14 June 2016
EMA/CVMP/413001/2016
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 17-19 May 2016 meeting

Chair: A. Holm – Vice-chair: D. Murphy

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 and interests were identified for the May 2016 meeting. In accordance with the Agency's policy and procedure on the handling of declarations of 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 Scientific Committee members and, where relevant, experts attending the plenary meeting, as announced by the Scientific Committee 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 April 2016 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 the extension of MRLs to bovine species for **monepantel** (EMEA/V/MRL/003200/EXTN/0003). The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted a peer review report and 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 establishment of MRLs in chickens for a substance (EMEA/V/MRL/004380/FULL/0001), following discussion of the rapporteur's revised assessment report including the critique from the co-rapporteur, two peer review reports and the report from the EU Reference Laboratory.

1.4 Re-examination of CVMP opinions

- There were no items for discussion.

1.5 Other issues

- The Committee was informed of the formal notification from the applicant of their decision to withdraw the application for modification of MRLs in *Equidae* for a substance (EMEA/V/MRL/003639/MODF/0002).

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

- The Committee adopted by majority (24 members in favour out of the 26 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for **DRAXXIN** (EMEA/V/C/000077/X/0029), recommending the refusal of the extension of the marketing authorisation to include a new target species (sheep). The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP. C. Munoz and S. Srčič signed a divergent position not supporting the aforementioned recommendation. The Committee noted the summary of opinion for publication.

2.2 Oral explanations and lists of outstanding issues

- The Committee adopted the updated scientific overview and benefit-risk assessment including the list of outstanding issues and comments on the draft product information for a marketing authorisation application for a new antiparasitic product for bees (EMEA/V/C/002723/0000). The Committee agreed to invite the applicant for an oral explanation in September 2016. The Committee noted a peer review report and the comments received from CVMP members.

- The Committee adopted the updated scientific overview and benefit-risk assessment including the list of outstanding issues and agreed comments on the draft product information for a marketing authorisation application for a new vaccine for rabbits (EMEA/V/C/004239/0000). 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 and benefit-risk assessment including the list of questions and agreed comments on the draft product information for a new vaccine for pigs (EMEA/V/C/004225/0000). 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 EPAR module 6 scientific discussion for **LETIFEND** (EMEA/V/C/003865/0000) 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 and the CVMP assessment report for a grouped type II variation for **Veraflox** (EMEA/V/C/000159/II/0008/G), recommending the variation of the marketing authorisation to implement quality changes. The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP.

3.2 Oral explanations and lists of outstanding issues

- There were no items for discussion.

3.3 Lists of questions

- The Committee adopted the list of questions for a worksharing type II variation for **CORTAVANCE** and **Easotic** (EMEA/V/C/xxxxxx/WS/0925), concerning quality changes.

- The Committee adopted the list of questions for a type II variation for **BLUEVAC BTV8** (EMEA/V/C/000156/II/0007), concerning quality changes.

3.4 Re-examination of CVMP opinions

- There were no items for discussion.

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 adopted by consensus (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 altrenogest to be administered orally to pigs and horses** (EMEA/V/A/095), recommending risk mitigation measures to be included in the product information concerning target species pigs, and variations to the terms of the marketing authorisations in order to amend the product information accordingly. The Committee also concluded that the use of veterinary medicinal products containing altrenogest in mares is not considered to pose a risk to the environment given the minimal environmental exposure associated with the use in individual animals and when used as specified in the product information. The Icelandic CVMP member agreed with the above-mentioned recommendations of the CVMP.
- The Committee adopted by majority (22 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 a combination of lincomycin and spectinomycin to be administered orally to pigs and/or poultry** (EMEA/V/A/110), recommending the withdrawal of the marketing authorisations for premixes for medicated feeding stuff and powders to be administered with the feed containing a combination of lincomycin and spectinomycin, and that the marketing authorisations for powders for use in drinking water containing a combination of lincomycin and spectinomycin should be varied in order to amend the product information accordingly. K. Baptiste, P. Hekman, J. Bureš, G. Kulcsár, E-M. Vestergaard, B. Zemann and the Icelandic CVMP member signed a divergent position not supporting the aforementioned recommendation of the CVMP concerning powders for use in drinking water and particularly the indications for chickens.
- The Committee considered the notification from Germany, for a referral procedure for **veterinary medicinal products containing methylprednisolone hydrogen succinate presented as solutions for injection for intramuscular use in cattle**, regarding concerns related to withdrawal periods in cattle (meat and offal) set for the aforementioned products. The Committee agreed to start a referral procedure (EMEA/V/A/119) under Article 35 and appointed C. Ibrahim as rapporteur and S. Louet as co-rapporteur for the procedure. The Committee adopted the list of questions and the timetable, and noted the list of products concerned.

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.

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 22.04.2016 – 19.05.2016:

Product	Period
CERTIFECT (EMEA/V/C/002002)	06/05/2015 – 05/05/2016
Equilis StrepE (EMEA/V/C/000078)	07/05/2015 – 06/05/2016
Improvac (EMEA/V/C/000136)	11/05/2015 – 10/05/2016
Meloxidolor (EMEA/V/C/002590)	22/04/2015 – 21/04/2016
Naxcel (EMEA/V/C/000079)	19/05/2015 – 18/05/2016
Oncept IL-2 (EMEA/V/C/002562)	03/05/2015 – 02/05/2016
Versican Plus DHPPi/L4 (EMEA/V/C/003678)	07/05/2015 – 06/05/2016
Versican Plus DHPPi/L4R (EMEA/V/C/002759)	07/05/2015 – 06/05/2016
Zuprevo (EMEA/V/C/002009)	06/05/2015 – 05/05/2016

5.4 Renewals

- 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 the renewal of the marketing authorisation for **Recocam** (EMEA/V/C/002247/R/0008), and recommended that the authorisation should now be indefinite. The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP.

5.5 Pharmacovigilance – PSURs and SARs

- The Committee endorsed the report to CVMP on 2015 signal detection outcomes.
- The Committee adopted the following CVMP PSUR assessment reports concluding that no changes to the product literature or other regulatory actions were required for:

Product	Period
Cerenia (EMEA/V/C/000106)	01.07.2015 – 31.12.2015
Contacera (EMEA/V/C/002612)	01.07.2015 – 31.12.2015
Nobilis OR inac (EMEA/V/C/000062)	01.02.2013 – 31.01.2016
Porcilis PCV ID (EMEA/V/C/003942)	28.08.2015 – 29.02.2016

Trifexis (EMEA/V/C/002635)	05.07.2015 – 04.01.2016
Vectra 3D (EMEA/V/C/002555)	01.07.2015 – 31.12.2015
Vectra Felis (EMEA/V/C/002746)	01.07.2015 – 31.12.2015
Veraflox (EMEA/V/C/000159)	01.11.2014 – 31.10.2015
Versican Plus Pi (EMEA/V/C/003681)	01.08.2015 – 31.01.2016
Versican Plus Pi/L4R (EMEA/V/C/003582)	01.08.2015 – 31.01.2016
Zulvac 8 Bovis (EMEA/V/C/000145)	01.08.2015 – 31.01.2016
Zulvac 8 Ovis (EMEA/V/C/000147)	01.08.2015 – 31.01.2016

- 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 the draft EU comments on the VICH discussion document on the definition of “Biologics” to be sent to the VICH Steering Committee.
- The Committee endorsed the draft EU comments on the draft VICH GL54 on studies to evaluate the safety of residues of veterinary drugs in human food: general approach to establish an acute reference dose (ARfD).
- The Committee discussed the draft EU comments on the concept paper on the need to elaborate on the next steps in the global approach to demonstrate bioequivalence, to be endorsed at the June 2016 CVMP meeting following discussion at EWP-V, QWP and SWP-V.
- The Committee discussed the draft EU comments on the concept paper for a general combination products guideline, to be endorsed at the June 2016 CVMP meeting following discussion at EWP-V, QWP and SWP-V.
- The Committee discussed the draft EU comments on the proposed draft document for climatic zones III and IV to the VICH GL3(R) on stability: stability testing of new veterinary drug substances and medicinal products, to be endorsed at the June 2016 CVMP meeting following discussion at QWP.

6.2 Codex Alimentarius

- The Committee endorsed the draft comments on the future work of Codex Alimentarius on Antimicrobial Resistance which will be sent to the EC for their consideration – *see also point 8.3*.

6.3 Other EU bodies and international organisations

- The Committee received a verbal report from the CVMP representative on the joint EC/EFSA scientific workshop on bee health, held on 10 March 2016 in Parma, Italy, and noted the report of the workshop.
- The Committee received a verbal report on the joint EMA/JECFA liaison meeting held on 14 March 2016, and noted that a follow-up virtual meeting is planned for September 2016.
- The Committee was informed of the Global Animal Health Conference and workshops on good regulatory practice of the registration of veterinary medicinal products in an Asian context, to be held on 14-17 November 2016 in New Delhi, India, and noted the conference leaflet, the outline of the workshops and the executive summary of the 2015 Global Animal Health Conference.

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 vice-chair of the SAWP-V on the meeting held on 17 May 2016, and noted the agenda of the meeting.
- The Committee was informed of the election of the chair of the SAWP-V for a 3-year term at the June 2016 CVMP meeting. A call for nominations had been circulated.

7.2 Quality Working Party (QWP)

- There were no items for discussion.

7.3 Safety Working Party (SWP-V)

7.4 Environmental Risk Assessment Working Party (ERAWP)

- The Committee adopted the draft guideline on the plant testing strategy for veterinary medicinal products (EMA/CVMP/ERA/689041/2015) for a 6-month period of public consultation.

7.5 Efficacy Working Party (EWP-V)

7.6 Antimicrobials Working Party (AWP)

- The Committee agreed to postpone until further notice the election of a vice-chair for the AWP as no nominations had been received.

7.7 Immunologicals Working Party (IWP)

- There were no items for discussion.

7.8 Pharmacovigilance Working Party (PhVWP-V)

- The Committee adopted the draft reflection paper on non-spontaneous adverse event reports (EMA/CVMP/PhVWP/357539/2015) for a 3-month period of public consultation.

7.9 Novel therapy groups and related issues

- There were no items for discussion.

7.10 Joint CVMP/CHMP AHEG on the application of the 3Rs (JEG-3Rs)

- 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:

- Draft minutes of the SAWP-V meeting held on 19 April 2016;
- Draft agenda for the 79th Joint CHMP/CVMP QWP meeting to be held on 31 May to 1 June 2016;
- Draft agenda for the EWP-V meeting to be held on 31 May 2016-1 June 2016;
- Draft agenda for the EWP-V interested parties meeting to be held on 1 June 2016;
- Draft agenda for the ADVENT meeting to be held on 19 May 2016.

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 endorsed the updated advice of the Expert Advisory Group on Antibiotic Resistance (AMEG) on the use of colistin products in animals within the European Union, which is foreseen to be endorsed by the CHMP.
- The Committee endorsed the draft comments on the future work of Codex Alimentarius on Antimicrobial Resistance which will be sent to the EC for their consideration – *see also point 6.2*.
- The Committee received feedback on the 2nd meeting of the EFSA BIOCONTAM – BIOHAZ Working Group held on 18 March 2016, concerning the request for a scientific opinion on the risk for the development of antimicrobial resistance due to feeding of calves with milk.
- The Committee was informed of the publication of the EMA-ESVAC defined daily doses for animals (DDDvet) and defined course doses (DCDvet), which is published on the ESVAC web page on the EMA website.
- The Committee received a verbal report on the meeting of the EFSA-EMA expert group on Reduction of Need for Antimicrobials in Food-producing Animals (RONAFA), held on 28-29 April 2016 in Parma, Italy.

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 Committee endorsed F. Klein to act as EMA-CVMP representative speaker at the consortium meeting of the project PARAGONE 'Vaccines for animal parasites' funded under the EU Horizon 2020 funded research and innovation programme, to be held on 29-30 August 2016 in Ghent, Belgium.
- The Committee was informed of the simulation exercise for the incident management plan for medicines for veterinary use foreseen to be held in June 2016.
- The Committee discussed the draft CVMP risk management strategy on the potential presence of replication competent endogenous retrovirus RD114 in feline and canine starting materials and vaccines, in preparation of a planned meeting with industry in June. The Committee also received an update on manufacturers' RD114 status in 2016 and their strategies for minimising the risk of RD114 in feline and canine vaccines. The Committee endorsed the risk management strategy for presentation to industry in June. The document will be further discussed at the July CVMP meeting.

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-)rapporteurship and peer reviewer responsibilities from A.-M. Brady to N. Garcia del Blanco.

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 meeting held on 21-22 April 2016, and noted the draft minutes of the meeting as well as the draft agenda of the meeting held on 19-20 May 2016.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee was informed of the election of the chair of CVMP for a 3-year term at the June 2016 CVMP meeting. A call for nominations had been circulated.

13. LEGISLATION

- There were no items for discussion.

14. ANY OTHER BUSINESS

- Upon the completion of the May 2016 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 May 2016 meeting

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
CHAIR	**Anja Holm**	**Full involvement**	
AT	Barbara Zemann	Cannot act as rapporteur or peer reviewer for:	• 10.1 one item
BE	Bruno Urbain	Full involvement	
BG	Emil Kozhuharov	Full involvement	
CY	Alia Michaelidou	Full involvement	
CZ	Jiří Bureš	Full involvement	
DE	Cornelia Ibrahim	Full involvement	
DK	Ellen-Margrethe Vestergaard	Full involvement	
EE	Toomas Tiirats	Full involvement	
ES	Cristina Muñoz Madero	Full involvement	
FR	Jean-Claude Rouby	Full involvement	
HR	Ljiljana Markuš-Cizelj	Full involvement	
HU	Gábor Kulcsár	Full involvement	
IE	David Murphy (vice-chair)	Full involvement	
IT	Maria Tollis	Full involvement	
LU	Marc Schmit	Full involvement	
LV	Zanda Auce	Full involvement	
PT	João Pedro Duarte da Silva	Full involvement	
RO	Lollita Taban	Full involvement	
SE	Eva Lander Persson	Full involvement	
SI	Stane Srčič	Cannot act as rapporteur or peer reviewer for:	• 3.3 CORTAVANCE and Easotic (EMEA/V/C/xxxxxx/WS/0925)
SK	Judita Hederová	Full involvement	
UK	Helen Jukes	Full involvement	
Co-opted	Keith Baptiste	Full involvement	
Co-opted	Rory Breathnach	Full involvement	
Co-opted	Christian Friis	Full involvement	
Co-opted	Wilhelm Schlumbohm	Full involvement	
Co-opted	Jason Weeks	Full involvement	
IS	Jóhann Lenharðsson	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	
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
ES	Consuelo Rubio Montejano	Cannot act as rapporteur or peer reviewer for:	• 1.3 EMEA/V/MRL/004380/FULL/0001 • 4.3 Altrenogest (EMEA/V/A/095) • 5.5 Nobilis OR inac, Porcilis PCV ID • 8.5 one item • 10.2 two items
FR	Sylvie Louet	Full involvement	
NL	Peter Hekman	Full involvement	
PL	Ewa Augustynowicz	Full involvement	
SE	Frida Hasslung Wikström	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	Sandy Vermout *(remotely)*	Full involvement	
DE	Silke Hickmann *(remotely)*	Full involvement	
DE	Gerd Maack *(remotely)*	Full involvement	
EMA	Anna-Maria Brady	Full involvement	
ES	Rosario Bullido Gomez-Heras *(remotely)*	Full involvement	
ES	Alberto de Prado Lopez *(remotely)*	Full involvement	
ES	Maria Jose Ferrer Montesa *(remotely)*	Full involvement	
ES	Ricardo Carapeto Garcia *(remotely)*	Full involvement	
NL	Piet-Hein Overhaus *(remotely)*	Full involvement	
NL	G. Johan Schefferlie *(remotely)*	Full involvement	
NL	Sandra ten Voorde *(remotely)*	Full involvement	
SI	Vlasta Jencic *(remotely)*	Full involvement	
UK	Noemi Garcia del Blanco	Full involvement	
UK	Sharon Reynolds	Full involvement	

CVMP working parties and CMDv	Chair
ADVENT	Jean-Claude Rouby
AWP	Helen Jukes

CVMP working parties and CMDv	Chair
CMDv	Gavin Hall
ERAWP	Jason Weeks
EWP-V	Gesine Hahn
IWP	Esther Werner
PhVWP-V	--
QWP	--
SAWP-V	Rory Breathnach
SWP-V	Eva Lander Persson

Observer from the European Commission	
Present	

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