10 April 2017
EMA/CVMP/250608/2017
Committee for Medicinal Products for Veterinary Use (CVMP)

# Committee for Medicinal Products for Veterinary Use

## Minutes of the 14-16 March 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 the addition of a new item under point 5.6.

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

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

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### iv. Adoption of the minutes of the previous meeting

The minutes of the February 2017 meeting were adopted with no amendments.

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

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

## 1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

### 1.1 Opinions

- There were no items for discussion.

### 1.2 Oral explanations and lists of outstanding issues

- There were no items for discussion.

### 1.3 Lists of questions

- The Committee discussed the rapporteur's evaluation for the establishment of MRLs in rabbits for a substance (EMEA/V/MRL/004706/FULL/0001), and agreed that a list of questions is not required. The Committee noted the draft EPMAR and two peer review reports. The adoption of the opinion is foreseen for the April 2017 meeting of the Committee.

### 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 (26 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Zeleris** (EMEA/V/C/004099/0000), recommending the granting of a marketing authorisation. Zeleris is a new fixed combination product containing florfenicol and meloxicam for subcutaneous use in cattle. 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 **ZACTRAN** (EMEA/V/C/000129/X/0034), recommending the extension of the marketing authorisation to add a new species: sheep, for the treatment of foot rot. 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 the duplicate application for **Ingelvac PCV FLEX** (EMEA/V/C/004645/0000), recommending the granting of a marketing authorisation. The product is a vaccine for the active immunisation of pigs against porcine circovirus type 2 (PCV2). 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 **Novem** (EMEA/V/C/000086/X/0018), recommending the extension of the marketing authorisation to add a new strength (40 mg/ml solution for injection) for cattle. 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 antiparasitic product for chickens (EMEA/V/C/004344/0000). The Committee agreed to invite the applicant for an oral explanation. 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 comments on the draft product information for a new product for foxes and raccoon dogs (EMEA/V/C/004387/0000). The Committee noted two peer review reports and the comments received from CVMP members.

### 2.4 Re-examination of CVMP opinions

- The Committee heard an oral explanation from IDT Biologika GmbH and discussed the report from the AHEG meeting held on 6 March 2017, concerning the re-examination of the CVMP opinion adopted for **RESPIPORC FLUpan H1N1** (EMEA/V/C/003993/0000), a new inactivated viral vaccine for the active immunisation of pigs against swine influenza caused by pandemic subtype H1N1v. The Committee adopted by majority (22 members in favour out of the 27 members present of those eligible to vote) the final CVMP opinion, the final CVMP assessment report and the product information recommending the granting of a marketing authorisation, further to the re-examination of the opinion adopted during the Committee meeting held on 6-8 December 2016. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. K. Baptiste, J. Hederova, G. Kulcsar, J.-C. Rouby and E.-M. Vestergaard signed a divergent position not supporting the aforementioned recommendation. The Committee noted the summary of opinion for publication.

### 2.5 Other issues

- The Committee endorsed the EPAR module 6 scientific discussion for **VarroMed** (EMEA/V/C/002723/0000) concerning the granting of the initial marketing authorisation.
- The Committee noted the updated EPAR module 6 scientific discussion for **Evalon** (EMEA/V/C/004013/0000) concerning the granting of the initial marketing authorisation.

## 3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

### 3.1 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 a type II variation for **NEXGARD SPECTRA** (EMEA/V/C/003842/II/0008), recommending the variation of the marketing authorisation to add two new therapeutic indications, for the prevention of angiostrongylosis (reduction of infestation by *Angiostrongylus vasorum*) with monthly administration, and for the treatment of infestations with adult gastrointestinal nematodes of

hookworms (*Ancylostoma ceylanicum*). 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 grouped type II variation for **ProZinc** (EMEA/V/C/002634/II/0010/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 (26 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a grouped type II variation for **Bravecto** (EMEA/V/C/002526/II/0017/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 (26 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a grouped type II variation for **Stronghold** (EMEA/V/C/000050/II/0055/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.

### 3.2 Oral explanations and lists of outstanding issues

- There were no items for discussion.

### 3.3 Lists of questions

- The Committee adopted the list of questions for a type II variation for **Comfortis** (EMEA/V/C/002233/II/0017), to change conditions regarding supply and use.

- The Committee adopted the list of questions for a worksharing type IB variation for **ProteqFlu, Purevax FeLV, Purevax RCP FeLV, Purevax RCPCh FeLV, Oncept IL-2, Proteq West Nile, ProteqFlu-Te, Purevax Rabies** (EMEA/V/C/xxxxxx/WS1095), concerning quality changes.

### 3.4 Re-examination of CVMP opinions

- There were no items for discussion.

### 3.5 Other issues

- The Committee agreed to a request from the MAH for 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 agreed that the full oral explanation from Elanco Animal Health, concerning the referral procedure for **Denagard 45% and associated names** (EMEA/V/A/114), was not necessary. The adoption of the opinion is foreseen for the April 2017 meeting of the Committee.

- The Committee discussed the rapporteur's assessment report including the co-rapporteur's critique for the referral procedure for **Lincocin and associated names** (EMEA/V/A/123). The Committee adopted the list of outstanding issues for the marketing authorisation holder to address in writing, and the revised timetable for the procedure. The Committee noted two peer review reports and the comments made by CVMP members.

### 4.3 Article 35 of Directive 2001/82/EC

- The Committee adopted by consensus (27 members present of those eligible to vote) the final CVMP opinion and assessment report following the re-examination of the CVMP opinion for the referral procedure for **veterinary medicinal products containing zinc oxide to be administered orally to food producing species** (EMEA/V/A/118). The Committee concluded that there were insufficient scientific grounds to revise its previous conclusions as included in its opinion of 8 December 2016, and recommended the refusal of the granting of the marketing authorisations and the withdrawal of the existing marketing authorisations for veterinary medicinal products containing zinc oxide administered orally to food producing species. 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 the referral procedure for **veterinary medicinal products containing methylprednisolone hydrogen succinate presented as solutions for injection for intramuscular use in cattle** (EMEA/V/A/119), recommending the refusal of the granting of the marketing authorisation for the target species cattle and the variation of the existing marketing authorisations in order to remove any reference to the target species cattle for the afore mentioned products. 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 the referral procedure for **veterinary medicinal products containing tylosin that are administered parenterally and intended for the treatment of bovine mastitis caused by *Mycoplasma* spp.** (EMEA/V/A/121), recommending variations to the terms of the marketing authorisations for veterinary medicinal products containing tylosin that are administered parenterally in order to remove the indications 'bovine mastitis caused by *Mycoplasma* spp.' or 'bovine mastitis caused by *Mycoplasma bovis*' from the product information. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee discussed the follow-up assessment procedure in relation to conditions set by the Commission Implementing Decision C(2014) 1484 following 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). The Committee appointed H. Jukes as rapporteur and C. Muñoz as co-rapporteur, and peer reviewers, and adopted the timetable for the procedure.

### 4.4 Article 78 of Directive 2001/82/EC

- There were no items for discussion.

### 4.5 Article 13 of Regulation (EC) No 1234/2008

- There were no items for discussion.

### 4.6 Article 30(3) of Regulation (EC) No 726/2004

- There were no items for discussion.

### 4.7 Other issues

- There were no items for discussion.

***The following document was circulated for information:***

- Veterinary medicinal products containing gentamicin presented as solutions for injection to be administered to cattle and pigs - Article 35 referral (EMEA/V/A/117) – questions and answers for publication.

## 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 recommendation for **Circovac** (EMEA/V/C/000114/REC/003.1).

### 5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 17.02.2017 – 16.03.2017:

| Product | Period |
|---|---|
| **Activyl** (EMEA/V/C/000163) | 18/02/2016 – 17/02/2017 |
| **Bovalto** Ibraxion (EMEA/V/C/000051) | 09/03/2016 – 08/03/2017 |
| **CaniLeish** (EMEA/V/C/002232) | 14/03/2016 – 13/03/2017 |
| **Cimalgex** (EMEA/V/C/000162) | 18/02/2016 – 17/02/2017 |
| **Coliprotec F4** (EMEA/V/C/003797) | 16/03/2016 – 15/03/2017 |
| **Econor** (EMEA/V/C/000042) | 12/03/2016 – 11/03/2017 |
| **Equisolon** (EMEA/V/C/002382) | 12/03/2016 – 11/03/2017 |
| **Fungitraxx** (EMEA/V/C/002722) | 12/03/2016 – 11/03/2017 |
| **Melosus** (EMEA/V/C/002001) | 21/02/2016 – 20/02/2017 |
| **Novem** (EMEA/V/C/000086) | 02/03/2016 – 01/03/2017 |
| **Pexion** (EMEA/V/C/002543) | 25/02/2016 – 24/02/2017 |
| **Porcilis Porcoli Diluvac Forte** (EMEA/V/C/000024) | 29/02/2016 – 28/02/2017 |
| **ProteqFlu** (EMEA/V/C/000073) | 06/03/2016 – 05/03/2017 |
| **ProteqFlu-Te** (EMEA/V/C/000074) | 06/03/2016 – 05/03/2017 |
| **Purevax Rabies** (EMEA/V/C/002003) | 18/02/2016 – 17/02/2017 |
| **Purevax RC** (EMEA/V/C/000091) | 23/02/2016 – 22/02/2017 |
| **Purevax RCP** (EMEA/V/C/000090) | 23/02/2016 – 22/02/2017 |

| Product | Period |
|---|---|
| **Purevax RCP FeLV** (EMEA/V/C/000089) | 23/02/2016 – 22/02/2017 |
| **Purevax RCPCh** (EMEA/V/C/000088) | 23/02/2016 – 22/02/2017 |
| **Purevax RCPCh FeLV** (EMEA/V/C/000085) | 23/02/2016 – 22/02/2017 |
| **ZULVAC 1+8 Bovis** (EMEA/V/C/002473) | 08/03/2016 – 07/03/2017 |
| **ZULVAC 1+8 Ovis** (EMEA/V/C/002251) | 14/03/2016 – 13/03/2017 |

### 5.4 Renewals

- The Committee adopted the list of outstanding issues for the renewal of the marketing authorisation for **Cardalis** (EMEA/V/C/002524/R/0009).
- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for the renewal of the marketing authorisation for **Poulvac E. coli** (EMEA/V/C/002007/R/0012), and recommended that the authorisation should now be indefinite. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (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 **Suprelorin** (EMEA/V/C/000109/R/0016), and recommended that the authorisation should now be indefinite. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.

### 5.5 Pharmacovigilance – PSURs and SARs

- The Committee adopted the CVMP assessment report of the PSUR for the period 13.03.2016 – 12.09.2016 for **Equisolon** (EMEA/V/C/002382) with a recommendation to amend the product literature.
- The Committee adopted the following CVMP assessment reports on PSURs concluding that no changes to the product literature or other regulatory actions were required for:

| Product | Period |
|---|---|
| **Comfortis** (EMEA/V/C/002233) | 01.10.2015 – 30.09.2016 |
| **LETIFEND** (EMEA/V/C/003865) | 20.04.2016 – 31.10.2016 |
| **Porcilis Pesti** (EMEA/V/C/000046) | 10.12.2013 – 09.12.2016 |

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

### 5.6 Supervision and sanctions

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

***The following document was circulated for information:***

- Status report on PSURs for centrally authorised veterinary medicinal products.

## 6. CO-OPERATION WITH OTHER EU OR INTERNATIONAL BODIES

### 6.1 VICH

- The Committee endorsed the EU response to the latest version of the draft of the VICH guideline on marker residue depletion studies to establish product withdrawal periods in aquatic species.
- The Committee endorsed the 2nd round of draft EU comments on the compiled comments on topics of group 1 for the revision of the VICH anthelmintic guidelines:
  - topic 1.1 adequacy of infection defining *a priori*;
  - topic 1.2 minimum numbers of cestodes for equines;
  - topic 1.3 experimental unit as pen in swine and poultry GLs;
  - topic 1.4 updating VICH GL 16;
  - topic 1.5 statistical considerations blocking.
- The Committee endorsed the draft VICH GL50 on harmonisation of criteria to waive target animal batch safety testing for inactivated vaccines for veterinary use and the draft VICH GL55 on harmonisation of criteria to waive target animal batch safety testing for live vaccines for veterinary use for sign off at step 5.
- The Committee deferred the verbal report on the 34th VICH Steering Committee meeting held on 27 February - 2 March 2017 in Buenos Aires, Argentina, to the April 2017 CVMP meeting.
- The Committee noted the chair's presentation on 'CVMP Strategy on Antimicrobials' given to the 8th VICH Outreach Forum meeting held on 28 February - 1 March 2017.

### 6.2 Codex Alimentarius

- There were no items for discussion.

### 6.3 Other EU bodies and international organisations

*Information relating to certain topics discussed under section 6.3 at this meeting cannot be released at the present time as it is deemed to be confidential.*

***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 chair of the SAWP-V on the meeting held on 14 March 2017, and noted the agenda of the meeting.
- The Committee elected J. Poot as new member of the SAWP-V.

### 7.2 Quality Working Party (QWP)

- There were no items for discussion.

### 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 2-3 February 2017, and noted the agenda of the 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 31 January – 1 February 2017, and noted the agenda and the draft minutes of the meeting.
- The Committee adopted the guideline on the plant testing strategy for veterinary medicinal products (EMA/CVMP/ERA/689041/2015) and the overview of comments received (EMA/CVMP/ERA/8138/2017). The new guideline will come into effect in October 2017.

### 7.5 Efficacy Working Party (EWP-V)

- The Committee received a verbal report from the chair of the EWP-V on the meeting held on 21-22 February 2017, and noted the agenda of the meeting. The Committee was informed that EWP-V agreed to have a EWP-V vice-chair and agreed to hold the election at the May 2017 CVMP meeting. A call for nominations will be launched shortly by the EMA secretariat.

### 7.6 Antimicrobials Working Party (AWP)

- The Committee received a verbal report from the chair of the AWP on the meeting held on 28 February – 1 March 2017, and noted the agenda of the meeting. The Committee was informed that AWP agreed to have an AWP vice-chair and agreed to hold the election at the May 2017 CVMP meeting. A call for nominations will be launched shortly by the EMA secretariat.

### 7.7 Immunologicals Working Party (IWP)

- The Committee received a verbal report from the chair of the IWP on the meeting held on 1-2 February 2017, and noted the agenda of the meeting.
- The Committee discussed the revised guideline on data requirements for immunological veterinary medicinal products intended for minor use or minor species (MUMS)/limited market, and the overview of comments received. The documents are foreseen to be adopted at the April 2017 CVMP meeting.
- The Committee received a verbal report from the chair of IWP on the IWP Interested parties meeting held on 2 February 2016, and noted the presentation by IFAH-Europe and the final agenda of the meeting.

### 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 24-25 January 2017, and noted the agenda and draft minutes of the 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)

- There were no items for discussion.

### 7.11 Other working party and scientific group issues

- The Committee was informed of the ASMF summary coming into force within the ASMF assessment worksharing procedure.

***The following documents were circulated for information:***

- Minutes of the SAWP-V meeting held on 14 February 2017;
- Final agenda of the 82nd Joint CHMP/CVMP QWP meeting held on 31 January – 2 February 2017 and table of decisions;
- Final minutes from the 81st Joint CHMP/CVMP QWP meeting held on 29 November – 1 December 2016;
- Draft minutes of the EWP-V meeting held on 21-22 February 2017;
- Draft agenda for the PhVWP-V meeting to be held on 21-22 March 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.*

- The Committee agreed to include **polyoxyethylene cetyl ethers** 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.35).

### 8.2 Environmental risk assessment

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

### 8.3 Antimicrobial resistance

- There were no items for discussion.

### 8.4 Pharmacovigilance

- There were no items for discussion.

### 8.5 Other issues

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

- There were no items for discussion.

***The following documents were circulated for information:***

- Publication of EFSA-ECDC Joint Scientific Report 'The European Union summary report on antimicrobial resistance in zoonotic and indicator bacteria from humans, animals and food in 2015' (link);
- Final report of a fact-finding mission carried out in Denmark from 1 February 2016 to 5 February 2016 in order to gather information on the prudent use of antimicrobials in animals http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=3642;
- Final report of a fact-finding mission carried out in Germany from 19 to 26 April 2016 in order to gather information on the prudent use of antimicrobials in animals http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=3676;

- Final report of a fact-finding mission carried out in Finland from 16 may 2016 to 20 May 2016 in order to gather information on the prudent use of antimicrobials in animals http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=3715;
- Final report of a fact-finding mission carried out in the Netherlands from 13 September 2016 to 20 September 2016 in order to gather information on the prudent use of antimicrobials in animals http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=3753;
- Open Public Consultation on possible activities under a 'Commission Communication on a One Health Action Plan to support Member States in the fight against Antimicrobial Resistance (AMR)' from 27 January to 28 April 2017 http://ec.europa.eu/newsroom/sante/newsletter-specific-archive-issue.cfm?newsletter_service_id=327&newsletter_issue_id=2199&page=1&fullDate=Fri%2027%20Jan%202017&lang=default.

## 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 received a report on the stakeholder focus group meeting on the availability of Lumpy Skin Disease (LSD) vaccines authorised to EU standards held on 31 January 2017, and endorsed the executive summary of aims and objectives of the meeting for publication on the EMA website.

## 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 responsibilities from S. Srčič to K. Straus and M. Turk.

### 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 received a verbal report from the chair of CMDv on the meetings held on 19-20 January and 16-17 February 2017, and noted the draft minutes of the February meeting as well as the draft agenda of the meeting held on 16 March 2017.

## 12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee discussed the CVMP operation and procedures: practical guidance document for CVMP members, intended for adoption at a future CVMP meeting.
- The Committee received a status update on the implementation of the Common Repository for Veterinary submissions coordinated by EMA.

- The Committee was informed of the timings for preparing the EMA work plan for 2018 and the need to initiate reflections on the CVMP work plan early enough to ensure inclusion of the relevant activities in the EMA work plan.
- The Committee noted the programme of the EMA Veterinary Medicines Info Day to be held on 16-17 March 2017.

## 13. LEGISLATION

## 14. ANY OTHER BUSINESS

- Upon the completion of the March 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 March 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** | |
| AT | Brigitte Hauser | Full involvement | |
| BE | Bruno Urbain | Full involvement | |
| CY | Alia Michaelidou | 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 | |
| HU | Gábor Kulcsár | Full involvement | |
| IE | J. Gabriel Beechinor | Full involvement | |
| LU | Marc Schmit | 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: | • 3.1 ProZinc (EMEA/V/C/002634/II/0010/G)<br>• 4.3 Enrofloxacin (EMEA/V/A/089) |
| 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 | |
| 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 | |
| DK | Merete Blixenkrone-Møller | Full involvement | |
| ES | Consuelo Rubio Montejano | Involvement in discussions only and cannot act as rapporteur or peer | • 2.2 EMEA/V/C/004344/0000<br>• 3.5 Porcilis ColiClos (EMEA/V/C/002011/II/0007) |

| Country | CVMP Alternate | Outcome restriction following evaluation of e-DoI for the meeting | Topics on current agenda for which restriction applies |
|---|---|---|---|
| | | reviewer for: | • 5.5 Bravecto, Porcilis Pesti<br>• 10.1 one item |
| FR | Sylvie Louet | Full involvement | |
| HR | Ljiljana Markuš-Cizelj | Full involvement | |
| LT | Laimis Jodkonis | Full involvement | |
| NL | Jacqueline Poot | Full involvement | |
| PT | Maria Azevedo Mendes | 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. | | | |
| | Lukas Bruckner - *remotely* | Full involvement | |
| DE | Anke Finnah | Full involvement | |
| DE | Gesine Hahn | Full involvement | |
| DE | Daniela Loos – *remotely* | Full involvement | |
| DK | Christian Friis – *remotely* | Full involvement | |
| DK | John Jensen | Full involvement | |
| ES | Luis Agote Casado – *remotely* | Full involvement | |
| ES | Ricardo Carapeto Garcia – *remotely* | Full involvement | |
| ES | Aranzazu González Canga – *remotely* | Full involvement | |
| ES | Maria Porrero Calonge – *remotely* | Full involvement | |
| FI | Katariina Kivilahti-Mantyla – *remotely* | Full involvement | |
| FI | Kristina Lehmann – *remotely* | Full involvement | |
| FI | Martti Nevalainen – *remotely* | Full involvement | |
| FR | Nathalie Bridoux – *remotely* | Full involvement | |
| IE | Sarah Buckley – *remotely* | Full involvement | |
| IE | Michele Johnson – *remotely* | Full involvement | |
| NL | Anita Bottger – *remotely* | Full involvement | |
| NL | Erlangga Hoogenkamp | Full involvement | |
| UK | John Mitchell | Full involvement | |

| Country | CVMP Expert* | Outcome restriction following evaluation of the e-DoI for the meeting | Topics on current agenda for which restriction applies |
|---|---|---|---|
| UK | Ralph Woodland | Full involvement | |

| CVMP working parties and CMDv | Chair |
|---|---|
| ADVENT | Jean-Claude Rouby |
| AWP | Helen Jukes |
| CMDv | Gavin Hall |
| ERAWP | Jason Weeks |
| EWP-V | Cristina Munoz Madero |
| IWP | Esther Werner |
| PhVWP-V | Lisbet Vesterager Borge - *remotely* |
| QWP | -- |
| 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 |