8 April 2014
EMA/CVMP/212566/2014
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 11-13 March 2014 meeting

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

Note on access to documents

Some documents mentioned in the minutes cannot be released at present following a request for access to documents under Regulation (EC) No 1049/2001 as 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).

1. Adoption of the Agenda

The Committee adopted the agenda with no modifications. The Chair welcomed the new CVMP member from Cyprus, A. Michaelidou-Patsia.

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 March 2014 meeting. In accordance with the Agency's revised policy and procedure on the handling of conflicts of interests, participants in this meeting were asked to declare any conflict of 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 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 18 members were needed for an absolute majority.

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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 present time as it is deemed to be commercially confidential.

4. Adoption of the minutes of the previous meeting

The minutes of the February 2014 meeting were adopted with no amendments.

5. Topics for rapporteurs' meetings, break-out sessions and oral explanations

Information relating to briefing meetings taking place with applicants cannot be released at 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 eggs for a substance (EMEA/V/MRL/003044/EXT/0005), following discussion of the rapporteur's assessment report, the EU-RL report and two peer review reports.
- The Committee discussed the rapporteur's assessment report for the modification of MRLs for bovine and ovine species for a substance (EMEA/V/MRL/003071/MODF/0002).
- The Committee discussed the draft list of outstanding issues, the rapporteur's assessment of the responses to the list of questions, the rapporteur's EPMAR and a peer review report for the extension of MRLs to sheep for a substance (EMEA/V/MRL/003262/EXT/0003), and agreed that an oral explanation would not be necessary but that the applicant should address the remaining outstanding issue in writing.

A.1.2 Recommendations for extrapolation of established MRLs

- There were no items for discussion.

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 (31 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Versican Plus DHPPi/L4** (EMEA/V/C/003678/0000), recommending the granting of a marketing authorisation. The product is a live and inactivated viral and bacterial vaccine for dogs. 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 **Versican Plus DHPPi/L4R** (EMEA/V/C/002759/0000), recommending the granting of a marketing authorisation. The product is a live and inactivated viral and bacterial vaccine for dogs. The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP. 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 type II variation for **Profender** (EMEA/V/C/000097/II/0024), to change the legal status of Profender spot-on solution for cats from prescription to non-prescription.
- The Committee adopted by consensus (30 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a grouped type IB variation under worksharing procedure for **EQUIOXX and Previcox** (EMEA/V/C/000142/WS0474/0012/G and EMEA/V/C/000082/WS0474/0037/G), recommending the variation of the marketing authorisations. The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP.
- 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 variation for **AFTOVAXPUR DOE** (EMEA/V/C/002292/II/0001), recommending the variation of the marketing authorisation to add a new virus antigen strain. The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication.

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 an extension application for **Rheumocam** (EMEA/V/C/000121/X/0015), relating to the inclusion of a new pharmaceutical form and new strength for horses. 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 for a new product (EMEA/V/C/003796/0000), a viral and bacterial vaccine for pigs. 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 heard an oral explanation from the marketing authorisation holder, Vet-Agro Trading Sp. z.o.o., and discussed the rapporteur's assessment report including the co-rapporteur's critique for the re-examination of the CVMP opinion on the referral procedure 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). The Committee noted four peer review reports. The adoption of the final opinion is foreseen for the April 2014 meeting of the Committee.
- The Committee considered the notification from the reference Member State, Spain, for a referral procedure for **AQUACOLI 2 000 000 IU/ml, Solution for use in drinking water or milk**. The Committee did not accept the referral procedure under Article 33(4) of Directive 2001/82/EC, on the grounds that the question to the CVMP within the referral notification is a regulatory matter and consequently not appropriate for consideration by the CVMP.

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

- The Committee discussed the rapporteur's assessment report with the co-rapporteur's comments to the responses to the list of outstanding issues, the updated rapporteur's assessment report following the responses to the list of outstanding issues and the draft product information for the referral procedure for **Linco-Spectin 100 and its associated names** (EMEA/V/A/088). The Committee noted a peer review report and written comments from a CVMP member. The Committee agreed that no oral explanation would be necessary. The adoption of the opinion is foreseen for the April 2014 meeting of the Committee.

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

- The Committee discussed the rapporteur's assessment of the responses to the list of outstanding issues, the updated rapporteur's assessment report following the responses to the list of outstanding issues and the co-rapporteur's comments for the referral procedure for **Baytril 2.5% injectable, Baytril 5% injectable, Baytril 10% injectable and associated names, and related veterinary medicinal products authorised under Article 13 of Directive 2001/82/EC** (EMEA/V/A/097). The Committee agreed that no oral explanation would be necessary. The adoption of the opinion is foreseen for the April 2014 meeting of the Committee.

- The Committee considered the notification from Denmark for a referral procedure under Article 35 of Directive 2001/82/EC for **all veterinary medicinal products containing gentamicin presented as solutions for injection to be administered to horses**, concerning the indications, dosing regimen and target animal safety of the products. The Committee agreed to start a referral procedure (EMEA/V/A/104) under Article 35 and appointed K. Baptiste as rapporteur and C. Muñoz Madero as co-rapporteur for the procedure. The Committee adopted a list of questions for the applicants/marketing authorisation holders and a timetable. The Committee noted the discussion document on the background and issues for referral, and the list of products concerned.

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 background information for publication for the Article 33(4) referral for **Norbonex 5 mg/ml Pour-On Solution for Beef and Dairy Cattle** (EMEA/V/A/098).

- The Committee noted the background information for publication for the Article 35 referral for **all veterinary medicinal products containing enrofloxacin to be administered via the drinking water to chickens and/or turkeys** (EMEA/V/A/089).

B. MARKETING AUTHORISATION APPLICATIONS FOR DISCUSSION AND DECISION

- The Committee received an oral explanation concerning a marketing authorisation application for a new product (EMEA/V/C/002746/0000), an ectoparasiticide for cats. The Committee discussed the joint rapporteurs' assessment of the responses to the list of outstanding issues, the joint rapporteurs' assessment of the responses to the list of outstanding issues on the restricted part of the ASMF, the updated scientific overview and benefit-risk assessment and the draft product information. An opinion is foreseen for the April 2014 meeting of the Committee.
- The Committee adopted the updated scientific overview and benefit-risk assessment including the list of outstanding issues for a new product (EMEA/V/C/002757/0000), a viral vaccine for pigs. The Committee agreed that an oral explanation would be necessary. The Committee discussed the draft product information and noted a peer review report and the comments received from CVMP members.
- The Committee adopted the updated scientific overview and benefit-risk assessment including the list of outstanding issues for a new product (EMEA/V/C/002762/0000), a viral and bacterial vaccine for pigs. The Committee agreed that an oral explanation would not be necessary. The Committee discussed the draft product information and noted the peer review report and the comments received from CVMP members.
- The Committee adopted the updated scientific overview and benefit-risk assessment including the list of outstanding issues for a new product (EMEA/V/C/002761/0000), a viral vaccine for pigs, and agreed that an oral explanation would not be necessary. The Committee discussed the draft product information and noted the peer review report and the comments received from CVMP members.
- The Committee adopted the updated scientific overview and benefit-risk assessment including the list of outstanding issues for a marketing authorisation application for a new product (EMEA/V/C/003681/0000), a viral vaccine for dogs. The Committee discussed the draft product information.
- The Committee adopted the updated scientific overview and benefit-risk assessment including the list of outstanding issues for a marketing authorisation application for a new product (EMEA/V/C/003679/0000), a viral vaccine for dogs. The Committee discussed the draft product information.
- The Committee adopted the list of outstanding issues for a new product (EMEA/V/C/003753/0000), an otological product for dogs. The Committee agreed that an oral explanation would not be necessary. The Committee discussed the draft product information and the joint rapporteur's assessment of the responses to the list of questions on the ASMF restricted parts, and noted a peer review report and the comments received from CVMP members.
- The Committee endorsed the extension of the time frame for the submission of the responses to the list of questions for a marketing authorisation application for a new product (EMEA/V/C/002590), a hormonal product for cattle, following a request from the applicant.

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

- There were no items for discussion.

C.3 Product anniversary list

- The Committee noted the product anniversary list for the period between 14.02.2014 - 13.03.2014:

Product	Period
Activyl (EMEA/V/C/000163)	18.02.2013 – 17.02.2014
Cimalgex (EMEA/V/C/000162)	18.02.2013 – 17.02.2014
Econor (EMEA/V/C/000042)	12.03.2013 – 11.03.2014
Ibraxion (EMEA/V/C/000051)	09.03.2013 – 08.03.2014
Melosus (EMEA/V/C/002001)	21.02.2013 – 20.02.2014
Novem (EMEA/V/C/000086)	02.03.2013 – 01.03.2014
Pexion (EMEA/V/C/002543)	25.02.2013 – 24.02.2014
Porcilis Porcoli (EMEA/V/C/000024)	29.02.2013 – 28.02.2014
ProteqFlu (EMEA/V/C/000073)	06.03.2013 – 05.03.2014
ProteqFlu-Te (EMEA/V/C/000074)	06.03.2013 – 05.03.2014
Purevax Rabies (EMEA/V/C/002003)	18.02.2013 – 17.02.2014
Purevax RC (EMEA/V/C/000091)	23.02.2013 – 22.02.2014
Purevax RCCh (EMEA/V/C/000092)	23.02.2013 – 22.02.2014
Purevax RCP (EMEA/V/C/000090)	23.02.2013 – 22.02.2014
Purevax RCP FeIV (EMEA/V/C/000089)	23.02.2013 – 22.02.2014
Purevax RCPCh (EMEA/V/C/000088)	23.02.2013 – 22.02.2014
Purevax RCPCh FeIV (EMEA/V/C/000085)	23.02.2013 – 22.02.2014
RevitaCAM (EMEA/V/C/002379)	23.02.2013 – 22.02.2014
Zulvac 1+8 Bovis (EMEA/V/C/002473)	08.03.2013 – 07.03.2014

C.4 Renewals of marketing authorisations

- The Committee adopted a list of outstanding issues for the renewal of **LEUCOGEN** (EMEA/V/C/000144/R/0002).
- The Committee adopted a list of outstanding issues for the renewal of **LEUCOFELIGEN FeLV/RCP** (EMEA/V/C/000143/R/0003).

C.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
Aivlosin (EMEA/V/C/000083)	01.10.2012-30.09.2013
Comfortis (EMEA/V/C/002233)	01.04.2013-30.09.2013
Incurin (EMEA/V/C/000047)	01.10.2010-30.09.2013
Econor (EMEA/V/C/000042)	01.10.2011-30.09.2013
Nobilis IB4-91 (EMEA/V/C/000036)	01.10.2010-30.09.2013
Procox (EMEA/V/C/002006)	01.05.2013-31.10.2013
Purevax FeLV (EMEA/V/C/000056)	01.11.2010-31.10.2013
Purevax Rabies (EMEA/V/C/002003)	01.03.2013-31.08.2013
Recuvyra (EMEA/V/C/002239)	01.05.2013-31.10.2013
Respiporc FLU3 (EMEA/V/C/000153)	01.08.2012-31.07.2013
Vaxxitek HVT + IBD (EMEA/V/C/000065)	01.03.2013-31.08.2013
Veraflox (EMEA/V/C/000159)	01.05.2013-31.10.2013

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

C.6 Supervisions and sanctions

- There were no items for discussion.

The following document was circulated for information:

- Status report on periodic safety update reports (PSURs) for centrally authorised veterinary medicinal products.

D. CO-OPERATION WITH OTHER EU OR INTERNATIONAL BODIES

D.1 VICH

- The Committee endorsed the EU comments on the revised draft VICH GL23(R) on genotoxicity testing at step 5.
- The Committee received an update from the CVMP subgroup regarding the EU input to the VICH task force to consider developing a guideline on combination products.
- The Committee discussed the proposal from the FDA for the topics and time schedule of the task force on the revision of the VICH anthelmintics guidelines.

D.2 Codex Alimentarius

- There were no items for discussion.

D.3 Other EU bodies and international organisations

- There were no items for discussion.

The following document was circulated for information:

- Status of active VICH Guidelines and action plan of CVMP and working parties.

E. WORKING PARTIES AND SCIENTIFIC ADVISORY GROUPS

E.1 Scientific Advice Working Party (SAWP-V)

Information relating to SAWP-V procedures cannot be released at present time as it is deemed to be commercially confidential.

- The Committee received a verbal report from the chair of the SAWP on the meeting held on 11 March 2014, and discussed the agenda of the meeting. The Committee was informed that a call for nominations for two additional members joining the SAWP-V would be circulated by the secretariat. The profile of experts should focus on clinical efficacy and new technologies / biotechnology areas.

E.2 Pharmacovigilance Working Party (PhVWP)

- The Committee endorsed the veterinary pharmacovigilance public bulletin 2013.

E.3 Efficacy Working Party (EWP)

- The Committee received a verbal report from the chair of the EWP on the meeting held on 18-19 February 2014 and discussed the draft minutes of the meeting.
- The Committee adopted the revised work programme (EMA/CVMP/EWP/515660/2013-Rev.1) to include information on the work regarding new VICH task forces on the development of a guideline on combination products.
- The Committee re-elected Fredrik Hultén as vice-chair of the EWP for a further 3-year mandate.
- The Committee discussed a new draft question and answer document on the CVMP fixed combinations guideline. The adoption of the document is foreseen for the April 2014 meeting of the Committee.
- The Committee discussed a new draft reflection paper on anthelmintic resistance. The adoption of the document is foreseen for the April 2014 meeting of the Committee.

E.4 Safety Working Party (SWP)

- The Committee received a verbal report from the vice-chair of the SWP on the meeting held on 20-21 February 2014 and discussed the draft agenda of the meeting.
- The Committee adopted the draft concept paper on user risk assessment of topically applied products for a 3-month period of public consultation (EMA/CVMP/SWP/92311/2014).
- The Committee adopted the revised 2014 work programme (EMA/CVMP/SWP/529692/2013-Rev.1).
- The Committee discussed the comments received in relation to the concept paper proposing a review of the Note for guidance on the approach towards harmonisation of withdrawal periods to reconsider treatment of residues below the LOQ.

E.5 Immunologicals Working Party (IWP)

- There were no items for discussion.

E.6 Quality Working Party (QWP)

- The Committee adopted a template and guidance notes for the Qualified Person's declaration concerning GMP compliance of the active substance and verification of its supply chain (EMEA/CHMP/CVMP/QWP/80360/2014) following the close of the public consultation. The Committee noted the overview of the comments received (EMA/CHMP/CVMP/QWP/649578/2013).
- The Committee adopted the revised guideline on the use of near infrared spectroscopy (NIRS) by the pharmaceutical industry and the data requirements for new submissions and variations (EMEA/CHMP/CVMP/QWP/17760/2009-Rev.1), the addendum (EMA/CHMP/CVMP/QWP/63699/2014) and the overview of comments (EMA/CHMP/CVMP/QWP/63698/2014).
- The Committee adopted a concept paper on the establishment of a guideline on the selection of sterilisation processes for drug products (EMA/CHMP/CVMP/QWP/128000/2014) for a 3-month period of public consultation.
- The Committee adopted a question and answer document on limits for unspecified impurities in veterinary medicinal products in marketing authorisations (EMA/CVMP/QWP/76848/2014).
- The Committee adopted a question and answer document on differences in the stability of generics versus the innovator product (EMA/CHMP/CVMP/QWP/95328/2014).
- The Committee discussed the expression of strength. The adoption of the document is foreseen at the April 2014 meeting of the Committee.
- The Committee discussed a question and answer document on the acceptability of two different appearances for a single strength tablet in a single marketing authorisation. The adoption of the document is foreseen at the April 2014 meeting of the Committee.
- The Committee discussed a question and answer document on particles originating from the container-closure system. The document has been adopted by CHMP and is due to be adopted by CVMP at the April 2014 meeting of the Committee.

E.7 Environmental Risk Assessment Working Party (ERAWP)

- The Committee adopted the CVMP mandate for considerations on the interpretation of the CVMP/VICH guideline on environmental impact assessment for veterinary medicinal products - Phase I (VICH GL6) with regard to the provisions in respect to exceptional deviation from the Phase I requirements ('however clause') and tailored risk assessment.
- The Committee received a verbal update on the progress of the revision of the draft PBT guideline following the closure of the public consultation and consideration of the comments received.

E.8 Antimicrobials Working Party (AWP)

- The Committee adopted the overview of comments received on the reflection paper on the risk of antimicrobial resistance transfer from companion animals and endorsed the task to the AWP to revise the reflection paper.

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

- The Committee adopted the revised 2013-2014 work programme, updated to include the development of guidance on product specific validation of 3Rs tests used for batch release purposes (EMA/CHMP/CVMP/JEG-3Rs/443879/2012-Rev.1).

- The Committee noted the draft concept paper proposing the development of a guideline on transferring methods validated in collaborative trials to a product/laboratory specific context.
- The Committee noted the presentation on JEG 3Rs to be given by E.-M. Vestergaard at an EPAA meeting on 21 March 2014.

E.10 Other working party issues

The following documents were circulated for information:

- Minutes of the Scientific Advice Working Party meeting held on 11 February 2014.
- Table of Decisions following the 70th Joint CHMP/CVMP QWP meeting held on 4-6 February 2014.

F. SAFETY OF VETERINARY MEDICINES AND RESIDUES

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

Information relating to letters of intent for new MRL applications cannot be released at 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 on critical issues related to centralised procedures cannot be released at 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 present time as it is deemed to be commercially confidential.

F.4 Antimicrobial resistance

- The Committee received a verbal report from the secretariat on the Antimicrobial advice ad hoc expert group (AMEG) meeting held on 27 February 2014 and on the meeting with stakeholders held on 28 February 2014 regarding the request from the European Commission for advice on the impact on public and animal health of the use of antibiotics in animals, and noted the conclusions of the meeting with the stakeholders.

F.5 Pharmacovigilance

- There were no items for discussion.

G. APPLICATIONS FOR GRANTING OF COMMUNITY MARKETING AUTHORISATIONS

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

Information concerning letters of intents and eligibility requests relating to community marketing authorisations cannot be released at 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.

G.3 Regulatory issues

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

The Committee endorsed the EPAR module 6 scientific discussion for the following products:

- **Vectra 3D** (EMEA/V/C/002555) on the initial marketing authorisation.
- **BROADLINE** (EMEA/V/C/002700) on the initial marketing authorisation.
- **Bravecto** (EMEA/V/C/002526) on the initial marketing authorisation.
- **NexGard** (EMEA/V/C/002729) on the initial marketing authorisation.
- **Contacera** (EMEA/V/C/002612/X/0002) concerning the extension to include meloxicam 15 mg/ml new pharmaceutical form for horses.

H. AVAILABILITY OF MEDICINES AND MUMS CLASSIFICATION

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

- The Committee endorsed the 4th annual report on veterinary MUMS/limited market for the year 2013.
- The Committee endorsed a clarification note concerning the financial incentives applicable to horses under the current MUMS/limited market policy (EMA/429080/2009-Rev.1). The clarification will be published as part of the question and answer document (EMEA/CVMP/370663/2009) on guidance for applicants requesting MUMS classification of products.
- The Committee noted the project management plan for the ongoing revision of the MUMS policy.

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

- The Committee received a verbal report from the chair of CMDv for the meetings held on 16-17 January and 13-14 February 2014, and noted the draft minutes of the February meeting and the draft agenda of the meeting held on 13-14 March 2014.

J. ORGANISATIONAL MATTERS

- The Committee adopted the revised CVMP work plan.
- The Committee noted the programme of the EMA/IFAH-Europe Info Day 2014 to be held on 13-14 March 2014.
- The Committee noted the CVMP Chair's presentation on the CVMP work plan and the WPs for the 2014 - EMA/IFAH-Europe Info Day, London 13-14 March 2014.
- The Committee received a presentation and discussed the recent procedural changes regarding the centralised procedure and their implications.

- The scheduled information session on the assessment procedure for new applications was deferred to the April meeting.
- The Committee noted a CHMP initiative concerning multinational assessment teams for future consideration by the CVMP. A presentation will be given during the April 2014 meeting of the Committee.
- The Committee noted the Annual Report from the SME Office 2013 – Focus on Veterinary SMEs.
- The Committee received an updated presentation on the Agency's move to its new premises in July 2014.

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 including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the March 2014 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	Damyan Iliev	Full involvement	
CY	Alia Michaelidou Patsia	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	Irmeli Happonen	Full involvement	
FR	Michael Holzhauser-Alberti	Full involvement	
HR	Ljiljana Markuš-Cizelj	No part in discussions, final deliberations and voting as appropriate, and cannot act as rapporteur for:	• A.2.4 product (EMEA/V/C/003796) • C.5 Incurin, Nobilis IB4-91 • G.1 one product • G.4 Bravecto
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 as appropriate, and cannot act as rapporteur for:	• A.2.2 AFTOVAXPUR DOE (EMEA/V/C/002292/II/0001) • A.2.2 EQUIOXX and Previcox (EMEA/V/C/000142/WS0474/0012/G and EMEA/V/C/000082/WS0474/0037/G) • A.3.1 Fiprex (EMEA/V/A/099) • A.3.3 Baytril (EMEA/V/A/097) • B. product (EMEA/V/C/003753) • C.5 Econor, Purevax FeLV, Purevax Rabies, Vaxxitek HVT + IBD • G.4 NexGard, BROADLINE
LV	Zanda Auce	Full involvement	
PL	Ewa Augustynowicz	Full involvement	
PT	João Duarte Da Silva	Full involvement	

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
RO	Lollita Taban	Full involvement	
SI	Stane Srčič	Cannot act as rapporteur or peer reviewer for:	• A.3.3 Gentamicin (EMEA/V/A/104)
SK	Judita Hederova	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	Cannot act as rapporteur or peer reviewer for:	• A.3.3 Gentamicin (EMEA/V/A/104)
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
BE	Frédéric Klein	Full involvement	
DE	Esther Werner	Full involvement	
DK	Merete Blixenkrone-Møller	Full involvement	
ES	Consuelo Rubio Montejano	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.3.3 Baytril (EMEA/V/A/097) • C.5 Procox, Veraflox • H. one product
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			
BE	Alan Fauconnier	Full involvement	
BE	Sandy Vermout *(remotely)*	Full involvement	
DE	Sabine Kalweit *(remotely)*	Full involvement	
DE	Stefan Scheid *(remotely)*	Full involvement	
DK	Trine Jensen *(remotely)*	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
DK	Nanna Aaby Kruse	Full involvement	
DK	Niels Kyvsgaard *(remotely)*	Full involvement	
ES	Raul Belmar Liberato *(remotely)*	Full involvement	
ES	Maria Dominguez Nicolas *(remotely)*	Full involvement	
ES	Aranzazu Gonzalez Canga *(remotely)*	Full involvement	
ES	Amparo Lopez Rivera *(remotely)*	Full involvement	
NL	Piet-Hein Overhaus *(remotely)*	Full involvement	
UK	Katharine Healey *(remotely)*	Full involvement	
UK	Sean Jones	Full involvement	
UK	Noel Joseph	Full involvement	

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

Observer from the European Commission	
Present	

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