15 March 2016
EMA/CVMP/199920/2016
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 16-18 February 2016 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 interests

The attendance list was completed and interests were identified for the February 2016 meeting. In accordance with the Agency's revised policy and procedure on the handling of declarations of interests, participants in this meeting were asked to declare any interests on the matters for discussion (in particular any changes, omissions or errors to the already declared interests). Discussions, deliberations and voting took place in full respect of the restricted involvement of Scientific Committee members and, where relevant, experts attending the plenary meeting, as announced by the Scientific Committee Secretariat at the start of the meeting (see Annex I). All decisions taken at this meeting were made in presence of a quorum of members i.e. 22 or more members were present in the room. It was noted that 17 members were needed for an absolute majority.

iii. Declaration of contacts between members and companies with regard to points on the agenda

Information relating to declared contacts between members and companies with regard to points on the agenda cannot be released at the present time as it is deemed to be commercially confidential.

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iv. Adoption of the minutes of the previous meeting

The minutes of the January 2016 meeting were adopted with no amendments.

v. Topics for rapporteur's meetings, break-out sessions and oral explanations

Information relating to briefing meetings taking place with applicants cannot be released at the present time as it is deemed to be commercially confidential.

1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

- The Committee adopted by consensus (28 members present of those eligible to vote) the CVMP opinion including the EPMAR and the CVMP assessment report recommending the establishment of MRLs in bovine species for **hydrocortisone aceponate** (EMEA/V/MRL/002993/FULL/0002). The Committee also agreed to extrapolate these MRLs to all ruminants and equine species. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The Committee noted the comments from the EU Reference Laboratory, two peer review reports, the comments received from CVMP members and the summary of opinion for publication.

1.2 Oral explanations and lists of outstanding issues

- There were no items for discussion.

1.3 Lists of questions

- The Committee adopted the scientific overview and list of questions for the establishment of MRLs in all food producing species for a substance (EMEA/V/MRL/004321/FULL/0001), following discussion of the rapporteur's assessment report including the critique from the co-rapporteur and two peer review reports.

1.4 Re-examination of CVMP opinions

- There were no items for discussion.

1.5 Other issues

- There were no items for discussion.

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

- The Committee adopted by consensus (29 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Poulvac E. coli** (EMEA/V/C/002007/X/0008), recommending the extension of the marketing authorisation to include a new target species, turkeys. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication. The product is classified as MUMS/limited market.
- 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 **Evalon** (EMEA/V/C/004013/0000), recommending the granting of a marketing authorisation. The product is a new live attenuated anti-coccidial vaccine to stimulate active immunity in chickens against coccidiosis caused by *Eimeria acervulina*, *Eimeria brunetti*, *Eimeria maxima*, *Eimeria*

necatrix and *Eimeria tenella*. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication.

- The Committee adopted by consensus (29 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Letifend** (EMEA/V/C/003865/0000), recommending the granting of a marketing authorisation. The product is a new vaccine containing a recombinant protein for the active immunisation of non-infected dogs against leishmaniasis. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication. The product is classified as MUMS/limited market.

2.2 Oral explanations and lists of outstanding issues

- There were no items for discussion.

2.3 Lists of questions

- The Committee adopted the scientific overview and benefit-risk assessment including the list of questions and agreed comments on the draft product information for a new antiparasitic product (EMEA/V/C/004201/0000). 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 vaccine for sheep (EMEA/V/C/004185/0000). The Committee noted two peer review reports and the comments received from CVMP members.

- The Committee adopted the scientific overview and benefit-risk assessment including the list of questions and agreed comments on the draft product information for a new vaccine for pigs (EMEA/V/C/003993/0000). The Committee noted two peer review reports and the comments received from CVMP members.

2.4 Re-examination of CVMP opinions

- Following the discussion of the draft rapporteurs' assessment report and the rapporteur's appendix to the re-examination report for the re-examination of the negative CVMP opinion adopted for an extension application for **Bravecto** (EMEA/V/C/002526/X/0005), the Committee adopted the list of questions to the ad hoc expert group (AHEG) and endorsed the list of AHEG members. The scope of the application is to add a new pharmaceutical form (spot-on solution) for dogs and a new target species (cats) for this spot-on formulation.

2.5 Other issues

- The Committee adopted the timetable for the 2nd phase of the procedure for a new vaccine for rabbits (EMEA/V/C/004239/0000).

- The Committee endorsed the list of participants and the list of questions for the 2nd AHEG meeting to be held on 25 February 2016 for a new vaccine for Atlantic salmon (EMEA/V/C/002390/0000).

- The Committee endorsed the EPAR module 6 scientific discussion for **Imrestor** (EMEA/V/C/002763/0000) concerning the granting of the initial marketing authorisation.

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- The Committee adopted by consensus (29 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a grouped type II variation for **BTVPUR AlSap 1-8** (EMEA/V/C/002231/II/0007/G), recommending the variation of the marketing authorisation to establish a multi-strain dossier and to add a new serotype BTV4. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication.
- The Committee adopted by majority (20 members in favour out of the 29 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a type II variation for **DRAXXIN** (EMEA/V/C/000077/II/0031), recommending the variation of the marketing authorisation to add a new indication, for use in swine respiratory disease (SRD) associated with *Bordetella bronchiseptica*. K. Baptiste, M. Blixenkrone-Møller, F. Božić, C. Friis, E. Kozhuharov, D. Murphy, M. Nevalainen, M. Tollis and E. Werner signed a divergent position not supporting the aforementioned recommendation. The Icelandic and Norwegian CVMP members also signed the divergent position. The Committee noted the summary of opinion for publication.
- The Committee adopted by consensus (29 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a grouped type II variation for **Bravecto** (EMEA/V/C/002526/II/0010/G) concerning quality changes, recommending the variation of the marketing authorisation. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.

3.2 Oral explanations and lists of outstanding issues

- The Committee adopted the list of outstanding issues to be addressed in writing for a grouped type II variation for **Metacam** (EMEA/V/C/000033/II/0118/G) concerning quality changes.
- The Committee adopted the list of outstanding issues to be addressed in writing for a worksharing type II variation for **Versican Plus Pi/L4R** and **Versican Plus DHPPi/L4R** (EMEA/V/C/xxxxxx/WS/0785), to extend the duration of immunity.

3.3 Lists of questions

- There were no items for discussion.

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 discussed the rapporteur's assessment report with the co-rapporteur's critique for the referral procedure for **CattleMarker IBR Inactivated emulsion for injection for cattle** (EMEA/V/A/115). The Committee noted four peer review reports and the comments made by CVMP members. The adoption of the CVMP opinion and assessment report is foreseen for the March 2016 meeting of the Committee.

4.2 Article 34 of Directive 2001/82/EC

- There were no items for discussion.

4.3 Article 35 of Directive 2001/82/EC

- The Committee discussed the rapporteur's assessment of the responses to the list of outstanding issues including the co-rapporteur's critique for the referral procedure for **all veterinary medicinal products containing altrenogest to be administered orally to pigs and horses** (EMEA/V/A/095). The Committee adopted a list of outstanding issues for the marketing authorisation holders to address in writing and at an oral explanation, and a revised timetable for the procedure. The oral explanation is scheduled for the April 2016 meeting and the adoption of the CVMP opinion is foreseen for the May 2016 meeting of the Committee.
- The Committee considered the notification from the Netherlands and France for a referral procedure for **all veterinary medicinal products containing zinc oxide to be administered orally to food producing species**, regarding concerns related to potential risk to the environment and increase of prevalence of antibiotic resistant bacteria from the use of products containing zinc oxide. The Committee agreed to start a referral procedure (EMEA/V/A/118) under Article 35, and appointed J. Schefferlie as rapporteur and J. Weeks as co-rapporteur for the procedure. The Committee adopted a list of questions and the timetable for the procedure, and noted the list of products concerned.

4.4 Article 78 of Directive 2001/82/EC

- There were no items for discussion.

4.5 Article 13 of Regulation (EC) No 1234/2008

- There were no items for discussion.

4.6 Article 30(3) of Regulation (EC) No 726/2004

- There were no items for discussion.

4.7 Other issues

- There were no items for discussion.

5. POST-AUTHORISATION ISSUES FOR COMMUNITY MARKETING AUTHORISATIONS (EXCLUDING VARIATIONS)

5.1 General issues

- There were no items for discussion.

5.2 Post-authorisation measures and annual reassessments

- The Committee adopted the rapporteur's assessment report on the data submitted concerning a condition for **Zulvac SBV** (EMEA/V/C/002781/ANX/004.1).

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 22.01.2016 – 18.02.2016:

Product	Period
Activyl (EMEA/V/C/000163)	18/02/2015 – 17/02/2016

Product	Period
Bravecto (EMEA/V/C/002526)	11/02/2015 – 10/02/2016
Cimalgex (EMEA/V/C/000162)	18/02/2015 – 17/02/2016
Comfortis (EMEA/V/C/002233)	11/02/2015 – 10/02/2016
Fevaxyn Pentofel (EMEA/V/C/000030)	05/02/2015 – 04/02/2016
Hiprabovis IBR Marker Live (EMEA/V/C/000158)	27/01/2015 – 26/01/2016
Ingelvac CircoFLEX (EMEA/V/C/000126)	13/02/2015 – 12/02/2016
Kexxtone (EMEA/V/C/002235)	28/01/2015 – 27/01/2016
Loxicom (EMEA/V/C/000141)	10/02/2015 – 09/02/2016
NexGard (EMEA/V/C/002729)	11/02/2015 – 10/02/2016
Nobilis OR inac (EMEA/V/C/000062)	24/01/2015 – 23/01/2016
PIRSUE (EMEA/V/C/000054)	29/01/2015 – 28/01/2016
Purevax Rabies (EMEA/V/C/002003)	18/02/2015 – 17/02/2016
Semintra (EMEA/V/C/002436)	13/02/2015 – 12/02/2016
STARTVAC (EMEA/V/C/000130)	11/02/2015 – 10/02/2016
Suvaxyn CSF Marker (EMEA/V/C/002757)	10/02/2015 – 09/02/2016
ZULVAC SBV (EMEA/V/C/002781)	06/02/2015 – 05/02/2016

5.4 Renewals

- The Committee adopted the list of outstanding issues for the renewal of **MS-H Vaccine** (EMEA/V/C/000161/R/0009).
- 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 the renewal of **Zulvac 1 Bovis** (EMEA/V/C/002334/R/0010), and agreed that the authorisation should now be indefinite. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (29 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for the renewal of **Zulvac 1 Ovis** (EMEA/V/C/002335/R/0011), and agreed that the authorisation should now be indefinite. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (29 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for the renewal of **CERTIFECT** (EMEA/V/C/002002/R/0011), and agreed that a further renewal is required. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.

5.5 Pharmacovigilance – PSURs and SARs

- The Committee adopted the CVMP assessment report of the PSUR for the period 01.10.2014 – 30.09.2015 for **Comfortis** (EMEA/V/C/002233).
- 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)	01.04.2015 – 30.09.2015
CaniLeish (EMEA/V/C/002232)	01.10.2014 – 30.09.2015
Coliprotec F4 (EMEA/V/C/003797)	16.03.2015 – 30.09.2015
Equisolon (EMEA/V/C/002382)	13.03.2015 – 12.09.2015
Fungitraxx (EMEA/V/C/002722)	01.04.2015 – 30.09.2015
Recocam (EMEA/V/C/002247)	01.04.2015 – 30.09.2015
Zulvac 1+8 Bovis (EMEA/V/C/002473)	01.04.2015 – 30.09.2015

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

5.6 Supervisions and sanctions

Information relating to supervisions and sanctions will not be published as it would be undermining the purpose of such inspections.

The following document was circulated for information:

- Status report on PSURs for centrally authorised veterinary medicinal products.

6. CO-OPERATION WITH OTHER EU OR INTERNATIONAL BODIES

6.1 VICH

- The Committee adopted the revised draft VICH GL 50 on Harmonisation of criteria to waive target animal batch safety testing for inactivated vaccines for veterinary use (EMA/CVMP/VICH/582610/2009), for release for public consultation in the EU at step 4 of the VICH process.
- The Committee adopted the draft VICH GL 55 on Harmonisation of criteria to waive target animal batch safety testing for live vaccines for veterinary use (EMA/CVMP/VICH/313610/2013), for release for public consultation in the EU at step 4 of the VICH process.

6.2 Codex Alimentarius

- There were no items for discussion.

6.3 Other EU bodies and international organisations

The following document was circulated for information:

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

7. WORKING PARTIES AND SCIENTIFIC ADVISORY GROUPS

Information relating to certain topics discussed under section 7 at this meeting cannot be released at the present time as it is deemed to be confidential.

7.1 Scientific Advice Working Party (SAWP-V)

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

- The Committee received a verbal report from the chair of the SAWP-V on the meeting held on 16 February 2016, and noted the agenda of the meeting.

7.2 Quality Working Party (QWP)

- The Committee adopted the guideline on the sterilisation of the medicinal product, active substance, excipient and primary container for a 6-month period of public consultation.
- The Committee adopted the question and answer document on the data requirements for sterilisation processes of primary packaging material subsequently used in an aseptic manufacturing process.
- The Committee adopted the reflection paper on the chemical structure and properties criteria to be considered for the evaluation of New Active Substance (NAS) status of chemical substances for a 3-month period of public consultation.
- The Committee was informed about the publishing of the question and answer document on the use of powders and granules in veterinary medicines composed of 100% active substance.
- The Committee was informed of the upcoming election of the veterinary vice chair of the QWP for a 3-year term at the March 2016 CVMP meeting.

7.3 Safety Working Party (SWP-V)

- The Committee elected Stefan Scheid as vice chair of the SWP-V for a 3-year term.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- The Committee was informed of the upcoming election of the chair and vice chair of the ERAWP for 3-year terms at the April 2016 CVMP meeting.

7.5 Efficacy Working Party (EWP-V)

- The Committee adopted the revised guideline on the conduct of efficacy studies for intramammary products for use in cattle (EMA/CVMP/EWP/344/1999-rev.2) and the overview of comments received (EMA/CVMP/EWP/335976/2014) for a second 3-month period of public consultation.
- The Committee adopted the revised question and answer document (EMA/CVMP/414812/2011-Rev.2) on the CVMP guideline on the SPC for antimicrobial products (EMEA/CVMP/SAGAM/383441/2005) in regard to pack sizes for antimicrobials – *see also 7.6*.

7.6 Antimicrobials Working Party (AWP)

- The Committee adopted the revised question and answer document (EMA/CVMP/414812/2011-Rev.2) on the CVMP guideline on the SPC for antimicrobial products EMEA/CVMP/SAGAM/383441/2005) in regard to pack sizes for antimicrobials – *see also 7.5*.

7.7 Immunologicals Working Party (IWP)

- The Committee received a verbal report from the chair of the IWP on the meeting held on 11-12 February 2016, and noted the agenda of the meeting.

7.8 Pharmacovigilance Working Party (PhVWP-V)

- The Committee endorsed the veterinary pharmacovigilance 2015 - public bulletin (EMA/CVMP/818155/2016).
- The Committee received a verbal report from the chair of the PhVWP-V on the meeting held on 26-27 January 2016, and noted the draft summary record of the meeting.

7.9 Novel therapy groups and related issues

- The Committee endorsed the ADVENT work methodology and pilot work procedure for the adopted ADVENT problem statements on monoclonal antibodies intended for veterinary use (EMA/CVMP/ADVENT/276476/2015) and on sterility in relation to stem cell-based products intended for veterinary use (EMA/CVMP/ADVENT/226871/2015), and agreed to their release for a 2-month public consultation. The problem statements will provide the basis for development of guidance by ADVENT in the form of questions and answers, following any comments received.

7.10 Joint CVMP/CHMP AHEG on the application of the 3Rs (JEG-3Rs)

7.11 Other working party and scientific group issues

- There were no items for discussion.

The following documents were circulated for information:

- Draft minutes of the SAWP-V meeting held on 19 January 2016;
- Draft agenda for the Joint CHMP/CVMP QWP meeting to be held on 1–3 March 2016;
- Draft agenda for the EWP meeting to be held on 23-24 February 2016;
- Final minutes of the IWP meeting held on 20-21 October 2015;
- Draft minutes of the ADVENT meeting held on 10 December 2015.

8. OTHER SCIENTIFIC MATTERS

8.1 MRLs issues

Information on certain MRL related issues cannot be released at the present time as it is deemed to be confidential.

- The Committee agreed to include **poly(lactic-co-glycolic acid)** as a new entry in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 under the heading of excipients, following the request from the applicant.
- The Committee agreed to include **polydimethyl siloxane dimethylvinyl** as a new entry in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 under the heading of excipients, following the request from the applicant.
- The Committee adopted the revised list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 (EMA/CVMP/519714/2009 – Rev.33).

8.2 Environmental risk assessment

- The Committee adopted a new reflection paper on the authorisation of veterinary medicinal products containing (potential) Persistent Bioaccumulative and Toxic (PBT) or very Persistent and very Bioaccumulative (vPvB) substances (EMA/CVMP/448211/2015) for a 3-month period of public consultation.

8.3 Antimicrobial resistance

- The Committee received a verbal report on the RONAFA (Joint EFSA/EMA Scientific Opinion on measures to reduce the need to use antimicrobial agents in animal husbandry in the European Union, and the resulting impacts on food safety) meeting held on 4-5 February 2016.
- The Committee received a verbal report on the request from the Commission for an update of the 2013 advice on the impact on public health and animal health of the use of antibiotics in animals (colistin), and the upcoming Antimicrobial Advice ad hoc Expert Group (AMEG) meeting to be held on 26 February 2016. The Committee agreed on a timetable for the update. The timetable includes a short period for a call for scientific data (29 February – 15 March 2016). Once adopted by the CVMP and CHMP, the draft revised opinion will be subject to a short period of consultation, anticipated for the end of May/beginning of June 2016.
- The Committee heard and discussed a presentation from the Veterinary Committee on Antimicrobial Susceptibility Testing (VetCAST) on the establishment of clinical breakpoints.

8.4 Pharmacovigilance

Information on certain pharmacovigilance related issues cannot be released at the present time as it is deemed to be confidential.

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.

9. AVAILABILITY OF MEDICINES AND MUMS CLASSIFICATION

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

10. PROCEDURAL AND REGULATORY MATTERS

10.1 Eligibility and appointment of rapporteurs, co-rapporteurs and peer reviewers

Information relating to notification of intent for new MRL applications and notification of intent and eligibility requests for Community marketing authorisations cannot be released at the present time as it is deemed to be commercially confidential.

10.2 Regulatory matters

Information relating to certain regulatory issues cannot be released at the present time as it is deemed to be commercially confidential.

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

- The Committee noted the draft minutes of the meeting held on 21-22 January 2016 as well as the draft agenda of the meeting held on 18-19 February 2016.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee adopted the public CVMP work plan for 2016 (EMA/CVMP/772237/2015), which highlights the priority areas for the Committee in the coming year.
- The Committee endorsed the final composition of the assessor guideline subgroup and the time schedule of actions for the revision of the scientific overview template guidance for immunological products.
- The Committee was informed of the streamlining of the procedure for the preparation of type II variation assessment reports.
- The Committee noted the table of actions following the January 2016 CVMP meeting.

13. LEGISLATION

Information on certain legislation related issues cannot be released at the present time as it is deemed to be confidential.

14. ANY OTHER BUSINESS

- Upon the completion of the February 2016 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 February 2016 meeting

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
CHAIR	**Anja Holm**	**Full involvement**	
AT	Barbara Zemann	Cannot act as rapporteur or peer reviewer for:	• 3.2 Metacam (EMEA/V/C/000033/II/0118/G)
BG	Emil Kozhuharov	Full involvement	
CY	Alia Michaelidou	Full involvement	
EE	Toomas Tiirats	Full involvement	
ES	Cristina Muñoz Madero	Full involvement	
FI	Martti Nevalainen	Full involvement	
FR	Jean-Claude Rouby	Full involvement	
HU	Gábor Kulcsár	Full involvement	
IE	David Murphy (vice-chair)	Full involvement	
IT	Maria Tollis	Full involvement	
LV	Zanda Auce	Full involvement	
NL	G. Johan Schefferlie	Full involvement	
PL	Ewa Augustynowicz	Full involvement	
PT	João Pedro Duarte da Silva	Full involvement	
SE	Eva Lander Persson	Full involvement	
SI	Stane Srčič	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	Wilhelm Schlumbohm	Full involvement	
Co-opted	Jason Weeks	Full involvement	
IS	Jóhann Lenharðsson	Full involvement	
NO	Hanne Bergendahl	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
BE	Frédéric Klein	Full involvement	
DE	Esther Werner	Full involvement	
DK	Merete Blixenkrone-Møller	Full involvement	
EL	Angeliki Tsigouri	Full involvement	
FR	Sylvie Louet	Full involvement	
HR	Frane Božić	Full involvement	
PL	Anna Wachnik-Święcicka	Full involvement	• 3.2 Metacam

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
			(EMEA/V/C/000033/II/0118/G)
RO	Simona Sturzu	Full involvement	
SE	Frida Hasslung Wikström	Full involvement	
SK	Eva Chobotová	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	Bruno Urbain *(remotely)*	Full involvement	
DE	Klaus Cussler *(remotely)*	Full involvement	
DE	Sabine Klee *(remotely)*	Full involvement	
DE	Ingun Lemke *(remotely)*	Full involvement	
DE	Gerd Maack	Full involvement	
DE	Stefan Scheid *(remotely)*	Full involvement	
DE	Jens Schönfeld *(remotely)*	Full involvement	
ES	Rosario Bullido Gomez-Heras *(remotely)*	Full involvement	
ES	Ricardo Carapeto Garcia *(remotely)*	Full involvement	
ES	Maria Dominguez Nicolas *(remotely)*	Full involvement	
ES	Noemi Garcia del Blanco	Full involvement	
ES	Javier Martinez de Velasco *(remotely)*	Full involvement	
ES	Marta Martin Juarez *(remotely)*	Full involvement	
ES	Mercedes Urena Montilla *(remotely)*	Full involvement	
FI	Kristina Lehmann *(remotely)*	Full involvement	
FR	Christine Miras	Full involvement	
UK	Sam Fletcher *(remotely)*	Full involvement	
UK	Javier Pozo	Full involvement	
UK	Steve Spencer	Full involvement	

CVMP working parties and CMDv	Chair
ADVENT	Jean-Claude Rouby

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