16 February 2016
EMA/CVMP/145891/2016
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 19-21 January 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 January 2016 meeting. In accordance with the Agency's revised 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.

No contacts were declared.

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iv. Adoption of the minutes of the previous meeting

The minutes of the December 2015 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

- The Committee discussed the rapporteurs' joint assessment of the responses to the list of questions and the draft EPMAR for the extension of MRLs to bovine tissues and milk for a substance (EMEA/V/MRL/003200/EXTN/0003). The Committee adopted a list of outstanding issues that should be addressed in writing and at an oral explanation, and noted the comments from the EU Reference Laboratory concerning the analytical method and a peer review report.

1.3 Lists of questions

- The Committee adopted the scientific overview and list of questions for the modification of MRLs in *Equidae* for a substance (EMEA/V/MRL/003639/MODF/0002), following discussion of the rapporteur's assessment report including the critique from the co-rapporteur and a peer review report.
- The Committee adopted the scientific overview and list of questions for the establishment of MRLs for porcine species for a substance (EMEA/V/MRL/004113/FULL/0001), following discussion of the rapporteur's assessment report including the critique from the co-rapporteur and two peer review reports.

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

- There were no items for discussion.

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 product

(EMEA/V/C/004239/0000), a vaccine for rabbits. The Committee noted two peer review reports and the comments received from CVMP members.

- 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 product (EMEA/V/C/004202/0000) for psycholeptic use in dogs and cats. The Committee noted a peer review report and the comments received from CVMP members.

2.4 Re-examination of CVMP opinions

- The Committee agreed to the request from the applicant for the re-examination of the CVMP opinion adopted for an extension application for **Bravecto** (EMEA/V/C/002526/X/0005) to add a new pharmaceutical form (spot-on solution) for dogs and for a new target species (cats). The Committee appointed C. Ibrahim as rapporteur and S. Louet as co-rapporteur for the procedure, and agreed to the applicant's request for the involvement of an ad hoc expert group (AHEG). The adoption of the opinion is foreseen for the March 2016 meeting of the Committee.

2.5 Other issues

- The Committee endorsed the EPAR module 6 scientific discussion for **Velactis** (EMEA/V/C/003739/0000) concerning the granting of the initial marketing authorisation.

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- The Committee adopted by consensus (29 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a quality grouped type II variation for **Nobilis IB4-91** (EMEA/V/C/000036/II/0021/G), recommending the variation of the marketing authorisation.

- The Committee adopted by consensus (29 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a quality type II variation for **Panacur AquaSol** (EMEA/V/C/002008/II/0010), recommending the variation of the marketing authorisation.

3.2 Oral explanations and lists of outstanding issues

- The Committee heard an oral explanation from Zoetis concerning a type II variation for **DRAXXIN** (EMEA/V/C/000077/II/0031), to add a new indication. The Committee also discussed the rapporteurs' assessment of the responses to the list of outstanding issues. An opinion is foreseen for the February 2016 CVMP meeting.

3.3 Lists of questions

- There were no items for discussion.

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 considered the notification from Belgium for a referral procedure for **all veterinary medicinal products containing gentamicin presented as solutions for injection to be administered to cattle and pigs**, regarding concerns related to the withdrawal periods set for these products. The Committee agreed to start a referral procedure (EMEA/V/A/117) under Article 35 and appointed B. Urbain as rapporteur and H. Jukes as co-rapporteur. The Committee adopted the list of questions and the timetable for the procedure, and noted the list of products concerned.
- The Committee agreed to the request from Zoetis Belgium SA for a 1-month extension to the clock-stop for the referral procedure for **all veterinary medicinal products containing a combination of lincomycin and spectinomycin to be administered orally to pigs and/or poultry** (EMEA/V/A/110), and adopted a 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

- There were no items for discussion.

The following document was circulated for information:

- Solamocta 697 mg/g Powder for Use in Drinking Water for Chickens, Ducks and Turkeys - Article 33(4) referral (EMEA/V/A/112) – Questions and answers for publication (EMA/23095/2016).

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 **Suprelorin** (EMEA/V/C/000109/REC/022).

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 11.12.2015 – 21.01.2016:

Product	Period
Activyl Tick Plus (EMEA/V/C/002234)	09/01/2015 – 08/01/2016
Bovela (EMEA/V/C/003703)	22/12/2014 – 21/12/2015
BTVPUR AlSap 1 (EMEA/V/C/002230)	17/12/2014 – 16/12/2015
BTVPUR AlSap 1-8 (EMEA/V/C/002231)	17/12/2014 – 16/12/2015
CORTAVANCE (EMEA/V/C/000110)	09/01/2015 – 08/01/2016
Gripovac 3 (EMEA/V/C/000157)	14/01/2015 – 13/01/2016
MELOXIDYL (EMEA/V/C/000115)	15/01/2015 – 14/01/2016
Metacam (EMEA/V/C/000033)	07/01/2015 – 06/01/2016
NEXGARD SPECTRA (EMEA/V/C/003842)	15/01/2015 – 14/01/2016
Onsior (EMEA/V/C/000127)	16/12/2014 – 15/12/2015
Porcilis PCV (EMEA/V/C/000135)	12/01/2015 – 11/01/2016
Prac-tic (EMEA/V/C/000103)	18/12/2014 – 17/12/2015
RESPIPORC FLU3 (EMEA/V/C/000153)	14/01/2015 – 13/01/2016
Rheumocam (EMEA/V/C/000121)	10/01/2015 – 09/01/2016
SevoFlo (EMEA/V/C/000072)	11/12/2014 – 10/12/2015
Ypozane (EMEA/V/C/000112)	11/01/2015 – 10/01/2016
ZULVAC 8 Bovis (EMEA/V/C/000145)	15/01/2015 – 14/01/2016
ZULVAC 8 Ovis (EMEA/V/C/000147)	15/01/2015 – 14/01/2016

5.4 Renewals

- The Committee adopted by consensus (28 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for the renewal of **Zuprevo** (EMEA/V/C/002009/R/0010), and agreed that the authorisation should now be indefinite.
- The Committee adopted the list of outstanding issues for the renewal of **CERTIFECT** (EMEA/V/C/002002/R/0011).

5.5 Pharmacovigilance – PSURs and SARs

- The Committee adopted the CVMP assessment report of the PSUR for the period 01.02.2015 – 31.07.2015 for **Kexxtone** (EMEA/V/C/002235) with a recommendation to amend the SPC.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.02.2015 – 31.07.2015 for **Nobivac L4** (EMEA/V/C/002010) with a recommendation to amend the SPC.

- The Committee adopted the CVMP assessment report of the PSUR for the period 01.08.2012 – 31.07.2015 for **Profender** (EMEA/V/C/000097) with a recommendation to amend the SPC.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.11.2009 – 31.07.2015 for **Zolvix** (EMEA/V/C/000154) with a recommendation to amend the SPC.
- The Committee adopted the following CVMP PSUR assessment reports concluding that no changes to the product literature or other regulatory actions were required at this stage for:

Product	Period
Activyl (EMEA/V/C/000163)	01.09.2014 – 31.08.2015
Bovilis BTV8 (EMEA/V/C/000148)	01.04.2015 – 30.09.2015
Bravecto (EMEA/V/C/002526)	01.03.2015 – 31.08.2015
Econor (EMEA/V/C/000042)	01.04.2015 – 30.09.2015
Ingelvac CircoFLEX (EMEA/V/C/000126)	01.09.2012 – 31.08.2015
NexGard (EMEA/V/C/002729)	01.03.2015 – 31.08.2015
Nobilis IB4-91 (EMEA/V/C/000036)	01.04.2015 – 30.09.2015
Nobilis IB Primo QX (EMEA/V/C/002802)	01.04.2015 – 30.09.2015
Semintra (EMEA/V/C/002436)	01.03.2015 – 31.08.2015
ZULVAC SBV (EMEA/V/C/002781)	06.02.2015 – 31.08.2015

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

5.6 Supervision and sanctions

Information relating to supervisions 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 (EMA/CVMP/497281/2006).

6. CO-OPERATION WITH OTHER EU OR INTERNATIONAL BODIES

6.1 VICH

- The Committee endorsed the revised species and breed lists of the VICH guideline 30 on pharmacovigilance - controlled list of terms.
- The Committee discussed the revised draft VICH guideline 54 on general approach to establish an acute reference dose (ARfD) and the draft overview of comments received during the public consultation. The Committee agreed on the EU comments to be submitted to the VICH Safety EWG.

6.2 Codex Alimentarius

- There were no items for discussion.

6.3 Other EU bodies and international organisations

- The Committee was informed of the summary and conclusions from the 81st Joint FAO/WHO Expert Committee on Food Additives (Residues of veterinary drugs), held on 17–26 November 2015 in Rome, Italy.

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 chair of the SAWP-V on the meeting held on 19 January 2016, and noted the agenda of the meeting.

7.2 Quality Working Party (QWP)

- The Committee was informed of the upcoming election of the veterinary vice chair of the QWP for a 3-year term at the March 2016 CVMP meeting.

7.3 Safety Working Party (SWP-V)

- The Committee was informed of the upcoming election of the vice chair of the SWP-V for a 3-year term at the February 2016 CVMP meeting.

7.4 Environmental Risk Assessment Working Party (ERAWP)

7.5 Efficacy Working Party (EWP-V)

- The Committee adopted the draft concept paper for the revision of guideline on the conduct of pharmacokinetic studies in target animal species (EMA/CVMP/EWP/706701/2015) for a 3-month period of public consultation.
- The Committee adopted the revised guideline for the demonstration of efficacy for veterinary medicinal products containing antimicrobial substances (EMA/CVMP/627/01-Rev.1) and the overview of comments received during the second round of public consultation (EMA/CVMP/EWP/374087/2015) – *see also 7.6*.

7.6 Antimicrobials Working Party (AWP)

- The Committee adopted the revised guideline for the demonstration of efficacy for veterinary medicinal products containing antimicrobial substances (EMA/CVMP/627/01-Rev.1) and the overview of comments received during the second round of public consultation (EMA/CVMP/EWP/374087/2015) – *see also 7.5*.

7.7 Immunologicals Working Party (IWP)

7.8 Pharmacovigilance Working Party (PhVWP-V)

- The Committee noted the draft agenda of the PhVWP-V meeting to be held on 26-27 January 2016.

7.9 Novel therapy groups and related issues

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

- The Committee adopted the following draft revised guidelines on data requirements for veterinary medicinal products intended for minor use minor species (MUMS)/limited market, to be released for a 6-month period of public consultation:

  - Efficacy (EMA/CVMP/EWP/117899/2004 – Rev.1);
  - Safety (EMA/CVMP/SWP/66781/2005 – Rev.1);
  - Quality (EMA/CVMP/QWP/128710/2004 – Rev.1);
  - Immunologicals (EMA/CVMP/IWP/123243/2006 – Rev.3).

The following documents were circulated for information:

- Minutes of the SAWP-V meeting held on 8 December 2015;
- Minutes of the Joint meeting of the CHMP/CVMP QWP and the GMDP Inspectors Working Group held on 30 September 2015;
- Draft minutes of the EWP meeting held on 1-2 December 2015;
- Draft minutes of the AWP meeting held on 2-3 December 2016;
- Draft minutes of the IWP meeting held on 20-21 October 2015;
- Draft agenda of the IWP meeting to be held on 11-12 February 2016;
- Draft minutes of the ADVENT meeting held on 10 December 2015.

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

Information relating to certain topics discussed under section 8.2 at this meeting cannot be released at the present time as it is deemed to be confidential.

8.3 Antimicrobial resistance

- The Committee discussed the request from the Commission for an update of the 2013 advice on the impact on public health and animal health of the use of antibiotics in animals (colistin) in view of recent publications on resistance to colistin in bacteria isolated from animals, food and humans in several countries worldwide. The Committee agreed to re-convene the

Antimicrobial Advice Ad Hoc Expert Group (AMEG), who prepared the 2013 advice. The group should evaluate all available information and assess whether in the light of new evidence there is a need to revise the 2013 advice for the use of colistin in animals within the EU.

- The Committee received from H. Jukes a verbal report on the RONAFA (Joint EFSA/EMA Scientific Opinion on measures to reduce the need to use antimicrobial agents in animal husbandry in the European Union, and the resulting impacts on food safety) meeting held on 15 December 2015.

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 deferred the verbal update on the first meeting of the ad hoc expert group on RD114 held on 2-3 December 2015, however noted the agenda and draft minutes of the meeting.

The following document was circulated for information:

- Mission report from the EC workshop: the impact on public health and animal health of the use of antibiotics in animals (Analysis of the EMA scientific advice) held on 26 November 2015.

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.

10.2 Regulatory matters

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

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

- The Committee received a verbal report from the chair of CMDv on the meetings held on 5-6 November and 10-11 December 2015, and noted the draft minutes of the December meeting as well as the draft agenda of the meeting held on 21-22 January 2016.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee discussed the revision of the scientific overview template guidance for immunological products.
- The Committee discussed the public CVMP work plan for 2016, which is foreseen to be adopted at the February CVMP and published on the Agency's website.
- The Committee received feedback from the roundtable with stakeholders in December 2015 on the 10-year anniversary of the micro-, small- and medium-sized-enterprise (SME) office. Veterinary SMEs were represented by IFAH-Europe and EGGVP.
- The Committee were given a demonstration of the proposed NCA dashboard, which is intended to replace the manually-produced reports with reports accessible for NCA colleagues.
- The Committee noted the announcement of the CVMP Interested Parties' meeting to be held on 20 April 2016, and the draft minutes of the previous meeting held on 6 May 2015.
- The Committee was informed of the meetings planned to be hosted during the Slovak Presidency in the second semester of 2016.
- The Committee noted the table of actions following the December 2015 CVMP meeting.

13. LEGISLATION

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

14. ANY OTHER BUSINESS

- Upon the completion of the January 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 January 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:	• 5.5 Ingelvac CircoFLEX, Semintra
BG	Emil Kozhuharov	Full involvement	
DE	Cornelia Ibrahim	Full involvement	
DK	Ellen-Margrethe Vestergaard	Full involvement	
EE	Toomas Tiirats	Full involvement	
EL	Ioannis Malemis	Full involvement	
ES	Cristina Muñoz Madero	Full involvement	
FI	Martti Nevalainen	Full involvement	
FR	Jean-Claude Rouby	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	
MT	Stephen Spiteri	Full involvement	
NL	Johan Schefferlie	Full involvement	
PL	Ewa Augustynowicz	Full involvement	
RO	Lollita Taban	Full involvement	
SI	Stane Srčič	Cannot act as rapporteur or peer reviewer for:	• 4.3 Gentamicin (EMEA/V/A/117)
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	

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	
ES	Consuelo Rubio Montejano	Cannot act as rapporteur or peer reviewer for:	• 2.4 Bravecto (EMEA/V/C/002526/X/0005)

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
			• 3.1 Nobilis IB4-91 (EMEA/V/C/000036/II/0021/G) • 3.1 Panacur Aquasol (EMEA/V/C/002008/II/0010) • 5.4 Zuprevo (EMEA/V/C/002009/R/0010) • 5.5 Activyl, Bovilis BTV8, Bravecto, Nobilis IB Primo QX, Nobilis IB4-91, Nobivac L4 • 10.1 one item
FR	Sylvie Louet	Full involvement	
HR	Frane Božić	Full involvement	
PL	Anna Wachnik-Święcicka	Cannot act as rapporteur or peer reviewer for:	• 5.5 Profender • 9 one item
SE	Frida Hasslung Wikström	Full involvement	
UK	Anna-Maria Brady	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	Jan Joseph *(remotely)*	Full involvement	
BE	Hilde Nelis *(remotely)*	Full involvement	
BE	Bruno Urbain *(remotely)*	Full involvement	
DE	Stefan Scheid *(remotely)*	Full involvement	
ES	María José Ferrer Montesa	Full involvement	
ES	Raúl Belmar Liberato *(remotely)*	Full involvement	
ES	Mercedes Conradi Monner *(remotely)*	Full involvement	
ES	María Domínguez Nicolás *(remotely)*	Full involvement	
ES	Alberto de Prado López	Full involvement	
SE	Fredrik Hulten *(remotely)*	Full involvement	
UK	Sam Fletcher *(remotely)*	Full involvement	

CVMP working parties and CMDv	Chair
ADVENT	Jean-Claude Rouby

CVMP working parties and CMDv	Chair
AWP	Helen Jukes
CMDv	Gavin Hall
ERAWP	*Vacant*
EWP-V	Gesine Hahn
IWP	Esther Werner
PhVWP-V	Peter Ekström *(remotely)*
QWP	Piet-Hein Overhaus *(Vet vice chair - remotely)*
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