10 May 2017
EMA/CVMP/301142/2017
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 10-12 April 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 April 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.

iv. Adoption of the minutes of the previous meeting

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

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

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

1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

- The Committee adopted by consensus (28 members present of those eligible to vote) the CVMP opinion including the EPMAR and the CVMP assessment report recommending the inclusion of **alarelin** (EMEA/V/MRL/004706/FULL/0001) in table 1 of the Annex to Regulation (EU) No 37/2010 with a 'No MRL required' classification for rabbits. Furthermore, and with reference to Article 5 of Regulation (EC) No 479/2009, the Committee agreed to extrapolate the recommendation for rabbits to all food producing species. The Committee noted two peer review reports, the comments received from CVMP members and the summary of opinion for publication.

1.2 Oral explanations and lists of outstanding issues

- The Committee discussed the draft CVMP EPMAR for the establishment of MRLs in porcine species for a substance (EMEA/V/MRL/004479/FULL/0001). 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

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

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

- 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 generic product **Prevomax** (EMEA/V/C/004331/0000), recommending the granting of a marketing authorisation. The product is a generic antiemetic product for dogs and cats, for the treatment and prevention of nausea induced by chemotherapy. The Committee noted the summary of opinion for publication.

2.2 Oral explanations and lists of outstanding issues

- The Committee adopted the updated scientific overview, including the list of outstanding issues, and agreed comments on the draft product information for a marketing authorisation application for a new vaccine for pigs (EMEA/V/C/004364/0000). The Committee agreed that an oral explanation would not be requested. The Committee noted two peer review reports and the comments received from CVMP members.

- The Committee adopted the updated scientific overview, including the list of outstanding issues, and agreed comments on the draft product information for a marketing authorisation

application for a new vaccine for pigs (EMEA/V/C/004276/0000). The Committee agreed that an oral explanation would not be requested. The Committee noted 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 antiparasitic product for cats (EMEA/V/C/004440/0000). The Committee noted two peer review reports and the comments received from CVMP members.

2.4 Re-examination of CVMP opinions

- There were no items for discussion.

2.5 Other issues

- The Committee was informed of the formal notification from Elanco Europe Ltd of their decision to withdraw the application for **Cheristin**, a new antiparasitic product for cats (EMEA/V/C/004316/0000). More information about this application and the current state of the scientific assessment at the time of the withdrawal will be made available in a public assessment report.
- The Committee endorsed the EPAR module 6 scientific discussion for **Credelio** (EMEA/V/C/004247/0000) concerning the granting of the initial marketing authorisation.
- The Committee endorsed the EPAR module 6 scientific discussion for **Zactran** (EMEA/V/C/000129/X/0034) concerning an extension of the marketing authorisation.
- The Committee endorsed the EPAR module 6 scientific discussion for **Cytopoint** (EMEA/V/C/003939/0000) concerning the granting of the initial marketing authorisation.
- The Committee endorsed the EPAR module 6 scientific discussion for **ZULVAC BTV Ovis** (EMEA/V/C/004185/0000) 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, the CVMP assessment report and the product information for a type II variation for **Activyl Tick Plus** (EMEA/V/C/002234/II/0008), recommending the variation of the marketing authorisation to add a new therapeutic indication for sand flies (*Phlebotomus perniciosus*). The Committee noted the summary of opinion for publication.
- 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 a grouped type II variation for **Suvaxyn Circo+MH RTU** (EMEA/V/C/003924/II/0004/G), recommending the variation of the marketing authorisation to increase the duration of immunity *for M. Hyopneumoniae* component (from 16 to 23 weeks), as well as to implement quality changes.
- 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 II variation for **ZULVAC 1+8 Bovis, ZULVAC 8 Ovis, ZULVAC 8 Bovis, ZULVAC 1+8 Ovis, ZULVAC 1 Ovis, ZULVAC SBV** and **ZULVAC 1 Bovis** (EMEA/V/C/xxxxxx/WS1039), recommending the variation of the marketing authorisations to implement quality changes.

3.2 Oral explanations and lists of outstanding issues

- The Committee adopted a list of outstanding issues to be addressed in writing for a grouped type II variation for **Suvaxyn Circo+MH RTU** (EMEA/V/C/003924/II/0005/G), concerning quality changes.
- The Committee adopted a list of outstanding issues to be addressed in writing for a type II variation for **Pexion** (EMEA/V/C/002543/II/0009), concerning changes in the SPC.

3.3 Lists of questions

- The Committee adopted a list of questions for a worksharing type IB variation for **ZULVAC 1+8 Ovis, ZULVAC 1+8 Bovis** and **ZULVAC 1 Bovis** (EMEA/V/C/xxxxxx/WS1096), concerning quality changes.
- The Committee adopted a list of questions for a worksharing type IB variation for **ZULVAC 8 Bovis** and **ZULVAC 8 Ovis** (EMEA/V/C/xxxxxx/WS1097), concerning quality changes.

3.4 Re-examination of CVMP opinions

- There were no items for discussion.

3.5 Other issues

- There were no items for discussion.

4. REFERRALS AND RELATED PROCEDURES

4.1 Article 33 of Directive 2001/82/EC

- There were no items for discussion.

4.2 Article 34 of Directive 2001/82/EC

- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for the referral procedure for **Denagard 45% and its associated names** (EMEA/V/A/114), recommending harmonised product information for the concerned products.
- The Committee discussed the rapporteur's revised assessment report including co-rapporteur's critique, the rapporteur's assessment report of the responses to the list of outstanding issues and the draft product information for the referral procedure for **Girolan and its associated name Apralan** (EMEA/V/A/122). The Committee adopted the list of outstanding issues for the marketing authorisation holder to address in writing, the draft product information 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 heard two oral explanations from two marketing authorisation holders, Zoetis Belgium SA and Norbrook Laboratories Ltd for the referral procedure for **veterinary medicinal products containing moxidectin to be administered to cattle, sheep and horses** (EMEA/V/A/116). The adoption of the opinion is foreseen for the May 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 two recommendations for **Stronghold Plus** (EMEA/V/C/004194/REC/001 & 002).
- The Committee adopted the rapporteur's assessment report on the data submitted concerning a recommendation for **BTVPUR** (EMEA/V/C/002231/REC/019).

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 17.03.2017 – 12.04.2017:

Product	Period
Advocate (EMEA/V/C/000076)	02/04/2016 – 01/04/2017
BTVPUR AlSap 8 (EMEA/V/C/000146)	17/03/2016 – 01/04/2017
Clomicalm (EMEA/V/C/000039)	01/04/2016 – 31/03/2017
ECOPORC SHIGA (EMEA/V/C/002588)	10/04/2016 – 09/04/2017
Eurican Herpes 205 (EMEA/V/C/000059)	26/03/2016 – 25/03/2017
Incurin (EMEA/V/C/000047)	24/03/2016 – 23/03/2017
Locatim (EMEA/V/C/000041)	29/03/2016 – 28/03/2017
Parvoduk (EMEA/V/C/002740)	11/04/2016 – 10/04/2017
Rabigen SAG2 (EMEA/V/C/000043)	06/04/2016 – 05/04/2017
Veraflox (EMEA/V/C/000159)	12/04/2016 – 11/04/2017

5.4 Renewals

- 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 **Cardalis** (EMEA/V/C/002524/R/0009), and recommended that the authorisation should now be indefinite.

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 **NexGard** (EMEA/V/C/002729) with a recommendation to request a targeted PSUR on all neurological adverse events.
- The Committee endorsed the recommendation from the PhVWP-V to the MAH following the surveillance analysis findings for **Metacam** (EMEA/V/C/000033).
- The Committee endorsed the recommendation from the PhVWP-V to the MAH following the surveillance analysis findings for **Purevax Rabies** (EMEA/V/C/000072).
- 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
Aivlosin (EMEA/V/C/000083)	01.04.2016 – 30.09.2016
Broadline (EMEA/V/C/002700)	01.07.2016 – 31.12.2016
BTVPUR AlSap 2-4 (EMEA/V/C/000139)	01.12.2015 – 30.11.2016
Contacera (EMEA/V/C/002612)	01.01.2016 – 31.12.2016
Draxxin (EMEA/V/C/000077)	01.12.2013 – 30.11.2016
Equip WNV (EMEA/V/C/000137)	01.06.2016 – 30.11.2016
Improvac (EMEA/V/C/000136)	01.12.2013 – 30.11.2016
Oncept IL-2 (EMEA/V/C/002562)	01.12.2015 – 30.11.2016
Panacur AquaSol (EMEA/V/C/002008)	01.01.2016 – 31.12.2016
Parvoduk (EMEA/V/C/002740)	01.05.2016 – 30.10.2016
Porcilis ColiClos (EMEA/V/C/002011)	01.01.2016 – 31.12.2016
Porcilis PCV M Hyo (EMEA/V/C/003796)	01.06.2016 – 30.11.2016
Purevax FeLV (EMEA/V/C/000056)	01.11.2013 – 30.10.2016
Suvaxyn Circo+Mh RTU (EMEA/V/C/003924)	01.06.2016 – 01.12.2016
Vectra Felis (EMEA/V/C/002746)	01.07.2016 – 31.12.2016
Versican Plus DHPPi/L4 (EMEA/V/C/003678)	01.06.2016 – 30.11.2016
Versican Plus DHPPi/L4R (EMEA/V/C/002759)	01.06.2016 – 30.11.2016
Zycortal (EMEA/V/C/003782)	01.06.2016 – 30.11.2016

- 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 received a verbal report on the 34th VICH Steering Committee meeting and the 8th Outreach Forum meeting held between 27 February and 2 March 2017, in Buenos Aires, Argentina.

6.2 Codex Alimentarius

- There were no items for discussion.

6.3 Other EU bodies and international organisations

- The Committee received a verbal report from the CVMP representative on the EFSA workshop on benchmark dose, held on 1-2 March 2017 in Brussels, Belgium, and noted the programme of the workshop.
- The Committee received a verbal report on the 3rd EMA/JECFA liaison meeting held on 7 March 2017, and noted the agenda of the meeting.
- The Committee received a verbal report from the CVMP representative on the 5th International Fresenius conference on environmental risk assessment of biocides, held on 23 24 March 2017 in Dusseldorf, Germany, and noted the programme of the conference.
- The Committee was informed of the participation of a CVMP representative at the upcoming EFSA-FEEDAP expert group meeting on ERA guidelines, held on 19-21 April 2017 in Parma, Italy.

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 10 April 2017, and noted the agenda of the meeting.

7.2 Quality Working Party (QWP)

- There were no items for discussion.

7.3 Safety Working Party (SWP-V)

- There were no items for discussion.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- There were no items for discussion.

7.5 Efficacy Working Party (EWP-V)

- The Committee adopted the reflection paper on anthelmintic resistance (EMA/CVMP/EWP/573536/2013) and the overview of comments received during the public consultation (EMA/CVMP/EWP/526298/2016).
- The Committee adopted the draft revised guideline on the conduct of bioequivalence studies for veterinary medicinal products (EMA/CVMP/016/00-Rev.3) for a 6-month period of public consultation.
- The Committee was informed of the upcoming election of the vice-chair of the EWP-V for a 3-year term at the May 2017 CVMP meeting, and noted the nominations received.

7.6 Antimicrobials Working Party (AWP)

- The Committee was informed of the upcoming election of the vice-chair of the AWP for a 3-year term at the May 2017 CVMP meeting, and noted the nomination received.

7.7 Immunologicals Working Party (IWP)

- The Committee adopted the revised guideline on data requirements for immunological veterinary medicinal products intended for minor use or minor species (MUMS)/limited market (EMA/CVMP/IWP/123243/2006-Rev.3) and the overview of comments received during the public consultation (EMA/CVMP/IWP/506137/2016).

7.8 Pharmacovigilance Working Party (PhVWP-V)

- The Committee adopted the updated question and answer document on serious non-fatal adverse events and reporting rules (EMA/CVMP/PhVWP/209556/2017-Rev.1).

7.9 Novel therapy groups and related issues

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

- There were no items for discussion.

The following documents were circulated for information:

- Minutes of the SAWP-V meeting held on 14 March 2017;
- Scientific Advice annual report 2016;
- Final agenda from the PhVWP-V meeting held on 21-22 March 2017 and draft minutes.

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.

8.2 Environmental risk assessment

- The Committee adopted the reflection paper on the authorisation of veterinary medicinal products containing (potential) persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances (EMA/CVMP/448211/2015), and the overview of comments received during the public consultation (EMA/CVMP/401418/2016). The reflection

paper would be presented to HMA for adoption and will then be published on the Agency's website.

8.3 Antimicrobial resistance

- The Committee noted the EC request and annex for a joint ECDC, EFSA and EMA scientific opinion on a list of outcome indicators as regards surveillance of antimicrobial resistance and antimicrobial consumption in humans and food-producing animals agreed on the proposed procedure for the adoption of the opinion.
- The Committee was informed of the ESVAC draft guidance on provision of data on antimicrobial use by animal species from national data collection systems, and of the questions and answers for the guidance on provision of data on antimicrobial use by animal species from national data collection systems. The guidance was published for public consultation until 24 September 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 following document was circulated for information:

- Final report of a fact-finding mission carried out in Slovenia from 7 to 11 March 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=3771.

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 28 February 2017.
- The Committee endorsed the need for participation of an expert from the USDA Centre for Biologics in the upcoming stakeholders focus group on field efficacy trials for veterinary vaccines.

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 previous (co-)rapporteurships and peer reviewer responsibilities from C. Ibrahim to G. Hahn.

10.2 Regulatory matters

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

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

- The Committee noted the draft minutes of the meeting held on 16 March 2017 as well as the draft agenda of the meeting held on 11-12 April 2017.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee discussed the CVMP operation and procedures: practical guidance document for CVMP members, which is foreseen to be adopted at the May 2017 meeting.
- The Committee received a verbal report from the chair of the Strategic Planning Group on the meeting held on 11 April 2017, and noted the agenda of the meeting and the minutes of the meeting held on 18 January 2017.
- The Committee received an update on developments following the triggering of Article 50 of the Lisbon Treaty by the UK.
- The Committee received a presentation on the EMA framework of collaboration with academia, which links to an objective of the CVMP work plan for 2017.
- The Committee discussed the timing of Interested Parties' Meeting in 2017, to be held either in September or October 2017 depending on other overlapping activities. Stakeholders would be informed of the timing and a call for topics would be initiated.
- The Committee was informed of the Chair's presentation to EMA Management Board meeting, held on 16 March 2017.

13. LEGISLATION

- There were no items for discussion.

14. ANY OTHER BUSINESS

- Upon the completion of the April 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 April 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	
BG	Emil Kozhuharov	Full involvement	
DE	Gesine Hahn	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	
RO	Lollita Taban	Full involvement	
SE	Eva Lander Persson	Full involvement	
SI	Katarina Straus	Full involvement	
UK	Helen Jukes	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	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
CZ	Leona Nepejchalová	Full involvement	
DE	Esther Werner	Full involvement	
FR	Sylvie Louet	Full involvement	
HR	Ljiljana Markus-Cizelj	Full involvement	
LT	Laimis Jodkonis	Full involvement	
NL	Jacqueline Poot	Full involvement	
PL	Ewa Augustynowicz	Full involvement	
PT	Maria Azevedo Mendes	Full involvement	
SE	Frida Hasslung Wikström	Full involvement	
SK	Eva Chobotová	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.			
AT	Petra Falb – *remotely*	Full involvement	
BE	Sandy Vermout - *remotely*	Full involvement	
DE	Ina Ebert	Full involvement	
DE	Silke Hickmann – *remotely*	Full involvement	
DE	Susanne Schmitz	Full involvement	
ES	Ricardo Carapeto Garcia	Full involvement	
ES	Aranzazu Gonzalez – *remotely*	Full involvement	
ES	Patricia Vera Luque	Full involvement	
NL	Kim Boerkamp	Full involvement	
NL	Celine Thiry - *remotely*	Full involvement	
NL	Wendy Wuyts – *remotely*	Full involvement	
UK	Ken Stapleton	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	--
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