3 October 2017
EMA/CVMP/659549/2017
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 5-7 September 2017 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 September 2017 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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5545
Send a question via our website www.ema.europa.eu/contact

iv. Adoption of the minutes of the previous meeting

The minutes of the July 2017 meeting and the August 2017 meeting via 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' joint assessment of the responses to the list of questions and the rapporteur's draft EPMAR for the extension of MRLs to eggs for a substance (EMEA/V/MRL/003517/EXTN/0003), as well as the comments from the EU Reference Laboratory concerning the analytical method, and adopted a list of outstanding issues that should be addressed in writing.
- The Committee heard an oral explanation from the applicant and discussed the rapporteur's assessment of the responses to the list of outstanding issues including the co-rapporteur's critique for the establishment of MRLs in all food producing species for a substance (EMEA/V/MRL/004321/FULL/0001). The adoption of the opinion is foreseen for the October 2017 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 rabbits for a substance (EMEA/V/MRL/004828/FULL/0001), 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 discussed the draft CVMP EPMAR, a peer review report and the report from the EU Reference Laboratory for the extension of MRLs to fin fish for a substance (EMEA/V/MRL/003471/EXTN/0002), and agreed that a list of questions was not necessary. The adoption of the opinion is foreseen for the October 2017 meeting of the Committee.
- The Committee adopted the scientific overview and list of questions for the extension of MRLs to porcine species for a substance (EMEA/V/MRL/003647/EXTN/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 consensus (27 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Oxybee** (EMEA/V/C/004296/0000), recommending the granting of a marketing authorisation. Oxybee is a new product for the treatment of varroosis (*Varroa destructor*) of honey bees (*Apis mellifera*) in brood free colonies. 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 (27 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Nobivac Leufel** (EMEA/V/C/004778/0000), recommending the granting of a marketing authorisation. Nobivac Leufel is a new inactivated feline leukemia vaccine containing purified p45 FeLV, indicated for the active immunisation of cats from eight weeks of age against feline leukaemia, for the prevention of persistent viraemia and clinical signs of the related disease. 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 (27 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Bovilis Blue-8** (EMEA/V/C/004776/0000), recommending the granting of a marketing authorisation. Bovilis Blue-8 is a new inactivated vaccine against bluetongue virus (BTV) serotype 8, indicated for the active immunisation of sheep from 2.5 months of age to prevent viraemia and to reduce clinical signs caused by BTV serotype 8, and for the active immunisation of cattle from 2.5 months of age to prevent viraemia caused by BTV serotype 8. 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 adopted the updated scientific overview including the list of outstanding issues and agreed comments on the draft product information for a marketing authorisation application for a new vaccine for foxes and raccoon dogs (EMEA/V/C/004387/0000). 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 the list of questions and agreed comments on the draft product information for a new vaccine for sheep and cattle (EMEA/V/C/004611/0000). 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 agreed to the request from the applicant for an extension to the clock-stop for a new antiparasitic product for honey bees (EMEA/V/C/002836/0000).

- The Committee endorsed the withdrawal EPAR, following the formal notification from the applicant to withdraw their application for **Cheristin** (EMEA/V/C/00436/0000).
- The Committee endorsed the EPAR module 6 scientific discussion for **Innovax-ND-IBD** (EMEA/V/C/004422/0000) concerning the granting of the initial marketing authorisation.
- The Committee endorsed the EPAR module 6 scientific discussion for **VEPURED** (EMEA/V/C/004364/0000) concerning the granting of the initial marketing authorisation.
- The Committee endorsed the EPAR module 6 scientific discussion for **Suvaxyn PRRS MLV** (EMEA/V/C/004276/0000) concerning the granting of the initial marketing authorisation.
- The Committee noted the updated withdrawal EPAR for **Somnena** (EMEA/V/C/004293/0000).

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a type II variation for **Simparica** (EMEA/V/C/003991/II/0006), recommending the variation of the marketing authorisation to add new indications for the treatment of ear mites and demodicosis in 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 (26 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a type II variation for **RESPIPORC FLU3** (EMEA/V/C/000153/II/0014), recommending the variation of the marketing authorisation to add a new pack size. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report for a type II variation for **RHINISENG** (EMEA/V/C/000160/II/0007), 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 (27 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a worksharing type II variation for **Eurican Herpes 205**, **Purevax RCPCh**, **Bovalto Ibraxion**, **Purevax RCP FeLV**, **Purevax RC**, **Purevax RCP**, **BTVPUR AlSap 2-4**, **BTVPUR**, **Parvoduk** and **Purevax RCPCh FeLV** (EMEA/V/C/xxxxxx/WS/1151), recommending the variation of the marketing authorisations to implement quality changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a type II variation for **NEXGARD SPECTRA** (EMEA/V/C/003842/II/0011), 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 (26 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a worksharing type IB variation for **Fevaxyn Pentofel** (EMEA/V/C/000030/WS1120), 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 (26 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a worksharing type IB variation for **Fevaxyn Pentofel** (EMEA/V/C/000030/WS1142), 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 (26 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a type II variation for **Reconcile** (EMEA/V/C/000133/II/0017), 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 the list of outstanding issues to be addressed in writing and at an oral explanation for a type II variation for **Metacam** (EMEA/V/C/000033/II/0127), to register an additional target species.
- The Committee adopted the list of outstanding issues to be addressed in writing for a worksharing type II variation for **Vectormune ND** (EMEA/V/C/003829/WS1082), concerning changes in the product information.

3.3 Lists of questions

- The Committee adopted the list of questions for a grouped type II variation for **Advocate** (EMEA/V/C/000076/II/0039/G), to add new therapeutic indications.
- The Committee adopted the rapporteur's assessment report with a list of questions for a grouped worksharing type II variation for **Vaxxitek HVT+IBD** (EMEA/V/C/000065/WS1209/G), concerning quality changes.

3.4 Re-examination of CVMP opinions

- There were no items for discussion.

3.5 Other issues

- The Committee agreed to an extension to the clock-stop for a type II variation for **Porcilis ColiClos** (EMEA/V/C/002011/II/0007), 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

- The Committee heard an oral explanation from the marketing authorisation holder, Elanco Animal Health for the referral procedure for **Girolan and its associated name Apralan** (EMEA/V/A/122). The adoption of the opinion is foreseen for the October 2017 meeting of the Committee.

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

- The Committee considered the notification from Germany for a referral procedure for **Seresto and its associated name Foresto** due to concerns expressed by the United Kingdom regarding potential serious risk to animal health. The Committee agreed to start a referral procedure (EMEA/V/A/125) under Article 13 and appointed H. Jukes as rapporteur and G. Hahn as co-rapporteur for the procedure. The Committee adopted the list of questions and the timetable for the procedure.

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 14.07.2017 – 07.09.2017:

Product	Period
AFTOVAXPUR DOE (EMEA/V/C/002292)	15/07/2016 – 14/07/2017
Bovilis BTV8 (EMEA/V/C/000148)	06/09/2016 – 05/09/2017
Cardalis (EMEA/V/C/002524)	23/07/2016 – 22/07/2017
Dexdomitor (EMEA/V/C/000070)	30/08/2016 – 29/08/2017
Emdocam (EMEA/V/C/002283)	18/08/2016 – 17/08/2017
Nobilis IB Primo QX (EMEA/V/C/002802)	04/09/2016 – 03/09/2017
Nobilis Influenza H5N2 (EMEA/V/C/000118)	01/09/2016 – 31/08/2017
Nobivac L4 (EMEA/V/C/002010)	16/07/2016 – 15/07/2017
Nobivac Myxo-RHD (EMEA/V/C/002004)	07/09/2016 – 06/09/2017
OSURNIA (EMEA/V/C/003753)	31/07/2016 – 30/07/2017
Porcilis PCV ID (EMEA/V/C/003942)	28/08/2016 – 27/08/2017
Profender (EMEA/V/C/000097)	27/07/2016 – 26/07/2017

Product	Period
Proteq West Nile (EMEA/V/C/002005)	05/08/2016 – 04/08/2017
Sedadex (EMEA/V/C/004202)	12/08/2016 – 11/08/2017
Suvaxyn Aujeszky 783 + O/W (EMEA/V/C/000038)	07/08/2016 – 06/08/2017
Suvaxyn PCV (EMEA/V/C/000149)	24/07/2016 – 23/07/2017
UpCard (EMEA/V/C/003836)	31/07/2016 – 30/07/2017
Vaxxitek HVT+IBD (EMEA/V/C/000065)	09/08/2016 – 08/08/2017
Versican Plus L4 (EMEA/V/C/003680)	31/07/2016 – 30/07/2017
Versican Plus Pi/L4 (EMEA/V/C/003683)	31/07/2016 – 30/07/2017
Versican Plus Pi/L4R (EMEA/V/C/003682)	31/07/2016 – 30/07/2017
ZACTRAN (EMEA/V/C/000129)	24/07/2016 – 23/07/2017
ZULVAC 1 Bovis (EMEA/V/C/002334)	05/08/2016 – 04/08/2017
ZULVAC 1 Ovis (EMEA/V/C/002335)	05/08/2016 – 04/08/2017

5.4 Renewals

- The Committee adopted by consensus (26 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 **Contacera** (EMEA/V/C/002612/R/0009), 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 the list of outstanding issues for the renewal of the marketing authorisation for **Pexion** (EMEA/V/C/002543/R/0010).

5.5 Pharmacovigilance – PSURs and SARs

- The Committee adopted the CVMP assessment report of the PSUR for the period 01.07.2016 – 31.12.2016 for **Bovela** (EMEA/V/C/003703) with a recommendation to amend the PI.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.08.2016 – 31.01.2017 for **Versican Plus DHPPi** (EMEA/V/C/003679) with a recommendation to amend the PI.
- 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
ERAVAC (EMEA/V/C/004239)	22.09.2016 – 31.03.2017
LETIFEND (EMEA/V/C/003865)	01.11.2016 – 30.04.2017
Meloxidolor (EMEA/V/C/002590)	22.04.2016 – 22.04.2017
Recuvyra (WD) (EMEA/V/C/002239)	01.05.2016 – 30.04.2017
ZOLVIX (EMEA/V/C/000154)	01.05.2014 – 30.04.2017

- 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.

The following documents were circulated for information:

- Locatim – prohibition of sale, supply and use in Denmark;
- 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 response on the comments regarding the VICH GL22 on studies to evaluate the safety of residues of veterinary drugs in human food: reproduction testing.
- The Committee confirmed its support for the FDA proposal for modification of the EU proposal for a revised testing approach for genotoxicity testing battery for inclusion in the VICH GL23 on studies to evaluate the safety of residues of veterinary drugs in human food: genotoxicity testing.
- The Committee agreed an EU position on the need for the revision of the following guidelines: VICH GL18(R) on residual solvents in new veterinary medicinal products, active substances and excipients; VICH GL46 on metabolism study to determine the quantity and identify the nature of residues; and VICH GL47 on laboratory animal comparative metabolism studies.
- The Committee endorsed the EU comments on the draft VICH guideline on marker residue depletion studies to establish product withdrawal periods in aquatic species.
- The Committee received feedback from the meeting of the VICH Anthelmintics Expert Working Group in Rockville, USA on 11-13 July 2017.

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 documents were circulated for information:

- Status of active VICH guidelines and action plan of CVMP and working parties;
- Agendas of the 35th VICH Steering Committee and the 9th VICH Outreach forum meetings to be held in Tokyo on 13-16 November 2017.

7. WORKING PARTIES AND SCIENTIFIC ADVISORY GROUPS

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

7.1 Scientific Advice Working Party (SAWP-V)

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

- The Committee received a verbal report from the chair of the SAWP-V on the meeting held on 5 September 2017, and noted the agenda of the meeting.

7.2 Quality Working Party (QWP)

- The Committee noted the election, by CHMP, of Blanka Hirschlerova as QWP vice-chairperson for a 3-year mandate.

7.3 Safety Working Party (SWP-V)

- There were no items for discussion.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- The Committee received a verbal report from the chair of the ERAWP on the meeting held on 20 June 2017, and noted the agenda and the draft minutes of the meeting.

7.5 Efficacy Working Party (EWP-V)

- There were no items for discussion.

7.6 Antimicrobials Working Party (AWP)

- The Committee adopted the joint ECDC, EFSA and EMA scientific opinion on a list of outcome indicators as regards surveillance of antimicrobial resistance and antimicrobial consumption in humans and food producing animals (EMA/CVMP/AWP/549799/2017). The opinion, once adopted by all the above mentioned Agencies, will be sent to the EC and will be published on the Agencies' websites in the second half of October 2017.

7.7 Immunologicals Working Party (IWP)

- The Committee adopted the guideline on data requirements for multi-strain dossiers for inactivated vaccines against avian influenza (AI), Bluetongue (BT) and Foot-and-Mouth disease (FMD) (EMA/CVMP/IWP/105506/2007-Rev.1) for a 6-month period of public consultation. The question and answer document (EMA/CVMP/IWP/466888/2017) was also adopted and will be published alongside the guideline.

7.8 Pharmacovigilance Working Party (PhVWP-V)

- The Committee received a verbal report from the vice-chair of the PhVWP-V on the meeting held on 18-19 July 2017, and noted the agenda and the draft minutes of the meeting.
- The Committee was informed of the upcoming election of the chair of the PhVWP-V for a 3-year term at the October 2017 CVMP meeting, and noted the call for nominations.
- The Committee was informed of the PhVWP-V Interested Parties meeting to be held on 27 September 2017, and noted the draft agenda 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)

- The Committee received a verbal report from the chair of the J3RsWG on the meeting held on 20 June 2017.

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 11 July 2017;
- Draft agenda for the Joint CHMP/CVMP QWP meeting to be held on 27–29 September 2017;
- Draft agenda of the EWP-V meeting to be held on 12-13 September 2017;
- Reflection paper on off-label use of antimicrobials in veterinary medicine in the European Union (EMA/CVMP/AWP/237294/2017) published for consultation; press release (link);
- Reflection paper on use of aminoglycosides in animals in the European Union: development of resistance and impact on human and animal health (EMA/CVMP/AWP/721118/2014), published for consultation; press release (link);
- Draft agenda of the CVMP ADVENT meeting held on 7 September 2017.

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.

8.2 Environmental risk assessment

- There were no items for discussion.

8.3 Antimicrobial resistance

- The Committee was informed of the WHO online consultation on the monitoring and evaluation approach to the global action plan on AMR (link).

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.

- The Committee endorsed the participation of E. Werner at the IABS Conference on next generation sequencing for adventitious virus detection in biologics, to be held on 26-27 October 2017 in Rockville, Maryland/USA.

The following documents were circulated for information:

- Publication of ECDC/EFSA/EMA second joint report on the integrated analysis of the consumption of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from humans and food-producing animals (JIACRA II) (EMA/605921/2016); press release (link);

- European Association of Fish Pathologists (EAFP). 18th International Conference on fish and shellfish diseases held on 4-8 September in Belfast, Northern Ireland:
  Programme of Targetfish Industry Forum workshop on "DNA vaccination: where do we stand and what's next?", held on 7 September 2017;
  EMA presentations on "Regulatory requirements for the authorisation of DNA vaccines for fish in the EU" and the "Role of the EMA in the regulation of veterinary medicines in the EU".

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 endorsed the draft minutes from the FishMed PLus Coalition breakout session held on 12 July 2017 and the barriers and solutions table with CVMP/EMA responses to the recommendations made by the FishMed Plus Coalition.
- The Committee endorsed the draft report of the focus group meeting with invited stakeholders on field efficacy trial requirements for the authorisation of veterinary vaccines in the EU, held on 22-23 June 2017. The draft report will be circulated to the participants for their review and comments.
- The Committee endorsed the minutes of the CVMP ad hoc group on veterinary vaccine availability (CADVVA) meeting held on 4 July 2017.

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.

- The Committee deferred the transfer of (co-)rapporteurship for **Zeleris** from L. Markus-Cizelj to the October 2017 CVMP meeting.

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 agenda of the CMDv meeting held on 7-8 September 2017, and the draft minutes of the meeting held on 13-14 July 2017.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee endorsed the draft agenda of the CVMP Interested parties meeting held on 6 September 2017.
- The Committee received a verbal report on the Presidency CVMP meeting held on 26-27 June 2017 in the Netherlands and discussed the recommendations arising from the meeting.
- The Committee was informed of the organisation and appointments in the Veterinary Medicines Division of the EMA.

- The Committee received a verbal update from the EMA working group on operational preparedness for veterinary medicines.
- The Committee noted the guide for rapporteurs and coordinators on multinational assessment teams.

13. LEGISLATION

- There were no items for discussion.

14. ANY OTHER BUSINESS

- Upon the completion of the September 2017 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 2017 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	
FR	Jean-Claude Rouby	Full involvement	
HR	Frane Božić	Full involvement	
NL	Peter Hekman	Full involvement	
PL	Anna Wachnik-Święcicka	Involvement in discussions only and cannot act as rapporteur or peer reviewer for:	• 3.3 Advocate (EMEA/V/C/000076/II/0039/G) • 7.1 one item
PT	João Pedro Duarte da Silva	Full involvement	
RO	Lollita Taban	Full involvement	
SE	Eva Lander Persson	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	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	
CZ	Leona Nepejchalová	Full involvement	
DE	Esther Werner	Full involvement	
FI	Kristina Lehmann	Full involvement	
FR	Sylvie Louet	Full involvement	
HU	Tibor Soós	Full involvement	
IE	Mary O'Grady	Full involvement	
LT	Laimis Jodkonis	Full involvement	
NL	Jacqueline Poot	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
SE	Frida Hasslung Wikström	Full involvement	
SI	Maja Turk	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
* Experts were only evaluated against the topics they have been invited to talk about.			
BE	Els Dewaele – *remotely*	Full involvement	
DE	Klaus Cussler – *remotely*	Full involvement	
DE	Anke Finnah	Full involvement	
DE	Uta Herbst - *remotely*	Full involvement	
DE	Nikola Lange – *remotely*	Full involvement	
DE	Svenja Rieke – *remotely*	Full involvement	
DE	Stefan Scheid – *remotely*	Full involvement	
DE	Yasemin Suzer	Full involvement	
ES	Aranzazu Gonzalez Canga – *remotely*	Full involvement	
ES	Patricia Vera Luque	Full involvement	
FI	Martti Nevalainen - *remotely*	Full involvement	
FR	Nathalie Bridoux - *remotely*	Full involvement	
FR	Lise Laborieux – *remotely*	Full involvement	
IE	Rory Cooney	Full involvement	
NL	Piet-Hein Overhaus – *remotely*	Full involvement	
SI	Maja Golobic – *remotely*	Full involvement	
SI	Petra Segina – *remotely*	Full involvement	
UK	Miguel Escribano – *remotely*	Full involvement	
UK	Sam Fletcher – *remotely*	Full involvement	
UK	Sharon Reynolds – *remotely*	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
PhVWP-V	Elisabeth Begon *(vice chair) - remotely*
QWP	Mary O'Grady *(Vet vice chair)*
SAWP-V	Rory Breathnach
SWP-V	Eva Lander Persson

Observer from the European Commission	
Present	

Observers from Swissmedic	
Remotely	

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