14 February 2017
EMA/CVMP/126626/2017
Committee for Medicinal Products for Veterinary Use (CVMP)

# Committee for Medicinal Products for Veterinary Use

## Minutes of the 17-19 January 2017 meeting

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

**Note on access to documents**

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

### i. Adoption of the Agenda

The Committee adopted the agenda with no modifications.

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

The attendance list was completed and competing interests were identified for the January 2017 meeting. In accordance with the Agency's policy and procedure on the handling of competing interests, participants in this meeting were asked to declare any interests on the matters for discussion (in particular any changes, omissions or errors to the already declared interests). Discussions, deliberations and voting took place in full respect of the restricted involvement of CVMP members and, where relevant, experts attending the plenary meeting, as announced by the CVMP secretariat at the start of the meeting (see Annex I). All decisions taken at this meeting were made in presence of a quorum of members i.e. 22 or more members were present in the room. It was noted that 17 members were needed for an absolute majority.

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

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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
**Telephone** +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5545
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### iv. Adoption of the minutes of the previous meeting

The minutes of the December 2016 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

- 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 agreed to the request from the applicant for a 5-month extension to the clock-stop for the application for the establishment of MRLs in bovine species for a substance (EMEA/V/MRL/004333/FULL/0001).

## 2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

### 2.1 Opinions

- There were no items for discussion.

### 2.2 Oral explanations and lists of outstanding issues

- There were no items for discussion.

### 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 antiparasitic product for cats (EMEA/V/C/004316/0000). The Committee noted two peer review reports and the comments received from CVMP members.

- The Committee adopted the scientific overview including the list of questions and agreed comments on the draft product information for a new vaccine for chickens (EMEA/V/C/004422/0000). The Committee noted two peer review reports and the comments received from CVMP members.

### 2.4 Re-examination of CVMP opinions

- The Committee discussed the request from the applicant for the re-examination, in accordance with Regulation (EC) No 726/2004, of the CVMP opinion adopted for **RESPIPORC FLUpan H1N1** (EMEA/V/C/003993/0000), a new inactivated viral vaccine with a proposed indication for active immunisation of pigs against swine influenza caused by pandemic subtype H1N1v, and

appointed N. Garcia del Blanco as rapporteur and G. Beechinor as co-rapporteur for the procedure. The Committee agreed to the applicant's request for the involvement of an ad hoc expert group (AHEG). The adoption of the opinion is foreseen for the March 2017 meeting of the Committee.

### 2.5 Other issues

- The Committee agreed to the request from the applicant for a 2-month extension to the clock-stop for a new product for dogs (EMEA/V/C/004375/0000), for disorders of the musculo-skeletal system.
- The Committee endorsed the EPAR module 6 scientific discussion for **Coliprotec F4/F18** (EMEA/V/C/004225/0000) concerning the granting of the initial marketing authorisation.

## 3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

### 3.1 Opinions

- The Committee adopted by consensus (28 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a worksharing type IB variation for **ZULVAC 1+8 Ovis**, **ZULVAC 8 Ovis**, **ZULVAC 1+8 Bovis**, **ZULVAC 1 Ovis**, **ZULVAC 1 Bovis** and **ZULVAC 8 Bovis** (EMEA/V/C/xxxxxx/WS1040), recommending the variation of the marketing authorisations to implement quality changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (28 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a grouped type II variation for **RESPIPORC FLU3** (EMEA/V/C/000153/II/0013/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 (28 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a worksharing type IB variation for **Clomicalm**, **OSURNIA**, **ZOLVIX**, **Econor**, **FORTEKOR PLUS**, **Onsior** and **Prac-tic** (EMEA/V/C/xxxxxx/WS1074), recommending the variation of the marketing authorisations to implement quality changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.

### 3.2 Oral explanations and lists of outstanding issues

- The Committee adopted the list of outstanding issues to be addressed in writing for a type II variation for **NEXGARD SPECTRA** (EMEA/V/C/003842/II/0008), to add new therapeutic indications.
- The Committee adopted the list of outstanding issues to be addressed in writing for a grouped type II variation for **Stronghold** (EMEA/V/C/000050/II/0055/G), concerning quality changes.

### 3.3 Lists of questions

- The Committee adopted the list of questions for a type II variation for **Pexion** (EMEA/V/C/002543/II/0009), concerning changes in the SPC.
- The Committee adopted the list of questions for a worksharing type II variation for **ZULVAC 8 Ovis**, **ZULVAC 1+8 Ovis**, **ZULVAC 1 Bovis**, **ZULVAC SBV**, **ZULVAC 1+8 Bovis**, **ZULVAC 1 Ovis** and **ZULVAC 8 Bovis** (EMEA/V/C/xxxxxx/WS1039), 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

- There were no items for discussion.

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

- The Committee considered four requests from the following marketing authorisation holders for a re-examination of the December 2016 CVMP opinion for **veterinary medicinal products containing zinc oxide to be administered orally to food producing species** (EMEA/V/A/118): from aniMedica GmbH, from Huvepharma N.V., a joint request from DSM Nutritional Products (UK) Ltd. and Provimi Ltd., and a joint request from Andrés Pintaluba S.A., Bio Vet Aps, Calier Portugal S.A., Dunavet-B Zrt., Industrial Veterinaria S.A., Laboratorios Calier S.A., Laboratorios Support Pharma S.L., S.C. Crida Pharm S.R.L., ScanVet Animal Health A/S, Sintofarm S.p.A, Tekro, spol. s r.o., Vepidan Aps, Vetlima S.A., Vetoquinol Biowet Sp. z o. o. and Vetpharma Animal Health, S.L. The Committee appointed E.-M. Vestergaard as rapporteur and C. Munoz Madero as co-rapporteur for the re-examination procedure. The submission of the detailed grounds for the re-examination is foreseen by 6 February 2017. The adoption of the opinion is foreseen for the March 2017 meeting of the Committee.

### 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 recommendations for **Simparica** (EMEA/V/C/003991/REC/008-010).

- The Committee adopted the rapporteur's assessment report on the data submitted concerning a recommendation for **ZOLVIX** (EMEA/V/C/000154/REC/011).

### 5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 09.12.2016 – 19.01.2017:

| Product | Period |
|---|---|
| **Acticam** (EMEA/V/C/000138) | 09/12/2015 – 08/12/2016 |
| **Imrestor** (EMEA/V/C/002763) | 09/12/2015 – 08/12/2016 |
| **Inflacam** (EMEA/V/C/002497) | 09/12/2015 – 08/12/2016 |
| **Panacur AquaSol** (EMEA/V/C/002008) | 09/12/2015 – 08/12/2016 |
| **SevoFlo** (EMEA/V/C/000072) | 11/12/2015 – 10/12/2016 |
| **Cepedex** (EMEA/V/C/004376) | 13/12/2015 – 12/12/2016 |
| **Onsior** (EMEA/V/C/000127) | 16/12/2015 – 15/12/2016 |
| **BTVPUR** (EMEA/V/C/002231) | 17/12/2015 – 16/12/2016 |
| **BTVPUR AlSap 1** (EMEA/V/C/002230) | 17/12/2015 – 16/12/2016 |
| **Prac-tic** (EMEA/V/C/000103) | 18/12/2015 – 17/12/2016 |
| **Bovela** (EMEA/V/C/003703) | 22/12/2015 – 21/12/2016 |
| **Metacam** (EMEA/V/C/000033) | 07/01/2016 – 06/01/2017 |
| **Activyl Tick Plus** (EMEA/V/C/002234) | 09/01/2016 – 08/01/2017 |
| **CORTAVANCE** (EMEA/V/C/000110) | 09/01/2016 – 08/01/2017 |
| **Rheumocam** (EMEA/V/C/000121) | 10/01/2016 – 09/01/2017 |
| **Ypozane** (EMEA/V/C/000112) | 11/01/2016 – 10/01/2017 |
| **Porcilis PCV** (EMEA/V/C/000135) | 12/01/2016 – 11/01/2017 |
| **Gripovac 3** (EMEA/V/C/000157) | 14/01/2016 – 13/01/2017 |
| **RESPIPORC FLU3** (EMEA/V/C/000153) | 14/01/2016 – 13/01/2017 |
| **MELOXIDYL** (EMEA/V/C/000115) | 15/01/2016 – 14/01/2017 |
| **NEXGARD SPECTRA** (EMEA/V/C/003842) | 15/01/2016 – 14/01/2017 |
| **ZULVAC 8 Bovis** (EMEA/V/C/000145) | 15/01/2016 – 14/01/2017 |
| **ZULVAC 8 Ovis** (EMEA/V/C/000147) | 15/01/2016 – 14/01/2017 |

### 5.4 Renewals

- The Committee adopted by consensus (29 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for the renewal of the marketing authorisation for **Nobivac L4** (EMEA/V/C/002010/R/0007), and recommended that

a further renewal would be required. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.

- 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 **Porcilis ColiClos** (EMEA/V/C/002011/R/0006), and recommended that the authorisation should now be indefinite. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.

### 5.5 Pharmacovigilance – PSURs and SARs

- The Committee adopted the CVMP assessment report of the PSUR for the period 01.03.2016 – 31.08.2016 for **Bravecto** (EMEA/V/C/002526) with a recommendation to amend the SPC to include lethargy and a request to the MAH to provide a targeted PSUR. This targeted PSUR should cover serious adverse events since the date of authorisation (i.e. between 11 February 2014 and 31 December 2016), involving death and those in which neurological disorders, skin and appendages disorders, hypersensitivity/immune mediated reactions and hepatopathy were assessed causality A, B or O/O1.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.01.2016 – 30.06.2016 for **Broadline** (EMEA/V/C/002700) with a recommendation to amend the SPC, including update information on adverse reactions already listed.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.02.2016 – 31.07.2016 for **Osurnia** (EMEA/V/C/003753) with a recommendation to amend the SPC, including the addition of deafness or impaired hearing as adverse reactions.
- 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 |
|---|---|
| **Activyl** (EMEA/V/C/000163) | 01.09.2015 – 31.08.2016 |
| **Bovilis BTV8** (EMEA/V/C/000148) | 01.10.2015 – 30.10.2016 |
| **Clomicalm** (EMEA/V/C/000039) | 01.08.2013 – 31.07.2016 |
| **Neocolipor** (EMEA/V/C/000035) | 01.09.2013 – 31.08.2016 |
| **Nobilis IB4-91** (EMEA/V/C/000036) | 01.04.2016 – 30.09.2016 |
| **Nobilis IB Primo QX** (EMEA/V/C/002802) | 01.04.2016 – 30.09.2016 |
| **Novaquin** (EMEA/V/C/003866) | 09.03.2016 – 08.09.2016 |
| **Pexion** (EMEA/V/C/002543) | 01.09.2015 – 31.08.2016 |
| **Semintra** (EMEA/V/C/002436) | 01.09.2015 – 31.08.2016 |
| **STARTVAC** (EMEA/V/C/002436) | 01.09.2013 - 31.08.2016 |
| **Vectormune ND** (EMEA/V/C/003829) | 01.04.2016 – 30.09.2016 |
| **Versican Plus DHPPi** (EMEA/V/C/003679) | 01.02.2016 – 31.07.2016 |
| **Versican Plus DHPPi L4** (EMEA/V/C/003678) | 01.12.2015 – 31.05.2016 |

| | |
|---|---|
| **Versican Plus Pi L4** (EMEA/V/C/003683) | 01.02.2016 – 31.07.2016 |

- 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 draft VICH guideline on general principles for detection of extraneous viruses in veterinary vaccines and defining the testing of the seeds and materials of animal origin, and the draft VICH guideline on a list of extraneous viruses that need to be covered to be circulated to the VICH Biologicals Quality Monitoring EWG for a first round of comments.
- The Committee endorsed the SWP-V position on the list of the VICH safety guidelines in need of revision.
- The Committee endorsed the draft EU response to the EWG comments relating to ongoing discussions on the possibility of updating VICH GL22 on reproduction testing to allow use of the extended one generation reproductive toxicity study (EOGRTS).
- The Committee noted the draft agenda of the 34th VICH Steering Committee meeting and the draft agenda of the Outreach Forum meeting, to be held on 27 February to 2 March 2017 in Buenos Aires, Argentina. The minutes of the 33rd VICH Steering Committee meeting held on 21-24 June 2016 were also noted.
- The Committee endorsed the draft EU comments on the Electronic Standards Implementation EWG analysis of the industry document 'Impact of disharmonisation on the day-to-day operations in pharmacovigilance'.

### 6.2 Codex Alimentarius

- The Committee received feedback on the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) meeting held on 17-21 October 2016 in Houston, USA, and noted the report of the meeting.

### 6.3 Other EU bodies and international organisations

- The Committee received a verbal report on the 2nd EMA/JECFA liaison meeting held on 26 September 2016.
- The Committee agreed for E. Lander Persson to represent CVMP at the EFSA workshop on benchmark dose to be held on 1-2 March 2017 in Brussels, and noted the draft programme.
- The Committee noted the EFSA 2nd report on 'Chemicals in food 2016': Overview of selected data collection' and the detailed report on residues of veterinary medicines.

***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 17 January 2017, and noted the agenda of the meeting.
- The Committee appointed J. Gabriel Beechinor as a new member of the SAWP-V.

### 7.2 Quality Working Party (QWP)

- The Committee adopted the concept paper on the need for revision of the note for guidance on the quality of water for pharmaceutical use (EMA/CHMP/CVMP/QWP/428135/2016) for a 3-month period of public consultation.
- The Committee adopted a correction to the reflection paper on the requirements for selection and justification of starting materials for the manufacture of chemical active substances (EMA/CHMP/CVMP/QWP/826771/2016).

### 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 23 November 2016, and on the training of assessors held on 24 November 2016, and noted the agenda of the SWP-V meeting.
- The Committee agreed for SWP-V to proceed with the finalisation of the guideline on user safety of topically administered products, following the comments received during the public consultation.

### 7.4 Environmental Risk Assessment Working Party (ERAWP)

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

- The Committee adopted the guideline on the conduct of efficacy studies for intramammary product for use in cattle (EMA/CVMP/344/1999-Rev2) and the overview of comments received during the second public consultation (EMA/CVMP/EWP/444475/2016).
- The Committee elected Cristina Munoz Madero as chair of the EWP-V for a 3-year term.

### 7.6 Antimicrobials Working Party (AWP)

- The Committee received a verbal report from the chair of the AWP on the meeting held on 14-15 December 2016, and noted the agenda and draft minutes of the meeting.

### 7.7 Immunologicals Working Party (IWP)

### 7.8 Pharmacovigilance Working Party (PhVWP-V)

- The Committee was informed of the upcoming election of the vice-chair of the PhVWP-V for a 3-year term at the February 2017 CVMP meeting, and noted the call for nominations.

### 7.9 Novel therapy groups and related issues

- The Committee confirmed the appointment of the core group members of the Ad Hoc Group on Novel Veterinary Therapies (ADVENT), following the ADVENT mandate's renewal for the period 2017-2019.
- The Committee was informed of the upcoming election of the chair of the ADVENT core group for a 3-year term at the February 2017 CVMP meeting, and noted the call for expressions of interest.

### 7.10 Joint CVMP/CHMP WG on the application of the 3Rs (J3RsWG)

- There were no items for discussion.

### 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 6 December 2016;
- Draft agenda for the 82nd Joint CHMP/CVMP QWP meeting to be held on 31 January – 2 February 2017;
- Draft minutes of the CVMP IWP meeting held on 19–20 October 2016;
- Draft agenda of the CVMP IWP meeting to be held on 1–2 February 2017;
- Draft agenda of the PhVWP-V meeting to be held on 24-25 January 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.*

- There were no items for discussion.

### 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

*Information relating to certain topics discussed under section 8.3 at this meeting cannot be released at the present time as it is deemed to be confidential.*

### 8.4 Pharmacovigilance

- There were no items for discussion.

### 8.5 Other issues

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

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

- Joint scientific opinion (EMA/EFSA) of the RONAFA Advisory Group on measures to reduce the need to use antimicrobial agents in animal husbandry in the EU (EMA/570771/2015), Annex (EMA/359/2017);
- Draft minutes of 2nd Joint Inter-Agency Antimicrobial Consumption and Resistance Analysis (JIACRA) meetings held on 27 October 2016, on 5 December 2016 and on 12 December 2016;
- JAC Publication Public health risk of antimicrobial resistance transfer from companion animals (based on the CVMP/AWP reflection paper on the subject) http://jac.oxfordjournals.org/content/early/2016/12/02/jac.dkw481.abstract;
- OIE first Annual report (2016) on the use of antimicrobial agents in animals http://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/AMR/Survey_on_monitoring_antimicrobial_agents_Dec2016.pdf.

## 9. AVAILABILITY OF MEDICINES AND MUMS CLASSIFICATION

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

- The Committee endorsed the draft minutes of the CVMP ad hoc group on veterinary vaccine availability (CADVVA) meeting held on 17 November 2016.
- The Committee was informed of the network action plan on the availability of veterinary vaccines – meeting with industry stakeholders held on 8 December 2016, and noted the agenda and draft minutes of the meeting.
- The Committee agreed to hold a breakout session between CVMP and FishMedPlus Coalition in the margins of the April CVMP meeting.
- The Committee was informed of the draft agenda of the stakeholder focus group meeting on the availability of Lumpy Skin Disease (LSD) vaccines authorised to EU standards to be held on 31 January 2017.

## 10. PROCEDURAL AND REGULATORY MATTERS

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

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

### 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 10-11 November and 8-9 December 2016, and noted the draft minutes of the meeting held on 8-9 December 2016 as well as the draft agenda of the meeting held on 19-20 January 2017.

## 12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee received a verbal report from the breakout session on the appointment of rapporteurs for CVMP procedures, and discussed the next steps.
- The Committee received a verbal report from the chair of the Strategic Planning Group on the meeting held on 18 January 2017, and noted the agenda and the minutes of the meeting held on 5 October 2016.
- The Committee was informed of the request from Swissmedic for regular observer participation in CVMP meetings.

## 13. LEGISLATION

- The Committee noted the Commission Implementing Regulation (EU) 2017/12 of 6 January 2017 regarding the form and content of the applications and requests for the establishment of maximum residue limits in accordance with Regulation (EC) No 470/2009 (link).

## 14. ANY OTHER BUSINESS

- Upon the completion of the January 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 January 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 | Barbara Zemann | Involvement in discussions only and cannot act as rapporteur or peer reviewer for: | • 3.3 Pexion (EMEA/V/C/002543/II/0009)<br>• 5.5 Pexion, Semintra<br>• 10.2 one item |
| BE | Bruno Urbain | Full involvement | |
| BG | Emil Kozhuharov | Full involvement | |
| CZ | Jiří Bureš | Full involvement | |
| DE | Cornelia Ibrahim | Full involvement | |
| DK | Ellen-Margrethe Vestergaard | Full involvement | |
| EE | Toomas Tiirats | Full involvement | |
| EL | Ioannis Malemis | Full involvement | |
| ES | Cristina Muñoz Madero | Full involvement | |
| FR | Jean-Claude Rouby | Full involvement | |
| HR | Frane Božić | Full involvement | |
| 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 | Full involvement | |
| PT | João Pedro Duarte da Silva | Full involvement | |
| RO | Lollita Taban | Full involvement | |
| SE | Eva Lander Persson | Full involvement | |
| SK | Judita Hederová | Full involvement | |
| UK | Helen Jukes | Full involvement | |
| Co-opted | Keith Baptiste | Full involvement | |
| Co-opted | Rory Breathnach | Full involvement | |
| Co-opted | G. Johan Schefferlie | Full involvement | |
| Co-opted | Wilhelm Schlumbohm | Full involvement | |
| Co-opted | Jason Weeks | Full involvement | |
| 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 | |
| DE | Esther Werner | Full involvement | |

| Country | CVMP Alternate | Outcome restriction following evaluation of e-DoI for the meeting | Topics on current agenda for which restriction applies |
|---|---|---|---|
| ES | Consuelo Rubio Montejano | Full involvement | • 2.3 EMEA/V/C/004422/0000<br>• 5.4 Nobivac L4 (EMEA/V/C/002010/R/0007)<br>• 5.4 Porcilis ColiClos (EMEA/V/C/002011/R/0006)<br>• 5.5 Activyl, Bovilis BTV8, Bravecto, Nobilis IB Primo QX, Nobilis IB 4-91 |
| FI | Kristina Lehmann | Full involvement | |
| FR | Sylvie Louet | Full involvement | |
| LT | Laimis Jodkonis | Full involvement | |
| SE | Frida Hasslung Wikström | Full involvement | |
| UK | Noemi Garcia del Blanco | 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. | | | |
| DK | Merete Blixenkrone-Moller - *remotely* | Full involvement | |
| IE | Michele Johnson - *remotely* | Full involvement | |
| NL | Jacqueline Poot | Full involvement | |
| NO | Tora Gauslaa - *remotely* | Full involvement | |
| UK | Anna-Maria Brady | Full involvement | |
| UK | Steve Spencer - *remotely* | Full involvement | |
| UK | Yasu Takeuchi | Full involvement | |
| UK | Brian Willett - *remotely* | Full involvement | |

| CVMP working parties and CMDv | Chair |
|---|---|
| ADVENT | *vacant* |
| AWP | Helen Jukes |
| CMDv | Gavin Hall |
| ERAWP | Jason Weeks |
| EWP-V | -- |
| IWP | Esther Werner |
| PhVWP-V | -- |
| QWP | Mary O'Grady *(Vet vice chair - remotely)* |
| SAWP-V | Rory Breathnach |
| SWP-V | Eva Lander Persson |

| Observer from the European Commission | |
|---|---|
| Present | |

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