11 February 2014
EMA/CVMP/95628/2014
Committee for Medicinal Products for Veterinary Use (CVMP)

Minutes of the 209th CVMP meeting of 14-16 January 2014

Committee for Medicinal Products for Veterinary Use (CVMP)

The meeting was chaired by A. Holm.

Note on access to documents

Documents mentioned in the minutes cannot be released at present (unless otherwise stated) as they are currently in draft format or are classified as confidential. Some documents will become public when adopted in their final form or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).

1. Adoption of the Agenda

The Committee adopted the agenda with no modifications.

2. CVMP delegates' list of intended participation and identified conflicts of interests with regards to agenda items

The attendance list was completed and conflicts of interests were identified for the January 2014 meeting, see Annex I. Discussions, deliberations and voting have taken place in full respect of the restricted involvement as announced by the Committee secretariat. It was noted that 22 members were needed for a quorum and 18 for an absolute majority.

3. 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.

4. Adoption of the minutes of the previous meeting

The minutes of the December 2013 meeting were adopted with no amendments.

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5. 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.

A. ADOPTION OF OPINIONS/LIST OF QUESTIONS

A.1 ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

A.1.1 Opinions on applications

- The Committee adopted the CVMP scientific overview and list of questions for the extension of MRLs to rabbits for a substance (EMEA/V/MRL/003660/EXTN/0003), and discussed the rapporteur's revised assessment report, the EU-RL report, a peer review report and the comments received from CVMP members.

A.1.2 Recommendations for extrapolation of established MRLs

- The Committee addressed the request from the European Commission for clarification in relation to the CVMP opinions adopted for clorsulon (EU/ART27/11/190/IMB), closantel (EU/ART27/11/191/IMB) and triclabendazole (EU/ART27/11/193/IMB) at its November and December 2013 meetings.

A.1.3 Re-examination of CVMP opinions

- There were no items for discussion.

A.2 COMMUNITY MARKETING AUTHORISATIONS

A.2.1 Opinions on applications

- 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 **Fungitraxx** (EMEA/V/C/002722/0000), recommending the granting of a marketing authorisation. The Icelandic and Norwegian CVMP members were not present during the adoption. The product is an antifungal containing itraconazole for ornamental birds. The Committee noted the summary of opinion for publication.

- 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 **Equisolon** (EMEA/V/C/002382/0000), recommending the granting of a marketing authorisation. The Icelandic and Norwegian CVMP members were not present during the adoption. Equisolon is a respiratory product containing prednisolone for horses. The Committee noted the summary of opinion for publication and the comments received from CVMP members.

- 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 **Panacur AquaSol** (EMEA/V/C/002008/X/0003), recommending the extension of the marketing authorisation to add a new target species, chickens. The Icelandic and Norwegian CVMP members were not present during the adoption. The Committee noted the summary of opinion for publication.

A.2.2 Variations to Community marketing authorisations

- The Committee adopted the CVMP list of outstanding issues for a grouped type II quality variation for **Profender** (EMEA/V/C/000097/II/0025/G).

- The Committee adopted the CVMP list of outstanding issues for a type II quality variation for **RESPIPORC FLU3** (EMEA/V/C/000153/II/0005). The Committee noted the comments received from CVMP members.
- The Committee adopted the CVMP list of questions for a type II variation for **Proteq Flu** (EMEA/V/C/000073/II/0014), concerning the substitution of a strain. The Committee noted a peer review report and the comments received from other CVMP members.
- The Committee adopted the CVMP list of questions for a type II variation for **Proteq Flu-Te** (EMEA/V/C/000074/II/0017), concerning the substitution of a strain. The Committee noted a peer review report and the comments received from other CVMP members.
- The Committee adopted by consensus (30 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a type II quality variation for **MS-H Vaccine** (EMEA/V/C/000161/II/0005). The Icelandic and Norwegian CVMP members were not present during the adoption. The Committee noted the comments received from CVMP members.

A.2.3 Re-examination of CVMP opinions

- There were no items for discussion.

A.2.4 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/002390/0000), a vaccine for Atlantic salmon. The Committee noted a peer review report 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 (EMA/795990/2013) for a new product (EMEA/V/C/002590/0000), a hormonal product for cattle. The Committee noted a peer review report and the comments received from CVMP members.

A.3 REFERRALS AND RELATED PROCEDURES

A.3.1 Article 33 of Directive 2001/82/EC

- The Committee adopted by consensus (30 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for the referral procedure for **Norbonex 5 mg/ml pour-on solution for beef and dairy cattle** (EMEA/V/A/098), recommending the granting of the marketing authorisation and having agreed that the summary of product characteristics and package leaflet include warnings relating to potential environmental impact and related risk mitigation measures. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee considered a request from the marketing authorisation holder, Vet-Agro Trading Sp. z.o.o., for a re-examination of the December 2013 CVMP opinion for **Fiprex CAT 52.5 mg spot-on solution for cats, Fiprex S 75 mg spot-on solution for dogs, Fiprex M 150 mg spot-on solution for dogs, Fiprex L 300 mg spot-on solution for dogs and Fiprex XL 412.5 mg spot-on solution for dogs** (EMEA/V/A/099), and appointed R. Breathnach as rapporteur and B. Zemann as co-rapporteur for the re-examination procedure. The procedure will be initiated once the grounds for the re-examination are submitted.

A.3.2 Article 34 of Directive 2001/82/EC

- There were no items for discussion.

A.3.3 Article 35 of Directive 2001/82/EC

- The Committee discussed the rapporteur's assessment report with the co-rapporteur's critique for the referral procedure for **all veterinary medicinal products containing tylosin to be administered orally via feed or the drinking water to pigs** (EMEA/V/A/100). The Committee endorsed the draft CVMP assessment report to be sent to the marketing authorisation holders concerned. The Committee noted the peer review reports and the comments made by CVMP members.

A.3.4 Article 39 of Directive 2001/82/EC

- There were no items for discussion.

A.3.5 Article 13 of Regulation (EC) No 1234/2008

- There were no items for discussion.

A.3.6 Article 78 of Directive 2001/82/EC

- There were no items for discussion.

A.3.7 Article 30(3) of Regulation 726/2004

- There were no items for discussion.

A.3.8 Article 45 of Regulation 726/2004

- There were no items for discussion.

A.3.9 Miscellaneous items

- The Committee noted the informal procedural advice for submission of referral notifications for veterinary medicinal products by Member States (EU/EEA) to the European Medicines Agency. Endorsement of the document was anticipated at the forthcoming HMA meeting.

B. MARKETING AUTHORISATION APPLICATIONS FOR DISCUSSION AND DECISION

- The Committee adopted the updated scientific overview and benefit-risk assessment and the list of outstanding issues, and discussed the draft product information for a marketing authorisation application for a new product (EMEA/V/C/003678/0000), a live and inactivated viral and bacterial vaccine for dogs. The Committee agreed that an oral explanation would not be necessary.

- The Committee noted the letter of withdrawal received from the applicant and the draft CVMP assessment report for an extension application for **Aivlosin** (EMEA/V/C/000083/X/0055) to add a new food-producing target species (chickens) to an authorised pharmaceutical form. Information on the application would be made publicly available shortly.

C. POST-AUTHORISATION ISSUES (EXCLUDING VARIATIONS)

C.1 General issues

- There were no items for discussion.

C.2 Specific obligations and follow up measures to CVMP opinions on the granting of Community marketing authorisations, annual reassessments

- 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 the annual reassessment of **Bovilis BTV8** (EMEA/V/C/000148/S/0005), recommending the conversion of the Community marketing authorisation to normal status for this product. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.

C.3 Product anniversary list

- The Committee noted the product anniversary list for the period between 16 December 2012 – 18 December 2013:
  - **Activyl Tick Plus** (EMEA/V/C/002234) – 09 January 2012 – 08 January 2013
  - **BTVPUR AlSap 1** (EMEA/V/C/002230) – 17 December 2012 – 16 December 2013
  - **BTVPUR AlSap 1-8** (EMEA/V/C/002231) – 17 December 2012 – 16 December 2013
  - **CORTAVANCE** (EMEA/V/C/000110) – 09 January 2012 – 08 January 2013
  - **Metacam** (EMEA/V/C/000033) – 07 January 2012 – 06 January 2013
  - **Onsior** (EMEA/V/C/000127) – 16 December 2012 – 15 December 2013
  - **Prac-Tic** (EMEA/V/C/000103) – 18 December 2012 – 17 December 2013
  - **ProMeris** (EMEA/V/C/000107) – 19 December 2012 – 18 December 2013
  - **ProMeris Duo** (EMEA/V/C/000108) – 19 December 2012 – 18 December 2013
  - **Rheumocam** (EMEA/V/C/000121) – 10 January 2012 – 09 January 2013
  - **Ypozane** (EMEA/V/C/000112) – 11 January 2012 – 10 January 2013

C.4 Renewals of marketing authorisations

- The Committee adopted by consensus (29 members present of those eligible to vote) the CVMP opinion and CVMP assessment report for the renewal of **BTVPUR AlSap 8** (EMEA/V/C/000146/R/0010). The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. It was agreed that the authorisation should now be indefinite.
- The Committee adopted by consensus (30 members present of those eligible to vote) the CVMP opinion and CVMP assessment report for the renewal of **Loxicom** (EMEA/V/C/000141/R/0018). The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The CVMP considered that a further renewal would be required.

C.5 Pharmacovigilance – PSURs and SARs

- The Committee discussed the proposed post-authorisation safety study protocol for **Trifexis** (EMEA/V/C/002635/0000).
- 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)	01.03.2013-31.08.2013
Cardalis (EMEA/V/C/002524)	01.02.2013-31.07.2013
Clomicalm (EMEA/V/C/000039)	01.08.2010-31.07.2013

Product	Period
Activyl (EMEA/V/C/000163)	01.03.2013-31.08.2013
Gripovac (EMEA/V/C/000157)	01.08.2012-31.07.2013
Kexxtone (EMEA/V/C/002235)	28.01.2013-31.07.2013
Loxicom (EMEA/V/C/000141)	11.08.2012-10.08.2013
Melosus (EMEA/V/C/002001)	01.03.2013-31.08.2013
Neocolipor (EMEA/V/C/000035)	01.09.2010-31.08.2013
Pexion (EMEA/V/C/002543)	25.02.2013-31.08.2013
Proteq West Nile (EMEA/V/C/002005)	01.03.2013-31.08.2013
RevitaCAM (EMEA/V/C/002379)	01.03.2013-31.08.2013
Semintra (EMEA/V/C/002436)	13.02.2013-31.08.2013
Zulvac 1 Bovis (EMEA/V/C/002334)	01.03.2013-31.08.2013
Zulvac 1 Ovis (EMEA/V/C/002335)	01.03.2013-31.08.2013

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

C.6 Supervisions and sanctions

- There were no items for discussion.

D. CO-OPERATION WITH OTHER EU OR INTERNATIONAL BODIES

D.1 VICH

- The Committee nominated EU experts for the following VICH task forces set up by the VICH Steering Committee for the development of concept papers for the preparation of VICH guidelines:
  - VICH task force for reviewing the draft concept paper for the revision of the VICH Stability guideline GL 3(R): N. Möller;
  - VICH task force for the development of a discussion document proposing a more focused scope for the development of (a) VICH guidelines(s) for efficacy studies for combination products: K. Hailey;
  - VICH task force for scientific review of the issues raised in the draft concept paper on the revision of the VICH anthelmintics guidelines: N.Bridoux, advisor N.Kyvsgaard.
- The Committee supported the proposed mandate for the VICH Task Force for efficacy studies for combination products subject to comments regarding a compilation of authorised combination products. The EMA secretariat will organise a teleconference for discussion of the EU position involving interested CVMP members.

D.2 Codex Alimentarius

- There were no items for discussion.

D.3 Other EU bodies and international organisations

- The Committee discussed a request from EFSA for cooperation on establishing “Reference Points for Action for non-allowed pharmacologically active substances present in food of animal origins” in relation to chloramphenicol and appointed N. Joseph as a hearing expert to the EFSA group.

- The Committee discussed a request from ECHA to nominate observers to join the Ad Hoc Working Group on the assessment of residues transfer to food (ARTFood) of the Biocidal Products Committee. The Committee appointed E. Lander Persson, S. Scheid, A. Schnipper, A. Wachnik-Święcicka as observers.

The following document was circulated for information:

- Status of VICH Guidelines and meeting schedule of the VICH Expert Working Groups.

E. WORKING PARTIES AND SCIENTIFIC ADVISORY GROUPS

E.1 Scientific Advice Working Party (SAWP)

Information relating to scientific advice requests cannot be released at the present time as it is deemed to be commercially confidential.

E.2 Pharmacovigilance Working Party (PhVWP)

- There were no items for discussion.

E.3 Efficacy Working Party (EWP)

- The Committee adopted the revised guideline for the conduct of efficacy studies for non-steroidal anti-inflammatory drugs (EMA/CVMP/EWP/1061/2001) and the overview of comments received from interested parties (EMA/CVMP/EWP/391540/2013).
- The Committee discussed a number of topics that have arisen from the Focus Group meeting on the revision of the draft guideline on "demonstration of efficacy for veterinary medicinal products containing antimicrobial substances". Some proposals will be further discussed by the EWP and AWP.

E.4 Safety Working Party (SWP)

- There were no items for discussion.

E.5 Immunologicals Working Party (IWP)

- There were no items for discussion.

E.6 Quality Working Party (QWP)

- The Committee adopted the revised guideline on process validation for finished products - information and data to be provided in regulatory submissions (EMA/CHMP/CVMP/QWP/BWP/70278/2012-Rev1) and the overview of comments received.
- The Committee adopted the revised guideline on stability testing for applications for variations to a marketing authorisation (EMA/CHMP/CVMP/QWP/441071/2011) and the overview of comments received.
- The Committee adopted the revised Questions and Answers document on the limits for microbiological quality for premixes for medicated feeding stuffs which contain excipients of natural origin.
- The Committee noted the table of decisions from the 69th Joint CHMP/CVMP QWP meeting held on 3-5 December 2013.

E.7 Environmental Risk Assessment Working Party (ERAWP)

- There were no items for discussion.

E.8 Antimicrobials Working Party (AWP)

- There were no items for discussion.

E.9 Joint CVMP/CHMP AHEG on the application of the 3Rs (JEG 3Rs)

- The Committee endorsed the draft CXMP/JEG 3Rs comments on the draft EURL ECVAM recommendation on the Zebrafish Embryo Acute Toxicity Test Method.

E.10 Other working party issues

- There were no items for discussion.

The following documents were circulated for information:

- Minutes of the Scientific Advice Working Party meeting held on 10 December 2013.
- Joint CHMP/CVMP Quality Working Party 69th meeting held on 3-5 December 2013: Table of decisions.

F. SAFETY OF VETERINARY MEDICINES AND RESIDUES

F.1 Appointment of rapporteurs, co-rapporteurs and peer reviewers for the establishment of new MRLs

Information on critical issues related to MRL centralised procedures cannot be released at the present time as it is deemed to be commercially confidential.

- There were no items for discussion.

F.2 Critical issues related to centralised procedures

Information relating to letters of intent for new MRL applications cannot be released at the present time as it is deemed to be commercially confidential.

- There were no items for discussion.

F.3 Other MRL items

Information on pending MRL-related issues cannot be released at the present time as it is deemed to be commercially confidential.

- The Committee considered the request for the inclusion of polyethyleneglycolether of lauryl alcohols in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009, and agreed to its inclusion as an excipient in the list.
- The Committee considered the request for the inclusion of polidocanol 600 in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009, and agreed to its inclusion as an excipient in the list.
- The Committee adopted the revised list of substances considered as not falling within the scope of Regulation (EC) No 470/2009.

F.4 Antimicrobial resistance

- The Committee reflected on improvements of the SPCs for old antimicrobials.
- The Committee received a verbal report on the Joint ECDC/EFSA/EMA Antimicrobial Consumption and Resistance Analysis EU Expert group meeting held on 17-18 December 2013 and noted the draft agenda of the meeting.

- The Committee noted the EFSA scientific opinion on carbapenem resistance in food animal ecosystems.

F.5 Pharmacovigilance

- The Committee received a presentation on post-authorisation safety studies.

The following documents were circulated for information:

- Publication in the journal of Antimicrobial Chemotherapy 'Correlation between veterinary antimicrobial use and antimicrobial resistance in food-producing animals: a report on seven countries', I. Chantziaras *et al.*

G. APPLICATIONS FOR GRANTING OF COMMUNITY MARKETING AUTHORISATIONS

G.1 Eligibility and appointment of rapporteurs, co-rapporteurs and peer reviewers

Information relating to letters of intent to submit and eligibility requests concerning community marketing authorisations cannot be released at the present time as it is deemed to be commercially confidential.

G.2 Inspections

Information relating to GMP and Pharmacovigilance inspections will not be published as it would be undermining the purpose of such inspections.

- The Committee adopted the re-inspection programme for 2014.

G.3 Regulatory issues

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

G.4 Miscellaneous items

Information relating to certain miscellaneous items on community marketing authorisations cannot be released at the present time as it is deemed to be commercially confidential.

- There were no items for discussion.

H. AVAILABILITY OF MEDICINES

Information relating to availability of medicines cannot be released at the present time as it is deemed to be commercially confidential.

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

- The Committee noted the draft minutes and received a verbal report from the chair of CMDv on the meeting held on 12-13 December 2013, and noted the draft agenda of the meeting held on 16-17 January 2014.

J. ORGANISATIONAL MATTERS

- The Committee discussed the draft minutes of the informal CVMP meeting and the joint CVMP/CMDv meeting, held on 21-23 October 2013 in Vilnius, Lithuania. The minutes will be adopted at the February meeting.

- The Committee noted that the EMA/IFAH-Europe Info Day would be held on 13-14 March 2014 and the draft outline of the programme.
- The Committee received a presentation on the Agency's move in 2014. The Committee would have a guided evening visit to the new premises at Churchill Place during the June meeting.
- The Committee received a report from the first Veterinary-only SME workshop held on 7 November 2013. The meeting had been successful, being much appreciated by the participants.

K. LEGISLATION

- There were no items for discussion.

L. ANY OTHER BUSINESS

- The draft Press Release was circulated for members to provide any comments within 24 hours.

ANNEX I - List of participants and conflicts of interests identified for the January 2014 CVMP meeting

Country	CVMP Member	Restriction	Items on current agenda for which conflicts of interests have been identified*
CHAIR	**Anja Holm**	**Full involvement**	
AT	Barbara Zemann	Cannot act as rapporteur or peer reviewer for:	• C.5 Pexion, Semintra
BG	Damyan Iliev	Full involvement	
CZ	Jiří Bureš	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	Irmeli Happonen	Full involvement	
FR	Michael Holzhauser-Alberti	Full involvement	
HU	Gábor Kulcsár	Full involvement	
IE	David Murphy (vice-chair)	Full involvement	
IT	Maria Tollis	Full involvement	
LU	Marc Schmit	No part in discussions, final deliberations and voting on:	• A.2.2 Proteq Flu (EMEA/V/C/000073/II/0014) • A.2.2 Proteq Flu-Te (EMEA/V/C/000074/II/0017) • A.2.4 product (EMEA/V/C/002390/0000) • C.4 BTVPUR AlSap 8 (EMEA/V/C/000146/R/0010) • C.5 Clomicalm (EMEA/V/C/000039), Gripovac (EMEA/V/C/000157), Neocolipor (EMEA/V/C/000035), Proteq West Nile (EMEA/V/C/002005) • G.3 product
LV	Zanda Auce	Full involvement	
PL	Ewa Augustynowicz	Full involvement	
PT	João Duarte Da Silva	Full involvement	
RO	Lollita Taban	Full involvement	
SE	Eva Lander Persson	Full involvement	
SI	Stane Srčič	Full involvement	
SK	Judita Hederova	Full involvement	

Country	CVMP Member	Restriction	Items on current agenda for which conflicts of interests have been identified*
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	Boris Kolar	Full involvement	
Co-opted	Wilhelm Schlumbohm	Full involvement	

*Procedure number shown where applicable.

Country	CVMP alternate	Restriction	Items on current agenda for which conflicts of interests have been identified*
BE	Frédéric Klein	Full involvement	
DE	Esther Werner	Full involvement	
ES	Consuelo Rubio Montejano	Full involvement	
FR	Jean-Claude Rouby	Full involvement	
HR	Frane Bozic	Full involvement	
NL	Peter Hekman	Full involvement	
NO	Hanne Bergendahl	Full involvement	
PL	Anna Wachnik-Święcicka	Cannot act as rapporteur or peer reviewer for:	• A.2.2 Profender (EMEA/V/C/000097/II/0025/G)
UK	Anna-Maria Brady	Full involvement	

*Procedure number shown where applicable.

Country	European experts participating for specific agenda items	Restriction	Items on current agenda for which conflicts of interests have been identified*
UK	Ralph Woodland	No restrictions were identified for the participation of the European experts attending the meeting for discussion on specific agenda items	
DE	Arne Hein *(remotely)*		
SE	Fredrik Hultén *(remotely)*		
ES	Noemi Garcia del Blanco *(remotely)*		
UK	Steve Spencer *(remotely)*		
NO	Hans Kristian Østensen *(remotely)*		

*Procedure number shown where applicable.

CVMP working parties and CMDv	Chair
AWP	Helen Jukes
ERAWP	Boris Kolar
EWP	Gesine Hahn
IWP and CMDv	Esther Werner
PhVWP	Peter Ekström
QWP	Piet-Hein Overhaus *(remotely)*
SAWP	Rory Breathnach

Other observers	
Hannah Reeves	