8 October 2019
EMA/CVMP/550956/2019
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 10-12 September 2019 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).

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 September 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 presence of a quorum of members i.e. 22 or more members of the 33 member eligible to vote 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.

iv. Adoption of the minutes of the previous meeting

The minutes of the July 2019 meeting and the August 2019 written procedure 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

- The Committee discussed the rapporteurs' assessments of the responses to the list of questions and the rapporteur's draft EPMAR for the modification of MRLs in sheep for a substance (EMEA/V/MRL/003131/MODF/0003). The Committee agreed that an oral explanation would not be requested. The adoption of the opinion is foreseen for the October 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 in horses for a substance (EMEA/V/MRL/005302/FULL/0001), following discussion of the rapporteur's assessment report including the critique from the co-rapporteur. The Committee noted a peer review report and the comments received from CVMP members.
- The Committee adopted the scientific overview and list of questions for the establishment of MRLs in *salmonidae* for a substance (EMEA/V/MRL/004481/FULL/0002), following discussion of the rapporteur's assessment report including the critique from the co-rapporteur. The Committee noted two peer review reports and the comments received from CVMP members.
- The Committee adopted the scientific overview and list of questions for the extension of MRLs in cattle for a substance (EMEA/V/MRL/003649/EXTN/0003), following discussion of the rapporteur's assessment report including the critique from the co-rapporteur. The Committee noted a peer review report and the comments received from CVMP members.
- The Committee adopted the scientific overview and list of questions for the establishment of MRLs in cattle for a substance (EMEA/V/MRL/005009/FULL/0002), following discussion of the rapporteur's assessment report including the critique from the co-rapporteur. 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 majority (29 members in favour out of the 30 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information

for **Gumbohatch** (EMEA/V/C/004967/0000), recommending the granting of a marketing authorisation. The product is a new vaccine for the active immunisation of 1 day-old broiler chicks and embryonated broiler chicken eggs to reduce clinical signs of and lesions to the bursa of Fabricius caused by very virulent avian infectious bursal disease virus. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. F. Klein signed a divergent position not supporting the aforementioned recommendation. The Committee noted the summary of the 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 **Nobivac Myxo RHD Plus** (EMEA/V/C/004989/0000), recommending the granting of a marketing authorisation. The product is a new vaccine for the active immunisation of rabbits from 5 weeks of age onwards to reduce mortality and clinical signs of myxomatosis and rabbit haemorrhagic disease (RHD) caused by classical RHD virus and RHD type 2 virus. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. 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 new product for cats (EMEA/V/C/004733/0000). The Committee discussed the rapporteurs' assessment of the responses to the list of outstanding issues and the draft product information, and noted the comments received from CVMP members. The adoption of the opinion is foreseen for the October 2019 CVMP meeting.

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 vaccine for pigs (EMEA/V/C/005272/0000). The Committee noted a peer review report 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 for pigs (EMEA/V/C/005149/0000). The Committee noted two 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 endorsed the European public assessment report (EPAR) scientific discussion for **Simparica Trio** (EMEA/V/C/004846/0000) concerning the granting of the initial marketing authorisation.
- The Committee endorsed the withdrawal EPAR, following the formal notification from the applicant to withdraw their application for **Coliprotec F4/F18** (EMEA/V/C/004225/II/0005), to add a new therapeutic indication for the improvement of daily weight gain in pigs at risk of *E. coli* related disease.

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 the CVMP assessment report for **Velactis** (EMEA/V/C/003739/II/0004), recommending the refusal of the variation of the marketing authorisation to change the current

conditions of use and update the product information with additional measures to mitigate the risk of adverse events following product administration. 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 (30 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a type II variation for **Vectra Felis** (EMEA/V/C/002746/II/0009), recommending the variation of the marketing authorisation to change the legal status from prescription-only to non-prescription veterinary medicine. The Norwegian CVMP member signed a divergent position not supporting the aforementioned recommendation. The Committee noted the summary of the 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 a type II grouped variation for **Bravecto** (EMEA/V/C/002526/II/0033/G), recommending the variation of the marketing authorisation to add new therapeutic indications. 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 a type II variation for **Bravecto** (EMEA/V/C/002526/II/0036), recommending the variation of the marketing authorisation to add a new therapeutic indication. 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 (30 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a type II variation for **Quadrisol** (EMEA/V/C/000032/II/0038), 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 CVMP assessment report for a type II variation for **Rhiniseng** (EMEA/V/C/000160/II/0009), recommending the variation of the marketing authorisation regarding quality changes. 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 CVMP assessment report for a type II grouped variation for **Posatex** (EMEA/V/C/000122/II/0027/G), recommending the variation of the marketing authorisation regarding quality changes. 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 type II grouped variation for **Onsior** (EMEA/V/C/000127/II/0024/G) to add a new therapeutic indication and to amend the product information due to new clinical data, and noted the comments received from CVMP members.

- The Committee adopted a list of questions for a type II variation for **CLYNAV** (EMEA/V/C/002390/II/0010) to extend the duration of immunity, and noted the comments received from CVMP members.
- The Committee adopted a list of questions for a type II grouped variation for **Circovac** (EMEA/V/C/000114/II/0016/G) concerning quality changes, and noted the comments received from CVMP members.
- The Committee adopted a list of questions for a type II variation for **Zulvac SBV** (EMEA/V/C/002781/II/0006) concerning quality changes, and noted the comments received from CVMP members.

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

- There were no items for discussion.

4.2 Article 34 of Directive 2001/82/EC

- The Committee considered the notification from Germany for a referral for **Ronaxan and its associated names** due to divergent decisions reached by Member States resulting in differences in the product information. The Committee agreed to start a referral procedure (EMEA/V/A/135) under Article 34 and appointed F. Hasslung Wikström as rapporteur and J. G. Beechinor as co-rapporteur for the procedure. The Committee adopted a list of questions and the timetable for the procedure.

4.3 Article 35 of Directive 2001/82/EC

- The Committee considered the notification from France for a referral for **Dinolytic 12.5 mg/ml and 5 mg/ml solutions for injection, and associated names, and their generic products**. The referral concerns the withdrawal periods (meat and offal) in cattle. The Committee agreed to start a referral procedure (EMEA/V/A/136) under Article 35 and appointed S. Louet as rapporteur and G.J. Schefferlie as co-rapporteur for the procedure. The Committee adopted a list of questions and the timetable for the procedure.
- The Committee discussed the rapporteur's assessment report including the co-rapporteur's critique for the referral procedure for **veterinary medicinal products containing tylosin base (as a single active substance) presented as solutions for injection for intramuscular use in pigs** (EMEA/V/A/131). The Committee noted a peer review report and the comments made by CVMP members, and adopted a list of outstanding issues and the revised timetable for the procedure.
- The Committee agreed to the request from Norbrook Laboratories Limited for a further extension to the clock-stop for the article 35 referral for **Betamox LA 150 mg/ml suspension for injection and its associated names, and generic products thereof**, and adopted the revised timetable for the procedure.

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 endorsed the comments on the open label post-marketing surveillance study protocol for monitoring efficacy and safety for **HorStem** (EMEA/V/C/004265/0000).
- The Committee adopted the rapporteur's assessment report on the data submitted concerning a recommendation for **BTVPUR** (EMEA/V/C/002231/REC/021).

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 19 July 2019 – 12 September 2019:

Product	Period
Aivlosin (EMEA/V/C/000083)	09.09.2018 – 08.09.2019
Apoquel (EMEA/V/C/002688)	12.09.2018 – 11.09.2019
Bovilis BTV8 (EMEA/V/C/000148)	06.09.2018 – 05.09.2019
Cardalis (EMEA/V/C/002524)	23.07.2018 – 22.07.2019
Cortacare (EMEA/V/C/004689)	27.08.2018 – 26.08.2019
Dexdomitor (EMEA/V/C/000070)	30.08.2018 – 29.08.2019
Emdocam (EMEA/V/C/002283)	18.08.2018 – 17.08.2019
Exzolt (EMEA/V/C/004344)	18.08.2018 – 17.08.2019
FORTEKOR PLUS (EMEA/V/C/002804)	08.09.2018 – 07.09.2019
Innovax-ND-IBD (EMEA/V/C/004422)	22.08.2018 – 21.08.2019
Nobilis IB Primo QX (EMEA/V/C/002802)	04.09.2018 – 03.09.2019
Nobilis Influenza H5N2 (EMEA/V/C/000118)	01.09.2018 – 31.08.2019
Nobivac Bb (EMEA/V/C/000068)	10.09.2018 – 09.09.2019

Product	Period
Nobivac Myxo-RHD (EMEA/V/C/002004)	07.09.2018 – 06.09.2019
Novaquin (EMEA/V/C/003866)	08.09.2018 – 07.09.2019
OSURNIA (EMEA/V/C/003753)	31.07.2018 – 30.07.2019
Porcilis PCV ID (EMEA/V/C/003942)	28.08.2018 – 27.08.2019
Profender (EMEA/V/C/000097)	27.07.2018 – 26.07.2019
Proteq West Nile (EMEA/V/C/002005)	05.08.2018 – 04.08.2019
Sedadex (EMEA/V/C/004202)	12.08.2018 – 11.08.2019
Suvaxyn Aujeszky 783 + O/W (EMEA/V/C/000038)	07.08.2018 – 06.08.2019
Suvaxyn PCV (EMEA/V/C/000149)	24.07.2018 – 23.07.2019
Suvaxyn PRRS MLV (EMEA/V/C/004276)	24.08.2018 – 23.08.2019
Trocoxil (EMEA/V/C/000132)	09.09.2018 – 08.09.2019
UBAC (EMEA/V/C/004595)	26.07.2018 – 25.07.2019
UpCard (EMEA/V/C/003836)	31.07.2018 – 30.07.2019
Vaxxitek HVT+IBD (EMEA/V/C/000065)	09.08.2018 – 08.08.2019
Vectormune ND (EMEA/V/C/003829)	08.09.2018 – 07.09.2019
VEPURED (EMEA/V/C/004364)	17.08.2018 – 16.08.2019
Versican Plus L4 (EMEA/V/C/003680)	31.07.2018 – 30.07.2019
Versican Plus Pi/L4 (EMEA/V/C/003683)	31.07.2018 – 30.07.2019
Versican Plus Pi/L4R (EMEA/V/C/003682)	31.07.2018 – 30.07.2019
ZACTRAN (EMEA/V/C/000129)	24.07.2018 – 23.07.2019
ZULVAC 1 Bovis (EMEA/V/C/002334)	05.08.2018 – 04.08.2019
ZULVAC 1 Ovis (EMEA/V/C/002335)	05.08.2018 – 04.08.2019

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 **Suvaxyn CSF Marker** (EMEA/V/C/002757/R/0006), 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 (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 **Bovela** (EMEA/V/C/003703/R/0014), 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 (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 **Nexgard Spectra** (EMEA/V/C/003796/R/0012), 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 of the PSUR for the period 01.03.2018-28.02.2019 for **Bravecto** (EMEA/V/C/002526) with a recommendation to amend the product information to include additional information on potential adverse reactions.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.12.2018-31.05.2019 for **Bravecto Plus** (EMEA/V/C/004440) with a recommendation to amend the product information to amend the user safety warnings and include additional information on potential adverse reactions.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.04.2016-31.03.2019 for **COXEVAC** (EMEA/V/C/000155) with a recommendation to amend the product information to include additional information on potential adverse reactions and amend the frequency of observation of known adverse reactions.
- The Committee endorsed the following rapporteur's assessment reports on PSURs concluding that no changes to the product literature or other regulatory actions were required for:

Product	Period
CYTOPOINT (EMEA/V/C/003939)	01.11.2018-30.04.2019
Vectormune ND (EMEA/V/C/003829)	01.04.2018-31.03.2019

- 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 concept paper for the revision of VICH GL22 Safety studies for veterinary drug residues in human food: reproduction studiesto include the extended one generation reproduction toxicity study, for discussion by VICH Steering Committee.
- The Committee endorsed the proposed EU revisions to the draft concept paper on the preparation of a VICH guideline on methods found suitable for demonstration of freedom from extraneous viruses of veterinary medicines. The updated concept paper will be forwarded to the VICH Steering Committee for further discussion.
- The Committee endorsed the proposed EU revisions to the draft concept paper proposing the development of a VICH guideline on safety evaluation of biotechnology-derived/biological

products. The updated concept paper will be forwarded to the VICH Steering Committee for further discussion.

- The Committee endorsed an updated draft concept paper proposing the development of a VICH guideline on *in vitro* dissolution testing and biowaivers for *in vivo* blood bioequivalence determination. The Committee further endorsed comments from an EU expert to forward to the VICH Expert Working Group for its consideration.
- The Committee noted the draft agenda for the VICH Steering Committee meeting scheduled to take place on 18–21 November 2019 in Tokyo, Japan.

6.2 Codex Alimentarius

- There were no items for discussion.

6.3 Other EU bodies and international organisations

- The Committee appointed an expert to participate as an observer at the EFSA BIOHAZ panel working group for an EFSA scientific opinion on the role played by the environment in the emergence and spread of antimicrobial resistance (AMR) through the food chain.

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 10 September 2019 and noted the agenda of the meeting.

7.2 Quality Working Party (QWP)

- There were no items for discussion.

7.3 Safety Working Party (SWP-V)

- There were no items for discussion.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- There were no items for discussion.

7.5 Efficacy Working Party (EWP-V)

- There were no items for discussion.

7.6 Antimicrobials Working Party (AWP)

- There were no items for discussion.

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 9-10 July 2019, and noted the agenda and draft minutes 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)

7.11 Other working party and scientific group issues

The following documents were circulated for information:

- Minutes of the SAWP-V meeting held on 16 July 2019;
- Draft agenda of the ADVENT meeting held on 12 September 2019.

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

8.2 Environmental risk assessment

Information relating to certain topics discussed under section 8.2 cannot be released at the present time as it is deemed to be commercially confidential.

8.3 Antimicrobial resistance

- The Committee noted the revised reflection paper on dose optimisation of established veterinary antibiotics in the context of SPC harmonisation and the overview of comments received during the public consultation.
- The Committee noted the response from the European Commission regarding the request for an extension of the deadline to submit the categorisation of antimicrobials by the Antimicrobial Advice ad hoc Expert Group (AMEG). The updated scientific advice will be discussed by CVMP and CHMP in November, aiming for adoption at the respective December meetings.

8.4 Pharmacovigilance

- The Committee endorsed the EMA response to the marketing authorisation holder's initial response letter dated 3 July 2019 concerning the use of gloves with **Bravecto Spot on / Bravecto Plus**.

8.5 Other issues

- 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.

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

- The Committee discussed the CMDv request for advice on identification of products not eligible for SPC harmonisation due to Article 72 of Regulation 2019/6.
- The Committee noted the draft agenda of the CMDv meeting held on 12-13 September 2019 and the minutes of the meeting held on 18-19 July 2019.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee adopted the revised procedural advice on appointment and responsibilities of the CVMP rapporteur and co-rapporteur for referral procedures.
- The Committee received a verbal report from the chair of the Strategic Planning Group meeting held on 11 September 2019 and noted the draft agenda for this meeting as well as the minutes of the 19 June 2019 meeting.
- The Committee endorsed the draft agenda of the CVMP Presidency meeting, including the agenda of the joint CVMP/CMDv Presidency meeting, to be held on to be held during the Finnish presidency on 25-27 September 2019 at Porvoo, Finland.
- The Committee discussed the upcoming appointment of CVMP co-opted members at the November 2019 meeting, with a view to identify additional expertise necessary for CVMP to accomplish its mandate. The Committee agreed to appoint three co-opted members, retaining the same areas of expertise (i.e. general clinical veterinary practice, MRLs/residues, quality of pharmaceuticals). A call for nominations will be circulated by the secretariat shortly after the meeting.
- The Committee noted the draft CVMP work plan for 2020.
- The Committed noted the draft presentation on "Novel veterinary medicines development: A CVMP perspective on regulatory challenges and opportunities" to be delivered at TOPRA Symposium on 30 September to 2 October 2019, in Dublin, Ireland.

13. LEGISLATION

- The Committee endorsed the draft interim report to the European Commission on the progress made by the 3 expert groups working on the scientific advice for the implementing act on **good pharmacovigilance practice** and the expert group working on the scientific advice on the **pharmacovigilance master file**.
- The Committee discussed the draft report on the **criteria to designate antimicrobials for human use** and noted the comments received from CVMP members.

14. ANY OTHER BUSINESS

- Upon the completion of the September 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 September 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**	
BG	Emil Kozhuharov	Full involvement	
DE	Gesine Hahn	Full involvement	
DK	Niels Christian Kyvsgaard	Full involvement	
EE	Toomas Tiirats	Full involvement	
EL	Angeliki Tsigouri	Full involvement	
ES	Cristina Muñoz Madero	Full involvement	
FI	Tita-Maria Muhonen	Full involvement	10.1 – One item
FR	Jean-Claude Rouby	Full involvement	
HR	Frane Božić	Full involvement	
HU	Gábor Kulcsár	Full involvement	
IE	J. Gabriel Beechinor	Full involvement	
IT	Paolo Pasquali	Full involvement	
LT	Snieguolė Trumpickaitė Dzekčiorienė	Full involvement	
LV	Zanda Auce	Full involvement	
NL	Peter Hekman	Full involvement	
PL	Anna Wachnik-Święcicka	Full involvement	
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	Full involvement	
Co-opted	Wilhelm Schlumbohm	Full involvement	
Co-opted	Ricardo Carapeto García	Full involvement	
IS	-	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of eDoI for the meeting	Topics on current agenda for which restriction applies
AT	Ines Lindner	Full involvement	
BE	Frédéric Klein	Full involvement	
CZ	Leona Nepejchalová	Full involvement	
DE	Esther Werner	Full involvement	
DK	Merete Blixenkrone-Møller	Full involvement	
ES	Consuelo Rubio Montejano	Full involvement	
FR	Sylvie Louet	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of eDoI for the meeting	Topics on current agenda for which restriction applies
NL	Jacqueline Poot	Full involvement	
PL	Ewa Augustynowicz	Full involvement	
NO	Tonje Høy	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the eDoI for the meeting	Topics on current agenda for which restriction applies
BE	Bruno Urbain – *remotely*	Full involvement	
CZ	Dana Halová – *remotely*	Full involvement	
CZ	Dana Studená – *remotely*	Full involvement	
CZ	Eva Pomezná – *remotely*	Full involvement	
CZ	Lucie Pokludová – *remotely*	Full involvement	
DE	Andrea Golombiewski	Full involvement	
DE	Anke Finnah	Full involvement	
DE	Daniela Loos – *remotely*	Full involvement	
DE	Henriette Rau – *remotely*	Full involvement	
DE	Jan Brosda – *remotely*	Full involvement	
DE	Judith Romberg – *remotely*	Full involvement	
DE	Kathrin Schirmann – *remotely*	Full involvement	
DE	Maike Gömmel – *remotely*	Full involvement	
DE	Nikola Lange – *remotely*	Full involvement	
DE	Rolf Beckmann – *remotely*	Full involvement	
DE	Sabine Klee – *remotely*	Full involvement	
DE	Sarah Adler-Flindt – *remotely*	Full involvement	
DE	Uta Herbst – *remotely*	Full involvement	
DE	Yasemin Süzer – *remotely*	Full involvement	
DK	Ellen-Margrethe Vestergaard – *remotely*	Full involvement	
DK	Lotte Dahl – *remotely*	Full involvement	
ES	Carles Cristòfol – *remotely*	Full involvement	
ES	Gema Cortés Ruiz – *remotely*	Full involvement	
ES	Maria Jose Ferrer – *remotely*	Full involvement	
ES	Raul Belmar Liberato – *remotely*	Full involvement	
ES	Rosario Bullido – *remotely*	Full involvement	
ES	Teresa Gómez Martínez – *remotely*	Full involvement	
FI	Kristina Lehmann – *remotely*	Full involvement	
FI	Martti Nevalainen – *remotely*	Full involvement	
FR	Anne Sagnier – *remotely*	Full involvement	
FR	Benoit Courty - *remotely*	Full involvement	
FR	Damien Bouchard – *remotely*	Full involvement	
FR	Gerard Moulin – *remotely*	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the eDoI for the meeting	Topics on current agenda for which restriction applies
FR	Florence Pillet – *remotely*	Full involvement	
FR	Pascal Sanders – *remotely*	Full involvement	
FR	Tiphaine Moreac – *remotely*	Full involvement	
PL	Anita Piwowarczyk	Full involvement	
PL	Marcin Glanda – *remotely*	Full involvement	
SE	Denise Laskowski – *remotely*	Full involvement	
SE	Fredrik Húlten – *remotely*	Full involvement	
UK	Miguel Escribano – *remotely*	Full involvement	
UK	Ruth Pearson – *remotely*	Full involvement	

CVMP working parties and CMDv	Chair
ADVENT	Jean-Claude Rouby
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 *(Vet vice chair) - remotely*
SAWP-V	Frida Hasslung Wikström
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