14 March 2017
EMA/CVMP/179328/2017
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 14-16 February 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 two new items under points 2.5 and 6.1.

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

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

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

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

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

iv. Adoption of the minutes of the previous meeting

The minutes of the January 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

- The Committee discussed the rapporteurs' joint assessment of the responses to the list of questions, as well as the comments from the EU Reference Laboratory concerning the analytical method for the establishment of MRLs in Salmonidae for a substance (EMEA/V/MRL/004481/FULL/0001), and adopted a list of outstanding issues that should be addressed in writing. The adoption of the opinion is foreseen for the May 2017 meeting of the Committee.

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

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

- 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 **Credelio** (EMEA/V/C/004247/0000), recommending the granting of a marketing authorisation. Credelio is a new antiparasitic product in the form of chewable tablets, indicated for the treatment of flea and tick infestations in dogs. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication.
- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Zulvac BTV Ovis** (EMEA/V/C/004185/0000), recommending the granting of a marketing authorisation. Zulvac BTV Ovis is a new multistrain vaccine containing BTV serotypes 1, 4 or 8, for the active immunisation of sheep against BTV serotypes 1, 4, 8. 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 (29 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **CYTOPOINT** (EMEA/V/C/003939/0000), recommending the granting of a marketing authorisation. CYTOPOINT is a new monoclonal antibody product for the treatment of clinical manifestations

of atopic dermatitis 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 agreed that the oral explanation from the applicant, scheduled for the February CVMP and concerning an application for a new product for cattle (EMEA/V/C/004099/0000), was not necessary. The Committee also discussed the rapporteurs' assessment of the responses to the list of outstanding issues and the draft product information. The adoption of the opinion is foreseen for the March 2017 CVMP meeting.
- The Committee discussed the draft CVMP assessment report and agreed comments on the draft product information for an extension application for **Zactran** (EMEA/V/C/000129/X/0034), to add a new species. The Committee noted the comments received from CVMP members. The adoption of the opinion is foreseen for the March 2017 CVMP meeting.
- 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 antiemetic product for cats and dogs (EMEA/V/C/004331/0000). The Committee noted a peer review report and the comments received from CVMP members.

2.3 Lists of questions

- The Committee adopted the scientific overview, including the list of questions, and agreed comments on the draft product information for a new product for dogs (EMEA/V/C/004417/0000). 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 product for bees (EMEA/V/C/004296/0000). 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 pigs (EMEA/V/C/004645/0000). The Committee noted a peer review report and the comments received from CVMP members.

2.4 Re-examination of CVMP opinions

- The Committee discussed the rapporteur's assessment report, and adopted the list of questions to the ad hoc expert group (AHEG) and endorsed the list of AHEG members for the re-examination of the negative CVMP opinion adopted for **RESPIPORC FLUpan H1N1** (EMEA/V/C/003993/0000), a new inactivated viral vaccine proposed for the active immunisation of pigs against swine influenza caused by pandemic subtype H1N1v.

2.5 Other issues

- The Committee agreed to the request from the applicant for a 7-month extension to the clock-stop for a new product for horses (EMEA/V/C/004265/0000).
- The Committee endorsed the EPAR module 6 scientific discussion for **Equioxx** (EMEA/V/C/000142/X/0015) concerning the extension of the marketing authorisation.

- The Committee endorsed the EPAR module 6 scientific discussion for **Stronghold Plus** (EMEA/V/C/004194/0000) concerning the granting of the initial marketing authorisation.

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- 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 a grouped type II variation for **BTVPUR** (EMEA/V/C/002231/II/0008/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

- The Committee adopted the list of outstanding issues to be addressed in writing for a type II variation for **Activyl Tick Plus** (EMEA/V/C/002234/II/0008), to add a new therapeutic indication.

3.3 Lists of questions

- The Committee adopted the list of questions for a type II variation for **Activyl** (EMEA/V/C/000163/II/0011), to change conditions regarding supply and use.
- The Committee adopted the list of questions for a worksharing type II variation for **Nobivac Bb** (EMEA/V/C/000068/WS1053), concerning quality changes.
- The Committee adopted the list of questions for a type II variation for **Porcilis ColiClos** (EMEA/V/C/002011/II/0007), 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 discussed the rapporteur's revised assessment report including the co-rapporteur's critique for the referral procedure for **veterinary medicinal products containing moxidectin to be administered to cattle, sheep and horses** (EMEA/V/A/116). The Committee agreed to the requests received from Zoetis and Norbrook Laboratories Limited to provide oral explanations scheduled for the April 2017 CVMP meeting. The Committee adopted separate lists of outstanding issues for Zoetis to address in writing and at an oral explanation and for Norbrook Laboratories Limited to address at an oral explanation, and the revised timetable for the procedure. The adoption of the CVMP opinion and assessment report is foreseen for the May 2017 meeting of the Committee.

- The Committee heard two oral explanations from Huvepharma N.V. and from DSM Nutritional Products (UK) Ltd. and Provimi Ltd., and discussed the rapporteurs' joint assessment report for the re-examination of the CVMP opinion on the referral procedure for **veterinary medicinal products containing zinc oxide to be administered orally to food producing species** (EMEA/V/A/118). The adoption of the final CVMP opinion and assessment report is foreseen for the March 2017 meeting of the Committee.

- The Committee discussed the rapporteur's revised assessment report including the co-rapporteur's critique 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), and agreed that no outstanding issues remained. The adoption of the CVMP opinion and assessment report is foreseen for the March 2017 meeting of the Committee.

- The Committee discussed the rapporteur's revised assessment report including the co-rapporteur's critique 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), and agreed that no outstanding issues remained. The Committee noted the comments made by Vetoquinol. The adoption of the CVMP opinion and CVMP assessment report is foreseen for the March 2017 meeting of the Committee.

- The Committee discussed the rapporteur's assessment report including the co-rapporteur's critique for the referral procedure for **Zanil and associated names, and generic products thereof** (EMEA/V/A/124). The Committee adopted the list of outstanding issues for the applicants and the marketing authorisation holders to address in writing, and the revised timetable for the procedure. The Committee noted three peer review reports and the comments made by CVMP members.

4.4 Article 78 of Directive 2001/82/EC

- There were no items for discussion.

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

- There were no items for discussion.

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

- There were no items for discussion.

4.7 Other issues

- There were no items for discussion.

5. POST-AUTHORISATION ISSUES FOR COMMUNITY MARKETING AUTHORISATIONS (EXCLUDING VARIATIONS)

5.1 General issues

- There were no items for discussion.

5.2 Post-authorisation measures and annual reassessments

- The Committee adopted the rapporteur's assessment report on the data submitted concerning a recommendation for **Suvaxyn CSF Marker** (EMEA/V/C/002757/REC/007).

- The Committee adopted the rapporteur's assessment report on the data submitted concerning a recommendation for **Letifend** (EMEA/V/C/003865/REC/007).
- The Committee adopted the rapporteur's assessment report on the data submitted concerning two recommendations for **Circovac** (EMEA/V/C/000114/REC/002.1 & 005.1).
- The Committee adopted the rapporteur's assessment report on the data submitted concerning a recommendation for **NexGard** (EMEA/V/C/002729/REC/014).
- The Committee adopted the rapporteur's assessment report on the data submitted concerning a recommendation for **FORTEKOR PLUS** (EMEA/V/C/002804/REC/014).
- The Committee adopted the rapporteur's assessment report on the data submitted concerning a condition for **Zulvac SBV** (EMEA/V/C/002781/ANX/004.2).
- The Committee adopted the rapporteur's assessment report on the data submitted concerning a recommendation for **ProZinc** (EMEA/V/C/002634/REC/010).

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 20.01.2017 – 16.02.2017:

Product	Period
Bravecto (EMEA/V/C/002526)	11/02/2016 – 10/02/2017
Comfortis (EMEA/V/C/002233)	11/02/2016 – 10/02/2017
Fevaxyn Pentofel (EMEA/V/C/000030)	05/02/2016 – 04/02/2017
Hiprabovis IBR Marker Live (EMEA/V/C/000158)	27/01/2016 – 26/01/2017
Ingelvac CircoFLEX (EMEA/V/C/000126)	13/02/2016 – 12/02/2017
Kexxtone (EMEA/V/C/002235)	28/01/2016 – 27/01/2017
Loxicom (EMEA/V/C/000141)	10/02/2016 – 09/02/2017
NexGard (EMEA/V/C/002729)	11/02/2016 – 10/02/2017
Nobilis OR inac (EMEA/V/C/000062)	24/01/2016 – 23/01/2017
PIRSUE (EMEA/V/C/000054)	29/01/2016 – 28/01/2017
Semintra (EMEA/V/C/002436)	13/02/2016 – 12/02/2017
STARTVAC (EMEA/V/C/000130)	11/02/2016 – 10/02/2017
Suvaxyn CSF Marker (EMEA/V/C/002757)	10/02/2016 – 09/02/2017
ZULVAC SBV (EMEA/V/C/002781)	06/02/2016 – 05/02/2017

5.4 Renewals

- The Committee adopted a list of outstanding issues for the renewal of the marketing authorisation for **Poulvac E. coli** (EMEA/V/C/002007/R/0012).

5.5 Pharmacovigilance – PSURs and SARs

- The Committee adopted the CVMP assessment report of the PSUR for the period 01.02.2016 – 31.07.2016 for **Canigen L4** (EMEA/V/C/004079) **and Nobivac L4** (EMEA/V/C/002010) with a

recommendation to amend the product information concerning the administration of the product.

- 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
Bovalto Ibraxion (EMEA/V/C/000051)	01.10.2013 – 30.09.2016
Coliprotec F4 (EMEA/V/C/003797)	01.04.2016 – 30.09.2016
Econor (EMEA/V/C/000042)	01.10.2015 – 30.09.2016
Evalon (EMEA/V/C/004013)	18.04.2016 – 31.10.2016
FORTEKOR PLUS (EMEA/V/C/002804)	01.04.2016 – 30.09.2016
Fungitraxx (EMEA/V/C/002722)	01.04.2016 – 30.09.2016
Imrestor (EMEA/V/C/002763)	01.04.2016 – 30.09.2016
Incurin (EMEA/V/C/000047)	01.10.2013 – 30.09.2016
Previcox (EMEA/V/C/000082)	01.10.2014 – 30.09.2016
ProteqFlu (EMEA/V/C/000073)	01.04.2016 – 30.09.2016
ProteqFlu-Te (EMEA/V/C/000074)	01.04.2016 – 30.09.2016
Vaxxitek HVT-IBD (EMEA/V/C/000065)	01.09.2013 – 31.08.2016
Zulvac 1+8 Bovis (EMEA/V/C/002473)	01.10.2015 – 30.09.2016

- 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 adopted the draft VICH guideline 56 on studies to evaluate the metabolism and residue kinetics of veterinary drugs in food-producing species: study design recommendations for residue studies in honey for establishing MRLs and withdrawal period, for release for public consultation in the EU at step 4 of the VICH process.
- The Committee endorsed the draft VICH guideline on the harmonisation of criteria to waive laboratory animal batch safety testing for vaccines for veterinary use, for circulation to the VICH EWG at step 2 of the VICH process.
- The Committee endorsed the revised draft VICH guideline 50 on harmonisation of criteria to waive target animal batch safety testing for inactivated vaccines for veterinary use, for circulation to the EWG for consideration at step 5 of the VICH process.

- The Committee endorsed the revised draft VICH guideline 55 on harmonisation of criteria to waive target animal batch safety testing for live vaccines for veterinary use, for circulation to the EWG for consideration at step 5 of the VICH process.
- The Committee noted the meeting documents for the 34th VICH Steering Committee meeting and the Outreach Forum meeting to be held from 27 February 2017 to 2 March 2017 in Buenos Aires, Argentina (draft Steering Committee agenda, draft Outreach Forum agenda, minutes of the 33rd VICH Steering Committee held on 21-24 June 2016, progress report from Quality EWG, progress report from BQM EWG, progress report from MRK EWG, progress report Anthelmintics GLs revision EWG, anthelmintics GLs revision revised plan, progress report on general combination products TF).

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 chair of the SAWP-V on the meeting held on 14 February 2017, and noted the agenda of the meeting.
- The Committee discussed the expertise needed in the SAWP-V, and agreed to launch a call for nomination for a new member.

7.2 Quality Working Party (QWP)

- The Committee deferred the verbal report from the veterinary vice-chair of the QWP on the meeting held on 31 January – 2 February 2017 to the March CVMP meeting.

7.3 Safety Working Party (SWP-V)

- The Committee deferred the verbal report from the chair of the SWP-V on the meeting held on 2-3 February 2017 to the March CVMP meeting.
- The Committee adopted the draft guideline on assessment and control of DNA reactive (mutagenic) impurities in veterinary medicinal products (EMA/CVMP/SWP/377245/2016) for a 6-month period of public consultation.
- The Committee adopted the draft guideline on assessing the toxicological risk to human health and groundwater communities from veterinary pharmaceuticals in groundwater (EMA/CVMP/103555/2015) for a 6-month period of public consultation – *see also 7.4*.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- The Committee deferred the verbal report from the chair of the ERAWP on the meeting held on 31 January – 1 February 2017 to the March CVMP meeting.
- The Committee adopted the draft guideline on assessing the toxicological risk to human health and groundwater communities from veterinary pharmaceuticals in groundwater (EMA/CVMP/103555/2015) for a 6-month period of public consultation – *see also 7.3*.
- The Committee discussed the proposal for a workshop to be organised on the higher tier testing of veterinary medicinal products to dung fauna, scheduled for 21 June 2017.

7.5 Efficacy Working Party (EWP-V)

- There were no items for discussion.

7.6 Antimicrobials Working Party (AWP)

7.7 Immunologicals Working Party (IWP)

- The Committee endorsed the EU Network Training Centre (EU NTC) veterinary immunologicals curriculum.

7.8 Pharmacovigilance Working Party (PhVWP-V)

- The Committee deferred the verbal report from the chair of the PhVWP-V on the meeting held on 24-25 January 2017 to the March CVMP meeting.
- The Committee received a report from the focus group on promotion of pharmacovigilance for food producing animals held on 23 November 2016, and noted the agenda of the meeting.
- The Committee adopted the Veterinary Pharmacovigilance Public Bulletin 2016 (EMA/568976/2016).
- The Committee adopted the draft revised recommendation for the basic surveillance of EVVet data for centrally authorised products (EMA/CVMP/PhVWP/171122/2016-Rev.1) for a 6-month period of public consultation.
- The Committee elected Elisabeth Begon as vice-chair of the PhVWP-V for a 3-year term.

7.9 Novel therapy groups and related issues

- The Committee re-elected Jean-Claude Rouby as chair of ADVENT for a further 3-year term.

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

- The Committee adopted the overview of comments received (EMA/CHMP/CVMP/JEG-3Rs/25975/2015) on the guideline on regulatory acceptance of 3R (replacement, reduction, refinement) testing approaches (EMA/CHMP/CVMP/JEG-3Rs/450091/2012).

7.11 Other working party and scientific group issues

- The Committee noted the CVMP working parties' highlights and achievements in 2016.

The following documents were circulated for information:

- Minutes of the SAWP-V meeting held on 17 January 2017;
- Draft agenda of the CVMP EWP meeting to be held on 21-22 February 2017;
- Final agenda of the IWP meeting;

- Final minutes of the IWP meeting held on 19–20 October 2016;
- Draft agenda of the IWP Interested Parties meeting held on 2 February 2017;
- Final agenda of the Stakeholder focus group meeting on availability of Lumpy Skin Disease (LSD) vaccines authorised to EU standards;
- Draft agenda of the ADVENT meeting to be held on 16 February 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

- There were no items for discussion.

8.3 Antimicrobial resistance

- The Committee was informed of the publication of the EFSA report on risk for the development of antimicrobial resistance due to feeding of calves with milk containing residues of antibiotics (link).
- The Committee received a verbal report on the first meeting on the pilot project on dose optimisation in the context of SPC harmonisation of established veterinary antibiotics, held on 20 January 2017.

8.4 Pharmacovigilance

- There were no items for discussion.

8.5 Other issues

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

- The Committee adopted the CVMP risk management strategy on the potential presence of replication competent endogenous retrovirus RD114 in feline and canine starting materials and vaccines (EMA/CVMP/IWP/592652/2014). The Committee reflected on the impact of the risk management strategy and agreed that the strategy should be implemented with full consideration given to minimising the impact of the measures taken on availability of vaccines in dogs and cats. They also considered that this was appropriate in view of the fact that the benefits of vaccination continue to outweigh any theoretical risk and that any changes proposed are intended to ensure that vaccines on the European market comply with current quality standards. The Committee endorsed the key messages and endorsed the communication to stakeholders.

The following document was circulated for information:

- Joint EMA/EFSA scientific opinion of the RONAFA Advisory Group on measures to reduce the need to use antimicrobial agents in animal husbandry in the EU, Annex. Press release on 24 January 2017.

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 reviewer responsibilities from B. Zemann to B. Hauser and P. Falb, with effect from 1 March 2017.
- The Committee agreed to the transfer of co-rapporteurship for Fungitraxx from B. Kolar to K. Straus.

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 was informed of the draft minutes of the meeting held on 19-20 January 2017 as well as the draft agenda of the meeting held on 16-17 February 2017.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee adopted a new guidance document for applicants on oral explanations (EMA/CVMP/519444/2016).
- The Committee deferred the update on the EMA Veterinary Medicines Portfolio Reviews - Horizon scanning 2015-2016 for the March CVMP meeting.
- The Committee noted the EMA veterinary medicines Info Day to be held on 16-17 March 2017, and noted the draft programme.
- The Committee noted the CVMP meeting dates for 2019-2021.

13. LEGISLATION

- The Committee discussed the draft CVMP recommendations for methodological principles for the risk assessment and risk management recommendations relating to MRL evaluations.

14. ANY OTHER BUSINESS

- Upon the completion of the February 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 February 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:	• 2.3 EMEA/V/C/004645/0000 • 5.2 ProZinc (EMEA/V/C/002634/REC/010) • 9. one item • 10.2 one item
BE	Bruno Urbain	Full involvement	
BG	Emil Kozhuharov	Full involvement	
CY	Alia Michaelidou	Full involvement	
CZ	Jiří Bureš	Full involvement	
DE	Cornelia Ibrahim	Full involvement	
DK	Ellen-Margrethe Vestergaard	Full involvement	
EE	Toomas Tiirats	Full involvement	
ES	Cristina Muñoz Madero	Full involvement	
FR	Jean-Claude Rouby	Full involvement	
HR	Frane Božić	Full involvement	
IE	J. Gabriel Beechinor	Full involvement	
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:	• 1.2 EMEA/V/MRL/004481/FULL/0001 • 3.2 Activyl Tick Plus (EMEA/V/C/002234/II/0008)
PT	João Pedro Duarte da Silva	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	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
DE	Esther Werner	Full involvement	
EL	Angeliki Tsigouri	Full involvement	
ES	Consuelo Rubio Montejano	Involvement in discussions only and cannot act as rapporteur or peer reviewer for:	• 3.2 Activyl Tick Plus (EMEA/V/C/002234/II/0008) • 3.3 Activyl (EMEA/V/C/000163/II/0011) • 3.3 Porcilis ColiClos (EMEA/V/C/002011/II/0007) • 4.3 Zanil (EMEA/V/A/124) • 5.5 PSURs for Canigen L4 & Nobivac L4, Bravecto, Incurin • 7.1 one item
FR	Sylvie Louet	Full involvement	
HU	Tibor Soós	Full involvement	
LT	Laimis Jodkonis	Full involvement	
RO	Simona Sturzu	Full involvement	
SE	Frida Hasslung Wikström	Full involvement	
SI	Katarina Straus	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.			
DE	Ina Ebert - *remotely*	Full involvement	
DE	Gesine Hahn	Full involvement	
DE	Silke Hickmann – *remotely*	Full involvement	
DE	Wolfgang Koch – *remotely*	Full involvement	
DE	Nikola Lange – *remotely*	Full involvement	
DE	Nadine Matzmohr	Full involvement	
DE	Stefan Scheid – *remotely*	Full involvement	
DE	Susanne Schmitz	Full involvement	
DE	Jens Schönfeld – *remotely*	Full involvement	
DE	Werner Terhalle – *remotely*	Full involvement	
DK	Merete Blixenkrone-Moller – *remotely*	Full involvement	
DK	Christian Friis	Full involvement	
DK	John Jensen	Full involvement	
ES	Ricardo Carapeto Garcia	Full involvement	
ES	Mercedes Conradi Moner	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
	– *remotely*		
ES	Miguel Escribano – *remotely*	Full involvement	
FI	Katariina Kivilahti Mantyla – *remotely*	Full involvement	
FI	Martti Nevalainen – *remotely*	Full involvement	
FR	Anne Chevance - *remotely*	Full involvement	
FR	Jean-Christophe Faucon – *remotely*	Full involvement	
FR	Martine Redureau	Full involvement	
HR	Ljiljana Markus-Cizelj - *remotely*	Full involvement	
IE	Sarah Buckley – *remotely*	Full involvement	
IE	Michele Johnson – *remotely*	Full involvement	
IT	Paolo Pasquali – *remotely*	Full involvement	
PL	Anita Piwowarczyk	Full involvement	
SI	Stanko Srcic – *remotely*	Full involvement	
UK	Anna-Maria Brady – *remotely*	Full involvement	
UK	Rory Cooney – *remotely*	Full involvement	
UK	Rutendo Manyarara – *remotely*	Full involvement	
UK	Javier Pozo	Full involvement	
UK	Jean-Paul Schmidt	Full involvement	
UK	Steve Spencer – *remotely*	Full involvement	
UK	Ken Stapleton – *remotely*	Full involvement	
UK	Ralph Woodland	Full involvement	

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