6 May 2014
EMA/CVMP/275244/2014
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 8-10 April 2014 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).

1. Adoption of the Agenda

The Committee adopted the agenda with no modifications. The Chair welcomed the new Commission representative.

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 April 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.

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.

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4. Adoption of the minutes of the previous meeting

The minutes of the March 2014 meeting were adopted with a minor amendment.

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 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 by consensus (31 members present of those eligible to vote) the CVMP opinion including the EPMAR and the CVMP assessment report recommending the modification of the current entry in Table 1 (Allowed substances) of the Annex to Commission Regulation (EU) No 37/2010 for **barium selenate** (EMEA/V/MRL/003071/MODF/0002), further to a request from Germany under Article 11 of Regulation (EC) No 470/2009. The recommendation restricts the use of the substance to non-injectable administration. The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted two peer review reports and the comments received from CVMP members.
- The Committee discussed the rapporteur's assessment report with the co-rapporteur's critique for the establishment of MRLs in equidae for a substance (EMEA/V/MRL/002860/FULL/0002), the EU-RL report, two peer review reports and the comments received from CVMP members. The Committee concluded that there were no outstanding issues and the opinion is now foreseen to be adopted at the May 2014 meeting of the Committee.
- The Committee adopted the CVMP scientific overview and list of questions for the establishment of MRLs in bovine species for a substance (EMEA/V/MRL/003915/FULL/0001), and discussed the rapporteur's assessment report with the co-rapporteur's critique, the EU-RL report, two peer review reports and the comments received from CVMP members.

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 **Vectra Felis** (EMEA/V/C/002746/0000), recommending the granting of a marketing authorisation. The product is a new ectoparasiticide containing dinotefuran and pyriproxyfen for cats. 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 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 **RESPIPORC FLU3** (EMEA/V/C/000153/II/0005), recommending the variation of the marketing authorisation. The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP.

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, the lists of questions on the applicant's and the restricted parts of the ASMF, and agreed comments on the draft product information for a new cardiovascular product (EMEA/V/C/002804/0000) for dogs. 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 for a new product (EMEA/V/C/002781/0000), a viral vaccine for cattle and sheep. The Committee noted two peer review reports 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 majority (21 members in favour out of the 31 members present of those eligible to vote) the final CVMP opinion and the final CVMP assessment report following the re-examination for 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), concluding that the recommendations included in the CVMP opinion of 11 December 2013 should be maintained, recommending the refusal of the granting of the marketing authorisations and the suspension of the existing marketing authorisations of the concerned products. A. Tsigouri, L. Markuš-Cizelj, S. Spiteri, P. Hekman, I. Lindner, A. Wachnik-Święcicka, S. Srčič, B. Kolar, D. Iliev, and J. Bureš signed a divergent position not supporting the aforementioned recommendation. The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP.

A.3.2 Article 34 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 referral procedure for **Linco-Spectin 100 and its associated names** (EMEA/V/A/088), recommending the harmonisation of the product information for the concerned products. The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP.

- The Committee adopted by majority (27 members in favour out of the 31 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for the referral procedure for **Baytril 2.5% injectable, Baytril 5% injectable and Baytril 10% injectable and their associated names** (EMEA/V/A/091), recommending the harmonisation of the product information for the concerned products. M. Holzhauser-Alberti, E-M. Vestergaard, K. Baptiste and I. Happonen signed a divergent position regarding the conclusions on the

target species rabbits. The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP.

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

- The Committee adopted by majority (27 members in favour out of the 31 present of those eligible to vote) the CVMP opinion and the CVMP assessment report 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), recommending changes to the product information of the concerned products related to the harmonisation of the indications, posology and withdrawal periods. M. Holzhauser-Alberti, E-M. Vestergaard, K. Baptiste and I. Happonen signed a divergent position regarding the conclusions on the target species rabbits. The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee discussed the revised rapporteur's assessment report including the co-rapporteur's critique following comments from the applicants and marketing authorisation holders 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 adoption of the CVMP opinion and assessment report is foreseen for the May 2014 meeting of the Committee.
- The Committee adopted a list of questions to the Antimicrobials Working Party and a list of questions to the Efficacy Working Party for the referral procedure for **all veterinary medicinal products containing gentamicin presented as solutions for injection to be administered to horses** (EMEA/V/A/104).

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

- The Committee adopted a revised timetable for the referral procedure for **lidocaine** (EMEA/V/A/092).

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 referral procedure for long-acting formulations for injection containing barium selenate for all food producing species (EMEA/V/A/077).

B. MARKETING AUTHORISATION APPLICATIONS FOR DISCUSSION AND DECISION

- 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/003680/0000), a bacterial vaccine for dogs. The Committee discussed the draft product information and noted two peer review reports 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/003683/0000), a viral and bacterial vaccine for dogs. The Committee discussed the draft product information and noted two peer review reports 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/003682/0000), a viral and bacterial vaccine for dogs. The Committee discussed the draft product information and noted two peer review reports 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/002802/0000), a viral vaccine for chickens. The Committee discussed the draft product information and noted two peer review reports 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 an extension application for **DRAXXIN** (EMEA/V/C/000077/X/0026), to add a new strength for pigs. 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/003703/0000), a viral vaccine for cattle. The Committee discussed the draft product information and noted two peer review reports 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/003703/0000), a hormonal preparation for cats. The Committee noted the draft product information and a peer review report, and agreed to invite the applicant for an oral explanation.
- The Committee adopted an amendment of the mandate of the ad-hoc expert group (AHEG) for a marketing authorisation application for a new product (EMEA/V/C/002390/0000), a vaccine for Atlantic salmon, to include an EFSA observer in the AHEG.

C. POST-AUTHORISATION ISSUES (EXCLUDING VARIATIONS)

C.1 General issues

- There were no items for discussion.

C.2 Post-authorisation measures to CVMP opinions on the granting of Community marketing authorisations and annual reassessments

- The Committee adopted the rapporteur's assessment report for **Zolvix** (EMEA/V/C/000154/18/0008/G).

- The Committee adopted the rapporteur's assessment report for **Bravecto** (EMEA/V/C/002526/0000).

C.3 Product anniversary list

- The Committee noted the product anniversary list for the period between 14.03.2014 – 10.04.2014:

Product	Period
Advocate (EMEA/V/C/000076)	02.04.2013 – 01.04.2014
BTVPUR Alsap 8 (EMEA/V/C/000146)	17.03.2013 – 16.03.2014
CaniLeish (EMEA/V/C/002232)	14.03.2013 – 13.03.2014
Clomicalm (EMEA/V/C/000039)	01.04.2013 – 31.03.2014
Ecoporc Shiga (EMEA/V/C/002588)	10.04.2013 – 09.04.2014
Eurican Herpes 205 (EMEA/V/C/000059)	26.03.2013 – 25.03.2014
Flexicam (EMEA/V/C/000102)	10.04.2013 – 09.04.2014
Incurin (EMEA/V/C/000047)	24.03.2013 – 23.03.2014
Locatim (EMEA/V/C/000041)	29.03.2013 – 28.03.2014
Rabigen SAG2 (EMEA/V/C/000043)	06.04.2013 – 05.04.2014
Zulvac 1+8 Ovis (EMEA/V/C/002251)	14.03.2013 – 13.03.2014

C.4 Renewals of marketing authorisations

- The Committee adopted by consensus (30 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for the renewal of **LEUCOFELIGEN FeLV/RCP** (EMEA/V/C/000143/R/0003). The Icelandic 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 the CVMP assessment report for the renewal of **LEUCOGEN** (EMEA/V/C/000144/R/0002). The Icelandic 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 (31 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for the renewal of **Suvaxyn PCV** (EMEA/V/C/000149/R/0016). The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP. It was agreed that a further renewal is required.
- The Committee adopted by consensus (30 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for the renewal of **Melovem** (EMEA/V/C/000152/R/0008). The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP. It was agreed that the authorisation should now be indefinite.

C.5 Pharmacovigilance – PSURs and SARs

- The Committee adopted the CVMP PSUR assessment report for **Comfortis** (EMEA/V/C/002233) for the period 11.02.11-31.03.13 and recommended amendments to the product information to add new adverse reactions.

- The Committee noted the final post approval surveillance study (PASS) protocol for **Trifexis** (EMA/V/C/002635) in dogs.
- 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)	12.09.2013-30.11.2013
BTVPUR AlSap 2-4 (EMEA/V/C/000139)	01.06.2013-30.11.2013
Certifect (EMEA/V/C/002002)	01.06.2013-30.11.2013
Equip WNV (EMEA/V/C/000137)	22.11.2012-21.11.2013
Improvac (EMEA/V/C/000136)	01.12.2012-30.11.2013
MS-H Vaccine (EMEA/V/C/000161)	01.10.2012-30.09.2013
Oncept IL-2 (EMEA/V/C/002562)	01.05.2013-30.11.2013
Palladia (EMEA/V/C/000150)	01.12.2012-30.11.2013
Porcilis ColiClos (EMEA/V/C/002011)	01.07.2013-31.12.2013
Porcilis Pesti (EMEA/V/C/000046)	10.12.2010-31.12.2013
Posatex (EMEA/V/C/000122)	01.10.2012-30.09.2013
TruScient (EMEA/V/C/002000)	01.07.2013-31.12.2013
Zuprevo (EMEA/V/C/002009)	01.10.2012-30.09.2013

- 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 revised draft guideline on study design recommendations for residue depletion studies in honey following the comments from the VICH EWG, and taking into account the comments received from SWP members, for circulation to the VICH EWG by the EU topic leader.
- The Committee endorsed the EU comments on the draft summary of discussion and proposal for actions for the Task Force on the draft concept paper for the revision of VICH Stability Guideline 3(R) to include climatic zones III and IV and noted the draft summary table of comments from the regions.
- The Committee endorsed the draft EU comments on the first topic for discussion for the VICH Task Force on the revision of the VICH Anthelmintics guidelines: adequacy of infection.

- The Committee endorsed the draft EU comments on pages 1 and 2 of the draft questionnaire of the VICH Task Force on Efficacy studies for combination products.

D.2 Codex Alimentarius

- There were no items for discussion.

D.3 Other EU bodies and international organisations

- The Committee endorsed the nomination of B. Kolar as CVMP representative to the workshop organised by the European Chemical Industry Council-Long Range Research Initiative (CEFIC-LRI) to take place on 24 September 2014 at the European Chemicals Agency (ECHA) to discuss recent scientific developments and assessment strategies in bioaccumulation.

The following documents were circulated for information:

- Status of active VICH guidelines and action plan of CVMP and working parties.
- Final minutes of 29th VICH Steering Committee, held in November 2013 in Auckland.

E. WORKING PARTIES AND SCIENTIFIC ADVISORY GROUPS

E.1 Scientific Advice Working Party (SAWP)

Information relating to SAWP 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 8 April 2014, and noted the agenda of the meeting.
- The Committee elected Gesine Hahn as a member of the SAWP-V.

E.2 Pharmacovigilance Working Party (PhVWP)

- The verbal report from the chair of the PhVWP on the meeting held on 25-26 March 2014 was deferred to the May 2014 CVMP meeting.

E.3 Efficacy Working Party (EWP)

- The Committee discussed the revised question and answer document on the CVMP fixed combinations guideline. The adoption of the document is foreseen for the May 2014 meeting of the Committee.
- The Committee adopted the reflection paper on anthelmintic resistance (EMA/CVMP/EWP/573536/2013) for a 3-month period of public consultation.

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 question and answer document on the acceptability of two different appearances for a single strength tablet in a single marketing authorisation.

- The Committee adopted the question and answer document on particles originating from the container-closure system.
- The Committee adopted a document on the expression of strength.

E.7 Environmental Risk Assessment Working Party (ERAWP)

- The Committee discussed the draft guideline on the assessment of persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances in veterinary medicinal products.

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 received a verbal report from the chair of the JEG 3Rs on the meeting held on 3 March 2014.

E.10 Other working party issues

- There were no items for discussion.

The following document was circulated for information:

- Minutes of the Scientific Advice Working Party meeting held on 11 March 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 notifications of intent for new MRL applications cannot be released at present time as it is deemed to be commercially confidential.

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.

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.

- The Committee considered the request for the inclusion of **di-polyethylene glycol-esters of oleic acid** 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.
- The secretariat informed the Committee that responses to the list of questions for four MRL procedures had been received and the opinions are foreseen to be adopted in the July meeting of the Committee. However with regard to one application, the rapporteur had agreed to aim for the adoption of the opinion in the June CVMP meeting.

F.4 Antimicrobial resistance

F.5 Pharmacovigilance

- There were no items for discussion.

The following documents were circulated for information:

- Scientific report of EFSA and ECDC: The European Union Summary Report on antimicrobial resistance in zoonotic and indicator bacteria from humans, animals and food in 2012.
- Publication in the Uppsala Journal of Medical Sciences 'Antibiotic resistance – consequences for animal health, welfare, and food production' B. Bengtsson and C. Greko.

G. APPLICATIONS FOR GRANTING OF COMMUNITY MARKETING AUTHORISATIONS

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

Information concerning notifications of intent 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 **Panacur AquaSol** (EMEA/V/C/002008/X/0003) concerning the extension to add a food-producing target animal species, chickens.
- The Committee endorsed the table on dossier requirements for applications for veterinary centralised marketing authorisations and MRLs.
- The Committee received an update on e-submission, including the update to the electronic application form and electronic submission of dossiers (including access to the e-submission gateway/Web client). The table of CVMP members' dossier requirements had been streamlined for improved clarity and to reflect the possibilities for applicants to use the Common European Submission Portal for those members able to receive submissions via this route.

The following documents were circulated for information:

- The Committee noted the EPAR module 6 scientific discussion for **Fungitraxx** (EMEA/V/C/002722) on the initial marketing authorisation.
- The Committee noted the EPAR module 6 scientific discussion for **Equisolon** (EMEA/V/C/002382) on the initial marketing authorisation.
- The Committee noted the EPAR module 6 scientific discussion for **Parvoduk** (EMEA/V/C/002740) on the initial marketing authorisation.

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.

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

- The Committee received a verbal report from the chair of CMDv on the meeting held on 13-14 March 2014 and noted the draft minutes of the March 2014 meeting and the draft agenda of the meeting held on 10-11 April 2014.
- The Committee noted that the CMDv meeting dates in May 2014 will be on 7-8 due to the EMA public holiday.

J. ORGANISATIONAL MATTERS

- The Committee discussed the draft agenda of the CVMP Interested Parties' meeting, to be held on 7 May 2014 at the EMA and the draft minutes of the previous meeting held on 15 May 2013.
- The Committee discussed the CHMP initiative concerning multinational assessment teams and concluded that it could be applied to CVMP procedures.
- The Committee reviewed the previously agreed recommendations for attending rapporteurs' meetings via Adobe Connect and agreed further recommendations for consideration by CVMP members and the secretariat in preparing and running rapporteurs' meetings.
- The Committee received a presentation on the revision of the pre-submission guidance – Questions and answers - on the Agency's website. The main changes concern the procedures and timelines for the notification of intended applications and appointment of rapporteur and co-rapporteur, the procedure for requests for eligibility for the centralised procedure, guidance regarding the Active Substance Master File (ASMF) procedures, new guidance on pre-submission meetings and the Innovation Task Force for use for veterinary medicines.
- The Committee noted the presentation on the upcoming move of the Agency.
- The Committee received a refreshers training on assessment of new product applications.

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 April 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**	
BE	Bruno Urbain	Full involvement	
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	
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:	• B. product (EMEA/V/C/002802) • B. product (EMEA/V/C/003703) • C.2 Bravecto • C.5 Porcilis ColiClos, Porcilis Pesti, Posatex, Zuprevo • G.3 one product • G.4 Panacur AquaSol
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.2.4 product (EMEA/V/C/002804) • A.3.3 Baytril (EMEA/V/A/097) • C.2 Zolvix • C.5 BTVPUR AlSap 2-4, CERTIFECT, Oncept IL-2 • G.3 one item • G.4 Parvoduk
LV	Zanda Auce	Full involvement	
MT	Stephen Spiteri	Full involvement	
PT	João Duarte Da Silva	Full involvement	
SE	Eva Lander Persson	Full involvement	
SI	Stane Srčič	Cannot act as rapporteur or peer reviewer for:	• A.2.4 product (EMEA/V/C/002804) • A.3.3 Gentamicin (EMEA/V/A/104)

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
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
AT	Ines Lindner	Full involvement	
BE	Frédéric Klein	Full involvement	
DE	Esther Werner	Full involvement	
EL	Angeliki Tsigouri	Full involvement	
ES	Consuelo Rubio Montejano	Full involvement	
NL	Peter Hekman	Full involvement	
PL	Anna Wachnik-Święcicka	Full involvement	
RO	Simona Sturzu	Full involvement	
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.			
DE	Stefan Scheid *(remotely)*	Full involvement	
DE	Anke Finnah *(remotely)*	Full involvement	
DK	Henrik Friberg-Johansen *(remotely)*	Full involvement	
DK	Niels Kyvsgaard *(remotely)*	Full involvement	
ES	Miguel Escribano Salazar *(remotely)*	Full involvement	
ES	Raul Belmar Liberato *(remotely)*	Full involvement	
ES	Maria Dominguez Nicolas	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
	(remotely)		
ES	Aranzazu Gonzalez Canga *(remotely)*	Full involvement	
ES	Amparo Lopez Rivera *(remotely)*	Full involvement	
ES	Rafael Ortega Huedo *(remotely)*	Full involvement	
FI	Outi Maki-Ikola *(remotely)*	Full involvement	
FR	Nathalie Bridoux *(remotely)*	Full involvement	
NL	Caroline Moermond *(remotely)*	Full involvement	
UK	Katherine Healey *(remotely)*	Full involvement	
UK	Sam Fletcher	Full involvement	
UK	Ralph Woodland	Full involvement	
UK	Javier Pozo *(remotely)*	Full involvement	

CVMP working parties and CMDv	Chair
AWP	Helen Jukes
ERAWP	Boris Kolar
EWP	Gesine Hahn
IWP and CMDv	Esther Werner
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