3 November 2021
EMA/CVMP/622424/2021
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 5-7 October 2021 meeting

Chair: D. Murphy – Vice-chair: G. J. Schefferlie

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).

Due to the COVID-19 pandemic, the October 2021 CVMP meeting took place by means of remote participation and decision making.

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 October 2021 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. 17 or more members of the 32 members eligible to vote were present. Furthermore, absolute majority requires that 17 members vote in favour of the proposed decision.

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 September 2021 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 (27 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Imoxat** (EMEA/V/C/005597/0000), recommending the granting of a marketing authorisation. Imoxat is a new generic product containing imidacloprid and moxidectin for the treatment and/or prevention of mixed parasitic infections in cats, ferrets and dogs. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of the 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 **Apoquel** (EMEA/V/C/002688/X/00019), recommending the extension of the marketing authorisation to add a new pharmaceutical form for dogs. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of the 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 **Suiseng Diff/A** (EMEA/V/C/005596/00000), recommending the granting of a marketing authorisation. The product is a new vaccine for the passive immunisation of neonatal piglets by means of the active immunisation of breeding sows and gilts to prevent mortality and reduce clinical signs and macroscopic lesions caused by *Clostridioides difficile,* toxins A and B, and to reduce clinical signs and macroscopic lesions caused by *Clostridium perfringens* Type A, α-toxin. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of the opinion for publication.
- The Committee adopted by consensus (22 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Zenalpha** (EMEA/V/C/005465/00000), recommending the granting of a marketing authorisation. Zenalpha is a new product containing medetomidine hydrochloride and vatinoxan hydrochloride, to provide restraint, sedation and analgesia during conduct of non-invasive, non-painful or mildly painful procedures and examinations intended to last no more than 30 minutes in dogs. The Committee noted the summary of the 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 marketing authorisation for a new vaccine (EMEA/V/C/005185/0000) in pigs. 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 November 2021 CVMP meeting.
- The Committee adopted the scientific overview including the list of outstanding issues and agreed comments on the draft product information for a marketing authorisation application for a new generic product (EMEA/V/C/005606/0000) in cattle, pigs, and sheep. The Committee agreed that an oral explanation would not be requested. The Committee noted a peer review report and the comments received from CVMP members.

2.3 Lists of questions

- The Committee adopted the scientific overview including a list of questions and agreed comments on the draft product information for a marketing authorisation application for a new product (EMEA/V/C/005829/0000) in dogs. The Committee noted peer review reports and the comments received from CVMP members.

2.4 Re-examination of CVMP opinions

- There were no items for discussion.

2.5 Other issues

- The Committee agreed to the request from the applicant for a further extension to the clock-stop for a new product (EMEA/V/C/005538/0000).
- The Committee endorsed the European public assessment report (EPAR) 'scientific discussion' for **Strangvac** (EMEA/V/C/005309/0000) concerning the granting of the initial marketing authorisation.

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- The Committee adopted by consensus (23 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information, for a grouped type II variation application for **NexGard Combo** (EMEA/V/C/005094/II/0002/G), recommending the variation of the marketing authorisation to add new therapeutic indications for the treatment of notoedric mange (caused by *Notoedres cati*), the treatment of infections with *Aelurostrongylus abstrusus* (L3, L4 larvae and adults) and prevention of aelurostrongylosis in cats; and to support the safe use of the product in breeding, pregnant and lactating queens. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of the opinion for publication.
- The Committee adopted by consensus (23 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information, for a type II variation application (subject to a work-sharing procedure) for **Nobivac L4** (EMEA/V/C/002010/WS2058/0012), recommending the variation of the marketing authorisation to change the product information to introduce the associated non-mixed use of Nobivac L4 with another related nationally authorised product. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report, for a type II variation application for **Reconcile** (EMEA/V/C/000133/II/0039), recommending the variation of the marketing authorisation to update the pharmacovigilance system. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion and the product information, and endorsed the rapporteur's assessment report, for a type IB variation application (subject to a work-sharing procedure) for **Vaxxitek HVT+IBD**, **Prevexxion RN+HVT+IBD** and **Prevexxion RN** (EMEA/V/C/xxxxxx/WS2107), recommending the variation of the marketing authorisation to implement quality-related 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 for a type II variation application (subject to a work-sharing procedure) for **Meloxidyl and Zeleris** (EMEA/V/C/xxxxxx/WS2038), concerning quality-related changes.

3.3 Lists of questions

- The Committee adopted a list of questions and agreed comments on the product information for a grouped type II variation application for **Evant** (EMEA/V/C/004902/II/0002/G), concerning quality-related changes.
- The Committee adopted a list of questions for a type II variation application for **Tulissin** (EMEA/V/C/005073/II/0005), concerning quality-related changes.
- The Committee adopted a list of questions for a type IB variation application (subject to a work-sharing procedure) for **Forceris** (EMEA/V/C/004329/WS/0003), concerning quality-related changes.

3.4 Re-examination of CVMP opinions

- There were no items for discussion.

3.5 Other issues

- The Committee endorsed the European public assessment report (EPAR) 'scientific discussion' for **Ingelvac CircoFLEX** (EMEA/V/C/WS1921) concerning the variation of the marketing authorisation.
- The Committee endorsed the European public assessment report (EPAR) 'scientific discussion' for **Suvaxyn CSF Marker** (EMEA/V/C/002757/II/0009) concerning the variation of the marketing authorisation.

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

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 10.09.2021 – 07.10.2021:

Product	Period
Apoquel (EMEA/V/C/002688)	12.09.2020 – 11.09.2021
Cerenia (EMEA/V/C/000106)	29.09.2020 – 28.09.2021
Coxevac (EMEA/V/C/000155)	30.09.2020 – 29.09.2021
Eravac (EMEA/V/C/004239)	22.09.2020 – 21.09.2021
Increxxa (EMEA/V/C/005305)	16.09.2020 – 15.09.2021
Innovax-ND-ILT (EMEA/V/C/005190)	16.09.2020 – 15.09.2021
Mhyosphere PCV ID (EMEA/V/C/005272)	18.09.2020 – 17.09.2021
Nobivac Bb (EMEA/V/C/000068)	10.09.2020 – 09.09.2021
Palladia (EMEA/V/C/000150)	23.09.2020 – 22.09.2021
Previcox (EMEA/V/C/000082)	13.09.2020 – 12.09.2021
Recocam (EMEA/V/C/002247)	13.09.2020 – 12.09.2021
Rhiniseng (EMEA/V/C/000160)	16.09.2020 – 15.09.2021
Simparica Trio (EMEA/V/C/004846)	17.09.2020 – 16.09.2021
Tulinovet (EMEA/V/C/005076)	16.09.2020 – 15.09.2021

5.4 Renewals

- The Committee adopted by consensus (27 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 **Varromed** (EMEA/V/C/002723/R/0005), 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 (27 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 **Stronghold Plus** (EMEA/V/C/004194/R/0008), 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 recommendations for changes to the summary of product characteristics for **Bravecto Plus** and **Ubac** as an outcome of signal detection activities.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.05.2020 – 30.04.2021 for **Letifend** (EMEA/V/C/003865) with a recommendation to amend the product information.

- The Committee adopted the CVMP assessment report of the PSUR for the period 01.03.2018 – 28.02.2021 for **Purevax RC** (EMEA/V/C/000091) with a recommendation to amend the product information.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.03.2018 – 28.02.2021 for **Purevax RCP** (EMEA/V/C/000090) with a recommendation to amend the product information.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.3.2018 – 28.02.2021 for **Purevax RCP FeLV** (EMEA/V/C/000089) with a recommendation to amend the product information.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.03.2018 – 28.02.2021 for **Purevax RCPCh** (EMEA/V/C/000088) with a recommendation to amend the product information.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.03.2018 – 28.02.2021 for **Purevax RCPCh FeLV** (EMEA/V/C/000085) with a recommendation to amend the product information.
- The Committee endorsed the following rapporteur's assessment reports on PSURs concluding that no changes to the product information or other regulatory actions were required for:

Product	Period
Apoquel (EMEA/V/C/002688)	01.06.2018 – 31.05.2021
Baycox Iron (EMEA/V/C/004794)	01.12.2020 – 31.05.2021
Bovilis Blue-8 (EMEA/V/C/004776)	01.07.2020 – 30.06.2021
Clevor (EMEA/V/C/004417)	01.11.2020 – 30.04.2021
Porcilis AR-T DF (EMEA/V/C/000055)	01.06.2018 – 31.05.2021
Recocam (EMEA/V/C/002247)	01.04.2018 – 31.03.2021
Respiporc FLUpan H1N1 (EMEA/V/C/003993)	01.06.2020 – 31.05.2021

- 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.

- There were no items for discussion.

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 revision of VICH GL18 on impurities: residual solvents in new veterinary medicinal products, active substances and excipients (EMA/CVMP/VICH/502/1999), updated to include tertiary-butyl alcohol, cyclopentyl methyl ether, 2-methyltetrahydrofuran, and triethylamine, for sign-off at Expert Working group level.

- The Committee discussed the draft VICH guideline on target animal safety evaluation for veterinary monoclonal antibody products.
- The Committee endorsed the EU comments on the following revised draft VICH guidelines on efficacy of anthelmintics:

  - VICH GL7 (general)
  - VICH GL12 (bovine)
  - VICH GL13 (ovine)
  - VICH GL14 (caprine)
  - VICH GL15 (equine)
  - VICH GL16 (porcine)
  - VICH GL19 (canine)
  - VICH GL20 (feline)
  - VICH GL21 (poultry)

6.2 Codex Alimentarius

- There were no items for discussion.

6.3 Other EU bodies and international organisations

- There were no items for discussion.

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 cannot be released at the present time as it is deemed to be commercially confidential.

7.1 Scientific Advice Working Party (SAWP-V)

- The Committee received a verbal report from the SAWP-V Chair on the meeting held on 4 October 2021, and noted the agenda of the meeting.

7.2 Quality Working Party (QWP)

- The Committee received a verbal report from the QWP veterinary vice-chair on the meeting held on 22-23 September 2021, and noted the agenda of the meeting, the minutes of the QWP meeting held on 25-27 May 2021, and the agenda of the Joint GMDP IWG - QWP meeting held on 22 September 2021.

7.3 Safety Working Party (SWP-V)

- The Committee adopted draft revised guidelines on determination of withdrawal periods for edible tissues (EMA/CVMP/SWP/735325/2012), on determination of withdrawal periods for milk (EMA/CVMP/SWP/735418/2012) and on injection site residues (EMA/CVMP/SWP/185470/2004) for a 2-month period of public consultation. These guidelines have been revised to align with the new definition for withdrawal periods provided in Regulation (EU) 2019/6.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- The Committee adopted a reflection paper on the interpretation of Article 72 of Regulation (EU) 2019/6 regarding environmental safety documentation and environmental risk assessment of certain veterinary medicinal products (EMA/CVMP/ERA/245311/2021) for a 3-month period of public consultation. This reflection paper has been developed to aid the procedure for the harmonisation of the summary of product characteristics (SPC) according to Articles 69–71 of Regulation (EU) 2019/6 with regards to environmental risk assessment.

7.5 Efficacy Working Party (EWP-V)

- There were no items for discussion.

7.6 Antimicrobials Working Party (AWP)

- The Committee received a report from the AWP chair on the meeting held on 21 - 22 September 2021, and noted the agenda of the meeting.
- The Committee adopted a concept paper, proposing updates to the CVMP's reflection paper on the use of macrolides, lincosamides and streptogramins (MLS) in food-producing animals in the European Union: development of resistance and impact on human and animal health (EMA/CVMP/AWP/266787/2021) for a 3-month period of public consultation. This concept paper has been developed to address the need to review the status of these antimicrobial classes, in particular considering their importance to treat zoonotic campylobacter infections in humans and their ability to select for certain multi-resistance genes which have been detected in isolates from animals in Europe. Furthermore, both the (approved) indications and the volumes of use of these antibiotic classes have changed. Therefore, an update of the reflection paper is now recommended.

7.7 Immunologicals Working Party (IWP)

7.8 Pharmacovigilance Working Party (PhVWP-V)

- The Committee received a verbal report from the PhVWP-V chair on the meeting held on 21-22 September 2021 and noted the agenda of the meeting.
- The Committee received a verbal report from the PhVWP-V chair on the PhVWP-V Interested Parties meeting held on 22 September 2021 and noted the agenda and summary of the participants' evaluation (EMA/556558/2021) of the meeting.

7.9 Novel therapy groups and related issues

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

The following document was circulated for information:

- Minutes of the SAWP-V meeting held on 6 September 2021.
- Minutes of the AWP meeting held on 25-26 May 2021.

8. OTHER SCIENTIFIC MATTERS

8.1 MRL issues

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

- There were no items for discussion.

8.2 Environmental risk assessment

- There were no items for discussion.

8.3 Antimicrobial resistance

- There were no items for discussion.

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 be commercially confidential.

- 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.

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 received a verbal report from the CMDv chair on the meetings held on 15-16 July 2021 and 9-10 September 2021, and noted the draft minutes of the meeting held on 9-10 September 2021 as well as the draft agenda of the meeting to be held on 7-8 October 2021, the draft agenda of the CMDv-Interested Parties meeting to be held on 8 October 2021, minutes of the CMDv-Interested Parties meeting held on 12 May 2021, and the agenda of the CMDv Presidency meeting to be held on 14 October 2021.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee discussed the revised procedural advice to applicants/marketing authorisation holders on re-examination of CVMP opinions.
- The Committee received information from K. Štraus on the CVMP Presidency meeting (to be held virtually during the Slovenian presidency) on 13 October 2021.
- The Committee was informed of an Info day for micro, small and medium-sized enterprises (SMEs) on the new Veterinary Medicinal Products Regulation that will take place virtually on 28 October 2021. Further information is available on the EMA website (link).

13. LEGISLATION

- The Committee adopted a concept paper on scientific guidelines for limited markets products deemed not eligible for authorisation under Article 23 of Regulation (EU) 2019/6 (EMA/CVMP/435071/2021) for a 2-month period of public consultation.
- The Committee discussed a concept paper on the revision of the CVMP recommendation on the evaluation of the benefit-risk balance of veterinary medicinal products.
- The Committee discussed draft veterinary good pharmacovigilance practice (VGVP) modules on: collection and recording of suspected adverse events for veterinary medicinal products; signal management; veterinary pharmacovigilance communication; pharmacovigilance inspections; pharmacovigilance systems and their PSMF and QMS.

14. ANY OTHER BUSINESS

- Upon the completion of the October 2021 CVMP meeting, the draft news highlights was circulated for members to provide 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 October 2021 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	
BG	Svetoslav Valentinov Branchev	Full involvement	
CZ	Leona Nepejchalová	Full involvement	
DE	Esther Werner	Full involvement	
DK	Niels Christian Kyvsgaard	Full involvement	
EE	Toomas Tiirats	Full involvement	
EL	Spyridon Farlopoulos	Full involvement	
ES	Cristina Muñoz Madero	Full involvement	
FI	Minna Leppänen	Full involvement	
FR	Sylvie Louet	Full involvement	
HR	Frane Božić	Full involvement	
HU	Gábor Kulcsár	Full involvement	
IE	J. Gabriel Beechinor	Full involvement	
IT	Paolo Pasquali	Full involvement	
LU	Marc Schmit	Full involvement	
LV	Zanda Auce	Full involvement	
NL	Jacqueline Poot	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**	5.5 Pharmacovigilance – PSURs and SARs
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	
Co-opted	Keith Baptiste	Full involvement	
Co-opted	Rory Breathnach	Full involvement	
Co-opted	G. Johan Schefferlie **VICE CHAIR**	Full involvement	
Co-opted	Mary O'Grady	Full involvement	
Co-opted	Ricardo Carapeto García	Full involvement	

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
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	Manuela Leitner	Full involvement	
BE	Frédéric Klein	Full involvement	
DE	Andrea Golombiewski	Full involvement	
DK	Merete Blixenkrone-Møller	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**	5.5 Pharmacovigilance – PSURs and SARs
FR	Christine Miras	Full involvement	
HR	Hrvoje Pasavovic	Full involvement	
IE	Paul McNeill	Full involvement	
LV	Santa Ansonska	Full involvement	
NL	Kim Boerkamp	Full involvement	
SE	Carina Bergman	Full involvement	
SI	Boris Kolar	Full involvement	
SK	Eva Chobotová	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.			
FR	Natalie Bridoux	Full involvement	
CZ	Ludek Blaha	Full involvement	
DK	Anja Silke Christensen	Full involvement	
DE	Yasemin Süzer	Full involvement	
DE	Nikola Lange	Full involvement	
SE	Jenny Larsson	Full involvement	
SE	Andreea Barbu	Full involvement	
ES	Rosario Bullido Gómez–Heras	Full involvement	
ES	Susana Casado Hernández	Full involvement	
ES	Carlos Ballesteros Vicente	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
ES	Rosa Donoso Carrero	Full involvement	
ES	Sonia Gil Morales	Full involvement	
ES	Raúl Belmar Liberato	Full involvement	
DE	Kathrin Dietze	Full involvement	
DE	Sarah Adler-Flindt	Full involvement	
DE	Anja Pfalzgraff	Full involvement	
DE	Wiebke Weiher	Full involvement	
ES	Patricia Vera Luque	Full involvement	
SE	Jonna Kumpulainen	Full involvement	
FI	Katariina Kivilahti-Mäntylä	Full involvement	
CZ	Radka Smítalová	Full involvement	
CZ	Zdena Malanová	Full involvement	
CZ	Vilma Dosedlová	Full involvement	
CZ	Lucie Pokludová	Full involvement	
FR	Gérard Moulin	Full involvement	
IE	Joseph DeCourcey	Full involvement	
IE	Susan Reid	Full involvement	
DE	Sandra Schack	Full involvement	
BE	Hilde Nelis	Full involvement	
IE	Sarah Buckley	Full involvement	
IE	Aideen Brownen	Full involvement	
IE	Tatyana Devine	Full involvement	
DK	Trine Jensen	Full involvement	
DK	Henrik Duelund Pedersen	Full involvement	

CVMP working parties and CMDv	Chair
NTWP	Jacqueline Poot
AWP	Christine Schwarz
CMDv	Laetitia Le Letty
ERAWP	Ricardo Carapeto García
EWP-V	Cristina Muñoz Madero
IWP	Esther Werner
J3Rs WG	---
PhVWP-V	Els Dewaele
QWP	Mary O'Grady *(veterinary vice chair)*
SAWP-V	Frida Hasslung Wikström
SWP-V	Carina Bergman

Observer from the European Commission	
Present	

Observers from Swissmedic	
Present	

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