19 June 2018
EMA/CVMP/303818/2018
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 23–25 May 2018 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 May 2018 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 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.

No contacts were declared.

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iv. Adoption of the minutes of the previous meeting

The minutes of the April 2018 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

- There were no items for discussion.

1.2 Oral explanations and lists of outstanding issues

- There were no items for discussion.

1.3 Lists of questions

- There were no items for discussion.

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 (28 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **UBAC** (EMEA/V/C/004595/0000), recommending the granting of a marketing authorisation. The product is a new vaccine for active immunisation of healthy cows and heifers to reduce the incidence of clinical intramammary infections caused by *Streptococcus uberis,* to reduce the somatic cell count in *Streptococcus uberis* positive quarter milk samples and to reduce milk production losses after *Steptocoocus uberis* intramammary infections. The Norwegian CVMP member 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 heard an oral explanation from the applicant concerning an application for a new product (EMEA/V/C/004291/0000), an antiparasitic product in cattle. The Committee also 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 June 2018 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 adopted the EPAR module 6 scientific discussion for **Bravecto Plus** (EMEA/V/C/004440/0000) concerning the granting of the initial marketing authorization.
- The Committee adopted the EPAR module 6 scientific discussion for **Dany's BienenWohl** (EMEA/V/C/004667/0000) concerning the granting of the initial marketing.
- The Committee adopted the EPAR module 6 scientific discussion for **Semintra** (EMEA/V/C/002436/X/0008) concerning the granting of the initial marketing authorisation.
- The Committee adopted the withdrawal EPAR, following the formal notification from the applicant to withdraw their application for **Zydax** (EMEA/V/C/004667/0000).

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- 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 a grouped type II variation for **Pexion** (EMEA/V/C/002543/II/0011/G), recommending the variation of the marketing authorisation to add a new therapeutic indication and to implement amendments related to the product information. 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 (28 members present of those eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report for a grouped type II variation for **Exzolt** (EMEA/V/C/004344/II/0003/G), recommending the variation of the marketing authorisation to implement quality changes. The Norwegian CVMP member 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 endorsed the rapporteur's assessment report for a grouped type II variation for **CLYNAV** (EMEA/V/C/002390/II/0001/G), recommending the variation of the marketing authorisation to implement quality changes. The Norwegian CVMP member 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 a type II variation for **Porcilis PCV M Hyo** (EMEA/V/C/003796/II/0007), recommending the variation of the marketing authorisation to modify the approved therapeutic indication. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.

3.2 Oral explanations and lists of outstanding issues

- There were no items for discussion.

3.3 Lists of questions

- The Committee adopted a list of questions for a worksharing type II variation for **Versican Plus DHPPI**, **Versican Plus DHPPi+L4**, **Versican Plus DHPPi+L4R**, **Versican Plus L4**, **Versican Plus Pi**, **Versican Plus Pi+L4** and **Versican Plus Pi+L4R** (and related nationally-authorised products) (EMEA/V/C/WS1337), concerning changes in the product information.
- The Committee adopted a list of questions for a type II variation for **RESPIPORC FLUpan H1N1** (EMEA/V/C/003993/II/0004), concerning quality changes.

3.4 Re-examination of CVMP opinions

- There were no items for discussion.

3.5 Other issues

- The Committee agreed to a request from the MAH for an extension to the clock-stop for a type II variation for **Galliprant** (EMEA/V/C/004222/II/0001), concerning quality changes.
- The Committee agreed to a request from the MAH for an extension to the clock-stop for a grouped type II variation, following a work sharing procedure for **NexGard** and **NEXGARD SPECTRA** (EMEA/V/C/WS1338/G), to add new therapeutic indications.
- The Committee agreed to a request from the MAH for an extension to the clock-stop for a grouped type II variation for **HALAGON** (EMEA/V/C/004201/II/0002/G), 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

- There were no items for discussion.

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

- The Committee noted the EMA response to a request from CP-Pharma GmbH for an extension to the clock-stop for the Art. 30(3) procedure for veterinary medicinal products containing gentamicin for parenteral administration to horses (EMEA/V/A/128).

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 endorsed the rapporteur's assessment report on the data submitted concerning a recommendation for **Exzolt** (EMEA/V/C/004344/REC/007-008-009).

- The Committee endorsed the rapporteur's assessment report on the data submitted concerning a recommendation for **LETIFEND** (EMEA/V/C/003865/REC/012).

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 20.04.2018 – 24.05.2018:

Product	Period
Credelio (EMEA/V/C/004247)	25.04.2017 – 24.04.2018
CYTOPOINT (EMEA/V/C/003939)	25.04.2017 – 24.04.2018
Equilis StrepE (EMEA/V/C/000078)	07.05.2017 – 06.05.2018
Improvac (EMEA/V/C/000136)	11.05.2017 – 10.05.2018
Ingelvac PCV FLEX (EMEA/V/C/004645)	24.05.2017 – 23.05.2018
LETIFEND (EMEA/V/C/003865)	20.04.2017 – 19.04.2018
Meloxidolor (EMEA/V/C/002590)	22.04.2017 – 21.04.2018
Naxcel (EMEA/V/C/000079)	19.05.2017 – 18.05.2018
Oncept IL-2 (EMEA/V/C/002562)	03.05.2017 – 02.05.2018
Procox (EMEA/V/C/002006)	20.04.2017 – 19.04.2018
RESPIPORC FLUpan H1N1 (EMEA/V/C/003993)	17.05.2017 – 16.05.2018
Versican Plus DHPPi/L4 (EMEA/V/C/003678)	07.05.2017 – 06.05.2018
Versican Plus DHPPi/L4R (EMEA/V/C/002759)	07.05.2017 – 06.05.2018
Zeleris (EMEA/V/C/004099)	15.05.2017 – 14.05.2018
Zulvac BTV Ovis (EMEA/V/C/004185)	25.04.2017 – 24.04.2018
Zuprevo (EMEA/V/C/002009)	06.05.2017 – 05.05.2018

5.4 Renewals

- 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 renewal of the marketing authorisation for **Reconcile** (EMEA/V/C/000133/R/0018), and recommended that the authorisation should now be indefinite. The Norwegian CVMP member 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 renewal of the marketing authorisation for **APOQUEL** (EMEA/V/C/002688/R/0013), and recommended that the authorisation should now be indefinite. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.

5.5 Pharmacovigilance – PSURs and SARs

- The Committee adopted the CVMP assessment report on the PSUR for the period 01.06.2017 - 30.11.2017 for **Suvaxyn Circo MH- RTU** (EMEA/V/C/003924) 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
BROADLINE (EMEA/V/C/002700)	01.01.2017 - 31.12.2017
Cerenia (EMEA/V/C/000106)	01.01.2017 - 31.12.2017
Circovac (EMEA/V/C/000114)	01.01.2015 - 31.12.2017
Contacera (EMEA/V/C/002612)	01.01.2017 - 31.12.2017
Innovax IL-T (EMEA/V/C/003869)	01.08.2017 - 31.01.2018
Panacur AquaSol (EMEA/V/C/002008)	01.01.2017 - 31.12.2017
Posatex (EMEA/V/C/000122)	01.01.2015 - 31.12.1207
Poulvac E. Coli (EMEA/V/C/002007)	01.07.2017 - 31.12.2017
Spironolactone Ceva (EMEA/V/C/000105)	01.01.2015 - 31.12.2017
Vectra Felis (EMEA/V/C/002746)	01.01.2015 - 31.12.2017
Velactis (EMEA/V/C/003739)	01.07.2017 - 31.12.2017
Zycortal (EMEA/V/C/003782)	01.06.2017 - 31.12.2017

- 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.

6. CO-OPERATION WITH OTHER EU OR INTERNATIONAL BODIES

6.1 VICH

- The Committee endorsed the revised draft VICH guideline 56 on residue studies in honey for establishing MRLs and withdrawal periods, for sign-off by the EWG at step 5 of the VICH process.
- The Committee endorsed the EU proposal to put the revision of VICH GL18(R) on residual solvents on hold until ongoing revisions of the related ICH guideline are complete.
- The Committee noted the draft agenda of the 36th VICH Steering Committee meeting to be held on 25-26 and 28 June 2018 in Bruges and the draft agenda of the 10th VICH Outreach Forum meeting to be held on 26-27 June 2018 also in Bruges.

6.2 Codex Alimentarius

- The Committee received a verbal report on the 24th session of the Codex Committee on Residues of Veterinary Drugs in Food held in Chicago, USA from 23 – 27 April 2018, and noted the meeting report and the agenda of the meeting.

6.3 Other EU bodies and international organisations

- The Committee discussed the report on the appropriateness of the existing 'No MRL required' classification of theophylline in view of ECHA's ongoing review of the classification and labelling of the substance, and noted the presentation from the rapporteur. The Committee confirmed that no further action is required.
- The Committee was informed of the recommendation of the European Chemicals Agency (ECHA) to include N-methyl-pyrrolidone in the List of Substances subject to Authorisation.

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 23 May 2018, and noted the agenda of the meeting.

7.2 Quality Working Party (QWP)

- The Committee was informed of the reflection paper on the Requirements for Selection and Justification of Starting Materials for the Manufacture of Chemical Active Substances (EMA/CHMP/CVMP/QWP/826771/2016), which has become invalid as a result of the entry into force of the Q&A on ICH Q11.

7.3 Safety Working Party (SWP-V)

- The Committee received a verbal report from the chair of the SWP-V on the meeting held on 17-18 May 2018, and noted the agenda of the meeting. The Committee noted that the SWP-V no longer plans to run a physical training event on user risk assessment of topically applied products in 2018, but that it still hopes to make training material available electronically this year. A physical training event will take place as a follow up activity.
- The Committee was informed of the upcoming election of the SWP-V vice-chair at the July 2018 CVMP meeting, and noted the call for nominations.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- The Committee discussed the draft reflection paper on antimicrobial resistance (AMR) in the environment: considerations for current and future risk assessment of veterinary medicinal products (VMPs). Committee members are invited to provide comments to the document until the 21 June. The document will be presented for adoption for release for consultation at the July 2018 CVMP meeting. – *see also 7.6*

7.5 Efficacy Working Party (EWP-V)

- There were no items for discussion.

7.6 Antimicrobials Working Party (AWP)

- The Committee discussed the draft reflection paper on antimicrobial resistance (AMR) in the environment: considerations for current and future risk assessment of veterinary medicinal products (VMPs). Committee members are invited to provide comments to the document until the 21 June. The document will be presented for adoption for release for consultation at the July 2018 CVMP meeting. – *see also 7.4*

- The Committee discussed the revision of the reflection paper on use of aminoglycosides in animals in the European Union: development of resistance and impact on human and animal health and the overview of comments received following a consultation period. The adoption of the revised reflection paper for release for consultation is foreseen for the June 2018 CVMP meeting.

7.7 Immunologicals Working Party (IWP)

- The Committee discussed the draft revised guideline on the use of adjuvanted veterinary vaccines. The adoption of the draft revised guideline for release for public consultation is foreseen for the June 2018 CVMP meeting.

- The Committee received a verbal report from E. Werner on the Joint EDQM/EMA 15V meeting in Strasbourg held on 12 April 2018 in relation to guidance regarding the implementation of extraneous agent (EA) testing.

7.8 Pharmacovigilance Working Party (PhVWP-V)

- The Committee adopted the revised recommendation for the basic surveillance of EudraVigilance Veterinary (EVVet) data for centrally authorised products (CAPs) (EMA/CVMP/PhVWP/171122/2016-Rev.1) and the overview of comments received (EMA/CVMP/PhVWP/519126/2017).

7.9 Novel therapy groups and related issues

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

- The Committee received a verbal report from the chair of the J3RsWG on the meeting held on 24 April 2018, and noted the agenda of the meeting.

- The Committee discussed the Review and update of EMA guidelines to implement best practice with regard to 3Rs (replacement, reduction and refinement) in regulatory testing of medicinal products – report on actions taken. The adoption of the review document and the overview of comments received are foreseen for the June 2018 CVMP meeting.

- The Committee discussed the reflection paper providing an overview of the current regulatory testing requirements for veterinary medicinal products and opportunities for implementation of the 3Rs. The adoption of the reflection paper and the overview of comments received are foreseen for the June 2018 CVMP meeting.

- The Committee was informed of the EU-NTC Assessors Training on 3Rs and immunological veterinary medicinal products (IVMPs), to be held on 25-26 June 2018 in Copenhagen, 'Challenges and opportunities for the application of 3Rs to the regulation of IVMPs', and noted the training programme and training event poster of the meeting.

7.11 Other working party and scientific group issues

The Committee adopted the revised mandates following a revision of the rules of procedure (RoP) of the CVMP working parties regarding the maximum duration for which a WP chair can serve with regard to Efficacy Working Party, Safety Working Party, Environmental Risk Assessment Working Party, Immunologicals Working Party, Scientific Advice Working Party, Pharmacovigilance Working Party and Antimicrobials Working Party.

The following documents were circulated for information:

- Minutes of the SAWP-V meeting held on 17 April 2018.
- Draft agenda of the Efficacy Working Party meeting held on 29-30 May 2018.
- Draft Agenda Pharmacovigilance Working Party (PhVWP-V) meeting held on the 29-30 May 2018.

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 received an update on the Pilot Project on Dose Optimisation of Established Veterinary Antibiotics (PPHOVA) in the context of SPC harmonisation and discussed the draft report prepared by the group as well as the draft PPHOVA recommendations. The Committee agreed that the above documents should be circulated for comments to the relevant CVMP WPs.
- The Committee received feedback on the development of the scientific advice prepared by the Antimicrobial Advice Ad Hoc Expert Group (AMEG) and noted the comments received on the questionnaire on the Early Hazard Characterisation from AnimalhealthEurope and EGGVP.
- The Committee was informed of the European Commission report on measures to tackle antimicrobial resistance through the prudent use of antimicrobials in animals.

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.

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 revised Terms of Reference for the CVMP ad hoc group on veterinary vaccine availability (CADVVA) extending the mandate of the group for two more years.

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 19 April 2018 as well as the draft agenda of the meeting held on 24-25 May 2018.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee received a presentation from S. Kennedy on the training needs of NCA assessors involved in the work of the CVMP: preliminary priority needs and plans for training 2018 – 2020.
- The Committee discussed the points for consideration identified following the review by the CVMP chair and secretariat of the CVMP Rules of Procedure and the CVMP guidance on appointment and responsibilities of rapporteurs, and noted the presentation. Further discussion is foreseen to take place at the July CVMP meeting.
- The Committee discussed the CVMP work plan for 2019, following the chair's presentation, where it was highlighted that ongoing activities should be completed within 2018. It was agreed that preliminary proposals will be available following the June SPG meeting.
- The Committee received a verbal report from C. Muñoz on the CVMP Presidency (during the Bulgarian presidency) meeting held on 7-8 May in Madrid, Spain and noted the agenda of the meeting.
- The Committee was informed that the next informal CVMP and joint CVMP/CMDv Presidency meeting will be hosted by Finland (during the Austrian presidency) on 25-26 October 2018 in Helsinki, Finland.

13. LEGISLATION

- There were no items for discussion.

14. ANY OTHER BUSINESS

- Upon the completion of the May 2018 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 May 2018 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**	
BE	Bruno Urbain	Full involvement	
BG	Emil Kozhuharov	Full involvement	
DE	Gesine Hahn	Full involvement	
DK	Ellen-Margrethe Vestergaard	Full involvement	
EE	Toomas Tiirats	Full involvement	
EL	Ioannis Malemis	Full involvement	
ES	Cristina Muñoz Madero	Full involvement	
FI	Tita-Maria Muhonen	**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 **Orion oyj**	• 3.3 Versican • 7.9 ITF briefing meeting
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**	• None
HU	Gábor Kulcsár	Full involvement	
IE	J. Gabriel Beechinor	Full involvement	
LV	Zanda Auce	**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 **Olainfarm JSC**	• None

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
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**	• 10.1 – one item
PT	João Pedro Duarte da Silva	Full involvement	
RO	Lollita Taban	Full involvement	
SE	Frida Hasslung Wikström	Full involvement	
SI	Katarina Straus	Full involvement	
SK	Judita Hederová	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	
Co-opted	Wilhelm Schlumbohm	Full involvement	
Co-opted	Jason Weeks	**No involvement** i.e. no part in discussions, final deliberations and voting as appropriate with respect to the medicinal product Salmosan, and cannot act as rapporteur or peer reviewer for this product	• None
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
AT	Petra Falb	Full involvement	
CZ	Leona Nepejchalová	Full involvement	
DE	Esther Werner	Full involvement	
FR	Sylvie Louet	Full involvement	
NL	Jacqueline Poot	Full involvement	
PL	Ewa Augustynowicz	Full involvement	
UK	Noemi Garcia del Blanco	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
BE	Sandy Vermout	Full involvement	
DE	Susanne Schmitz	Full involvement	
DE	Jean Bachmann	Full involvement	
DE	Stefan Scheid – *remotely*	Full involvement	
DE	Uta Herbst – *remotely*	Full involvement	
DE	Simon Schwarz – *remotely*	Full involvement	
DE	Babett Kobe – *remotely*	Full involvement	
DK	Merete Blixenkrone-Møller – *remotely*	Full involvement	
DK	John Jensen – *remotely*	Full involvement	
FI	Kristina Lehmann – *remotely*	Full involvement	
FR	Benoit Courty – *remotely*	Full involvement	
FR	Florence Pillet – *remotely*	Full involvement	
FR	Jean-Christophe Faucon – *remotely*	Full involvement	
FR	Damien Bouchard – *remotely*	Full involvement	
IE	Michele Johnson – *remotely*	**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 **Jansen Pharmaceutical**	• None
NL	Engeline van Duijkeren – *remotely*	Full involvement	
PL	Anita Piwowarczyk	Full involvement	
UK	Kenneth Stapleton – *remotely*	Full involvement	
UK	Jean-Paul Schmidt	Full involvement	

CVMP working parties and CMDv	Chair
ADVENT	Jean-Claude Rouby
AWP	Helen Jukes
CMDv	---

CVMP working parties and CMDv	Chair
ERAWP	Jason Weeks
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	Stefan Scheid

Observer from the European Commission	
Present	

Observers from Swissmedic	
Remotely	

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