13 March 2018
EMA/CVMP/93469/2018
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 13-15 February 2018 meeting

Chair: D. Murphy – Vice-chair: H. Jukes

Note on access to documents

Some documents mentioned in the agenda/minutes cannot be released at present within the framework of Regulation (EC) No 1049/2001 on access to documents because they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).

i. Adoption of the Agenda

The Committee adopted the agenda of the meeting with minor amendments to point 9 and the addition of a new item under point 12.

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

The attendance list was completed and competing interests were identified for the February 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.

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iv. Adoption of the minutes of the previous meeting

The minutes of the January 2018 meeting were adopted with no amendments.

v. Topics for rapporteur's meetings, break-out sessions and oral explanations

Information relating to briefing meetings taking place with applicants cannot be released at the present time as it is deemed to be commercially confidential.

1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

- The Committee adopted by consensus (29 members present of those eligible to vote) the CVMP opinion, including the EPMAR, and the CVMP assessment report recommending the establishment of a MRL in chicken eggs for **paromomycin** (EMEA/V/MRL/003517/EXTN/0003). Furthermore, and with reference to Article 5 of Regulation (EC) No 470/2009, the Committee agreed to extrapolate the recommended MRL for paromomycin in chicken eggs to eggs of other poultry species. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted a peer-review report and the summary of opinion for publication.

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 porcine species for a substance (EMEA/V/MRL/003647/EXTN/0002). The Committee noted a peer-review report and the comments received from CVMP members. The adoption of the opinion is foreseen for the March 2018 meeting of the Committee.

1.3 Lists of questions

- The Committee adopted the scientific overview and a list of questions for the establishment of MRLs in bovine species for a substance (EMEA/V/MRL/004933/FULL/0001), following the discussion of the rapporteur's assessment report, including the critique from the co-rapporteur and of a peer-review report and the comments received from CVMP members.

1.4 Re-examination of CVMP opinions

- The Committee discussed the rapporteur's assessment report and the rapporteur's draft EPMAR for the review of MRLs in *Salmonidae* for a substance (EMEA/V/MRL/003135/MODF/003). The adoption of the opinion is foreseen for the March 2018 meeting of the Committee.

1.5 Other issues

- There were no items for discussion.

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

- 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 **Clevor** (EMEA/V/C/004417/0000), recommending the granting of a marketing authorisation. The product is presented as eye drops, solution in single-dose container, and is intended for the induction of vomiting in dogs. 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 a list of outstanding issues and discussed the product information for a new antiparasitic product for cats (EMEA/V/C/004440/0000). The Committee agreed to invite the applicant for an oral explanation in March 2018.
- 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 for musculo-skeletal disorders (EMEA/V/C/004222/0000). The Committee agreed to invite the applicant for an oral explanation in April 2018, and 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 for musculo-skeletal disorders (EMEA/V/C/004265/0000). The Committee agreed to invite the applicant for an oral explanation in March 2018, and 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 an extension application for **Credelio** (EMEA/V/C/004485/X/0001), to add a new strength for a new target species. The Committee agreed that an oral explanation would not be requested, and 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 comments on the draft product information for an extension application for **Zulvac BTV Ovis** (EMEA/V/C/004185/X/0001), to add a new food-producing target animal species. 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 (EMEA/V/C/004291/0000).
- The Committee agreed to the request from the applicant for an extension to the clock-stop for a new vaccine (EMEA/V/C/004611/0000) for sheep and cattle.
- The Committee was informed of the formal notification from Parnell Technologies (UK) Limited of their decision to withdraw the application for a new marketing authorisation for **Zydax** (EMEA/V/C/004375/0000), a product for musculo-skeletal disorders in dogs. More information about this application and the current state of the scientific assessment at the time of the withdrawal will be made available in a public assessment report.

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- The Committee adopted by majority (27 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 a type II variation for **Metacam** (EMEA/V/C/000033/II/0127), recommending the variation of the marketing authorisation to register an additional non-food producing target

species, the guinea pig, for treatment with Metacam 0.5 mg/ml oral suspension. G. Hahn, F. Hasslung Wikström, B. Urbain and the Norwegian CVMP member signed a divergent position not supporting the aforementioned recommendation. The Committee noted the summary of opinion for publication.

- The Committee adopted by consensus (30 members present of those eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a type II variation, following a worksharing procedure for **Oncept IL2**, **Parvoduk**, **ProteqFlu**, **Proteq West Nile**, **ProteqFlu Te**, **Purevax FeLV**, **Purevax Rabies**, **Purevax RC**, **Purevac RCP**, **Purevax RCP FeLV**, **Pu8revax RCPCh**, **Purevax RCPCh FeLV** and **Vaxxitek HVT+IBD** (and related nationally-authorised products) (EMEA/V/C/WS/1195), 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 (30 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/003942/WS1277/0002) for **Porcilis PCV ID** and **Porcilis M Hyo ID ONCE** (and nationally-authorised products: **Porsilis M Hyo ID ONCE and Porcilis M Hyo ID ONCE vakcina A.U.V.**), recommending the variation of the marketing authorisation to implement changes to the SPC and package leaflet concerning wording on associated non-mixed use. 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 (30 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a grouping of type II variation for **ERAVAC** (EMEA/V/C/004239/II/0003/G), recommending the variation of the marketing authorisation regarding a change to the duration of immunity and safety, as well as associated changes in the product information. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication.
- The Committee adopted by consensus (30 members present of those eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report for a group of type IA, IA(IN) and type II variations, following a worksharing procedure for **Vaxxitek HVT + IBD** (and related nationally-authorised products) (EMEA/V/C/WS1209/G), recommending the variation of the marketing authorisation to implement quality changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (29 members present of those eligible to vote) the CVMP opinion and the product information, and endorsed the rapporteur's assessment report for a type II variation for **STARTVAC** (EMEA/V/C/000130/II/0005), 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 (29 members present of those eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report for a group of type IA and type IB variations, following a worksharing procedure for **Ingelvac CircoFLEX** and **Ingelvac PCV FLEX** (EMEA/V/C/WS1249/G), recommending the variation of the marketing authorisation to implement quality changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (29 members present of those eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report for a worksharing type IB

variation for **Vaxxitek HVT + IBD** (and related nationally-authorised products) (EMEA/V/C/WS1242), 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 a list of outstanding issues for a type II variation for **Porcilis ColiClos** (EMEA/V/C/002011/II/0007), concerning quality changes.

3.3 Lists of questions

- The Committee adopted a list of questions for a type II variation for **BTVPUR** (EMEA/V/C/002231/II/0010), to add a new serotype.
- The Committee adopted a list of questions for a grouped type II variation for **CLYNAV** (EMEA/V/C/002390/II/0001/G), concerning quality changes.

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 adopted by majority (25 members in favour out of the 30 members present of those eligible to vote) the final CVMP opinion, the final CVMP assessment report and the product information for the referral procedure for **Girolan and its associated name Apralan** (EMEA/V/A/122). The Committee re-examined the data related to the shelf-life, which had been set at 18 months during the initial referral procedure, and recommended a two-year shelf-life for the products. The Committee agreed a harmonised product information for the concerned products and recommended variations to the marketing authorisations of the concerned products to amend the product information accordingly. K. Baptiste, E. Kozhuharov, T.-M. Muhonen, L. Nepejchalová and E-M. Vestergaard, and the Norwegian member signed divergent positions not supporting the aforementioned opinion.

4.3 Article 35 of Directive 2001/82/EC

- The Committee adopted by majority (27 members in favour out of the 28 members present of those eligible to vote) the CVMP follow-up assessment report for the referral procedure for **veterinary medicinal products containing enrofloxacin to be administered via the drinking water to chickens and/or turkeys** (EMEA/V/A/089), recommending the deletion of the indication for treatment of infections caused by *E. coli* susceptible to enrofloxacin in chickens and turkeys from the product information of the concerned products. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
  L. Nepejchalová signed a divergent position not supporting the aforementioned recommendation.

- The Committee considered the notification from the United Kingdom for a referral procedure for **veterinary medicinal products containing 50 mg closantel per ml presented as solutions for injection for subcutaneous use in sheep**. The referral concerns the appropriateness of withdrawal periods (meat and offal) in sheep for the aforementioned veterinary medicinal products containing closantel as a single active substance. The Committee agreed to start a referral procedure (EMEA/V/A/126) under Article 35 and appointed S. Louet as rapporteur and J. Schefferlie as co-rapporteur 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

- The Committee adopted by consensus (29 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for the referral procedure for **Seresto** (EMEA/V/A/125), concluding that the objections raised by the United Kingdom should not prevent the granting of the variation to the terms of the marketing authorisations, subject to changes in the product information to amend the proposed indication. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.

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 19.01.2018 – 15.02.2018:

Product	Period
Bravecto (EMEA/V/C/002526)	11/02/2017 – 10/02/2018
Comfortis (EMEA/V/C/002233)	11/02/2017 – 10/02/2018
Fevaxyn Pentofel (EMEA/V/C/000030)	05/02/2017 – 04/02/2018
Hiprabovis IBR Marker Live (EMEA/V/C/000158)	27/01/2017 – 26/01/2018
Ingelvac CircoFLEX (EMEA/V/C/000126)	13/02/2017 – 12/02/2018
Kexxtone (EMEA/V/C/002235)	28/01/2017 – 27/01/2018

Product	Period
Loxicom (EMEA/V/C/000141)	10/02/2018 – 09/02/2018
NexGard (EMEA/V/C/002729)	11/02/2017 – 10/02/2018
Nobilis OR inac (EMEA/V/C/000062)	24/01/2017 – 23/01/2018
PIRSUE (EMEA/V/C/000054)	29/01/2017 – 28/01/2018
Semintra (EMEA/V/C/002436)	13/02/2017 – 12/02/2018
STARTVAC (EMEA/V/C/000130)	11/02/2017 – 10/02/2018
Stronghold Plus (EMEA/V/C/004194)	09/02/2017 – 08/02/2018
Suvaxyn CSF Marker (EMEA/V/C/002757)	10/02/2017 – 09/02/2018
VarroMed (EMEA/V/C/002723)	02/02/2017 – 01/02/2018
ZULVAC SBV (EMEA/V/C/002781)	06/02/2017 – 05/02/2018

5.4 Renewals

- The Committee adopted by consensus (28 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for the renewal of the marketing authorisation for **ProZinc** (EMEA/V/C/002634/R/0013), 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 a list of outstanding issues for the renewal of the marketing authorisation for **Meloxidolor** (EMEA/V/C/002590/R/0007).

5.5 Pharmacovigilance – PSURs and SARs

- The Committee endorsed the revised rapporteur's assessment report of the PSUR for the period 01.03.2017-31.08.2017 for **Bravecto** (EMEA/V/C/002526).
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.02.2017 – 31.07.2017 for **Versican Plus L4** (EMEA/V/C/003680) with a recommendation to amend the product information.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.02.2017 – 31.07.2017 for **Versican Plus PiL4** (EMEA/V/C/003683) with a recommendation to amend the product information.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.02.2017 – 31.07.2017 for **Versican PiL4R** (EMEA/V/C/003682) 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
Aivlosin (EMEA/V/C/000083)	01.04.2017 – 30.09.2017
Bovela (EMEA/V/C/003703)	01.01.2017 – 30.06.2017

Coliprotec F4 (EMEA/V/C/003797)	01.04.2017 – 30.09.2017
Econor (EMEA/V/C/000042)	01.10.2016 – 30.09.2017
Eravac (EMEA/V/C/004239)	01.04.2017 – 30.09.2017
Eurican Herpes (EMEA/V/C/000059)	01.10.2016 - 30.09.2017
Fortekor Plus (EMEA/V/C/002804)	01.04.2017 – 30.09.2017
Proteq Flu (EMEA/V/C/000073)	01.10.2016 - 30.09.2017
Proteq Flu Te (EMEA/V/C/000074)	01.10.2016 - 30.09.1207

- The Committee endorsed the list of products and calendar for signal detection analysis.

5.6 Supervision and sanctions

Information relating to supervision and sanctions will not be published as it would be undermining the purpose of such inspections.

6. CO-OPERATION WITH OTHER EU OR INTERNATIONAL BODIES

6.1 VICH

- The Committee endorsed the EU comments on the Japanese Ministry of Agriculture, Forestry and Fisheries (JMAFF) proposal for advancing the work on extraneous viruses in veterinary vaccines.
- The Committee endorsed the EU comments on the revised concept paper proposing the development of a VICH guideline on safety evaluation of biotechnology-derived/biological products.
- The Committee endorsed the draft concept paper for a VICH guideline providing guidance on the establishment and running of a basic pharmacovigilance system.

6.2 Codex Alimentarius

- There were no items for discussion.

6.3 Other EU bodies and international organisations

- There were no items for discussion.

The following document was circulated for information:

- Status of active VICH guidelines and action plan of CVMP and working parties.

7. WORKING PARTIES AND SCIENTIFIC ADVISORY GROUPS

Information relating to certain topics discussed under section 7 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 vice-chair of the SAWP-V on the meeting held on 13 February 2018, and noted the agenda of the meeting.

7.2 Quality Working Party (QWP)

- The Committee adopted the guideline on manufacture of the veterinary finished dosage form (EMA/CVMP/QWP/798401/2015) for a 6-month period of public consultation.

7.3 Safety Working Party (SWP-V)

- The Committee received a verbal report from the chair of the SWP-V on the meeting held on 1-2 February 2018, and noted the agenda of the meeting.
- The Committee discussed the draft guideline on user safety of topically administered veterinary medicinal products, which is foreseen to be adopted at the March 2018 CVMP meeting.

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 30-31 January 2018, and noted the agenda and the draft minutes of the meeting.

7.5 Efficacy Working Party (EWP-V)

- The Committee discussed the revised guideline on the summary of product characteristics (SPC) for antimicrobial products (EMA/CVMP/383441/2005). The revised guideline is foreseen to be adopted for release for public consultation at the April 2018 CVMP meeting - *See point 7.6.*

7.6 Antimicrobials Working Party (AWP)

- The Committee discussed the revised guideline on the summary of product characteristics (SPC) for antimicrobial products (EMA/CVMP/383441/2005). The revised guideline is foreseen to be adopted for release for public consultation at the April 2018 CVMP meeting - *See point 7.5.*
- The Committee agreed for AWP to proceed with the revision of the reflection paper on off-label use of antimicrobials in veterinary medicine in the European Union, following the overview of comments received during the public consultation.

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 chair of the PhVWP-V on the meeting held on 23-24 January 2018, and noted the agenda of the meeting.
- The Committee discussed the draft Veterinary Pharmacovigilance Public bulletin 2017 (EMA/697615/2017), which is foreseen to be adopted at the March 2018 CVMP meeting.

7.9 Novel therapy groups and related issues

- There were no items for discussion.

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

- The Committee endorsed the Biennial Report 2016 – 2017 (EMA/CHMP/CVMP/3Rs/502136/2017) of the CVMP/CHMP Working Group on the Application of the 3Rs (replacement, reduction, refinement) in Regulatory Testing of Medical Products (J3RsWG), which is aimed at informing pharmaceutical companies and the public of the EMA activities in relation to the 3Rs.

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 held 16 January 2018.
- Minutes of the 84th QWP meeting held on 27-29 September 2017 and the agenda of the 85th QWP Veterinary Breakout Session meeting held on 28 November 2017.
- Minutes of the Joint Meeting of the GMP/GDP Inspectors Working Group and CHMP/CVMP Quality Working Party held on 27 September 2017.
- Draft agenda of the Efficacy Working Party meeting held on 20-21 February 2018.
- Draft agenda of the Immunological Working Party meeting held on 28 February 2018 – 1 March 2018.
- Draft agenda of the ADVENT meeting held on 15 February 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 agreed to include **methacrylic acid - ethyl acrylate copolymer** as a new entry in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 under the heading of excipients, following the request from the applicant, and adopted the revised list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 (EMA/CVMP/519714/2009 – Rev.38).
- The Committee endorsed the review of the current entry for **diethanolamine** in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009.

8.2 Environmental risk assessment

- There were no items for discussion.

8.3 Antimicrobial resistance

- The Committee noted the abstract on the joint pilot project on dose optimisation of veterinary antibiotics for the European Association for Veterinary Pharmacology and Toxicology congress.

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.

- There were no items for discussion.

The following documents were circulated for information:

- World Health Organization (WHO) guidelines on use of medically important antimicrobials in food-producing animals: https://aricjournal.biomedcentral.com/articles/10.1186/s13756-017-0294-9
- Agenda (EMA/18338/2018) and draft minutes (EMA/54553/2018) of the Adobe Connect meeting of the Antimicrobial Advice Ad Hoc Expert Group (AMEG) held on 25 January 2018.

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.

- The Committee agreed to the transfer of all (co-)rapporteurships and peer-review responsibilities from Martti Nevalainen and Kristina Lehmann to Tita-Maria Muhonen and Katariina Kivilahti-Mäntylä.
- The Committee agreed to the transfer of (co-)rapporteurships from Eva Lander Persson to Frida Hasslung Wikström.

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.

- The Committee noted the publication of the immunological module on “Completing EMA template for Scientific Overview: pharmaceutical and immunological products” as part of the training on the EU NTC in January 2018.

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

- The Committee received a verbal report from the chair of CMDv on the meetings held on 7-8 December 2017 and 18-19 January 2018, and noted the draft minutes of the meeting held on 18-19 January 2018 as well as the draft agenda of the meeting held on 15-16 February 2018.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee received a verbal report from the chair of the Strategic Planning Group on the meeting held on 14 February 2018, and noted the agenda of the meeting and the minutes of the meeting held on 8 November 2018.
- The Committee received a verbal update on the EMA working group on operational preparedness for veterinary medicines.
- The Committee noted the draft agenda of the ‘Veterinary Innovation Day to be held on 19 April 2018’; and the draft agenda of the ‘Update on Brexit regulatory preparedness activities for veterinary companies’ meeting to be held on 20 April 2018.

- The Committee was informed about an Advance notice on eSubmission matters: exception to the VNees format and on common repository - Vet NCAs readiness.

13. LEGISLATION

- The Committee adopted the draft CVMP view on whether the 'other provisions' included in Table 1 of the annex to Commission Regulation (EU) 37/2010 are necessary for the establishment of MRLs and for the protection of human health, or whether they reflect only the lack of data.

14. ANY OTHER BUSINESS

- Upon the completion of the February 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 February 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**	
AT	Brigitte Hauser	Full involvement	
BE	Bruno Urbain	Full involvement	
BG	Emil Kozhuharov	Full involvement	
CY	Alia Michaelidou	Full involvement	
DE	Gesine Hahn	Full involvement	
DK	Ellen-Margrethe Vestergaard	Full involvement	
EE	Toomas Tiirats	Full involvement	
EL	Ioannis Malemis	Full involvement	
ES	Cristina Muñoz Madero	Full involvement	
FI	Tita-Maria Muhonen	**Involvement only in discussions** i.e. no part in final deliberations and voting, and cannot act as rapporteur, other leading/co-ordinating role or formally appointed peer reviewer in relation to any medicinal product from **Orion Oyj**.	• 2.1 - one item • 5.6 - one item
FR	Jean-Claude Rouby	Full involvement	
HR	Frane Božić	**Involvement only in discussions** i.e. no part in final deliberations and voting, and cannot act as rapporteur, other leading/co-ordinating role or formally appointed peer reviewer in relation to any medicinal product from **Genera Research**	• 4.3 - one item (Enrofloxacin) • 5.4 - one item (Meloxidolor) • 8.1 - one item
HU	Gábor Kulcsár	Full involvement	
IE	Jeremiah Gabriel Beechinor	Full involvement	
LU	Marc Schmit	Full involvement	
LV	Zanda Auce	**Involvement only in discussions** i.e. no part in final deliberations and voting, and cannot act as rapporteur, other	• None

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
		leading/co-ordinating role or formally appointed peer reviewer in relation to any medicinal product from **Olainfarm JSC**	
NL	Peter Hekman	Full involvement	
PL	Anna Wachnik-Święcicka	**Involvement only in discussions** i.e. no part in final deliberations and voting, and cannot act as rapporteur, other leading/co-ordinating role or formally appointed peer reviewer in relation to any medicinal product from **Bayer**	• 4.3 - one item • 4.5 - one item • 5.4 - one item
PT	João Pedro Duarte da Silva	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	Gerrit Johan Schefferlie	Full involvement	
Co-opted	Wilhelm Schlumbohm	Full involvement	
Co-opted	Jason Weeks	**No involvement** i.e. no part in discussions, final deliberations and voting as appropriate with respect to the medicinal product **Salmosan**, and cannot act as rapporteur or peer reviewer for this product	• None
NO	Hanne Bergendahl	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
BE	Frédéric Klein	Full involvement	
CZ	Leona Nepejchalová	Full involvement	
FR	Sylvie Louet	Full involvement	
IT	Antonio Battisti	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
RO	Simona Sturzu	Full involvement	
SE	Frida Hasslung Wikström	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*	No interests	
DE	Klaus Cussler - *remotely*	No interests	
DE	Karin Duchow - *remotely*	No interests	
DE	Andrea Golombiewski - *remotely*	No interests	
DE	Uta Herbst - *remotely*	No interests	
DE	Birgit Kegel - *remotely*	No interests	
DE	Nikola Lange - *remotely*	No interests	
DE	Svenja Rieke - *remotely*	No interests	
DE	Kristin Schallschmidt - *remotely*	No interests	
DE	Stefan Scheid - *remotely*	No interests	
DE	Werner Terhalle - *remotely*	No interests	
ES	Javier Alonso - *remotely*	No interests	
ES	Carlos Ballesteros - *remotely*	No interests	
ES	Rosario Bullido Gómez-Heras - *remotely*	No interests	
ES	María José Ferrer Montesa - *remotely*	No interests	
ES	Marta Martín Juarez - *remotely*	No interests	
ES	Raul Belmar Liberato	Indirect interests	Full involvement
ES	Alberto de Prado López -	No interests	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
	remotely		
ES	Javier Martínez - *remotely*	No interests	
ES	Sonia Gil Morales	No interests	
IE	Mary O'Grady - *remotely*	No interests	
NL	Kim Boerkamp- *remotely*	No interests	
PL	Anita Piwowarczyk	No interests	
SE	Helena Back	No interests	
SE	Andreea Barbu - *remotely*	Indirect interests	Full involvement
SE	Eva Lander Persson	No interests	
UK	Rory Cooney	No interests	
UK	Miguel Escribano - *remotely*	No interests	
UK	Samuel Fletcher - *remotely*	No interests	
UK	John Mitchell	Indirect interests	Full involvement
UK	Steve Spencer	No interests	

CVMP working parties and CMDv	Chair
ADVENT	Jean-Claude Rouby
AWP	Helen Jukes
CMDv	Laetitia Le Letty- *remotely*
ERAWP	Jason Weeks
EWP-V	Cristina Munoz Madero
IWP	--
PhVWP-V	Els Dewaele - *remotely*
QWP	Mary O'Grady *(Vet vice chair) - remotely*
SAWP-V	--
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