19 March 2019
EMA/CVMP/117144/2019
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 19-21 February 2019 meeting

Chair: D. Murphy – Vice-chair: H. Jukes

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 competing interests were identified for the February 2019 meeting. In accordance with the Agency's policy and procedure on the handling of competing 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 CVMP members and, where relevant, experts attending the plenary meeting, as announced by the CVMP secretariat at the start of the meeting (see Annex I). All decisions taken at this meeting were made in the 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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Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

iv. Adoption of the minutes of the previous meeting

The minutes of the January 2019 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 (30 members present of those eligible to vote) the CVMP opinion including the EPMAR and the CVMP assessment report recommending the establishment of MRLs in horses for ciclesonide (EMEA/V/MRL/005010/FULL/0001). The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication.

1.2 Oral explanations and lists of outstanding issues

- The Committee discussed the rapporteurs' assessment of the responses to the list of questions and the rapporteur's draft EPMAR for the establishment of MRLs in rabbits for a substance (EMA/V/MRL/004828/FULL/0001), and adopted a list of outstanding issues. The adoption of the opinion is foreseen for the April 2019 meeting of the Committee.

1.3 Lists of questions

- The Committee adopted the scientific overview and list of questions for the establishment of MRLs for a substance (EMEA/V/MRL/005072/FULL/0001) in bovine and porcine species. The Committee noted a peer review report and the comments received from CVMP members.

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 (30 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Forceris** (EMEA/V/C/004329/0000), recommending the granting of a marketing authorisation. Forceris is a new veterinary medicinal product for the concomitant prevention of iron deficiency anaemia and prevention of clinical signs of coccidiosis (diarrhoea) as well as reduction in oocyst excretion, in piglets in farms with a confirmed history of coccidiosis caused by *Cystoisospora suis*. The Norwegian 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 (30 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for the generic product **Chanhold** (EMEA/V/C/004824/0000), recommending the granting of a marketing authorisation. Chanhold is a new antiparasitic product containing selamectin for the treatment and prevention of infestation and/or diseases caused by different species of fleas, worms, lice and mites in cats and

dogs. The Norwegian 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 (30 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **ReproCyc ParvoFLEX** (EMEA/V/C/004858/0000), recommending the granting of a marketing authorisation. ReproCyc ParvoFLEX is a new vaccine for the active immunisation of gilts and sows from the age of 5 months to protect progeny against transplacental infection caused by porcine parvovirus. The Norwegian 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 (30 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Felisecto Plus** (EMEA/V/C/005093/0000), recommending the granting of a marketing authorisation. Felisecto Plus is a new veterinary medicinal product for the treatment and/or prevention of mixed parasitic infestations by ticks and fleas, lice, mites, gastrointestinal nematodes or heartworm in cats. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication. This is an informed consent application.

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 including the list of questions and agreed comments on the draft product information for a new product (EMEA/V/C/005018/0000) for dogs. The Committee noted two peer review reports and the comments received from CVMP members.
- The Committee adopted the scientific overview including the list of questions and agreed comments on the draft product information for a new vaccine (EMEA/V/C/004989/0000) for rabbits. The Committee noted two peer review reports and the comments received from CVMP members.

2.4 Re-examination of CVMP opinions

- The Committee heard a verbal report from an AHEG member and an oral explanation from the applicant concerning the re-examination of the CVMP opinion adopted for **HorStem** (EMEA/V/C/004265/0000). The Committee adopted by majority (27 members in favour out of the 30 members present of those eligible to vote) the final CVMP opinion, the final CVMP assessment report and product information recommending the granting of a marketing authorisation, further to the re-examination of the opinion adopted during the Committee meeting held in October 2018. HorStem is a new product (equine umbilical cord mesenchymal stem cells) for the reduction of lameness associated with mild to moderate degenerative join disease (osteoarthritis) in horses. K. Baptiste, E.-M. Vestergaad, F. Hasslung-Wikström and the Norwegian CVMP member signed a divergent position not supporting the aforementioned recommendation. The Committee noted the summary of opinion for publication.

2.5 Other issues

- The Committee adopted the EPAR module scientific discussion for **EVANT** (EMEA/V/C/004868/0000) concerning the granting of the initial marketing authorisation.
- The Committee adopted the withdrawal EPAR for **EQUITEND** (EMEA/V/C/002774/0000) concerning the granting of the initial marketing authorisation.

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- The Committee adopted by consensus (30 members present of those eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a type II variation for **Zycortal** (EMEA/V/C/003782/II/0003), recommending the variation of the marketing authorisation to introduce a new pharmacovigilance system. The Norwegian 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 endorsed the rapporteur's assessment report for a type II variation for **MS-H Vaccine** (EMEA/V/C/000161/II/0012), recommending the variation of the marketing authorisation to introduce a new pharmacovigilance system. The Norwegian 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 endorsed the rapporteur's assessment report for a type II variation for **LETIFEND** (EMEA/V/C/003865/II/0012), recommending the variation of the marketing authorisation to implement quality changes. The Norwegian CVMP member 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 **Clomicalm** (EMEA/V/C/000039/II/0027), concerning quality changes.

3.3 Lists of questions

- The Committee adopted a list of questions for a type II grouped variation for **Posatex** (EMEA/V/C/000122/II/0027/G), concerning quality changes.
- The Committee adopted a list of questions for a type II grouped variation for **Ingelvac CircoFLEX** (EMEA/V/C/000126/II/0030/G), concerning quality changes.
- The Committee adopted a list of questions for a type II variation for **MS-H Vaccine** (EMEA/V/C/000161/II/0013), concerning quality changes.
- The Committee adopted a list of questions for a type II grouped variation for **Porcilis PCV M Hyo** (EMEA/V/C/003796/II/0011/G), concerning quality changes.

3.4 Re-examination of CVMP opinions

- There were no items for discussion.

3.5 Other issues

- The Committee noted the extension to the clock-stop for a type II variation for **Rhiniseng** (EMEA/V/C/000160/II/0009), concerning quality changes.
- The Committee noted the extension to the clock-stop for a type II variation for **Suprelorin** (EMEA/V/C/00109/II/0022), concerning quality changes.

4. REFERRALS AND RELATED PROCEDURES

4.1 Article 33 of Directive 2001/82/EC

- There were no items for discussion.

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 considered the notification from Germany, for a referral procedure for **Betamox LA 150 mg/ml suspension for injection and associated names, and generic products thereof**. The referral concerns the appropriateness of withdrawal periods in cattle, sheep and pigs for the above-mentioned veterinary medicinal products. The Committee agreed to start a referral procedure (EMEA/V/A/132) under Article 35 and appointed G. Hahn as rapporteur and P. Hekman as co-rapporteur for the procedure. The Committee adopted the list of questions and the timetable.
- The Committee adopted by consensus (30 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for the referral procedure for **veterinary medicinal products containing 50 mg closantel per ml (as a single active substance) presented as solutions for injection for subcutaneous use in sheep** (EMEA/V/A/126), recommending a withdrawal period (meat and offal) for sheep to provide assurance for consumer safety. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. Where necessary, the marketing authorisations of relevant products will require amendment to reflect the harmonised withdrawal period.
- The Committee discussed the rapporteur's assessment report including the co-rapporteur's critique for the referral procedure for **veterinary medicinal products containing tylosin presented as solution for injection to be administered to sheep** (EMEA/V/A/130). The Committee adopted a list of outstanding issues for the applicants and marketing authorisation holders to address in writing, and the revised timetable for the procedure. The adoption of the CVMP opinion and assessment report is foreseen for the June 2019 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

- 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

- There were no items for discussion.

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 25.01.2019 – 21.02.2019:

Product	Period
Activyl (EMEA/V/C/000163)	18.02.2018 – 17.02.2019
Bravecto (EMEA/V/C/002526)	11.02.2018 – 10.02.2019
Cimalgex (EMEA/V/C/000162)	18.02.2018 – 17.02.2019
Comfortis (EMEA/V/C/002233)	11.02.2018 – 10.02.2019
Fevaxyn Pentofel (EMEA/V/C/000030)	05.02.2018 – 04.02.2019
Hiprabovis IBR Marker Live (EMEA/V/C/000158)	27.01.2018 – 26/01.2019
Ingelvac CircoFLEX (EMEA/V/C/000126)	13.02.2018 – 12.02.2019
Kexxtone (EMEA/V/C/002235)	28.01.2018 – 27.01.2019
Loxicom (EMEA/V/C/000141)	10.02.2018 – 09.02.2019
Melosus (EMEA/V/C/002001)	21.02.2018 – 20.02.2019
MiPet Easecto (EMEA/V/C/004732)	31.01.2018 – 30.01.2019
NexGard (EMEA/V/C/002729)	11.02/2018 – 10.02.2019
Oxybee (EMEA/V/C/004296)	01.02.2018 – 31.01.2019
PIRSUE (EMEA/V/C/000054)	29.01.2018 – 28.01.2019
Purevax Rabies (EMEA/V/C/002003)	18.02.2018 – 17.02.2019
Semintra (EMEA/V/C/002436)	13.02.2018 – 12.02.2019
STARTVAC (EMEA/V/C/000130)	11.02.2018 – 10/02/2019
Stronghold Plus (EMEA/V/C/004194)	09.02.2018 – 08.02.2019
Suvaxyn Circo (EMEA/V/C/004242)	07.02.2018 – 06.02.2019
Suvaxyn CSF Marker (EMEA/V/C/002757)	10.02.2018 – 09.02.2019

5.4 Renewals

- The Committee adopted by consensus (30 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for the renewal of the marketing authorisation for **Versican Plus L4** (EMEA/V/C/003680/R/0007), and recommended that a further 5-year renewal would be required based on pharmacovigilance grounds. The Norwegian 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, the CVMP assessment report and the product information for the renewal of the marketing authorisation for **Versican Plus Pi/L4** (EMEA/V/C/003683/R/0011), and

recommended that a further 5-year renewal would be required based on pharmacovigilance grounds. The Norwegian 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, the CVMP assessment report and the product information for the renewal of the marketing authorisation for **Versican Plus DHPPi/L4** (EMEA/V/C/003678/R/0013), and recommended that a further 5-year renewal would be required based on pharmacovigilance grounds. The Norwegian 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, the CVMP assessment report and the product information for the renewal of the marketing authorisation for **Versican Plus DHPPi/L4R** (EMEA/V/C/002759/R/0014), and recommended that a further 5-year renewal would be required based on pharmacovigilance grounds. The Norwegian 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, the CVMP assessment report and the product information for the renewal of the marketing authorisation for **ERYSENG** (EMEA/V/C/002761/R/0004), and recommended that the renewal should now be indefinite. The Norwegian 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, the CVMP assessment report and the product information for the renewal of the marketing authorisation for **ERYSENG PARVO** (EMEA/V/C/002762/R/0006), and recommended that the renewal should now be indefinite. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted a list of outstanding issues for the renewal of the marketing authorisation for **Versican Plus Pi/L4R** (EMEA/V/C/003682/R/0013).
- The Committee adopted a list of outstanding issues for the renewal of the marketing authorisation for **Suvaxyn PCV** (EMEA/V/C/000149/R/0028).

5.5 Pharmacovigilance – PSURs and SARs

- The Committee adopted the CVMP assessment report of the PSUR for the period 01.04.2018-30.09.2018 for **ERAVAC** (EMEA/V/C/004239) with a recommendation to amend the product information.
- The Committee endorsed the following rapporteurs' assessment reports on PSURs concluding that no changes to the product literature or other regulatory actions were required for:

Product	Period
Exzolt (EMEA/V/C/4344)	01.03.2018 - 31.08.2018
FORTEKOR PLUS (EMEA/V/C/002804)	01.04.2018 – 30.09.2018
Galliprant (EMEA/V/C/004222)	01.04.2018 – 30.09.2018
NexGard (EMEA/V/C/002729)	01.09.2018 – 31.08.2018
ProteqFlu (EMEA/V/C/000073)	01.10.2017 – 30.09.2018

ProteqFlu-Te (EMEA/V/C/000074)	01.10.2017 – 30.09.2018
Semintra (EMEA/V/C/002436)	01.09.2018 – 31.08.2018
VarroMed (EMEA/V/C/002723)	03.02.2018 – 02.08.2018

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

5.6 Supervision and sanctions

Information relating to supervision 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 endorsed the draft EU comments on the choice of mean in dose confirmation studies, in relation to the revision of the VICH anthelmintics guidelines.
- The Committee endorsed the nomination of P. McNeill as a backup EU Expert for the VICH Expert Working Group for the development of a new general guideline on pharmaceutical combination products.
- The Committee discussed the revision of the VICH GL23 on genotoxicity testing with specific reference to the latest version of a decision tree. EU comments will be finalised at the March 2019 meeting.
- The Committee discussed the draft concept paper proposing the development of a VICH guideline on safety evaluation of biotechnology-derived/biological products and agreed that the EU would support the proposed activity, noting the restricted scope of the proposed work.
- The Committee noted the draft agendas of 37th VICH Steering Committee meeting to be held on 24-25 February and 1 March 2019, of the 11th VICH Outreach Forum meeting to be held on 25-26 February 2019, and of the draft programme of the 6th VICH Conference to be held on 27-28 February, all to be held in Cape Town, South Africa. The Committee also noted the draft reports of the Quality Expert Working Group (EWG), the Electronic Standards Implementation EWG, the Biologicals Quality Monitoring EWG, the Metabolism and Residue Kinetics EW, the Safety EWG, the Anthelmintics EWG and the Combination products EWG.

6.2 Codex Alimentarius

- There were no items for discussion.

6.3 Other EU bodies and international organisations

- The Committee noted the EFSA guidance on communication of uncertainty in scientific assessments (link).

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 SAWP-V chair on the meeting held on 20 February 2019, and noted the agenda of the meeting.
- The Committee appointed K. Baptiste as a new member of the SAWP-V.

7.2 Quality Working Party (QWP)

- The Committee elected M. O'Grady as the new veterinary vice-chair of the QWP for a 3-year term, renewable once.
- The Committee noted the nominations for the upcoming chair election of the QWP.

7.3 Safety Working Party (SWP-V)

- There were no items for discussion.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- The Committee elected R. Carapeto García as the new chair of the ERAWP for a 3-year term, renewable once.

7.5 Efficacy Working Party (EWP-V)

- There were no items for discussion.

7.6 Antimicrobials Working Party (AWP)

- The Committee elected C. Schwarz as the new chair of the AWP for a 3-year term, renewable once.

7.7 Immunologicals Working Party (IWP)

- There were no items for discussion.

7.8 Pharmacovigilance Working Party (PhVWP-V)

- The Committee received a verbal report from the PhVWP-V chair on the meeting held on 29-30 January 2019, and noted the agenda of the meeting.
- The Committee adopted the veterinary pharmacovigilance public bulletin of 2018 (EMA/CVMP/809750/2018).
- The Committee noted an update from the PhVWP-V antiparasitics subgroup.

7.9 Novel therapy groups and related issues

- There were no items for discussion.

7.10 Joint CVMP/CHMP Working Group on the application of the 3Rs (J3RsWG)

- There were no items for discussion.

7.11 Other working party and scientific group issues

- There were no items for discussion.

The following documents were circulated for information:

- Minutes of the SAWP-V meeting held on 22 January 2019;
- Agenda of the ADVENT meeting held on 29 January 2019.

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.

- There were no items for discussion.

8.2 Environmental risk assessment

- There were no items for discussion.

8.3 Antimicrobial resistance

- The Committee deferred to the March CVMP meeting the update on the report of the 6th session of the Codex Ad Hoc intergovernmental task force on antimicrobial resistance, held on 10–14 December 2018 in Busan, Republic of Korea.

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.

The following document was circulated for information:

- Draft AMEG scientific advice on the categorisation of antimicrobials as published on the EMA's website for public consultation (link)

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.

- There were no items for discussion.

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

- The Committee deferred the update on the draft minutes of the meeting held on 24-25 January 2019 and the draft agenda of the meeting to be held on 21-22 February 2019.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee noted proposals for topics to be included in the draft agenda for the upcoming informal presidency CVMP/CMDv meeting to be held at Lake Balaton, Hungary on 6-8 May 2019, under the Romanian Presidency of the Council of the European Union. A draft agenda will be presented at the March CVMP meeting.
- The Committee received an update on the Agency's relocation to Amsterdam.

13. LEGISLATION

- The Committee received a verbal update on the work progress concerning the provision of scientific recommendations on delegated and implementing acts to Regulation 2019/6 on veterinary medicinal products.

14. ANY OTHER BUSINESS

- Upon the completion of the February 2019 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 2019 meeting

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
CHAIR	**David Murphy**	Full involvement	
AT	Petra Falb	Full involvement	
BE	Bruno Urbain	Full involvement	
CY	Alia Michaelidou-Patsia	Full involvement	
DE	Gesine Hahn	Full involvement	
DK	Ellen-Margrethe Vestergaard	Full involvement	
EE	Toomas Tiirats	Full involvement	
ES	Cristina Muñoz Madero	Full involvement	
FI	Tita-Maria Muhonen	Full involvement	
FR	Jean-Claude Rouby	Full involvement	
HR	Frane Božić	**Involvement only** in discussions i.e. no part in final deliberations and voting, and cannot act as rapporteur, other leading /co-ordinating role or formally appointed peer reviewer in relation to any medicinal product from **Genera Research**	• 4.3 - Art. 35 - Betamox
HU	Gábor Kulcsár	Full involvement	
IE	J. Gabriel Beechinor	Full involvement	
IT	Paolo Pasquali	Full involvement	
LU	Marc Schmit	Full involvement	
NL	Peter Hekman	Full involvement	
PL	Anna Wachnik-Święcicka	**Involvement only** in discussions i.e. no part in final deliberations and voting, and cannot act as rapporteur, other leading /co-ordinating role or formally appointed peer reviewer in relation to any medicinal product from **Bayer**	• 4.3 - Art. 35 - Betamox
SE	Frida Hasslung Wikström	Full involvement	
SI	Katarina Straus	Full involvement	
UK	Helen Jukes	Full involvement	
Co-opted	Keith Baptiste	Full involvement	
Co-opted	Rory Breathnach	Full involvement	
Co-opted	G. Johan Schefferlie	Full involvement	

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
Co-opted	Wilhelm Schlumbohm	Full involvement	
Co-opted	Ricardo Carapeto García	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	
BG	Svetoslav Branchev	**Involvement only** in discussions i.e. no part in final deliberations and voting, and cannot act as rapporteur, other leading /co-ordinating role or formally appointed peer reviewer in relation to any medicinal product from **KRKA**	• 4.3 Art. 35 - Closantel
CZ	Leona Nepejchalová	Full involvement	
DE	Esther Werner	Full involvement	
EL	Angeliki Tsigouri	Full involvement	
FR	Sylvie Louet	Full involvement	
NL	Jacqueline Poot	Full involvement	
PT	Cristina Gonçalves Santos	Full involvement	
RO	Gabriela Tuchila	Full involvement	
SK	Eva Chobotová	Full involvement	
UK	Rory Cooney	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			
CZ	Ivana Haunerová *(remotely)*	Full involvement	
DE	Andrea Golombiewski	Full involvement	
DE	Kathrin Dietze	Full involvement	
DE	Stefan Scheid *(remotely)*	Full involvement	
DE	Anke Finnah *(remotely)*	Full involvement	
DE	Svenja Rieke *(remotely)*	Full involvement	
DE	Uta Herbst *(remotely)*	Full involvement	
DE	Nikola Lange *(remotely)*	Full involvement	
DE	Daniela Loos *(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
DE	Dagmar Sommer *(remotely)*	Full involvement	
DE	Yasemin Süzer *(remotely)*	Full involvement	
DE	Rolf Beckmann *(remotely)*	Full involvement	
ES	María José Ferrer *(remotely)*	Full involvement	
ES	Alberto de Prado *(remotely)*	Full involvement	
ES	Rosario Bullido *(remotely)*	Full involvement	
ES	Carlos Ballesteros *(remotely)*	Full involvement	
ES	Raúl Belmar *(remotely)*	Full involvement	
ES	Sonia Gil Morales *(remotely)*	Full involvement	
IE	Sarah Buckley *(remotely)*	Full involvement	
IE	Susan Reid *(remotely)*	Full involvement	
FR	Florence Pillet *(remotely)*	Full involvement	
FR	Karen Millet *(remotely)*	Full involvement	
FR	Damien Bouchard *(remotely)*	Full involvement	
FR	Martine Redureau *(remotely)*	Full involvement	
FR	Anne-Marie Jacques *(remotely)*	Full involvement	
FR	Anne Sagnier *(remotely)*	Full involvement	
FR	Nathalie Bridoux	Full involvement	
NL	Kim Boerkamp	Full involvement	
NO	Annelin Bjelland *(remotely)*	Full involvement	
SE	Malin Öhlund	Full involvement	
SE	Catarina Eriksson *(remotely)*	Full involvement	
SE	Jennie Sanberg *(remotely)*	Full involvement	
SE	Andreea Barbu *(remotely)*	Full involvement	
UK	Peter Clegg *(remotely)*	Full involvement	

CVMP working parties and CMDv	Chair
ADVENT	Jean-Claude Rouby
AWP	Helen Jukes
CMDv	---
ERAWP	Ricardo Carapeto García
EWP-V	Cristina Muñoz Madero
IWP	Esther Werner
J3Rs WG	Ellen-Margrethe Vestergaard
PhVWP-V	Els Dewaele - *remotely*
QWP	---
SAWP-V	Rory Breathnach
SWP-V	---

Observer from the European Commission	
Present	

Observers from Swissmedic	
Remotely	

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