9 December 2014
EMA/CVMP/768792/2014
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 4-6 November 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).

i. Adoption of the Agenda

The Committee adopted the agenda with no modifications.

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

The attendance list was completed and conflicts of interests were identified for the November 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 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.

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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.

iv. Adoption of the minutes of the previous meeting

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

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 discussed the principles for the approach in respect to the review of the MRLs for **potassium selenate, sodium selenate and sodium selenite** (EMEA/V/MRL/003225/MODF/0002), and agreed that the existing MRL status should be maintained. A draft opinion reflecting this was adopted in principle. The Committee agreed that the rapporteurs would update the draft assessment report and EPMAR to reflect the discussion at the meeting and the formal documents would be circulated for adoption by written procedure, with the final opinion date being 4 December. The Committee noted a peer review report and the comments received from CVMP members.
- The Committee adopted by consensus (29 members present of those eligible to vote) the CVMP opinion, including the EPMAR and the CVMP assessment report, recommending the inclusion of **propyl 4-hydroxybenzoate and its sodium salt** for all food producing species in table 1 of the Annex to regulation 37/2010 with a "No MRL required" classification (EMEA/V/MRL/004039/FULL/0001). The Icelandic and Norwegian CVMP members 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 adopted by consensus (29 members present of those eligible to vote) the CVMP opinion, including the EPMAR and the CVMP assessment report, recommending the establishment of MRLs in chickens for **virginiamycin** (EMEA/V/MRL/003878/FULL/0001) and their extrapolation to poultry. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The Committee noted the report from the EU-RL, a peer review report and the comments received from CVMP members.

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 establishment of MRLs in caprine species, *Equidae*, fin fish and rabbits for a substance (EMEA/V/MRL/004047/FULL/0001), following discussion of the rapporteur's assessment report including the critique from the co-rapporteur and two peer review reports.

- The Committee received an update following the meeting held on 15 October 2014 between the EMA/CVMP, ECHA and EFSA representatives, concerning the review of the MRLs established in *salmonidae* for **diflubenzuron** (EMEA/V/MRL/003135/MODF/0003).

1.4 Re-examination of CVMP opinions

- There were no items for discussion.

1.5 Other issues

- The Committee addressed the request from the European Commission for clarification in relation to the CVMP opinion adopted for **tylvalosin** (EMEA/V/MRL/003044/EXTN/0005) at its July 2014 meeting.

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 **NEXGARD SPECTRA** (EMEA/V/C/003842/0000), recommending the granting of a marketing authorisation. The product is a new parasiticide for dogs, containing afoxolaner and milbemycin oxime in chewable tablets. 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 adopted the updated scientific overview and benefit-risk assessment including the list of outstanding issues for an extension application for **Metacam** (EMEA/V/C/000033/X/0107), to include a new strength for cattle and horses. The Committee agreed that an oral explanation would not be necessary. The Committee discussed the draft product information and noted the comments received from CVMP members.

- The Committee agreed that the information provided by the applicant in their presentation concerning an application for a new viral vaccine for sheep and cattle (EMEA/V/C/002781/0000), circulated prior to the meeting, had already satisfactorily addressed the Committee's concerns, and thus no further clarification was required at an oral explanation. The Committee discussed the draft product information and the rapporteurs' assessment of the responses to the list of outstanding issues. The adoption of the opinion is foreseen for the December 2014 CVMP meeting.

- The Committee heard an oral explanation from the applicant, concerning an application for a new haematological product for dogs (EMEA/V/C/002794/0000). The Committee discussed the draft product information and concurred with the rapporteurs' assessment of the responses to the list of outstanding issues. The adoption of the opinion is foreseen for the December 2014 CVMP meeting.

- The Committee noted the scientific overview and benefit-risk assessment updated after the responses to the second list of outstanding issues for a marketing authorisation application for a new viral vaccine for pigs (EMEA/V/C/002757/0000). The Committee discussed the draft product information and concurred with the rapporteurs' assessment of the responses to the second list of outstanding issues. The adoption of the opinion is foreseen for the December 2014 CVMP meeting.

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

- The Committee endorsed the EPAR module 6 scientific discussion for **Porcilis PCV M Hyo** (EMEA/V/C/003796/0000) concerning the granting of the initial marketing authorisation.

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a quality worksharing type IB variation for **ZULVAC 1 Bovis, ZULVAC 8 Bovis, ZULVAC 1+8 Bovis, ZULVAC 1 Ovis, ZULVAC 8 Ovis and ZULVAC 1+8 Ovis** (EMEA/V/C/xxxxxx/WS/0597), 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 (28 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a quality worksharing type II variation for **Purevax RCPCh FeLV, Purevax FeLV and Purevax RCP FeLV** (EMEA/V/C/xxxxxx/WS/0608), 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

- The Committee adopted a list of outstanding issues to be addressed in writing for a type II variation for **NexGard** (EMEA/V/C/002729/II/0001), to change the SPC and the package leaflet due to new clinical data.

3.3 Lists of questions

- The Committee adopted a list of questions for a quality type II variation for **Acticam** (EMEA/V/C/000138/II/0014).

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 considered the notification from Hungary for a referral procedure for **Coglapix vakcina A.U.V. suspension for injection for pigs** (*Actinobacillus pleuropneumoniae* strains

serotype 1 and 2), due to concerns expressed by Italy related to efficacy which may present a potential serious risk to animal health. The Committee agreed to start a referral procedure (EMEA/V/A/109) under Article 33(4) of Directive 2001/82/EC, and appointed M. Tollis as rapporteur and G. Kulcsár as co-rapporteur for the procedure. The Committee adopted a list of questions and the timetable for the procedure.

4.2 Article 34 of Directive 2001/82/EC

- There were no items for discussion.

4.3 Article 35 of Directive 2001/82/EC

- The Committee adopted by consensus (28 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report 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), recommending harmonised indications and dosing regimen, thereby also addressing the concerns on target animal safety for these veterinary medicinal products, concluding that the marketing authorisations of the concerned products should be varied in order to amend the product information accordingly. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.
- The Committee discussed the draft CVMP assessment report for the referral procedure for **all veterinary medicinal products containing colistin to be administered orally** (EMEA/V/A/106). The adoption of the CVMP opinion and assessment report is foreseen for the December 2014 meeting of the Committee.

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

- The Committee received presentations from relevant stakeholders and discussed the joint rapporteurs' assessment report for the procedure **on the risks to vultures and other necrophagous bird populations in the European Union in connection with the use of veterinary medicinal products containing the substance diclofenac** (EMEA/V/A/107). The adoption of the opinion is foreseen for the December 2014 meeting of the Committee.

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 by consensus (28 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for the annual

reassessment of **COXEVAC** (EMEA/V/C/000155/S/0007), recommending the conversion of the Community marketing authorisation from under exceptional circumstances to normal status as the specific obligations have been fulfilled. 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 annual reassessment of **BLUEVAC BTV8** (EMEA/V/C/000156/S/0003), recommending the continuation of the Community marketing authorisation under exceptional circumstances. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted the rapporteur's recommendation assessment report for **Loxicom** (EMEA/V/C/000141).
- The Committee adopted the rapporteur's recommendation assessment report for **Suvaxyn PCV** (EMEA/V/C/000149).

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 10.10.2014 – 06.11.2014:

Product	Period
BTVPUR AlSap 2-4 (EMEA/V/C/000139)	05.11.2013 – 04.11.2014
Halocur (EMEA/V/C/000040)	29.10.2013 – 28.10.2014

5.4 Renewals

- There were no items for discussion.

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
Acticam (EMEA/V/C/000138)	01.07.2013 – 30.06.2014
BTVPUR AlSap 1 (EMEA/V/C/002230)	01.01.2014 – 30.06.2014
BTVPUR AlSap 1-8 (EMEA/V/C/002231)	01.01.2014 – 30.06.2014
Cardalis (EMEA/V/C/002524)	01.02.2014 – 31.07.2014
Cerenia (EMEA/V/C/000106)	01.01.2014 – 30.06.2014
Contacera (EMEA/V/C/002612)	01.01.2014 – 30.06.2014
Equilis Prequenza (EMEA/V/C/000094)	01.02.2014 – 31.07.2014
Equilis Prequenza Te (EMEA/V/C/000095)	01.02.2014 – 31.07.2014
Hiprabovis IBR Marker Live (EMEA/V/C/000158)	01.08.2013 – 31.07.2014

Inflacam (EMEA/V/C/002497)	01.01.2014 – 30.06.2014
LEUCOFELIGEN FeLV/RCP (EMEA/V/C/000143)	01.07.2013 – 30.06.2014
MELOXIDYL (EMEA/V/C/000115)	01.08.2011 – 31.07.2014
Panacur AquaSol (EMEA/V/C/002008)	01.01.2014 – 30.06.2014
Porcilis ColiClos (EMEA/V/C/002011)	01.01.2014 – 30.06.2014
Poulvac E. coli (EMEA/V/C/002007)	01.01.2014 – 30.06.2014
Prac-tic (EMEA/V/C/000103)	01.07.2013 – 30.06.2014
ProZinc (EMEA/V/C/002634)	01.02.2014 – 31.07.2014
Trifexis (EMEA/V/C/002635)	05.01.2014 – 04.07.2014
TruScient (EMEA/V/C/002000)	01.01.2014 – 30.06.2014

- 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 adopted the draft revision of VICH guidelines GL48 on marker residue depletion studies and GL49 on method used in residue depletion studies, from the VICH Expert Working Group on Metabolism and Residue Kinetics, both for sign-off by the EU members of the Steering Committee at step 6 of the VICH procedure.
- The Committee noted the draft EU comments on topic 4 (dose determination) of the VICH Task Force on the revision of anthelmintic guidelines.
- The Committee endorsed draft 7 of the guideline on electronic file formats (EFF) prepared by the topic leader following comments from the VICH Expert Working Group on electronic exchange of documents, which is intended to be circulated to the Expert Working Group for sign off at step 5 of the VICH procedure. The CVMP noted that some comments were still outstanding and potentially additional changes may become necessary.
- The Committee was informed of the development of comments on the draft VICH guideline on marker residue depletion studies to establish withdrawal periods for veterinary medicinal products for use in aquatic species - residue depletion in fish groups. The draft EU comments will be discussed at the November Safety Working Party meeting and then brought to the December CVMP meeting for endorsement.
- The Committee noted the corrected version of draft 3 of the VICH Guideline on harmonisation of criteria to waive target animal batch safety testing for live vaccines for veterinary use and the corrected version of the overview of comments received.

- The Committee adopted the revised VICH guideline GL23(R) Studies to evaluate the safety of residues of veterinary drugs in human food: genotoxicity testing for implementation in the EU, following the sign-off by the VICH Steering Committee at step 6 of the VICH procedure.

6.2 Codex Alimentarius

Information relating to certain topics discussed under section 6.2 at this meeting cannot be released at the present time as it is deemed to be confidential.

- The Committee endorsed the draft CVMP/SWP comments on the draft Codex MRLs for consideration at the 22nd session of the Codex Committee on residues of veterinary drugs in food (CCRVDF).

6.3 Other EU bodies and international organisations

- The Committee noted the draft report on regulatory considerations for nanopesticides and veterinary nanomedicines and the information leaflet on nanotechnology regulation symposium from the Australian Pesticides and Veterinary Medicines Authority (APVMA), and was informed that any comments can be sent to the secretariat by the end of the year.
- The Committee received an update on the draft EFSA CONTAM Opinion on reference points for action for chloramphenicol.

The following documents were circulated for information:

- Status of active VICH guidelines and action plan of CVMP and working parties;
- Final minutes of the 30th VICH Steering Committee meeting held on 23-26 June 2014 in Brussels.

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 4 November 2014 and noted the agenda of the meeting. The Committee was informed of the resignation of E. Lander Persson.

7.2 Quality Working Party (QWP)

- The Committee received a verbal report from the veterinary vice-chair of the QWP on the meeting held on 17-19 September 2014.

7.3 Safety Working Party (SWP-V)

- There were no items for discussion.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- The Committee agreed the draft CVMP reflection paper regarding the environmental risk assessment for avermectins in veterinary medicinal products for further discussion with the HMA.

- The Committee agreed the draft strategy for the consideration of veterinary medicinal products containing (potential) PBT substances for further discussion with the HMA.
- The Committee adopted the answers to the comments received from stakeholders to the first public consultation on the draft PBT guideline on the assessment of persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances in veterinary medicinal products (EMA/CVMP/ERA/102239/2013).

7.5 Efficacy Working Party (EWP-V)

- The Committee adopted the concept paper recommending the drafting of a new guideline on data requirements for the prevention of transmission of canine and feline vector-borne diseases (EMA/CVMP/EWP/309734/2014) for a 3-month period of public consultation.

7.6 Antimicrobials Working Party (AWP)

- There were no items for discussion.

7.7 Immunologicals Working Party (IWP)

- The Committee adopted the guideline on data requirements for changes to the strain composition of authorised equine influenza vaccines in line with the OIE requirements (EMA/CVMP/IWP/97961/2013) and the overview of comments received (EMA/CVMP/IWP/36240/2014).

7.8 Pharmacovigilance Working Party (PhVWP-V)

- There were no items for discussion.

7.9 Novel therapy groups and related issues

- The Committee discussed the draft mandate and rules of procedure of the Ad Hoc Group on Novel Veterinary Therapies (ADVENT)
- The Committee endorsed the document including the profile and expertise of the ADVENT core group, the selection procedure, the topic groups and the overall schedule for the establishment of ADVENT

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 adopted the work plans for 2015 for the CVMP Working Parties on Scientific Advice (EMA/CVMP/SAWP/515808/2014), Safety (EMA/CVMP/SWP/427315/2014), Environmental Risk Assessment (EMA/CVMP/ERA/359952/2014), Efficacy (EMA/CVMP/EWP/475153/2014), Immunologicals (EMA/CVMP/AWP/513645/2014), Antimicrobials (EMA/CVMP/IWP/338065/2014) and Pharmacovigilance (EMA/CVMP/PhVWP/339510/2014), as well as for the Joint CHMP/CVMP Quality Working Party (EMA/CHMP/CVMP/QWP/375436/2014) and the Joint CVMP/CHMP ad hoc expert group on the application of 3Rs in regulatory testing of medicinal products (EMA/CHMP/CVMP/JEG-3Rs/468821/2014), subject to the amendments agreed.

The following documents were circulated for information:

- Minutes of the SAWP-V meeting held on 7 October 2014;
- Minutes of the 72st Joint CHMP/CVMP QWP meeting held on 17–19 September 2014.

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

- There were no items for discussion.

8.3 Antimicrobial resistance

- The Committee was informed of the overview of comments received on the answers to the request for scientific advice on the impact on public health and animal health of the use of antibiotics in animals, which is expected to be endorsed at the December CVMP 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.

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.

- The Committee adopted the concept paper for the revision of the CVMP guidelines on data requirements for veterinary medicinal products for minor use minor species (MUMS) (EMA/CVMP/505827/2014) for a 3-month period of public consultation.

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 noted the draft minutes of the meeting held on 9-10 October 2014, and the draft agenda of the meeting held on 6-7 November 2014.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee reviewed the revised document on the appointment and responsibilities of the rapporteur and the co-rapporteur for procedures regarding veterinary medicinal products for the CVMP implementation of multinational assessment teams, which is foreseen to be adopted at the December CVMP meeting.
- The Committee noted the draft minutes of the CVMP Interested Parties' Meeting, held on 7 May 2014.
- The Committee received an update on the revised EMA policy on conflicts of interest.
- The Committee noted the table of actions following the October 2014 CVMP meeting.

13. LEGISLATION

- There were no items for discussion.

14. ANY OTHER BUSINESS

- Upon the completion of the November 2014 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 November 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	Cannot act as rapporteur or peer reviewer for:	• 2.2 – Metacam (EMEA/V/C/000033/X/0107) • 5.2 – BLUEVAC BTV8 (EMEA/V/C/000156/S/0003) • 5.5 - ProZinc
BE	Bruno Urbain	Full involvement	
BG	Emil Kozhuharov	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	
HR	Ljiljana Markuš-Cizelj	Involvement in discussions only and cannot act as rapporteur for:	• 2.5 – Porcilis PCV M Hyo • 5.5 - Equilis Prequenza, Equilis Prequenza Te, Panacur Aquasol, Porcilis ColiClos • 10.2 item
IE	David Murphy (vice-chair)	Full involvement	
IT	Maria Tollis	Full involvement	
LU	Marc Schmit	Involvement in discussions only and cannot act as rapporteur for:	• 2.1 - NexGard Spectra (EMEA/V/C/003842) • 3.1 – Purevax range (EMEA/V/C/xxxxxx/WS/0608) • 3.2 – NexGard (EMEA/V/C/002729/II/0001) • 5.5 - Prac-tic, BTVPUR AlSap 1, BTVPUR AlSap 1-8 • 7.1 item • 10.2 item
LV	Zanda Auce	Full involvement	
NL	Johan Schefferlie	Full involvement	
PL	Ewa Augustynowicz	Full involvement	
PT	João Pedro Duarte da Silva	Full involvement	
RO	Lollita Taban	Full involvement	
SE	Eva Lander Persson	Full involvement	

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
SI	Stane Srčič	Cannot act as rapporteur or peer reviewer for:	• 4.3 – Gentamicin (EMEA/V/A/104)
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	Cannot act as rapporteur or peer reviewer for:	• 4.3 – 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	
FI	Kristina Lehmann	Full involvement	
FR	Jean-Claude Rouby	Full involvement	
HU	Tibor Soós	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	Anke Finnah *(remotely)*	Full involvement	
DE	Sabine Kalweit *(remotely)*	Full involvement	
DE	Stefan Scheid *(remotely)*	Full involvement	
ES	Ricardo Carapeto Garciá	Full involvement	
ES	Miguel Quevedo *(remotely)*		
FI	Martti Nevalainen	Full restrictions apply throughout the meeting. The expert is attending for training purposes only.	
FR	Hélène Amar *(remotely)*	Full involvement	
FR	Anne-Marie Jacques	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
FR	Sylvie Louet	Full involvement	
UK	Noel Joseph	Full involvement	
UK	Javier Pozo	Full involvement	

Organi-sation	CVMP Expert witness*	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.			
BirdLife	Ana Carricondo	Full involvement	
RSPB	Toby Galligan	Full involvement	
BirdLife	Wouter Langhout	Full involvement	
	Miguel Quevedo *(remotely)*	Full involvement	
BirdLife	Ivan Ramirez *(remotely)*	Full involvement	

CVMP working parties and CMDv	Chair / Vice-chair
AWP	Helen Jukes
CMDv	--
ERAWP	Boris Kolar
EWP-V	Gesine Hahn
IWP	Esther Werner
PhVWP-V	--
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