8 September 2020
EMA/CVMP/473597/2020
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 14-16 July 2020 meeting

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

Note on access to documents

Some documents mentioned in the agenda and 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 July 2020 CVMP meeting took place by means of remote participation and decision making.

i. Adoption of the Agenda

The Committee adopted the agenda with the addition of two new items: under point 7.1 regarding scientific advice on a new veterinary medicinal product and under point 10.2 regarding a CMDv position paper on implementation of the revision of the Ph. Eur.

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

The attendance list was completed and competing interests were identified for the July 2020 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 attended the meeting. It was noted that 17 members were needed for an absolute majority.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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 June 2020 meeting were adopted with minor 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

- The Committee adopted by consensus (24 members attending of those eligible to vote) the CVMP opinion including the EPMAR and the CVMP assessment report recommending the extension of MRLs to porcine (no MRL required) for **lidocaine** (EMEA/V/MRL/003649/EXTN/0002). The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of the opinion for publication.

- The Committee adopted by consensus (27 members attending of those eligible to vote) the CVMP opinion including the EPMAR and the CVMP assessment report recommending the extension of MRLs to bovine for **lidocaine** (EMEA/V/MRL/003649/EXTN/0002). The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of the opinion for publication.

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 consensus (27 members attending of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for the generic product **Increxxa** (EMEA/V/C/005305/0000), containing tulathromycin, recommending the granting of a marketing authorisation. The product is indicated for the treatment and metaphylaxis of bovine respiratory disease, treatment of infectious bovine keratoconjunctivitis, treatment and metaphylaxis of swine respiratory disease and treatment of the early stages of infectious pododermatitis in sheep. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of the opinion for publication.

- The Committee adopted by consensus (27 members attending of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for the generic product **Tulinovet** (EMEA/V/C/005076/0000), containing tulathromycin, recommending the granting of a marketing authorisation. The product is indicated for the treatment and metaphylaxis of bovine respiratory disease, treatment of infectious bovine keratoconjunctivitis, treatment and metaphylaxis of swine respiratory disease and treatment of the early stages of infectious pododermatitis in sheep. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of the opinion for publication.
- The Committee adopted by consensus (26 members attending of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Mhyosphere PCV ID** (EMEA/V/C/005272/0000), recommending the granting of a marketing authorisation. The product is a new vaccine for the active immunisation against porcine enzootic pneumonia and porcine circovirus type 2 related diseases. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of the opinion for publication.
- The Committee adopted by consensus (27 members attending of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Innovax-ND-ILT** (EMEA/V/C/005190/0000), recommending the granting of a marketing authorisation. The product is a new vaccine for the active immunisation of one-day-old chicks or embryonated chicken eggs against Newcastle disease, avian infectious laryngotracheitis and Marek’s disease. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of the opinion for publication.

2.2 Oral explanations and lists of outstanding issues

- The Committee adopted the scientific overview including the list of outstanding issues and agreed comments on the draft product information for a marketing authorisation application for a new generic product (EMEA/V/C/005384/0000). The Committee noted a peer review report and the comments received.
- The Committee adopted the 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 (EMEA/V/C/005184/0000). The Committee noted a peer review report and the comments received.
- The Committee adopted the 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 (EMEA/V/C/005251/0000). The Committee noted the comments received.

2.3 Lists of questions

- The Committee adopted the scientific overview including a list of questions and agreed comments on the draft product information for a new vaccine (EMEA/V/C/005309/0000) for horses and ponies. The Committee noted two peer review reports and the comments received.

2.4 Re-examination of CVMP opinions

- There were no items for discussion.

2.5 Other issues

- The Committee endorsed the withdrawal EPAR following the formal notification from the applicant to withdraw their application for the generic product **Tulatrixx** (EMEA/V/C/005364/0000), containing tulathromycin, for treatment and metaphylaxis of bovine respiratory disease, treatment of infectious bovine keratoconjunctivitis, treatment and metaphylaxis of swine respiratory disease and treatment of the early stages of infectious pododermatitis in sheep.

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- The Committee adopted by consensus (27 members attending of those eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a type II grouped variation for **Aivlosin** (EMEA/V/C/000083/II/0080/G), recommending the variation of the marketing authorisation to implement quality-related changes. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (27 members attending of those eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a type II grouped variation for **UpCard** (EMEA/V/C/003836/II/0005/G), recommending the variation of the marketing authorisation to implement quality-related changes. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (27 members attending of those eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a type II grouped variation for **Posatex** (EMEA/V/C/000122/II/0028/G), recommending the variation of the marketing authorisation to implement quality-related changes. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (27 members attending of those eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a type IB variation (subject to a worksharing procedure) for **Panacur AquaSol** (EMEA/V/C/xxxx/WS1837), recommending the variation of the marketing authorisation to implement quality-related changes. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.

3.2 Oral explanations and lists of outstanding issues

- The Committee adopted a list of outstanding issues and the comments on the product information for a type II variation for **Cytopoint** (EMEA/V/C/003939/II/0009), to add a new therapeutic indication and amend the package leaflet.

3.3 Lists of questions

- The Committee adopted a list of questions and the comments on product information for a type II variation for **Cortavance** (EMEA/V/C/000110/II/0015) to add a new therapeutic indication.
- The Committee adopted a list of questions and the comments on product information for a type II grouped variation for **Sevohale** (EMEA/V/C/004199/II/0006/G) concerning quality-related changes.
- The Committee adopted a list of questions for a type II variation for **Clynav** (EMEA/V/C/002390/II/0011) concerning quality-related changes.
- The Committee adopted a list of questions and the comments on product information for **Equilis Prequenza** and **Equilis Prequenza Te** for a type IB variation (subject to a worksharing procedure) (EMEA/V/C/xxxx/WS1836) concerning quality-related changes.

3.4 Re-examination of CVMP opinions

- There were no items for discussion.

3.5 Other issues

- The Committee agreed to a request from the MAH for an extension to the clock-stop period for a type II variation for **Simparica Trio** (EMEA/V/C/004846/II/0001) concerning quality-related changes.

- The Committee agreed to a request from the MAH for an extension to the clock-stop period for a type II variation for **Advocate** (EMEA/V/C/000076/II/0043) concerning changes in the SPC.

4. REFERRALS AND RELATED PROCEDURES

4.1 Article 33 of Directive 2001/82/EC

- There were no items for discussion.

4.2 Article 34 of Directive 2001/82/EC

- The Committee agreed to the request from the marketing authorisation holder Boehringer-Ingelheim Vetmedica GmbH for a further extension to the clock-stop for the referral procedure for **Ronaxan and its associated names** (EMEA/V/A/135) and adopted a revised timetable for the procedure.

4.3 Article 35 of Directive 2001/82/EC

- The Committee considered the notification from Germany for a referral procedure for **injectable veterinary medicinal products containing vitamin A for use in food producing species**. The referral concerns the appropriateness of withdrawal periods (milk, meat and offal) and user safety warnings in food producing species for the aforementioned veterinary medicinal products. The Committee agreed to start a referral procedure (EMEA/V/A/141) and appointed A. Golombiewski as rapporteur and B. Urbain as co-rapporteur for the procedure. The Committee adopted the list of questions and the timetable for the procedure.

- The Committee considered the notification from the European Commission for a referral procedure for **modified live porcine respiratory and reproductive syndrome (PRRS) virus vaccines**. The referral concerns potential risk management measures that could protect animal health and limit the risk of recombination between PRRS viruses, including PRRS vaccine strains. The Committee agreed to start a referral procedure (EMEA/V/A/142) and appointed E. Werner as rapporteur and F. Klein as co-rapporteur for the procedure. The Committee adopted the list of questions and the timetable for the procedure.

- The Committee adopted by consensus (24 members attending of those eligible to vote) the CVMP opinion and the CVMP assessment report for the referral procedure for **Stresnil 40 mg/ml solution for injection for pigs and associated names, and generic products thereof** (EMEA/V/A/138), recommending an eighteen-days withdrawal period for meat and offal derived from treated pigs and a limitation of the maximum injection volume to 5 ml per injection site to provide assurance of consumer safety. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.

- The Committee adopted by consensus (23 members attending of those eligible to vote) the CVMP opinion and the CVMP assessment report for the referral procedure for **Betamox LA 150 mg/ml suspension for injection and associated names, and generics products thereof** (EMEA/V/A/132). The Committee recommended the amendment of the withdrawal periods following intramuscular use (i.e. 39 days for cattle meat and offal and 108 hours (4.5 days) for cattle milk; 42 days for pig meat and offal and 29 days for sheep meat and offal) and a limitation of the maximum injection volume to 15 ml per injection site for cattle and to 4 ml for sheep and pigs to provide assurance of consumer safety. In addition, a statement in the product information was added in order to exclude the use in sheep producing milk for human consumption. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.

- The Committee discussed the rapporteur's assessment report including co-rapporteur's critique following the MAH's responses to the list of outstanding issues and the rapporteur's assessment of the responses to the list of outstanding issues for the referral procedure for **veterinary medicinal products containing tiamulin hydrogen fumarate presented as premix for medicated feeding stuff and oral powder for in-feed use to be administered to pigs** (EMEA/V/A/137). The Committee noted a peer review report and the comments received.

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 endorsed the rapporteur's assessment report on the data submitted following the Committee's recommendations for **Versican Plus DHPPi/L4R** (EMEA/V/C/002759/REC/016), **Versican Plus DHPPi/L4** (EMEA/V/C/003679/REC/011), **Versican Plus DHPPi** (EMEA/V/C/003678/REC/016), **Versican Plus Pi** (EMEA/V/C/003681/REC/011), **Versican Plus Pi/L4R** (EMEA/V/C/003682/REC/013) and **Versican Plus Pi/L4** (EMEA/V/C/003683/REC/012), which are now considered completed.

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 19.06.2020 – 16.07.2020:

Product	Period
Aftovaxpur DOE (EMEA/V/C/002292)	15.07.2019 – 14.07.2020
Canigen L4 (EMEA/V/C/004079)	03.07.2019 – 02.07.2020
Circovac (EMEA/V/C/000114)	21.06.2019 – 20.06.2020

Product	Period
Clynav (EMEA/V/C/002390)	27.06.2019 – 26.06.2020
Convenia (EMEA/V/C/000098)	19.06.2019 – 18.06.2020
Equilis Prequenza (EMEA/V/C/000094)	08.07.2019 – 07.07.2020
Equilis Prequenza Te (EMEA/V/C/000095)	08.07.2019 – 07.07.2020
Equilis Te (EMEA/V/C/000093)	08.07.2019 – 07.07.2020
Equioxx (EMEA/V/C/000142)	25.06.2019 – 24.06.2020
Eryseng (EMEA/V/C/002761)	04.07.2019 – 03.07.2020
Eryseng Parvo (EMEA/V/C/002762)	08.07.2019 – 07.07.2020
HorStem (EMEA/V/C/004265)	19.06.2019 – 18.06.2020
Innovax-ILT (EMEA/V/C/003869)	03.07.2019 – 02.07.2020
Leucofeligen FeLV/RCP (EMEA/V/C/000143)	25.06.2019 – 24.06.2020
Melovem (EMEA/V/C/000152)	07.07.2019 – 06.07.2020
Nobivac L4 (EMEA/V/C/002010)	16.07.2019 – 15.07.2020
Posatex (EMEA/V/C/000122)	23.06.2019 – 22.06.2020
Prevomax (EMEA/V/C/004331	19.06.2019 – 18.06.2020
ProZinc (EMEA/V/C/002634)	12.07.2019 – 11.07.2020
Reconcile (EMEA/V/C/000133)	08.07.2019 – 07.07.2020
Sevohale (EMEA/V/C/004199)	21.06.2019 – 20.06.2020
Spironolactone Ceva (EMEA/V/C/000105)	20.06.2019 – 19.06.2020
Suprelorin (EMEA/V/C/000109)	10.07.2019 – 09.07.2020
Versican Plus DHPPi (EMEA/V/C/003679)	04.07.2019 – 03.07.2020
Versican Plus Pi (EMEA/V/C/003681)	04.07.2019 – 03.07.2020

5.4 Renewals

- The Committee adopted by consensus (27 members attending of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for the renewal of the marketing authorisation for **Suvaxyn Circo + MH RTU** (EMEA/V/C/003924/R/0015), and recommended that the authorisation should now be indefinite. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.

- The Committee adopted by consensus (27 members attending of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for the renewal of the marketing authorisation for **Imrestor** (EMEA/V/C/002763/R/0015), and recommended that the authorisation should now be indefinite. The Icelandic and Norwegian CVMP members 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 01.02.2017-31.01.2020 for **Activyl Tick Plus** with a recommendation to amend section 4.6 'Adverse reactions (frequency and seriousness)' of the SPC and the corresponding section of the package leaflet.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.02.2017-31.01.2020 for **Cardalis** with a recommendation to amend the section 4.6 'Adverse reactions (frequency and seriousness)' of the SPC and the corresponding section of the package leaflet.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.01.2017-31.12.2019 for **Onsior** with a recommendation to amend the section 4.6 'Adverse reactions (frequency and seriousness)' of the SPC and the corresponding section of the package leaflet.
- The Committee endorsed the following rapporteur's assessment reports on PSURs concluding that no changes to the product literature or other regulatory actions were required for:

Product	**Period**
Equilis Prequenza (EMEA/V/C/000094)	01.02.2017-31.01.2020
Equilis Prequenza Te (EMEA/V/C/000095)	01.02.2017-31.02.2020
Eravac (EMEA/V/C/004239)	01.04.2019-31.03.2020
Exzolt (EMEA/V/C/004344)	01.09.2019-29.02.2020
Innovax ND IBD (EMEA/V/C/004422)	01.09.2019-29.02.2020
Sedadex (EMEA/V/C/004202)	13.02.2019-29.02.2020
Suvaxyn Circo (EMEA/V/C/004242)	01.09.2019-29.02.2020
Suvaxyn PRRS MLV (EMEA/V/C/004276)	01.09.2019-29.02.2020
UpCard (EMEA/V/C/003836)	01.02.2019-31.01.2020

- 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 concept paper on the development of further guidance on medicated premixes which will be forwarded to the VICH Steering Committee.

- The Committee endorsed the draft VICH concept paper proposing adoption of ICH Q7 on good manufacturing practice for active pharmaceutical ingredients. The EMA Secretariat will inform the VICH Steering Committee.

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 expert group on models of consumer exposure concerning alternative intake calculation models for estimation of consumer exposure to residues.

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 13 July 2020 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)

- There were no items for discussion.

7.6 Antimicrobials Working Party (AWP)

- The Committee received a verbal report from the AWP chair on the meeting held on 26-27 May 2020 and noted the draft minutes of the meeting.

7.7 Immunologicals Working Party (IWP)

- The Committee re-elected E. Werner as IWP chair for a 3-year mandate. The Committee also endorsed the recommendation of the selection committee and appointed a new panel of members under the revised mandate, objectives and rules of procedure for the IWP.

7.8 Pharmacovigilance Working Party (PhVWP-V)

- The Committee received a verbal report from the PhVWP-V chair on the meeting held on 7-8 July 2020 and noted the agenda and draft summary record of the meeting.
- The Committee adopted a revised question and answer document on adverse event reporting (EMA/CVMP/PhVWP/145186/2013).

7.9 Novel therapy groups and related issues

- The Committee adopted a questions and answers document on evaluation of target animal safety for stem cell products for veterinary use (EMA/CVMP/ADVENT/791717/2016).

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 document was circulated for information:

- Minutes of the SAWP-V meeting held on 15 May 2020.

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 commercially confidential

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.

- There were no items for discussion.

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 (CMDv)

- The Committee noted the minutes of the 18-19 June 2020 CMDv meeting as well as the draft agenda of the meeting held on 16-17 July 2020.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee was informed of the outcome of the EMA survey to applicants and MAHs on intended submissions and potential delays until December 2020.
- The Committee was informed of the potential issues or procedures requiring CVMP decision via written procedure during August 2020.
- The Committee noted the launch (link) of a two-month public consultation of the draft European Medicines Agencies Network Strategy to 2025 with the deadline for comments (link) on 4 September 2020.

13. LEGISLATION

- The Committee adopted a scientific problem analysis and recommendations to ensure a safe and efficient oral administration of veterinary medicinal products via routes other than medicated feed, further to the request from the European Commission related to implementing measures under Article 106(6) of Regulation (EU) 2019/6.
- The Committee adopted a draft concept paper for the development of a reflection paper on criteria for the application of Article 40(5) of Regulation (EU) 2019/6 (EMA/CVMP/340959/2020) for a two-month period of public consultation from 20 July 2020.
- The Committee received a verbal report on work progress of the expert group concerning provision of scientific recommendations on implementing act to Regulation (EU) 2019/6 on the list of antimicrobials reserved for the treatment of certain infections in humans.

14. ANY OTHER BUSINESS

- Upon the completion of the July 2020 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 July 2020 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 Branchev	Involvement in discussions only and cannot act as rapporteur or peer reviewer for **KRKA**	4.3 – Injectable Vitamin A
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	Tita-Maria Muhonen	Involvement in discussions only and cannot act as rapporteur or peer reviewer for **Orion oyj**	5.6 – One item
FR	Sylvie Louet	Full involvement	
HU	Gábor Kulcsár	Full involvement	
IE	J. Gabriel Beechinor	Full involvement	
IT	Paolo Pasquali	Full involvement	
LU	Marc Schmit	Full involvement	
LV	Zanda Auce	Full involvement	
NL	Peter Hekman	Full involvement	
PL	Anna Wachnik-Święcicka	Involvement in discussions only and cannot act as rapporteur or peer reviewer for **Bayer**	4.3 - Betamox LA 5.6 – One item
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	Rory Breathnach	Full involvement	
Co-opted	G. Johan Schefferlie	Full involvement	
Co-opted	Mary O'Grady	Full involvement	
Co-opted	Ricardo Carapeto García	Full involvement	
IS	Peter Zsolt Fekete	Full involvement	

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
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
AT	Manuela Leitner	Full involvement	
CZ	Leona Nepejchalová	Full involvement	
DE	Andrea Golombiewski	Full involvement	
DK	Merete Blixenkrone-Møller	Full involvement	
FR	Christine Miras	Full involvement	
IE	Paul McNeill	Full involvement	
NL	Jacqueline Poot	Full involvement	
PL	Ewa Augustynowicz	Full involvement	
SE	Carina Bergman	Full involvement	
SI	Boris Kolar	Full involvement	
NO	Annelin Aksdal Bjelland	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	Jan Joseph	Full involvement	
BE	Michel Goret	Full involvement	
CZ	Dana Halová	Full involvement	
CZ	Eva Pomezná	Full involvement	
CZ	Lucie Pokludová	Full involvement	
DE	Anke Finnah	Full involvement	
DE	Christina Bredtmann	Full involvement	
DE	Nikola Lange	Full involvement	
DE	Roswitha Merkel	Full involvement	
DE	Uta Herbst	Full involvement	
DK	Kathrine Just Andersen	Full involvement	
DK	Nanna Aaby Kruse	Full involvement	
DK	Susanne Havn Aamand	Full involvement	
ES	Carles Cristòfol Adell	Full involvement	
ES	Teresa Gómez Martínez	Full involvement	
FI	Minna Leppänen	Full involvement	
FR	Damien Bouchard	Full involvement	
FR	Hicham Ait Lbacha	Full involvement	
FR	Nathalie Bridoux	Full involvement	
NL	Anita Bottger	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
PT	Luisa Vieira Peixe	Full involvement	

CVMP working parties and CMDv	Chair
ADVENT	---
AWP	Christine Schwarz
CMDv	---
ERAWP	Ricardo Carapeto García
EWP-V	Cristina Muñoz Madero
IWP	Esther Werner
J3Rs WG	---
PhVWP-V	Els Dewaele
QWP	Mary O'Grady *(Veterinary vice chair)*
SAWP-V	Frida Hasslung Wikström
SWP-V	Stefan Scheid

Observer from the European Commission	
Attended	

Observers from Swissmedic	
Remotely	

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