** (EMEA/V/C/003796/WS1467/0010), recommending the variation of the marketing authorisation to change the product information to allow concurrent administration with Porcilis PRRS. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (31 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a type II variation (subject to a worksharing procedure) for **LEUCOGEN, LEUCOFELIGEN FeLV-RCP** and **Nobivac LeuFeL** (EMEA/V/C/xxxx/WS1483), recommending the variation of the marketing authorisation to include implement changes to the product information to reflect that a beneficial effect of the feline leukaemia virus (FeLV) vaccination is observed 3 weeks after the first injection of the primary vaccination. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.

- The Committee adopted by consensus (31 members present of those eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report for a type II variation for **Broadline** (EMEA/V/C/002700/II/0023), recommending the variation of the marketing authorisation to implement quality 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 to be addressed in writing and at an oral explanation for a type II variation for **Velactis** (EMEA/V/C/003739/II/0004), concerning target animal safety.

3.3 Lists of questions

- The Committee adopted a list of questions for a type II variation for **Vectra Felis** (EMEA/V/C/002746/II/0009) to change the legal status.
- The Committee adopted a list of questions for a type II variation for **NEXGARD SPECTRA** (EMEA/V/C/003842/II/0019) to add a new therapeutic indication.
- The Committee adopted a list of questions for a type II variation (subject to a worksharing procedure) for **NexGard/NEXGARD SPECTRA** (EMEA/V/C/WS1559) to add a new therapeutic indication.
- The Committee adopted a list of questions for a type II grouped variation for **Melovem** (EMEA/V/C/000152/II/0011/G) concerning quality changes.

3.4 Re-examination of CVMP opinions

- There were no items for discussion.

3.5 Other issues

- The Committee agreed to a request for an extension to the clock-stop for a grouped type II variation application for **Bravecto** (EMEA/V/C/002526/II/0033/G) to add new therapeutic indications.
- The Committee noted the formal notification from MSD Animal Health of their decision to withdraw an application for a grouped type II variation application for **Bravecto** (EMEA/V/C/002526/II/0035/G) concerning changes in the product information.

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 agreed to a request for an extension to the clock-stop for the article 35 referral for **Betamox LA 150 mg/ml Suspension for Injection and its associated names, and generic products thereof**, and adopted the revised timetable for 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

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

- There were no items for discussion.

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 22.03.2019–17.04.2019:

Product	Period
Advocate (EMEA/V/C/000076)	02.04.2018 – 01.04.2019
BLUEVAC BTV8 (EMEA/V/C/000156)	14.04.2018 – 13.04.2019
Clevor (EMEA/V/C/004417)	13.04.2018 – 12.04.2019
Clomicalm (EMEA/V/C/000039)	01.04.2018 – 31.03.2019
Ecoporc SHIGA (EMEA/V/C/002588)	10.04.2018 – 09.04.2019
Eurican Herpes 205 (EMEA/V/C/000059)	26.03.2018 – 25.03.2019
Incurin (EMEA/V/C/000047)	24.03.2018 – 23.03.2019
Locatim (EMEA/V/C/000041)	29.03.2018 – 28.03.2019
Neocolipor (EMEA/V/C/000035)	14.04.2018 – 13.04.2019
Parvoduk (EMEA/V/C/002740)	11.04.2018 – 10.04.2019
Purevax FeLV (EMEA/V/C/000056)	13.04.2018 – 12.04.2019
Rabigen SAG2 (EMEA/V/C/000043)	06.04.2018 – 05.04.2019
Veraflox (EMEA/V/C/000159)	12.04.2018 – 11.04.2019

5.4 Renewals

- The Committee adopted by consensus (31 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for the renewal of the marketing authorisation for **OSURNIA** (EMEA/V/C/003753/R/0014), and recommended that the authorisation should now be indefinite. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.

5.5 Pharmacovigilance – PSURs and SARs

- The Committee adopted the CVMP assessment report of the PSUR for the period 01.05.2018-31.10.2018 for **CYTOPOINT** (EMEA/V/C/003939) with a recommendation to amend the product information.
- 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
RESPIPORC FLUPan H1N1 (EMEA/V/C/0003993)	01.06.2018-30.11.2018
SevoFlo (EMEA/V/C/000072)	01.06.2018-30.11.2018
Suvaxyn Circo MH+RTU (EMEA/V/C/003924)	01.06.2018-30.11.2018
Virbagen Omega (EMEA/V/C/000061)	01.12.2015-30.11.2018
Zeleris (EMEA/V/C/004099)	01.06.2018-30.11.2018

- 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 endorsed a draft list of the EU essential minimum requirements for inclusion in the VICH guideline for fixed pharmaceutical combination products to send to the Expert Working Group.
- The Committee agreed that no comments were needed on either the latest version of the draft VICH GL58 on stability testing in climatic zones III and IV, or on the draft responses to comments received from the public consultation.
- The Committee noted the topic summary document on the revision of the anthelmintics guidelines, which will be presented for endorsement at the May 2019 CVMP meeting.

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 at this meeting cannot be released at the present time as it is deemed to be confidential.

7.1 Scientific Advice Working Party (SAWP-V)

Information relating to SAWP-V procedures cannot be released at the present time as it is deemed to be commercially confidential.

- The Committee received a verbal report from the SAWP-V chair on the meeting held on 15 April 2019, and noted the agenda of the meeting.
- The Committee was informed of the upcoming election of the chair of SAWP-V for a 3-year term at the May 2019 CVMP meeting and noted the call for nominations circulated by the Secretariat.

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)

- 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 26-27 March 2019, and noted the agenda and draft summary record 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

- There were no items for discussion.

The following document was circulated for information:

- Minutes of the SAWP-V meeting held on 19 March 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 confidential.

8.2 Environmental risk assessment

- There were no items for discussion.

8.3 Antimicrobial resistance

- The Committee was informed of the comments received following the close of the public consultation on the "AMEG Scientific advice on the impact on public health and animal health of the use of antibiotics in animals - Preliminary risk profiling for new antimicrobials", and agreed for these to be forwarded to the AMEG for their consideration at their meeting on 8 May.

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 contain commercially confidential information.

The following document was circulated for information:

- List of medically important antimicrobial drugs affected by GFI #213 (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.

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 E.-M. Vestergaard to N. C. Kyvsgaard and M. Blixenkrone-Møller.

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.

- There were no items for discussion.

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 in January, February and March 2019, and noted the draft minutes of the meeting held on 21-22 March 2019 as well as the draft agenda of the meeting held on 16-17 April 2019.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee adopted the agenda of the CVMP Presidency meeting, including the agenda of the joint CVMP/CMDv Presidency meeting, to be held on 6-8 May 2019 at Lake Balaton, Hungary, under the Romanian presidency of the EU.
- The Committee discussed and agreed the follow-on actions to the revised guidance on 'Appointment and responsibilities of the rapporteur and co-rapporteur for procedures regarding veterinary medicinal products' and the revised CVMP (co-)rapp assessment teams form.
- The Committee was informed of the upcoming election of the chair of the Committee for Medicinal Products for Veterinary Use for a 3-year term at the May 2019 CVMP meeting and noted the call for nominations circulated by the Secretariat.
- The Committee received an update on Brexit preparedness and the extension of the period under Article 50.

13. LEGISLATION

- The Committee received verbal reports from the expert group leaders on work progress concerning 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 April 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 April 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	
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	
ES	Cristina Muñoz Madero	Full involvement	
FI	Tita-Maria Muhonen	Full involvement	
HR	Frane Božić	Full involvement	
HU	Gábor Kulcsár	Full involvement	
IE	J. Gabriel Beechinor	Full involvement	
IT	Paolo Pasquali	Full involvement	
LT	Snieguolė Trumpickaitė Dzekčiorienė	Full involvement	
LV	Zanda Auce	Full involvement	
MT	Stephen Spiteri	Full involvement	
NL	Peter Hekman	Full involvement	
PL	Anna Wachnik-Święcicka	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 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	
EL	Angeliki Tsigouri	Full involvement	
FR	Sylvie Louet	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
NL	Jacqueline Poot	Full involvement	
PT	Cristina Gonçalves Santos	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	Beate Gasser	Full involvement	
BE	Koenraad Brusselmans	Full involvement	
DE	Andrea Golombiewski	Full involvement	
DE	Dagmar Sommer	Full involvement	
DE	Lukasz Japtok	Full involvement	
DE	Anke Finnah *(remotely)*	Full involvement	
DE	Birgit Kegel *(remotely)*	Full involvement	
DE	Brigitte Küchler *(remotely)*	Full involvement	
DE	Daniela Loos *(remotely)*	Full involvement	
DE	Judith Romberg *(remotely)*	Full involvement	
DE	Kathrin Schirmann *(remotely)*	Full involvement	
DE	Rolf Beckmann *(remotely)*	Full involvement	
DE	Sabine Kalweit *(remotely)*	Full involvement	
DE	Sabine Klee *(remotely)*	Full involvement	
DE	Svenja Rieke *(remotely)*	Full involvement	
DE	Werner Terhalle *(remotely)*	Full involvement	
ES	Cristina Villegas *(remotely)*	Full involvement	
ES	Rosario Bullido *(remotely)*	Full involvement	
FR	Anne Sagnier *(remotely)*	Full involvement	
FR	Gérard Moulin *(remotely)*	Full involvement	
FR	Martine Redureau *(remotely)*	Full involvement	
FR	Tiphaine Moreac *(remotely)*	Full involvement	
IE	Paul McNeill *(remotely)*	Full involvement	
NO	Kari Grave *(remotely)*	Full involvement	
PL	Anita Piwowarczyk (remotely)	Full involvement	
PL	Ewa Zarzycka *(remotely)*	Full involvement	
PL	Grzegorz Kontny *(remotely)*	Full involvement	
PL	Marcin Glanda *(remotely)*	Full involvement	
SE	Catarina Eriksson *(remotely)*	Full involvement	
SE	Denise Laskowski *(remotely)*	Full involvement	
SE	Fredrik Hultén *(remotely)*	Full involvement	
SE	Jenny Larsson *(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	Sam Fletcher *(remotely)*	Full involvement	

CVMP working parties and CMDv	Chair
ADVENT	---
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	Rory Breathnach
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