4 November 2015
EMA/CVMP/729333/2015
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 6-8 October 2015 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 minor amendments.

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

The attendance list was completed and interests were identified for the October 2015 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.

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iv. Adoption of the minutes of the previous meeting

The minutes of the September 2015 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 recommending the extrapolation of MRLs for **gentamicin** to all mammalian food producing species and to fin fish (EMEA/V/MRL/003669/EXPL/0002). The Icelandic and Norwegian CVMP members 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

- There were no items for discussion.

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

- 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 **Velactis** (EMEA/V/C/003739/0000), recommending the granting of a marketing authorisation. Velactis is a new hormonal product containing cabergoline 1.12 mg/ml prolactin inhibitor for cattle for reducing the milk production at drying-off. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication.
- The Committee adopted by majority (24 members in favour out of the 31 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Imrestor** (EMEA/V/C/002763/0000), recommending the granting of a marketing authorisation. Imrestor is a new immunostimulating product containing pegbovigastrim for subcutaneous use, for the prevention of mastitis in cattle post-partum. K. Baptiste, J. Bureš, J. Hederová, J-C. Rouby, S. Srčič, E.M. Vestergaard, B. Zemann and the Norwegian CVMP member signed a divergent position not supporting the aforementioned recommendation. The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication.

- 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 **Inflacam** (EMEA/V/C/002497/X/0009), recommending the extension of the marketing authorisation to add a new pharmaceutical form (granules in sachet) and strength (330 mg) for the existing target species, horses. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication.

2.2 Oral explanations and lists of outstanding issues

- The Committee received a verbal report from the chair of the ad hoc expert group on the meeting held on 21-22 September 2015, and discussed the report from the meeting for a marketing authorisation application for a new product (EMEA/V/C/002390/0000), a vaccine for Atlantic salmon. The Committee adopted the revised scientific overview and benefit-risk assessment including the list of outstanding issues to be addressed in writing, and agreed that an oral explanation will not be requested. The Committee discussed the draft product information and noted a peer review report and the comments received from CVMP members.

2.3 Lists of questions

- There were no items for discussion.

2.4 Re-examination of CVMP opinions

- There were no items for discussion.

2.5 Other issues

- There were no items for discussion.

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 and the CVMP assessment report for a quality type II variation for **Hiprabovis IBR Marker Live** (EMEA/V/C/000158/II/0005), recommending the variation of the marketing authorisation. The Icelandic and Norwegian CVMP members 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 the CVMP assessment report for a quality worksharing type IB variation for **Ibraxion**, **Purevax RCPCh** and **Purevax RCPCh FeLV** (EMEA/V/C/xxxxxx/WS/0818), recommending the variation of the marketing authorisations. The Icelandic and Norwegian CVMP members 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 the CVMP assessment report for a quality type II variation for **Vaxxitek HVT+IBD** (EMEA/V/C/000065/II/0016), recommending the variation of the marketing authorisation. The Icelandic and Norwegian CVMP members 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 quality grouped type II variation for **Nobilis IB4-91** (EMEA/V/C/000036/II/0021/G).

3.4 Re-examination of CVMP opinions

- There were no items for discussion.

3.5 Other issues

- The Committee agreed to a request from the marketing authorisation holder for a 3-month extension to the clock-stop for a type II variation for **DRAXXIN** (EMEA/V/C/000077/II/0031), to add a new indication.

4. REFERRALS AND RELATED PROCEDURES

4.1 Article 33 of Directive 2001/82/EC

- The Committee discussed the rapporteur's and the co-rapporteur's assessment reports for the referral procedure for **Solamocta 697 mg/g Powder for Use in Drinking Water for Chickens, Ducks and Turkeys** (EMEA/V/A/112). The Committee agreed that no outstanding issues remained. The adoption of the CVMP opinion and assessment report is foreseen for the November 2015 meeting of the Committee. The Committee noted four peer review reports and the comments made by CVMP members.
- The Committee considered the notification from the reference member state, Belgium, for a referral procedure for **CattleMarker IBR Inactivated emulsion for injection for cattle**, due to concerns expressed by Germany regarding a potential serious risk to animal health. The Committee agreed to start a referral procedure (EMEA/V/A/115) under Article 33 and appointed E. Werner as rapporteur and F. Klein as co-rapporteur for the procedure. The Committee adopted the list of questions and the timetable. The adoption of the opinion is foreseen for the March 2016 meeting of the Committee.

4.2 Article 34 of Directive 2001/82/EC

- There were no items for discussion.

4.3 Article 35 of Directive 2001/82/EC

- There were no items for discussion.

4.4 Article 78 of Directive 2001/82/EC

- The Committee adopted by consensus (31 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for the Article 78 procedure for **Closamectin Pour-On Solution and associated names** (EMEA/V/A/113), concluding that overall the benefit-risk balance for the products concerned is positive subject to variation of the product information and conditions concerning risk mitigation and surveillance measures. Accordingly, the Committee recommended that the suspension of the marketing authorisation for CLOSAMECTIN POUR-ON SOLUTION POUR BOVINS in France be lifted. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.

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

- The Committee adopted the rapporteur's assessment report on the data submitted concerning a recommendation for **ZOLVIX** (EMEA/V/C/000154/REC/027-028).

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 11.09.2015 – 08.10.2015:

Product	Period
APOQUEL (EMEA/V/C/002688)	12/09/2014 – 11/09/2015
Cerenia (EMEA/V/C/000106)	29/09/2014 – 28/09/2015
COXEVAC (EMEA/V/C/000155)	30/09/2014 – 29/09/2015
Palladia (EMEA/V/C/000150)	23/09/2014 – 22/09/2015
Previcox (EMEA/V/C/000082)	13/09/2014 – 12/09/2015
Recocam (EMEA/V/C/002247)	13/09/2014 – 12/09/2015
Recuvyra (EMEA/V/C/002239)	06/10/2014 – 05/10/2015
RHINISENG (EMEA/V/C/000160)	16/09/2014 – 15/09/2015
Trifexis (EMEA/V/C/002635)	19/09/2013 – 18/09/2015

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 **Purevax Rabies** (EMEA/V/C/002003/R/0004), and agreed that the authorisation should now be indefinite. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted the list of outstanding issues for the renewal of **Activyl** (EMEA/V/C/000163/R/0008).
- The Committee adopted the list of outstanding issues for the renewal of **CaniLeish** (EMEA/V/C/002232/R/0004).
- The Committee adopted the list of outstanding issues for the renewal of **Cimalgex** (EMEA/V/C/000162/R/0002).

- The Committee adopted the list of outstanding issues for the renewal of **Comfortis** (EMEA/V/C/002233/R/0015).
- The Committee adopted the list of outstanding issues for the renewal of **Melosus** (EMEA/V/C/002001/R/0006).

5.5 Pharmacovigilance – PSURs and SARs

- The Committee adopted the CVMP assessment report on the post authorisation safety study for **Nobivac Myxo RHD** (EMEA/V/C/002004) concluding that no changes to the product literature or other regulatory actions were required.
- 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
Apoquel (EMEA/V/C/002688)	01.12.2014 – 31.05.2015
Bovela (EMEA/V/C/003703)	22.12.2014 – 30.06.2015
BTVPUR AlSap 2-4 (EMEA/V/C/000139)	01.12.2014 – 31.05.2015
Contacera (EMEA/V/C/002612)	01.01.2015 – 30.06.2015
Equip WNV (EMEA/V/C/000137)	22.11.2014 – 31.05.2015
Fevaxyn Pentofel (EMEA/V/C/000030)	01.07.2012 – 30.06.2015
Meloxivet (EMEA/V/C/000124)	01.06.2012 – 31.05.2015
MS-H vaccine (EMEA/V/C/000161)	15.06.2014 – 14.06.2015
Oncept IL-2 (EMEA/V/C/002562)	01.12.2014 – 31.05.2015
Panacur AquaSol (EMEA/V/C/002008)	01.01.2015 – 30.06.2015
Vectra Felis (EMEA/V/C/002746)	01.01.2015 – 30.06.2015

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

5.6 Supervisions 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.

6. CO-OPERATION WITH OTHER EU OR INTERNATIONAL BODIES

6.1 VICH

- The Committee noted the documents for the 32nd VICH Steering Committee meeting to be held on 25-26 and 30 October 2015 in Tokyo, Japan, including the draft agenda and the minutes of the 31st VICH Steering Committee.

6.2 Codex Alimentarius

- The Committee noted the public request for information and comments launched by Codex Alimentarius on Antimicrobial Resistance and agreed to prepare comments during its November meeting.

6.3 Other EU bodies and international organisations

- The Committee received feedback on the EFSA expert meeting on reference points for action for malachite green.
- The Committee received feedback on the EFSA expert meeting on review of diflubenzuron.
- The Committee received feedback on the EFSA expert meeting developing guidance on the establishment of the residue definition for dietary risk assessment, and noted the mandate for the EFSA work.

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 6 October 2015, and noted the agenda of the meeting. The Committee agreed for the secretariat to launch a call for nominations for a new member to be elected for the Scientific Advice CVMP working party, following the departure of one of its members.

7.2 Quality Working Party (QWP)

- The Committee received a verbal report from the veterinary vice-chair of the QWP on the 76th Joint CHMP/CVMP QWP meeting held on 30 September to 2 October 2015, and on the Joint meeting of the GMP/GDP Inspectors Working Group (IWG) and the Joint CHMP/CVMP QWP held on 30 September 2015, and noted the agendas of the meetings.

7.3 Safety Working Party (SWP-V)

- The Committee received a verbal report from the chair of the SWP-V on the meeting held on 24-25 September 2015, and noted the agenda of the meeting.

7.4 Environmental Risk Assessment Working Party (ERAWP)

7.5 Efficacy Working Party (EWP-V)

- The Committee received a verbal report from the chair of the EWP-V on the meeting held on 15-16 September 2015, and noted the agenda of the meeting.

7.6 Antimicrobials Working Party (AWP)

- The Committee received a verbal report from the chair of the AWP on the meeting held on 23-24 September 2015, and noted the agenda of the meeting.

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 chair of the PhVWP-V on the meeting held on 22-23 September 2015, and noted the agenda of the meeting and the summary of feedback from the PhVWP-V interested parties meeting held on 23 September 2015.

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

The Committee discussed the draft work plans for 2016 of the CVMP working parties, foreseen to be adopted at the November 2015 meeting of the Committee:

- The SAWP-V draft work plan.
- The QWP draft work plan.
- The SWP-V draft work plan.
- The ERAWP draft work plan.
- The EWP-V draft work plan.
- The AWP draft work plan.
- The IWP draft work plan.
- The PhVWP-V draft work plan.
- The ADVENT draft work plan.

The following documents were circulated for information:

- Draft minutes of the SAWP meeting held on 8 September 2015;
- Final minutes of the QWP meeting held on 26–28 May 2015;
- Draft minutes of the EWP meeting held on 15–16 September 2015;
- Draft minutes of the IWP meeting held on 17-18 June 2015;
- Draft agenda of the IWP meeting to be held on 20-21 October 2015;
- Draft minutes of the PhVWP meeting held on 22-23 Sept 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 on certain environmental risk assessment related issues cannot be released at the present time as it is deemed to be confidential.

8.3 Antimicrobial resistance

- The Committee received a verbal report on the ESVAC 5th annual report: sales of veterinary antimicrobial agents in 26 EU/EEA countries in 2013. The Committee noted that overall sales of antimicrobials for use in animals continues to decrease, and was informed about a new ESVAC interactive database.
- The Committee received 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 September 2015 in Parma, Italy, and noted the agenda of the meeting.

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.

- There were no items for discussion.

The following document was circulated for information:

- Commission Notice – Guidelines for the prudent use of antimicrobials in veterinary medicine (2015/C 299/04) (http://ec.europa.eu/food/food/biosafety/antimicrobial_resistance/index_en.htm)

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 (co-)rapporteurships and peer review responsibilities from J.-C. Rouby to S. Louet for the concerned products.

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 noted the draft minutes of the meeting held on 10-11 September 2015 as well as the draft agenda of the meeting held on 8-9 October 2015.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee discussed the draft minutes of the CVMP Presidency meeting and the joint CVMP/CMDv Presidency meeting, held on 21-22 September 2015 in Luxembourg.
- The Committee received a verbal report from the chair of the Strategic Planning Group on the meeting held on 8 October 2015, and noted the agenda of the meeting and the minutes of the meeting held on 3 June 2015.
- The Committee was informed of the lunch-time event for staff and delegates on "Veterinary medicines as part of assuring global food security", which is planned for 5 November 2015 as part of the programme series to mark the 20th Anniversary of the European Medicines Agency.
- The Committee was informed of the Agency's new booking policy for non-reimbursed delegates.
- The Committee noted the table of actions following the September 2015 CVMP meeting.

13. LEGISLATION

- There were no items for discussion.

14. ANY OTHER BUSINESS

- Upon the completion of the October 2015 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 October 2015 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	Full involvement	
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	
EL	Ioannis Malemis	Full involvement	
ES	Cristina Muñoz Madero	Full involvement	
FI	Martti Nevalainen	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	
PL	Ewa Augustynowicz	Full involvement	
SE	Eva Lander Persson	Full involvement	
SI	Stane Srčič	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	Christian Friis	Full involvement	
Co-opted	Boris Kolar	Full involvement	
Co-opted	Wilhelm Schlumbohm	Full involvement	
IS	Jóhann Lenharðsson	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	Frederic Klein	Full involvement	
DE	Esther Werner	Full involvement	
ES	Consuelo Rubio	Cannot act as rapporteur	• 3.1 Hiprabovis IBR Marker Live

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
	Montejano	or peer reviewer for:	(EMEA/V/C/000158/II/0005) • 3.1 Vaxxitek HVT+IBD (EMEA/V/C/000065/II/0016) • 3.3 Nobilis IB4-91 (EMEA/V/C/000036/II/0021/G) • 5.4 Activyl (EMEA/V/C/000163/R/0008) • 5.5 Nobivac Myxo-RHD • 5.5 PSURs for Nobivac Myxo-RHD and Panacur AquaSol
FR	Sylvie Louet	Full involvement	
NL	Peter Hekman	Full involvement	
PL	Anna Wachnik-Święcicka	Full involvement	
PT	Maria Azevedo Mendes	Full involvement	
RO	Simona Sturzu	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.			
EC	Marlies Halder *(remotely)*		
ES	Noemi Garcia del Blanco	Full involvement	
FR	Elisabeth Begon *(remotely)*	Full involvement	
NO	Ruth Torill Kongtorp *(remotely)*	Full involvement	
UK	Niall O'Brien *(remotely)*	Full involvement	
UK	Steve Spencer	Full involvement	
UK	Bryan Ward *(remotely)*	Full involvement	
UK	Jason Weeks	Full involvement	
UK	Ralph Woodland *(remotely)*	Full involvement	

CVMP working parties and CMDv	Chair
AWP	Helen Jukes
CMDv	--
ERAWP	Boris Kolar
EWP-V	Gesine Hahn
IWP	Esther Werner
PhVWP-V	Peter Ekström *(remotely)*

CVMP working parties and CMDv	Chair
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