9 October 2018
EMA/CVMP/574963/2018
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the September 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 the addition of a new item under point 2.5.

ii. CVMP delegates' list of intended participation and identified interests

The attendance list was completed and competing interests were identified for the September 2018 meeting. In accordance with the Agency's policy and procedure on the handling of competing interests, participants in this meeting were asked to declare any interests on the matters for discussion (in particular any changes, omissions or errors to the already declared interests). Discussions, deliberations and voting took place in full respect of the restricted involvement of CVMP members and, where relevant, experts attending the plenary meeting, as announced by the CVMP secretariat at the start of the meeting (see Annex I). All decisions taken at this meeting were made in presence of a quorum of members i.e. 22 or more members were present in the room. It was noted that 17 members were needed for an absolute majority.

iii. Declaration of contacts between members and companies with regard to points on the agenda

Information relating to declared contacts between members and companies with regard to points on the agenda cannot be released at the present time as it is deemed to be commercially confidential.

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 2018 meeting and the August 2018 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

- 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

- The Committee was informed of the formal notification from the applicant of their decision to withdraw the application for establishment of MRLs in bovine species for a substance (EMEA/V/MRL/004933/FULL/0001).
- The Committee agreed to the request from the applicant for an extension to the clock-stop for the establishment of MRLs in rabbits for a substance (EMEA/V/MRL/004828/FULL/0001).

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

- The Committee adopted by consensus (25 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Inflacam** (EMEA/V/C/002497/X/0015), recommending the extension of the marketing authorisation to add a new pharmaceutical form (oral suspension) and strength (0.5 mg/ml) for the alleviation of mild to moderate post-operative pain and inflammation following surgical procedures, and alleviation of pain and inflammation in acute and chronic musculo-skeletal disorders in cats. 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 (25 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Rheumocam** (EMEA/V/C/000121/X/0022), recommending the extension of the marketing authorisation to add a new pharmaceutical form (oral suspension) and strength (0.5 mg/ml) for the alleviation of mild to moderate post-operative pain and inflammation following surgical procedures, and alleviation of pain and inflammation in acute and chronic musculo-skeletal disorders in cats. 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 (EMEA/V/C/004611/0000), in sheep and cattle. The Committee agreed that an oral explanation would not be requested. The Committee noted two peer review reports and the comments received from CVMP members.
- 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 product (EMEA/V/C/004329/0000). The Committee agreed that an oral explanation would not be requested. The Committee noted two peer review reports 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 the comments on the draft product information for a new vaccine (EMEA/V/C/004967/0000) in chickens. The Committee noted three peer review reports and the comments received from CVMP members.

2.4 Re-examination of CVMP opinions

- The Committee adopted the list of questions to the ad hoc expert group (AHEG) and endorsed the list of AHEG members for the re-examination of the negative CVMP opinion adopted for **Horse Allo 20** (EMEA/V/C/004222/0000), which contains equine adipose-derived mesenchymal stem cells for the treatment of lameness associated with osteoarthritis in adult non-food producing horses. The Committee noted two peer review reports and the comments received from CVMP members. The adoption of the final opinion is foreseen for the October 2018 CVMP meeting.
- The Committee adopted the list of questions to the ad hoc expert group (AHEG) and endorsed the list of AHEG members, for the re-examination of the negative CVMP opinion adopted for **Longrange** (EMEA/V/C/004291/0000), a new antiparasitic product containing eprinomectin for the treatment and prevention of reinfections with certain specified parasites in cattle. The Committee noted two peer review reports and the comments received from CVMP members. The adoption of the final opinion is foreseen for the October 2018 CVMP meeting.

2.5 Other issues

- The Committee agreed to the request from the applicant for an extension to the clock-stop for a new product for cats.
- The Committee adopted the EPAR module 6 scientific discussion for Cortacare (EMEA/V/C/004689/0000) concerning the granting of the initial marketing authorization.

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- The Committee adopted by consensus (24 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a type II grouped variation under a worksharing procedure (EMEA/V/C/WS1338/G) for **NEXGARD SPECTRA** and **NexGard,** recommending the variation of the marketing authorisation to add new therapeutic indications for the treatment of demodicosis (caused by *Demodex canis*) and sarcoptic mange

(caused by *Sarcoptes scabiei* var. canis). The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.

- The Committee adopted by consensus (24 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a type II variation for **Econor** (EMEA/V/C/000042/II/0052), recommending the variation of the marketing authorisation to implement changes in the SPC due to new preclinical data. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (25 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a worksharing type II variation (EMEA/V/C/xxxxxx/WS1337) for **Versican Plus DHPPI**, **Versican Plus DHPPi/L4**, **Versican Plus DHPPi/L4R**, **Versican Plus L4**, **Versican Plus Pi**, **Versican Plus Pi/L4** and **Versican Plus Pi/L4R**, recommending the variation of the marketing authorisation to introduce changes to the product information. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (25 members present of those eligible to vote) the CVMP opinion, the rapporteur's assessment report and the product information for a worksharing type II variation (EMEA/V/C/xxxxxx/WS1397) for **Versican Plus DHPPi** and **Versican Plus Pi**, recommending the variation of the marketing authorisation to introduce changes to the product information following PSUR assessment. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (25 members present of those eligible to vote) the CVMP opinion, the rapporteur's assessment report and the product information for a worksharing type II variation (EMEA/V/C/xxxxxx/WS1398) for **Versican Plus DHPPi/L4R**, **Versican Plus DHPPi/L4**, **Versican Plus L4**, **Versican Plus Pi/L4R** and for **Versican Plus Pi/L4**, recommending the variation of the marketing authorisation to introduce changes to the product information following the PSUR assessment. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (24 members present of those eligible to vote) the CVMP opinion and the rapporteur's assessment report for a worksharing type IB variation (EMEA/V/C/xxxxxx/WS1413) for **Versican Plus DHPPI**, **Versican Plus Pi**, **Versican Plus Pi/L4**, **Versican Plus DHPPi/L4**, **Versican Plus DHPPi/L4R** and for **Versican Plus Pi/L4R**, recommending the variation of the marketing authorisation concerning quality changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (24 members present of those eligible to vote) the CVMP opinion and the rapporteur's assessment report for a worksharing type IB variation (EMEA/V/C/xxxxxx/WS1414) for **Versican Plus DHPPI**, **Versican Plus Pi**, **Versican Plus DHPPi/L4R**, **Versican Plus DHPPi/L4**, **Versican Plus Pi/L4R** and for **Versican Plus Pi/L4**, recommending the variation of the marketing authorisations concerning quality changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (24 members present of those eligible to vote) the CVMP opinion and the rapporteur's assessment report for a grouped type II variation for **ZACTRAN** (EMEA/V/C/000129/II/0039/G), recommending the variation of the marketing authorisation concerning quality changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.

- The Committee adopted by consensus (24 members present of those eligible to vote) the CVMP opinion and the rapporteur's assessment report for a type II variation for **OSURNIA** (EMEA/V/C/003753/II/0008), recommending the variation of the marketing authorisation concerning quality changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (24 members present of those eligible to vote) the CVMP opinion and the rapporteur's assessment report for a type II variation for **Porcilis PCV M Hyo** (EMEA/V/C/003753/II/0008), recommending the variation of the marketing authorisation concerning quality changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (24 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a type II variation (EMEA/V/C/003993/II/0004) for **RESPIPORC FLUpan H1N1**, recommending the variation of the marketing authorisation concerning quality changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.

3.2 Oral explanations and lists of outstanding issues

- No items.

3.3 Lists of questions

- The Committee adopted a list of questions for a type II variation for **Aivlosin** (EMEA/V/C/000083/II/0072) concerning changes to the SPC warnings.
- The Committee adopted a list of questions for a type II variation for **ProZinc** (EMEA/V/C/002634/II/0015) to add a new target species.
- The Committee adopted a list of questions for a grouped type II variation for **OSURNIA** (EMEA/V/C/003753/II/0009/G) concerning quality changes.
- The Committee adopted a list of questions for a grouped worksharing type II variation for **Canigen L4** and **Nobivac L4** (EMEA/V/C/xxxx/WS1439/G) concerning quality changes.

3.4 Re-examination of CVMP opinions

- There were no items for discussion.

3.5 Other issues

- The Committee was informed of the formal notification from IDT Biologika GmbH of their decision to withdraw the application for a type II variation for **Ecoporc SHIGA** (EMEA/V/C/002588/II/0007), to modify the therapeutic indication.

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

- 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 adopted the rapporteur's assessment report on the data submitted concerning a condition for **CYTOPOINT** (EMEA/V/C/003939/ANX/001.1).

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 21.07.2018 – 13.09.2018:

Product	Period
Aivlosin (EMEA/V/C/000083)	09/09/2017 – 08/09/2018
APOQUEL (EMEA/V/C/002688)	12/09/2017 – 11/09/2018
Bovilis BTV8 (EMEA/V/C/000148)	06/09/2017 – 05/09/2018
Cardalis (EMEA/V/C/002524)	23/07/2017 – 22/07/2018
Dexdomitor (EMEA/V/C/000070)	30/08/2017 – 29/08/2018
Emdocam (EMEA/V/C/002283)	18/08/2017 – 17/07/2018
Exzolt (EMEA/V/C/004344)	18/08/2017 – 17/07/2018
FORTEKOR PLUS (EMEA/V/C/002804)	08/09/2017 – 07/09/2018
Innovax-ND-IBD (EMEA/V/C/004422)	22/08/2017 – 21/08/2018
Nobilis IB Primo QX (EMEA/V/C/002802)	04/09/2017 – 03/09/2018
Nobilis Influenza H5N2 (EMEA/V/C/000118)	01/09/2017 – 31/08/2018
Nobivac Bb (EMEA/V/C/000068)	10/09/2017 – 09/09/2018
Nobivac Myxo-RHD (EMEA/V/C/002004)	07/09/2017 – 06/09/2018

Product	Period
Novaquin (EMEA/V/C/003866)	08/09/2017 – 07/09/2018
OSURNIA (EMEA/V/C/003753)	31/07/2017 – 30/07/2018
Porcilis PCV ID (EMEA/V/C/003942)	28/08/2017 – 27/08/2018
Previcox (EMEA/V/C/000082)	13/09/2017 – 12/09/2018
Profender (EMEA/V/C/000097)	27/07/2017 – 26/07/2018
Proteq West Nile (EMEA/V/C/002005)	05/08/2017 – 04/08/2018
Recocam (EMEA/V/C/002247)	13/09/2017 – 12/09/2018
Sedadex (EMEA/V/C/004202)	12/08/2017 – 11/08/2018
Suvaxyn Aujeszky 783 + O/W (EMEA/V/C/000038)	07/08/2017 – 06/08/2018
Suvaxyn PCV (EMEA/V/C/000149)	24/07/2017 – 23/07/2018
Suvaxyn PRRS MLV (EMEA/V/C/004276)	24/08/2017 – 23/08/2018
Trocoxil (EMEA/V/C/000132)	09/09/2018 – 08/09/2018
UpCard (EMEA/V/C/003836)	31/07/2017 – 30/07/2018
Vaxxitek HVT+IBD (EMEA/V/C/000065)	09/08/2017 – 08/08/2018
Vectormune ND (EMEA/V/C/003829)	08/09/2017 – 07/09/2018
VEPURED (EMEA/V/C/004364)	17/08/2017 – 16/08/2018
Versican Plus L4 (EMEA/V/C/003680)	31/07/2017 – 30/07/2018
Versican Plus Pi/L4 (EMEA/V/C/003683)	31/07/2017 – 30/07/2018
Versican Plus Pi/L4R (EMEA/V/C/003682)	31/07/2017 – 30/07/2018
ZACTRAN (EMEA/V/C/000129)	24/07/2017 – 23/07/2018
ZULVAC 1 Bovis (EMEA/V/C/002334)	05/08/2017 – 04/08/2018
ZULVAC 1 Ovis (EMEA/V/C/002335)	05/08/2017 - 04/07/2018

5.4 Renewals

- The Committee adopted a list of outstanding issues for the renewal of the marketing authorisation for **Bravecto** (EMEA/V/C/2526/R/0028).

5.5 Pharmacovigilance – PSURs and SARs

- The Committee adopted the CVMP assessment report of the PSUR for the period 01.11.17-30.04.18 for **CYTOPOINT** (EMEA/V/C/003939) with a recommendation to amend the product information.

- The Committee adopted the CVMP assessment report of the targeted PSUR for the period 01.01.09-31.12.17 for **Easotic** (EMEA/V/C/000140) with a recommendation to amend the product information.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.04.17-31.03.18 for **Nobilis IB4-91** (EMEA/V/C/000036) with a recommendation to amend the product information.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.08.17-31.01.18 for **OSURNIA** (EMEA/V/C/003753) with a recommendation to amend the product information.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.04.15-31.03.18 for **RHINISENG** (EMEA/V/C/000160) 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 literature or other regulatory actions were required for:

Product	Period
LETIFEND (EMEA/V/C/003865)	01.11.17-30.04.18
Meloxidolor (EMEA/V/C/002590)	23.04.17-22.04.18
Nobilis IB Primo QX (EMEA/V/C/002802)	01.04.17-31.03.18
Zeleris (EMEA/V/C/004099)	01.12.17-31.05.18

- 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 discussed the draft training slides referring to VICH quality guidelines on stability and impurities: GL3 and GL4 on stability testing of new veterinary drug substances and medicinal products, GL5 on photo stability testing of new veterinary drug substances and medicinal products, GL8 on stability testing for medicated premixes, GL10 on impurities in new veterinary drug substances, GL11 on impurities in new veterinary medicinal products and GL18 on impurities in residual solvents in new veterinary medicinal products, active substances and excipients.

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;
- Externally organised projects and events for CVMP to note.

7. WORKING PARTIES AND SCIENTIFIC ADVISORY GROUPS

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

7.1 Scientific Advice Working Party (SAWP-V)

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

- The Committee received a verbal report from the SAWP-V chair on the meeting held on 11 September 2018, 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)

- The Committee adopted a guideline on the approach towards harmonisation of withdrawal periods (EMA/CVMP/SWP/735325/2012) and the overview of comments received (EMA/CVMP/SWP/81095/2017) following the period of public consultation. The guideline replaces and updates the previous note for guidance (EMA/CVMP/036/95 FINAL) on this topic and will come into effect in April 2019.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- The Committee adopted the revised mandate, objectives and rules of procedure for the CVMP Environmental Risk Assessment Working Party (EMA/CVMP/ERA/705470/2009 – Rev. 5).

7.5 Efficacy Working Party (EWP-V)

- The Committee adopted the draft reflection paper (EMA/CVMP/EWP/310225/2014) on ectoparasitic resistance for release for an 11-month period of public consultation.
- The Committee agreed to extend the consultation period of the draft guideline on the summary of product characteristics (SPC) for veterinary medicinal products containing antimicrobial substances (EMA/CVMP/383441/2005-Rev.1) until the end of August 2019. – *see also 7.6*

7.6 Antimicrobials Working Party (AWP)

- The Committee adopted the draft reflection paper (EMA/CVMP/AWP/842786/2015) on the use of aminopenicillins and their beta-lactamase inhibitor combinations in animals in the European Union, development of resistance and impact on human and animal health for release for a 3-month period of public consultation.
- The Committee agreed to extend the consultation period of the draft guideline on the summary of product characteristics (SPC) for veterinary medicinal products containing

antimicrobial substances (EMA/CVMP/383441/2005-Rev.1) until the end of August 2019. – *see also 7.5*

7.7 Immunologicals Working Party (IWP)

- There were no items for discussion.

7.8 Pharmacovigilance Working Party (PhVWP-V)

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

- There were no items for discussion.

The following documents were circulated for information:

- Draft minutes of the SAWP-V meeting held on 17 July 2018.
- Draft agenda of the Efficacy Working Party meeting to be held on 18-19 September 2018.
- Draft agenda of the Risk Assessment Guideline Focus Group Meeting to be held on 19 September 2018 and invitation sent to CVMP.
- Draft agenda of the Pharmacovigilance Working Party meeting to be held on 25-26 September 2018.
- Draft agenda of the ADVENT core group meeting held on 13 September 2018.
- Draft minutes of the ADVENT core group meeting held on 10 July 2018.

8. OTHER SCIENTIFIC MATTERS

8.1 MRLs issues

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

- The Committee decided not to include a substance as a new entry in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009, following the request from the applicant.

8.2 Environmental risk assessment

- There were no items for discussion.

8.3 Antimicrobial resistance

- The Committee was informed about the ESVAC pilot project to estimate the consumption of veterinary antimicrobials sales by the different animal species (stratification) and noted the stratification data collection protocol 2017.
- The Committee received information on the draft agenda of the focus group meeting on the pilot project on dose optimisation of established veterinary antibiotics in the context of SPC harmonisation (PPHOVA) to be held on 12 October 2018 with invited stakeholders.

8.4 Pharmacovigilance

- There were no items for discussion.

8.5 Other issues

Information on other critical issues related to centralised procedures cannot be released at the present time as it is deemed to contain commercially confidential information.

9. AVAILABILITY OF MEDICINES AND MUMS CLASSIFICATION

Information relating to availability of medicines cannot be released at the present time as it is deemed to be commercially confidential.

10. PROCEDURAL AND REGULATORY MATTERS

10.1 Eligibility and appointment of rapporteurs, co-rapporteurs and peer reviewers

Information relating to notification of intent for new MRL applications and notification of intent and eligibility requests for Community marketing authorisations cannot be released at the present time as it is deemed to be commercially confidential.

10.2 Regulatory matters

Information relating to certain regulatory issues cannot be released at the present time as it is deemed to be commercially confidential.

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

- The Committee noted the draft minutes of the meeting held on 19-20 July 2018 as well as the draft agenda of the meeting held on 13-14 September 2018.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee endorsed the recommendations arising from the CVMP informal presidency meeting held on 7-8 May 2018 in Madrid, Spain, and noted the agenda of the meeting and the minutes. The Committee endorsed the draft agenda of the CVMP/CMDv informal presidency meeting to be held on 24-26 October 2018 in Helsinki, Finland.
- The Committee received an update from the secretariat on the appointment of co-opted members, as the mandates of K. Baptiste and J. Weeks are expiring in December 2018.
- The Committee discussed the revised draft guidance on 'Appointment and responsibilities of the rapporteur and co-rapporteur for procedures regarding veterinary medicinal products', and agreed on the general principles proposed in the document. The document will be brought back to a future CVMP meeting for further discussion and/or endorsement.
- The Committee received a verbal report from the chair of the Strategic Planning Group on the meeting held on 12 September 2018, and noted the agenda of the meeting and the minutes of the meeting held on 20 June 2018.
- The Committee received an update to the implementation of EMA Business Continuity Phase (BCP) 3.
- The Committee received a verbal update on the concept paper on EU Telematics Strategy 2020-2025 (EMA/456818/2018).

13. LEGISLATION

- The Committee noted the Commission Implementing Regulation (EU) 2018/470 of 21 March 2018 on detailed rules on the MRL to be considered for control purposes for

foodstuffs derived from animals which have been treated in the EU under Article 11 of Directive /2001/82/EC (cascade).

14. ANY OTHER BUSINESS

- Upon the completion of the September 2018 CVMP meeting, the draft press release was circulated for members to provide any comments within 24 hours.

ANNEX I - List of participants including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the September 2018 meeting

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
CHAIR	**David Murphy**	**Full involvement**	
BE	Bruno Urbain	Full involvement	
DE	Gesine Hahn	Full involvement	
DK	Ellen-Margrethe Vestergaard	Full involvement	
EE	Toomas Tiirats	Full involvement	
ES	Cristina Muñoz Madero	Full involvement	
FR	Jean-Claude Rouby	Full involvement	
HR	Frane Božić	Full involvement	
IE	J. Gabriel Beechinor	Full involvement	
IT	Paolo Pasquali	Full involvement	
LV	Zanda Auce	Full involvement	
NL	Peter Hekman	Full involvement	
PL	Anna Wachnik-Święcicka	Involvement in discussions only and cannot act as rapporteur or peer reviewer for:	**7.1** One item
RO	Lollita Taban	Full involvement	
SE	Frida Hasslung Wikström	Full involvement	
SI	Katarina Straus	Full involvement	
SK	Judita Hederová	Full involvement	
UK	Helen Jukes	Full involvement	
Co-opted	Keith Baptiste	Full involvement	
Co-opted	Rory Breathnach	Full involvement	
Co-opted	G. Johan Schefferlie	Full involvement	
Co-opted	Jason Weeks	Full involvement	
NO	Hanne Bergendahl	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
BE	Frédéric Klein	Full involvement	
CZ	Leona Nepejchalová	Full involvement	
DE	Esther Werner	Full involvement	
EL	Angeliki Tsigouri	Full involvement	
FI	Katariina Kivilahti-Mantyla	Full involvement	
FR	Sylvie Louet	Full involvement	
HU	Tibor Soós	Full involvement	
UK	Noemi Garcia del Blanco *(remotely)*	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
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.			
DE	Anke Finnah	Full involvement	
DE	Stefan Steuber *(remotely)*	Full involvement	
DE	Sandra Bertulat *(remotely)*	Full involvement	
ES	Ámparo López *(remotely)*	Full involvement	
ES	Ricado Carapeto *(remotely)*	Full involvement	
ES	Rócio Fernández *(remotely)*	Full involvement	
FI	Merja Rantala *(remotely)*	Full involvement	
FR	Florence Pillet *(remotely)*	Full involvement	
FR	Khadija Selouaoiu *(remotely)*	Full involvement	
FR	Mathilde Harvey *(remotely)*	Full involvement	
IE	Michele Johnson *(remotely)*	Full involvement	
IE	Susan Reid *(remotely)*	Full involvement	
IE	Sarah Buckley *(remotely)*	Full involvement	
UK	John Mitchell	Full involvement	
UK	Kenneth Stapleton	Full involvement	
ES	Consuelo Rubio Montejano *(remotely)*	Full involvement	
UK	Rory Cooney	Full involvement	
UK	Sam Fletcher *(remotely)*	Full involvement	
UK	Sharon Reynolds	Full involvement	

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

Observer from the European Commission	
Present	

Observers from Swissmedic	
Remotely	

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