5 October 2021
EMA/562594/2021
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 7-9 September 2021 meeting

Chair: D. Murphy – Vice-chair: G. J. Schefferlie

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).

Due to the COVID-19 pandemic, the September 2021 CVMP meeting took place by means of remote participation and decision making.

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 September 2021 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. 17 or more members of the 32 members eligible to vote were present. Furthermore, absolute majority requires that 17 members vote in favour of the proposed decision.

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.

No contacts were declared.

iv. Adoption of the minutes of the previous meeting

The minutes of the July 2021 CVMP meeting and the August written procedure 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

- There were no items for discussion.

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

- The Committee adopted by majority (23 members in favour out of the 25 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Felpreva** (EMEA/V/C/005464/0000), recommending the granting of a marketing authorisation. Felpreva spot-on contains the active substances tigolaner, emodepside and praziquantel, and is indicated for cats with, or at risk from, mixed parasitic infestations. S. Louet and N. C. Kyvsgaard signed a divergent position not supporting the aforementioned recommendation. The Committee noted the summary of the opinion for publication.

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 a list of questions for a new vaccine (EMEA/V/C/005819/0000) for chickens. The Committee noted peer review reports and the comments received from CVMP members.
- The Committee adopted the scientific overview including a list of questions for a new product (EMEA/V/C/005528/0000) for dogs. The Committee noted peer review reports and the comments received from CVMP members.

2.4 Re-examination of CVMP opinions

- There were no items for discussion.

2.5 Other issues

- The Committee agreed to the request from the applicant for an oral explanation for a new vaccine (EMEA/V/C/005184/0000).
- The Committee endorsed the European public assessment report (EPAR) 'scientific discussion' for **Fatrovax RHD** (EMEA/V/C/005301/0000) concerning the granting of the initial marketing authorisation.
- The Committee endorsed the European public assessment report (EPAR) 'scientific discussion' for **Tessie** (EMEA/V/C/005427/0000) concerning the granting of the initial marketing authorisation.

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- The Committee adopted by consensus (25 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a type II variation for **Frontpro** (EMEA/V/C/005126/II/0010), recommending the variation of the marketing authorisation to change the legal status from prescription-only to non-prescription veterinary medicine. The Committee noted the summary of the opinion for publication.
- The Committee adopted by consensus (25 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a type II variation for **Poulvac E. coli** (EMEA/V/C/002007/II/0018), recommending the variation of the marketing authorisation to change the product information to highlight that the safety of the product has been demonstrated when administered to chickens during lay.
- 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 type II grouped variation for **Porcilis PCV ID** (EMEA/V/C/003942/II/0005/G) recommending the variation of the marketing authorisation to change the product information to add an indication on associated mixed-use with Porcilis Lawsonia ID, and to broaden the target species category from fattening pigs to pigs.
- 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 (subject to a work-sharing procedure) for **Circovac** (EMEA/V/C/000114/WS1945/0018) recommending the variation of the marketing authorisation to change the product information to add the associated mixed use with other related nationally authorised products and to extend the duration of immunity to 23 weeks in case of mixed use.

- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a type II grouped variation (subject to a work-sharing procedure) for **Innovax-ILT** and **Innovax-ND-IBD** (EMEA/V/C/xxxxxx/WS2102/G), recommending the variation of the marketing authorisation to implement quality-related changes.
- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a type II variation for **Locatim** (EMEA/V/C/000041/II/0018), recommending the variation of the marketing authorisation to implement quality-related changes.
- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report for a type II grouped variation for **Prevomax** (EMEA/V/C/004331/II/0006/G), recommending the variation of the marketing authorisation to implement quality-related changes.
- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a type II variation for **ProZinc** (EMEA/V/C/002634/II/0024), recommending the variation of the marketing authorisation to implement quality-related changes.
- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a type II variation for **Innovax-ND-IBD** (EMEA/V/C/004422/II/0007), recommending the variation of the marketing authorisation to implement quality-related changes.
- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a type II grouped variation for **Startvac** (EMEA/V/C/000130/II/0008/G), recommending the variation of the marketing authorisation to implement quality-related changes.

3.2 Oral explanations and lists of outstanding issues

- The Committee adopted a list of outstanding issues for a type II variation for **Improvac** (EMEA/V/C/000136/II/0036), to add a new therapeutic indication and target species.
- The Committee adopted a list of outstanding issues for a type II grouped variation for **Veraflox** (EMEA/V/C/000159/II/0024/G), concerning quality-related changes.

3.3 Lists of questions

- The Committee adopted a list of questions and comments on the draft product information for a type II grouped variation for **Suprelorin** (EMEA/V/C/000109/II/0032/G), to add a new therapeutic indication and target species.
- The Committee adopted a list of questions and comments on the draft product information for a type II variation for **Bravecto** (EMEA/V/C/002526/II/0051), to add a new therapeutic indication.
- The Committee adopted a list of questions for a type II grouped variation for **Cytopoint** (EMEA/V/C/003939/II/0014/G), concerning quality-related changes.
- The Committee adopted a list of questions for a type II grouped variation for **Mhyosphere PCV ID** (EMEA/V/C/005272/II/0001/G), concerning quality-related changes.
- The Committee adopted a list of questions for a type II variation (subject to a work-sharing procedure) for **Simparica, Felisecto Plus, Stronghold Plus, MiPet Easecto and Simparica Trio** (EMEA/V/C/xxxxxx/WS2073), concerning quality-related changes.

3.4 Re-examination of CVMP opinions

- There were no items for discussion.

3.5 Other issues

- The Committee was informed of the formal notification from MSD Animal Health of their decision to withdraw the type II variation application for **Bravecto** chewable tablets for dogs (EMEA/V/C/002526/II/0047), to add a new therapeutic indication against sand flies. 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 agreed to a request from the MAH for a further extension to the clock-stop for a type II grouped variation for **Neocolipor** (EMEA/V/C/000035/II/0018/G), concerning quality-related 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

- There were no items for discussion.

4.3 Article 35 of Directive 2001/82/EC

- There were no items for discussion.

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

- There were no items for discussion.

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 16.07.2021 – 09.09.2021:

Product	Period
Aivlosin (EMEA/V/C/000083)	09.09.2020 – 08.09.2021
Bovilis BTV8 (EMEA/V/C/000148)	06.09.2020 – 05.09.2021
Cardalis (EMEA/V/C/002524)	23.07.2020 – 22.07.2021
Dexdomitor (EMEA/V/C/000070)	30.08.2020 – 29.08.2021
Emdocam (EMEA/V/C/002283)	18.08.2020 – 17.08.2021
Evicto (EMEA/V/C/004973)	19.07.2020 – 18.07.2021
Exzolt (EMEA/V/C/004344)	18.08.2020 – 17.08.2021
Fortekor Plus (EMEA/V/C/002804)	08.09.2020 – 07.09.2021
Hydrocortisone aceponate Ecuphar (EMEA/V/C/004689)	27.08.2020 – 26.08.2021
Innovax-ND-IBD (EMEA/V/C/004422)	22.08.2020 – 21.08.2021
Nasym (EMEA/V/C/004897)	29.07.2020 – 28.07.2021
Nobilis IB Primo QX (EMEA/V/C/002802)	04.09.2020 – 03.09.2021
Nobilis Influenza H5N2 (EMEA/V/C/000118)	01.09.2020 – 31.08.2021
Nobivac L4 (EMEA/V/C/002010)	16.07.2020 – 16.05.2021
Nobivac Myxo-RHD (EMEA/V/C002004)	07.09.2020 – 06.09.2021
Novaquin (EMEA/V/C/003866)	08.09.2020 – 07.09.2021
Osurnia (EMEA/V/C/003753)	31.07.2020 – 30.07.2021
Porcilis PCV ID (EMEA/V/C/003942)	28.08.2020 – 27.08.2021
Prevexxion RN (EMEA/V/C/005058	20.07.2020 – 19.07.2021
Prevexxion RN+HVT+IBD (EMEA/V/C/005057	20.07.2020 – 19.07.2021
Profender (EMEA/V/C/000097)	27.07.2020 – 26.07.2021
Proteq West Nile (EMEA/V/C/002020)	05.08.2020 – 04.08.2021
Sedadex (EMEA/V/C/004202)	12.08.2020 – 11.08.2021
Suvaxyn Aujeszky 783 + O/W (EMEA/V/C/000038)	07.08.2020 – 06.08.2021
Suvaxyn PRRS MLV (EMEA/V/C/004276)	24.08.2020 – 23.08.2021
Trocoxil (EMEA/V/C/000132)	09.09.2020 – 08.09.2021

Product	Period
Ubac (EMEA/V/C/004595)	26.07.2020 – 25.07.2021
UpCard (EMEA/V/C/003836)	31.07.2020 – 30.07.2021
Vaxxitek HVT+IBD (EMEA/V/C/000065)	09.08.2020 – 08.08.2021
Vectormune ND (EMEA/V/C/003829)	08.09.2020 – 07.09.2021
Vepured (EMEA/V/C/004364)	17.08.2020 – 16.08.2021
Versican Plus L4 (EMEA/V/C/003680)	31.07.2020 – 30.07.2021
Versican Plus Pi/L4 (EMEA/V/C/003683)	31.07.2020 – 30.07.2021
Versican Plus Pi/L4R (EMEA/V/C/003682)	31.07.2020 – 30.07.2021
Zactran (EMEA/V/C/000129)	24.07.2020 – 23.07.2021

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 **Coliprotec F4/F18** (EMEA/V/C/004225/R/0009), and recommended that the authorisation should now be indefinite.
- 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 **Cepedex** (EMEA/V/C/004376/R/0007), and recommended that the authorisation should now be indefinite.

5.5 Pharmacovigilance – PSURs and SARs

- The Committee adopted a recommendation for changes to the SPC for **Vepured** as an outcome of signal detection activities.
- The Committee endorsed the following rapporteur's assessment reports on PSURs concluding that no changes to the product information or other regulatory actions were required for:

Product	Period
Forceris (EMEA/V/C/004329)	01.11.2020 – 30.04.2021
Meloxidolor (EMEA/V/C/002590)	23.04.2018 – 30.04.2021
Reprocyc ParvoFLEX (EMEA/V/C/004858)	01.11.2020 – 30.04.2021

- 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 comments on the draft VICH guideline on good manufacturing practice guide for active pharmaceutical ingredients, for circulation to the VICH Expert Working Group.
- The Committee endorsed the EU comments on the draft VICH GL8 on stability testing for medicated premixes for circulation to the VICH Expert Working Group.

6.2 Codex Alimentarius

6.3 Other EU bodies and international organisations

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 cannot be released at the present time as it is deemed to be commercially confidential.

7.1 Scientific Advice Working Party (SAWP-V)

- The Committee received a verbal report from the SAWP-V chair on the meeting held on 6 September 2021, and noted the draft agenda of the meeting.

7.2 Quality Working Party (QWP)

7.3 Safety Working Party (SWP-V)

- There were no items for discussion.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- The Committee received a verbal report from the ERAWP chair on the meeting held on 30 June-1 July 2021.
- The Committee adopted a reflection paper on higher tier testing to investigate the effects of parasiticidal veterinary medicinal products on dung fauna (EMA/CVMP/ERA/87473/2021). The comments received during the public consultation on the draft guideline on the higher tier testing of veterinary medicinal products to dung fauna (EMA/CVMP/ERA/409350/2010) have been taken into account for the drafting of the reflection paper. This reflection paper has been developed to address the concern and potential risk towards dung fauna associated with the use of parasiticides in livestock.
- The Committee adopted a draft reflection paper on the interpretation of Article 18(7) of Regulation (EU) 2019/6 (EMA/CVMP/ERA/622045/2021) for a 3-month period of public consultation. This reflection paper has been developed to provide guidance on when an environmental risk assessment can be requested by competent authorities in the frame of marketing authorisation applications for generic veterinary medicinal products.

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 adopted the revised reflection paper on methods found suitable within the EU for demonstrating freedom from extraneous agents of the seeds used for the production of immunological veterinary medicinal products and the overview of comments received during the public consultation.

7.8 Pharmacovigilance Working Party (PhVWP-V)

- There were no items for discussion.

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

The following documents were circulated for information:

- Scientific publication on ERA for VMPs intended for use in aquaculture in Europe: the need for developing a harmonised approach (link)

8. OTHER SCIENTIFIC MATTERS

8.1 MRL issues

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

- There were no items for discussion.

8.2 Environmental risk assessment

- There were no items for discussion.

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 be commercially confidential.

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.

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 agenda of the CMDv meeting to be held on 9-10 September 2021 and the minutes of the meeting held on 15-16 July 2021.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee received a verbal report from the chair of the Veterinary Domain on the meeting held on 3 September 2021, and noted the agenda of the meeting and the minutes of the meeting held on 7 June 2021.
- The Committee discussed the format and adopted the agenda items for the CVMP Presidency meeting under the Slovenian Presidency to be held virtually on 13 October 2021.

13. LEGISLATION

- The Committee adopted an overview of comments on the guideline on safety and residue data requirements for applications for non-immunological veterinary medicinal products intended for limited markets submitted under Article 23 of Regulation (EU) 2019/6 (EMA/CVMP/148001/2021).
- The Committee adopted an overview of comments on the guideline on efficacy and target animal safety data requirements for applications for non-immunological veterinary medicinal products intended for limited markets submitted under Article 23 of Regulation (EU) 2019/6 (EMA/CVMP/147926/2021).
- The Committee adopted an overview of comments on the guideline on data requirements for applications for immunological veterinary medicinal products intended for limited markets applications submitted under Article 23 of Regulation (EU) 2019/6 (EMA/CVMP/147910/2021).

14. ANY OTHER BUSINESS

- Upon the completion of the September 2021 CVMP meeting, the draft news highlights were circulated for members to provide 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 September 2021 CVMP 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	Petra Falb	Full involvement	
BE	Bruno Urbain	Full involvement	
BG	Svetoslav Valentinov Branchev	Full involvement	
CZ	Leona Nepejchalová	Full involvement	
DE	Esther Werner	Full involvement	
DK	Niels Christian Kyvsgaard	Full involvement	
EE	Toomas Tiirats	Full involvement	
EL	Spyridon Farlopoulos	Full involvement	
ES	Cristina Muñoz Madero	Full involvement	
FI	Minna Leppänen	Full involvement	
FR	Sylvie Louet	Full involvement	
HR	Frane Božić	Full involvement	
HU	Gábor Kulcsár	Full involvement	
IE	J. Gabriel Beechinor	Full involvement	
IT	Paolo Pasquali	Full involvement	
LV	Zanda Auce	Full involvement	
MT	Stephen Spiteri	Full involvement	
NL	Jacqueline Poot	Full involvement	
PL	Anna Wachnik-Święcicka	Full involvement	
PT	João Pedro Duarte da Silva	Full involvement	
RO	Lollita Taban	Full involvement	
SE	Frida Hasslung Wikström	Full involvement	
SI	Katarina Straus	Full involvement	
SK	Judita Hederová	Full involvement	
Co-opted	Keith Baptiste	Full involvement	
Co-opted	Rory Breathnach	Full involvement	
Co-opted	G. Johan Schefferlie *(vice chair)*	Full involvement	
Co-opted	Mary O'Grady	Full involvement	
Co-opted	Ricardo Carapeto García	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
AT	Manuela Leitner	Full involvement	
BE	Frédéric Klein	Full involvement	
DE	Andrea Golombiewski	Full involvement	
DK	Merete Blixenkrone-Møller	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
FR	Christine Miras	Full involvement	
HR	Hrvoje Pasavovic	Full involvement	
LV	Santa Ansonska	Full involvement	
NL	Kim Boerkamp	Full involvement	
SE	Carina Bergman	Full involvement	
SI	Boris Kolar	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
SE	Oskar Nilsson	Full involvement	
IE	Joseph DeCourcey	Full involvement	
IE	Sarah Buckley	Full involvement	
(EFSA)	Beatriz Guerra	Full involvement	
FR	Gérard Moulin	Full involvement	
DE	Stefan Scheid	Full involvement	
DK	Henrik Duelund Pedersen	Full involvement	
DE	Norbert Möller	Full involvement	
BE	Sandy Vermout	Full involvement	
DE	Stephan Steuber	Full involvement	
DE	Sarah Adler-Flindt	Full involvement	
DE	Katja Kaulich	Full involvement	
DE	Martina Kern	Full involvement	
DE	Thilo Nölke	Full involvement	
DE	Sandra Bertulat	Full involvement	
DE	Uta Herbst	Full involvement	
DE	Anke Finnah	Full involvement	
DE	Nikola Lange	Full involvement	
CZ	Ludek Blaha	Full involvement	
DE	Silke Hickmann	Full involvement	
CZ	Radka Smítalová	Full involvement	
CZ	Zdenka Mašková	Full involvement	
CZ	Lucie Pokludova	Full involvement	
FR	Nathalie Bridoux	Full involvement	
DK	Rita Neel Jansen	Full involvement	
DK	Anja Silke Christensen	Full involvement	
DK	Mette T. Madsen	Full involvement	
DK	Kathrine Just Andersen	Full involvement	

* Experts were only evaluated against the topics they have been invited to talk about.

CVMP working parties and CMDv	Chair
NTWP	Jacqueline Poot
AWP	Christine Schwarz
ERAWP	Ricardo Carapeto García
EWP-V	Cristina Muñoz Madero
IWP	Esther Werner
J3Rs WG	---
QWP	Mary O'Grady *(veterinary vice chair)*
SAWP-V	Frida Hasslung Wikström
SWP-V	Carina Bergman

Observer from the European Commission	
Present	

Observers from Swissmedic	
Present	

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