7 July 2015
EMA/CVMP/458812/2015
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 2-4 June 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 the addition of a new item under point 10.1.

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

The attendance list was completed and interests were identified for the June 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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No contacts were declared.

iv. Adoption of the minutes of the previous meeting

The minutes of the May 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

- There were no items for discussion.

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 extension of MRLs to bovine tissues and milk for a substance (EMEA/V/MRL/003200/EXTN/0003), following discussion of the rapporteur's revised assessment report, a peer review report and written comments. Comments from the EU-RL were noted.

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 (29 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **UpCard** (EMEA/V/C/003836/0000), recommending the granting of a marketing authorisation. UpCard is a new cardiovascular product containing torasemide anhydrous for the treatment of clinical signs, including oedema and effusion, related to congestive heart failure in dogs. 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

- 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 comments on the draft product information for a new product for bees

(EMEA/V/C/002723/0000). 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 vaccine for chickens (EMEA/V/C/004013/0000). The Committee noted a peer review report 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 discussed the rapporteurs' joint assessment on the responses to the list of outstanding issues and the draft CVMP assessment report for a new cardiovascular product for dogs (EMEA/V/C/002804/0000), and noted the draft product information.
- The Committee discussed the rapporteurs' joint assessment on the responses to the list of outstanding issues and the updated scientific overview and benefit-risk assessment for a new anti-inflammatory product for horses (EMEA/V/C/003866/0000).
- The Committee was informed of the formal notification from Pfizer Limited of their decision to withdraw the marketing authorisation for **ProMeris Duo** (EMEA/V/C/000108).
- The Committee was informed of the formal notification from Pfizer Limited of their decision to withdraw the marketing authorisation for **ProMeris** (EMEA/V/C/000107).
- The Committee endorsed the EPAR module 6 scientific discussion for **Sileo** (EMEA/V/C/003764/0000), concerning the granting of the initial marketing authorisation.
- The Committee endorsed the EPAR module 6 scientific discussion for **Cerenia** (EMEA/V/C/000106/X/0023), concerning the granting of an extension to the 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 type II variation for **Poulvac E.coli** (EMEA/V/C/002007/II/0006), recommending the variation of the marketing authorisation to include drinking water as a route of administration. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (28 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a quality, grouped type II variation for **COXEVAC** (EMEA/V/C/000155/II/0008/G), 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 (28 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a quality, worksharing type IB variation for the **BTVPUR AlSap range** (EMEA/V/C/xxxxxx/WS/0669), recommending the variation of the

marketing authorisations. 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 grouped type II variation for **Advocate** (EMEA/V/C/000076/II/0026/G), to add a new indication for dogs and to change the local representatives.
- The Committee adopted the list of questions for a type II variation for **Ingelvac CircoFLEX** (EMEA/V/C/000126/II/0019), to update the product information with a statement on use during pregnancy and lactation.
- The Committee adopted the list of questions for a quality type II variation for **Ingelvac CircoFLEX** (EMEA/V/C/000126/II/0020).
- The Committee adopted the list of questions for a quality, grouped type II variation for **STARTVAC** (EMEA/V/C/000130/II/0003/G).
- The Committee adopted the list of questions for a grouped type II variation for **ZULVAC SBV** (EMEA/V/C/002781/II/0002/G), to update the product information.

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

- The Committee adopted by majority (26 members in favour out of the 29 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for the referral procedure for **Coglapix suspension for injection for pigs** (EMEA/V/A/109), concluding that the objections raised by Italy during the mutual recognition procedure should not prevent the granting of a marketing authorisation, subject to changes in the product information regarding the indication for use and immunological properties of the product. The Icelandic and Norwegian CVMP members agreed with the above-mentioned conclusions of the CVMP. K. Baptiste, J-C. Rouby and B. Urbain signed a divergent position not supporting the aforementioned conclusions of the CVMP.
- The Committee considered the notification from the United Kingdom for a referral procedure for **Solamocta 697 mg/g Powder for Use in Drinking Water for Chickens, Ducks and Turkeys**, due to concerns expressed by Denmark related to demonstration of bioequivalence of the product with the reference product and prudent use advice in the product information. The Committee agreed to start a referral procedure (EMEA/V/A/112) under Article 33(4) and appointed E-M. Vestergaard as rapporteur and H. Jukes 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 November 2015 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

- 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

Information relating to certain topics discussed under section 4.7 at this meeting cannot be released at the present time as it is deemed to be confidential.

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 **LEUCOFELIGEN FeLV/RCP** (EMEA/V/C/000143/REC/015).
- The Committee adopted the rapporteur's assessment report on the data submitted concerning a condition for **Coliprotec F4** (EMEA/V/C/003797/ANX/001).

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 08.05.2015 – 04.06.2015:

Product	Period
Improvac (EMEA/V/C/000136)	11.05.2014 – 10.05.2015
Naxcel (EMEA/V/C/000079)	19.05.2014 – 18.05.2015

5.4 Renewals

- The Committee adopted the list of outstanding issues for the renewal of **Meloxoral** (EMEA/V/C/000151/R/0006).

- The Committee adopted by consensus (29 members present of those eligible to vote) the final CVMP opinion, the final CVMP assessment report and the product information following the re-examination of the CVMP opinion for the renewal of **COXEVAC** (EMEA/V/C/000155/R/0009), 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 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 **BTVPUR AlSap 2-4** (EMEA/V/C/000139/R/0006), and agreed that the authorisation should now be indefinite. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.

5.5 Pharmacovigilance – PSURs and SARs

- 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 Tick Plus (EMEA/V/C/002234)	01.08.2014 – 31.01.2015
ECOPORC SHIGA (EMEA/V/C/002588)	01.08.2014 – 31.01.2015
Emdocam (EMEA/V/C/002283)	01.03.2014 – 28.02.2015
Equilis Te (EMEA/V/C/000093)	01.02.2014 – 31.01.2015
Kexxtone (EMEA/V/C/002235)	01.08.2014 – 31.02.2015
Nobilis Influenza H5N2 (EMEA/V/C/000118)	01.03.2014 – 28.02.2015
ProZinc (EMEA/V/C/002634)	01.08.2014 – 31.01.2015
Stronghold (EMEA/V/C/000050)	01.02.2012 – 31.01.2015
Suprelorin (EMEA/V/C/000109)	01.02.2014 – 31.01.2015
Suvaxyn PCV (EMEA/V/C/000149)	01.08.2014 – 31.01.2015
Ypozane (EMEA/V/C/000112)	01.02.2012 – 31.01.2015
ZULVAC 1 Bovis (EMEA/V/C/002334)	01.09.2014 – 28.02.2015
ZULVAC 1 Ovis (EMEA/V/C/002335)	01.09.2014 – 28.02.2015
ZULVAC 8 Bovis (EMEA/V/C/000145)	01.08.2014 – 31.01.2015
ZULVAC 8 Ovis (EMEA/V/C/000147)	01.08.2014 – 31.01.2015

- 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 nominated B. Zemann as advisor to support the EU expert in relation to the review of VICH guideline 23 on safety studies for veterinary drug residues in human food: genotoxicity studies.
- The Committee endorsed the EU comments on the discussion paper of the VICH Task Force on anthelmintic guidelines.

6.2 Codex Alimentarius

- There were no items for discussion.

6.3 Other EU bodies and international organisations

- The Committee discussed the request from EFSA for cooperation on establishing "Reference Points for Actions (RPAs) for non-allowed pharmacologically active substances present in food of animal origin" in relation to malachite green, and agreed that E. Lander Persson will be the expert representing CVMP.
- The Committee was informed of the joint EFSA/FAO/WHO stakeholder meeting and scientific workshop on revisiting the International Estimate of Short-Term Intake (IESTI), to be held on 7-9 September 2015 in Geneva, Switzerland.

The following documents were circulated for information:

- Status of active VICH guidelines and action plan of CVMP and working parties;
- Externally organized projects and events of potential relevance to the safety assessment and assessment methodologies.

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 2 June 2015, and noted the agenda of the meeting.

7.2 Quality Working Party (QWP)

- The Committee adopted the reflection paper on the use of cocrystals of active substances in medicinal products, and the overview of comments following the close of the public consultation.

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 21-22 May 2015, and noted the agenda of the meeting.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- The Committee adopted the concept paper on the testing strategy and risk assessment for plants in Phase II of the environmental risk assessment for veterinary medicinal products (EMA/CVMP/ERA/698394/2014) for a 3-month period of public consultation.

7.5 Efficacy Working Party (EWP-V)

7.6 Antimicrobials Working Party (AWP)

- The Committee received a verbal report from the chair of the AWP on the meeting held on 12-13 May 2015, and noted the agenda of the meeting.
- The Committee appointed D. Bouchard, C. Schwarz and A. L. Wester as new members of the AWP.

7.7 Immunologicals Working Party (IWP)

7.8 Pharmacovigilance Working Party (PhVWP-V)

- The Committee adopted the revised CVMP combined VeDDRA list of clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products (EMA/CVMP/90241/2009) and the list of changes. The implementation of the VeDDRA list in EudraVigilance Veterinary is scheduled for 1 October 2015.
- The Committee adopted the revised guidance notes on the use of VeDDRA terminology for reporting suspected adverse reactions in animals and humans.
- The Committee received a verbal report from the chair of the PhVWP-V on the meeting held on 25-26 May 2015, and noted the agenda and the draft minutes of the meeting.

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 was informed of the HMPC concept paper on the revision of the guideline on quality of herbal medicinal products / traditional herbal medicinal products and the HMPC concept paper on the revision of the guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products.

The following documents were circulated for information:

- Minutes of the SAWP-V meeting held on 5 May 2015;
- Final agenda for the 75th QWP meeting held on 26-28 May 2015;
- Final minutes of the EWP meeting held on 3 February 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.

- The Committee agreed to include **monophosphoryl lipid A (MPL)** as a new entry in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 under the heading of excipients, following the request from the applicant.
- The Committee adopted the revised list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 (EMA/CVMP/519714/2009–Rev.29).

8.2 Environmental risk assessment

8.3 Antimicrobial resistance

- The Committee discussed the request from the European Commission for a joint EFSA and 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, and appointed the CVMP and AWP members for the joint (EMA/EFSA) ad hoc expert group for the preparation of the advice.
- The Committee was informed that the call for the collection on sales data for veterinary antimicrobial agents in the EU in 2014 has been launched under the ESVAC project.

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.

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 in April and May 2015, and noted the draft minutes of the meeting held on 7-8 May 2015 as well as the draft agenda of the meeting held on 4-5 June 2015.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee discussed the draft of the EU Medicines Agencies Network Strategy to 2020.
- The Committee received a presentation on the experience gained on multinational assessment teams (MNATs) and discussed various aspects and points for further consideration on MNATs.
- The Committee received a verbal report from the chair of the Strategic Planning Group on the meeting held on 3 June 2015 and noted the agenda of the meeting; the minutes of the meeting held on 11 March 2015 were also noted.
- The Committee noted the table of actions following the May 2015 CVMP meeting.

13. LEGISLATION

- There were no items for discussion.

14. ANY OTHER BUSINESS

- Upon the completion of the June 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 June 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	Cannot act as rapporteur or peer reviewer for:	• 3.3 Ingelvac CircoFLEX (EMEA/V/C/000126/II/0019) • 3.3 Ingelvac CircoFLEX (EMEA/V/C/000126/II/0020) • 5.5 ProZinc
BE	Bruno Urbain	Full involvement	
BG	Emil Kozhuharov	Full involvement	
CZ	Jiří Bureš	Full involvement	
DE	Cornelia Ibrahim	Full involvement	
EE	Toomas Tiirats	Full involvement	
EL	Ioannis Malemis	Full involvement	
ES	Cristina Muñoz Madero	Full involvement	
FI	Martti Nevalainen	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	
SE	Eva Lander Persson	Full involvement	
SI	Stane Srčič	Cannot act as rapporteur or peer reviewer for:	• 2.5 EMEA/V/C/002804/0000
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	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
DE	Esther Werner	Full involvement	
FR	Jean-Claude Rouby	Full involvement	
HR	Frane Božić	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
NL	Peter Hekman	Full involvement	
PL	Anna Wachnik-Święcicka	Cannot act as rapporteur or peer reviewer for:	• 3.3 Advocate (EMEA/V/C/000076/II/0026/G)
RO	Simona Sturzu	Full involvement	
SE	Frida Hasslung Wikström	Full involvement	
UK	Anna-Maria Brady	Full involvement	
NO	Tonje Høy	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
* Experts were only evaluated against the topics they have been invited to talk about.			
DE	Silke Hickmann *(remotely)*	Full involvement	
FR	Nathalie Bridoux *(remotely)*	Full involvement	
FR	Sylvie Louet	Full involvement	
NL	Engeline van Duijkeren *(remotely)*	Full involvement	
UK	Sharon Reynolds	Full involvement	

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