



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 February 2023
EMA/CHMP/68823/2023
Human Medicines Division

Committee for medicinal products for human use (CHMP) PROM¹ minutes for the meeting on 13 February 2023

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

13 February 2023, 09:00–14:00, virtual meeting

Disclaimers

Some of the information contained in this document is considered commercially confidential or sensitive and therefore not disclosed.

Of note, agendas and minutes are working documents primarily designed for CHMP members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned in the agenda/minutes cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as 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).

¹ The CHMP PROM is a meeting to discuss CHMP organisational matters and other topics in preparation for the CHMP Plenary meeting. It is a virtual meeting, which usually takes place on Monday before the CHMP Plenary meeting. CHMP members, working party chairs and national experts together with EMA staff are participating in this forum. Depending on the nature of the issue and availability of documents and experts some PROM topics can be discussed at the CHMP Plenary.



Table of contents

1.	Agenda and Minutes	4
1.1.	Welcome and declarations of interest of members, alternates and experts.....	4
1.2.	Adoption of agenda.....	4
1.3.	Adoption of the minutes	4
2.	Quality Domain	4
2.1.	Biologics Working Party (BWP)	4
2.2.	Quality Working Party (QWP).....	5
2.3.	Biosimilar Medicinal Product Working Party (BMWP)	5
2.4.	Action: For information Quality Innovation Group (QIG).....	5
2.5.	Formulation Expert Group (FEG).....	5
3.	Non-Clinical Domain	6
3.1.	Non-Clinical Working Party (NcWP).....	6
3.2.	Joint 3Rs Replacement, Reduction and Refinement Working Party (3Rs).....	6
4.	Methodology Domain	7
4.1.	Methodology Working Party (MWP).....	7
4.2.	Pharmacokinetics Working Party (PKWP).....	8
5.	Clinical Domain	8
5.1.	Central Nervous System Working Party (CNSWP)	8
5.2.	Cardiovascular Working Party (CVSWP)	8
5.3.	Oncology Working Party (ONCWP)	8
5.4.	Rheumatology and Immunology Working Party (RIWP).....	9
5.5.	Infectious Disease Working Party (IDWP).....	9
5.6.	Vaccines Working Party (VWP).....	9
5.7.	Haematology Working Party (HaemWP).....	10
5.8.	Scientific Advisory Groups (SAGs) and Ad-hoc Expert Groups (AHEG).....	10
6.	Patients, Healthcare Professionals and Consumers	10
6.1.	Patients and Consumers Working Party (PCWP) Healthcare Professionals Working Party (HCPWP)	10
7.	Harmonisation and consistency groups	10
7.1.	International Council on Harmonisation (ICH)	10
7.2.	Guideline Consistency Group (GCG).....	10
7.3.	Summary of product characteristics Advisory Group	10

8.	Joint groups and collaboration with other Scientific committees	10
8.1.	Joint CHMP/CVMP/CMDh/CMDv Working Group on Active Substance Master File Procedures (ASMF WG)	10
8.2.	Collaboration with other Scientific committees	11
9.	Regulatory/Organisational matters	11
9.1.	Regulatory Issues/new legislation	11
9.2.	CHMP organisation/templates	11
10.	Product development support	12
10.1.	Scientific Advice Working Party (SAWP).....	12
10.2.	Innovation Task Force	13
11.	Product related topics	13
11.1.	Preview CHMP Plenary.....	13
11.2.	glofitamab - Orphan - EMEA/H/C/005751; epcoritamab - Orphan - EMEA/H/C/005985	13
12.	Any Other Business	14
12.1.	Rapporteurships	14
12.2.	Real World Evidence update, including DARWIN EU	14
12.3.	OPEN experts – phase 2.....	14
12.4.	Call for membership of the CHMP drafting group on patient experience data	14
12.5.	Update on collaboration with HTA-bodies	15
12.6.	CHMP strategic, review and learning meeting under the Swedish presidency of the Council of the European Union.....	15
13.	List of Participants	16

1. Agenda and Minutes

1.1. Welcome and declarations of interest of members, alternates and experts

In accordance with the Agency's policy on handling of declarations of interests of scientific Committees' members and experts, based on the declarations of interest submitted by the Committee members, alternates and experts and based on the topics in the agenda of the current meeting, the Committee Secretariat announced the restricted involvement of some meeting participants in upcoming discussions as included in the pre-meeting list of participants and restrictions. See Annex of the current document for the list of participants and restrictions in relation to declarations of interests applicable to the items of this meeting. As the PROM is a preparatory meeting for the CHMP plenary session, restrictions and declarations of interests applicable to the items in the draft agenda of the upcoming CHMP plenary session were also considered.

Participants in this meeting were asked to declare any changes, omissions or errors to their declared interests and/or additional restrictions concerning the matters for discussion. No new or additional interests or restrictions were declared. Discussions, deliberations and voting took place in full respect of the restricted involvement of Committee members and experts in line with the relevant provisions of the Rules of Procedure and as included in the list of participants. All decisions taken at this meeting were made in the presence of a quorum of members. All decisions, recommendations and advice were agreed by consensus, unless otherwise specified.

1.2. Adoption of agenda

The CHMP adopted the PROM agenda for the 13 February 2023 meeting.

1.3. Adoption of the minutes

The CHMP PROM Minutes of 13 February 2023 meeting will be adopted at the February 2023 CHMP plenary.

2. Quality Domain

2.1. Biologics Working Party (BWP)

Chairs: Sol Ruiz, Sean Barry

2.1.1. Call for nomination for the BWP Chair

Sol Ruiz's last term as BWP chair will expire in February 2023. A call for nomination for a new BWP chair was launched during the December 2022 PROM meeting. Nominations should be sent to the Agency by **10 February 2023**.

Action: For information

The CHMP noted that the call for nomination for a BWP Chair was extended until **17 February 2023**. Nominations should be sent to the Agency.

The election is planned for the February 2023 CHMP Plenary meeting.

2.1.2. Agenda and Minutes

- Draft agenda of the BWP meeting to be held F2F on 13-15 February 2023
- Final minutes of the BWP meeting held via Webex on 5-7 December 2022

Action: For information

The CHMP noted the agenda and minutes.

2.2. Quality Working Party (QWP)

Chairs: Blanka Hirschlerova, Marie-Hélène Sabinotto, Laivi Saaremäe

2.2.1. Agenda and Minutes

- Final agenda and minutes for QWP-CT meeting held virtually on 18 January 2023

Action: For information

The CHMP noted the agenda and minutes.

2.3. Biosimilar Medicinal Product Working Party (BMWP)

Chairs: Elena Wolff-Holz, Niklas Ekman

2.3.1. Call for nominations for the BMWP members - extended till 28 February 2023

Call for nominations for members of the BMWP following the stepping down of 4 members. The BMWP would welcome candidates with expertise primarily in clinical assessment of biosimilars including PK aspects.

Nominations should be sent to the Agency **by 28 February 2023**. Candidates are kindly asked to submit a brief CV in support of their candidature together with a cover letter highlighting their expertise.

Action: For information

The CHMP noted the call for nomination for BMWP members which is extended until 28 February 2023.

2.4. Action: For information Quality Innovation Group (QIG)

No topics

2.5. Formulation Expert Group (FEG)

No topics

3. Non-Clinical Domain

3.1. Non-Clinical Working Party (NcWP)

Chairs: Susanne Brendler-Schwaab, Karen van Malderen

3.1.1. Agenda and minutes

- Draft minutes for the NcWP meeting held virtually on 11 and 18 January 2023
- Draft agenda for the NcWP meeting to be held virtually on 14-15 February 2023

Action: For information

The CHMP noted the agenda and minutes.

3.1.2. CMDh questions to NcWP on new nitrosamines

The CMDh requests that the NcWP determines the acceptable intake for:

- N-nitroso-2,6-pipecoloxilidide
- N-nitroso-valaciclovir (impurity C)

based on lifetime daily exposure including information on the points of departure and methodology used.

Action: For adoption

The CHMP endorsed the CMDh questions to NcWP on new nitrosamines. The Committee requested an update on the nitrosamine implementation at a future meeting.

3.2. Joint 3Rs Replacement, Reduction and Refinement Working Party (3Rs)

Chairs: Sonja Beken, Sarah Adler-Flindt

3.2.1. Agenda and minutes

- Draft minutes for the 3RsWP meeting held virtually on 23 November 2022
- Draft agenda for the 2-day face-to-face 3RsWP plenary meeting on 28 February and 1 March 2023. The first day will be dedicated to a targeted stakeholder meeting to be held in a virtual setting.

Action: For information

The CHMP noted the agenda and minutes.

3.2.2. 3RsWP expert attendance to EDQM-EPAA conference on pyrogenicity testing

This international conference jointly hosted by the EDQM, Council of Europe, and the European Partnership for Alternative Approaches to Animal Testing (EPAA), European Commission, will shed light on how the European Pharmacopoeia is, after 50 years of loyal – but animal-based – service, withdrawing the rabbit pyrogen test (RPT) from its texts.

Scientific progress has delivered new and humane methods (the in vitro monocyte-activation test, or MAT) and, together with the EPAA, the EDQM wishes to present how the transition to the MAT and the challenges encountered in the process are being successfully managed in the pharmaceutical world.

Sonja Beken, chair of the 3RsWP, will be delivering the 3RsWP regulatory perspective on the pyrogenicity testing based on the strategic vision towards the regulatory acceptance of new alternative methods from the EMA Regulatory Science strategy 2025 and 3RsWP 3-year workplan which has already been endorsed by CHMP.

Action: For endorsement

The CHMP endorsed the attendance of the 3RsWP chair, Sonja Beken, at the EDQM-EPAA conference on pyrogenicity testing.

4. Methodology Domain

4.1. Methodology Working Party (MWP)

Chairs: Kit Roes, Kristin Karlsson

4.1.1. Nomination of Methodology ESEC experts

Nomination by MWP of the experts to enter the Methodology European Specialised Expert Community (ESEC).

Action: For endorsement

The CHMP endorsed the list of experts for the Methodology European Specialised Expert Community (ESEC).

4.1.2. Nomination of Methodology Modelling & Simulation Operational Expert Group (MSOEG)

Nomination by MWP of the experts to enter the Modelling and Simulation Operational Expert Group (MSOEG).

Action: For endorsement

The CHMP endorsed the list of experts for the Modelling and Simulation Operational Expert Group (MSOEG).

4.1.3. Nomination of Methodology Biostatistics Operational Expert Group (BSOEG)

Nomination by MWP of the experts to Biostatistics Operational Expert Group (BSOEG).

Action: For endorsement

The CHMP endorsed the list of experts for the Biostatistics Operational Expert Group (BSOEG).

4.1.4. Agenda and Minutes

- Final Agenda and Minutes for MWP meeting held by teleconference on 19 January 2023

Action: For information

The CHMP noted the agenda and minutes.

4.2. Pharmacokinetics Working Party (PKWP)

Chair: Carolien Versantvoort

4.2.1. MWP (PKWP) response to CMDh questions on lapatinib product-specific bioequivalence guidance (PSBGL)

CMDh sent a query for MWP (PKWP) input in November 2022 in the context of two ongoing MAAs via DCP for lapatinib containing products regarding the acceptability of the supporting bioequivalence studies and the lapatinib PSBGL.

PKWP (MWP) has discussed the issue in the meantime and agreed a response.

Action: For adoption

The CHMP adopted the MWP (PKWP) response to CMDh on lapatinib product-specific bioequivalence guidance (PSBGL).

5. Clinical Domain

5.1. Central Nervous System Working Party (CNSWP)

No topics

5.2. Cardiovascular Working Party (CVSWP)

Chairs: Alar Irs, Patrick Vrijlandt

5.2.1. Agenda and Minutes

- Final Agenda and Minutes for CVS WP meeting held by teleconference on 2 February 2023

Action: For information

The CHMP noted the agenda and minutes.

5.2.2. Nomination of Cardiovascular ESEC experts

Update on the ongoing call of experts to enter the Cardiovascular European Specialised Expert Community (ESEC).

Action: For endorsement

The CHMP endorsed the list of experts for the Cardiovascular European Specialised Expert Community (ESEC). It was also clarified that external experts can be nominated for ESECs.

5.3. Oncology Working Party (ONCWP)

Chair: Pierre Demolis, Vice-Chair: Olli Tenhunen

5.3.1. Nomination of Oncology ESEC experts

Nomination by ONCWP of an expert to enter the Oncology European Specialised Expert Community (ESEC).

Nomination(s) received

Action: For endorsement

The CHMP endorsed the additional experts for the Oncology European Specialised Expert Community (ESEC).

5.3.2. Proposed Oncology ESEC webinar on AML (Acute Myeloid Leukaemia)

3rd Oncology ESEC webinar is proposed on AML following the same organisation of the 2 webinars. PDCO representative will also be invited together with external paediatric experts. Tentative date of the webinar: 17-03-2023.

Action: For endorsement

The CHMP endorsed the proposed Oncology ESEC webinar on AML (Acute Myeloid Leukaemia), to be scheduled on 17 March 2023, possibly from 2 – 3:30 pm.

5.3.3. Agenda and Minutes

- Agenda of the ONCWP meeting held by teleconference on 13 January 2023
- Minutes of the ONCWP meeting held by teleconference on 25 November 2022

Action: For information

The CHMP noted the agenda and minutes.

5.4. Rheumatology and Immunology Working Party (RIWP)

Chair: Caroline Auriche Benichou

5.4.1. Call for nominations for the RIWP Vice-Chair

Candidates are kindly asked to submit a brief CV in support of their candidature together with a cover letter highlighting their expertise. Nominations should be sent to the Agency **by 13 March 2023**. Proposed candidates must be already members of the RIWP.

Elections will take place at the March 2023 CHMP Plenary meeting.

Action: For information

The CHMP noted the call for nominations for the RIWP Vice-Chair.

5.5. Infectious Disease Working Party (IDWP)

No topics

5.6. Vaccines Working Party (VWP)

No topics

5.7. Haematology Working Party (HaemWP)

No topics

5.8. Scientific Advisory Groups (SAGs) and Ad-hoc Expert Groups (AHEG)

No topics

6. Patients, Healthcare Professionals and Consumers

6.1. Patients and Consumers Working Party (PCWP) Healthcare Professionals Working Party (HCPWP)

PCWP: Co-chair: Juan Garcia Burgos (EMA)

HCPWP: Co-chair: Juan Garcia Burgos (EMA)

6.1.1. Agenda and minutes

- Agenda from the PCWP and HCPWP meeting to be held on 03 March 2023
- Minutes from the PCWP and HCPWP meeting held virtually on 15 November 2022

Action: for information

The CHMP noted the agenda and minutes.

7. Harmonisation and consistency groups

7.1. International Council on Harmonisation (ICH)

No topics

7.2. Guideline Consistency Group (GCG)

No topics

7.3. Summary of product characteristics Advisory Group

No topics

8. Joint groups and collaboration with other Scientific committees

8.1. Joint CHMP/CVMP/CMDh/CMDv Working Group on Active Substance Master File Procedures (ASMF WG)

No topics

8.2. Collaboration with other Scientific committees

8.2.1. PRAC report to CHMP

Chair: Sabine Straus

Summary of recommendations and advice of PRAC meeting held on 06-09 February 2023.

Action: For information

The CHMP noted the summary of recommendations and advice.

8.2.2. CMDh proposal regarding mutagenic impurity in products containing Tenofovir Disoproxil

Proposed letter to all MAHs.

Action: For endorsement

The CHMP endorsed the letter to marketing authorisation holders. Furthermore, the lines-to-take document was endorsed.

9. Regulatory/Organisational matters

9.1. Regulatory Issues/new legislation

No topics

9.2. CHMP organisation/templates

9.2.1. Readers Guidance template

Introduction of tick boxes for RWD/RWE as possibly included in the product dossier and possible request for research questions with the support of EMA.

See also 12.2.

CHMP: Johann Lodewijk Hillege

Action: For adoption

The CHMP adopted the updated Readers Guidance template.

9.2.2. CHMP co-opted membership

Launch of a call for nominations for a CHMP co-opted member with biostatistics/clinical trial methodology expertise.

Nominations may include persons who have been nominated as alternates in the Committee. Nominations should be accompanied by a recommendation specifying the competence. Where possible, a detailed CV to support the specific expertise required should be included, although reference may also be made to the information held by the EMA with respect to the European Expert List, which includes information on areas of expertise and a CV for each expert.

Nominations should be sent to the CHMP secretariat by **15 February 2022**. The election is planned during the February 2023 plenary meeting.

Nomination(s) received

Action: For information

The CHMP noted the call for nominations for the CHMP co-opted membership.

9.2.3. CHMP meeting calendar

Logistics of 3-day remote CHMP plenary meeting in April 2023 and meeting dates for 2025 and 2026.

Action: For information

The CHMP noted the meeting dates for 2025 and 2026.

Furthermore, the members noted that a preparatory meeting might be scheduled on 21 April to allow pre-discussions for the 3-day CHMP plenary meeting on 24 – 26 April 2023.

9.2.4. Practical working instructions for Multinational Assessment Teams (MNATs)

5-year update of informal working instructions for MNATs.

Action: For information

The CHMP noted the updated informal working instructions for MNATs.

9.2.5. CHMP learnings

Collection, discussion and recording of CHMP learnings.

CHMP: Outi Mäki-Ikola

Action: For discussion

The CHMP endorsed the proposed learnings.

10. Product development support

10.1. Scientific Advice Working Party (SAWP)

Chair: Paolo Foggi, Vice-Chair: Pierre Demolis

10.1.1. Appointment of CHMP peer review for SA

Action: For information

The CHMP noted the list.

10.1.2. Agenda and Table of Decisions

- Agenda from 06-09 February 2023 meeting held by Webex
- Draft Table of Decisions from 06-09 February 2023 meeting held by Webex

Action: For information

The CHMP noted the agenda and the table of decisions.

10.1.3. Revised SAWP mandate

SAWP mandate, revision 17

Action: For adoption

The CHMP adopted the revised SAWP mandate.

10.2. Innovation Task Force

10.2.1. ITF meeting

Meeting date: 22 February 2023

Action: For adoption

The CHMP endorsed the meeting.

10.2.2. ITF meeting

Meeting date: 02 March 2023

Action: For adoption

The CHMP endorsed the meeting.

11. Product related topics

11.1. Preview CHMP Plenary

CHMP: Harald Enzmann

Action: For information

The CHMP chair flagged some procedures on the agenda of the upcoming plenary.

11.2. glofitamab - Orphan - EMEA/H/C/005751; epcoritamab - Orphan - EMEA/H/C/005985

Roche Registration GmbH; treatment of diffuse large B-cell lymphoma

AbbVie Deutschland GmbH & Co. KG; treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL)

Scope: Pre-discussion in view of the adoption of D180 LoOI at February plenary

Action: For discussion

The CHMP had a pre-discussion in view of the adoption of D180 LoOI at the February plenary.

12. Any Other Business

12.1. Rapporteurships

Update.

Action: For information

The CHMP noted the update.

12.2. Real World Evidence update, including DARWIN EU

This is a quarterly progress update on RWE and the establishment of DARWIN EU. The objective of the presentation is to inform the CHMP of the finalisation of year 1 studies conducted via DARWIN EU, prioritisation and selection of studies and data partners for year 2, and the RWE experience report and new RWE MMD folder.

Action: For information

The CHMP noted the quarterly progress update on RWE and the establishment of DARWIN EU.

The CHMP noted the summary on the DARWIN EU - drug utilisation of Antibiotics in the 'Watch' category of the WHO AWaRe classification of antibiotics for evaluation and monitoring of use, [EU PAS Register study code: EUPAS103381](#).

The members noted the completion of the first DARWIN EU studies and related plans for a press release. Furthermore, they were informed that a report on the RWE experience gained in the past 1.5 years will be prepared by Q2 2023.

12.3. OPEN experts – phase 2

Discuss and agree on the process and products to be considered for the expansion of the OPEN scope.

Action: For adoption

The CHMP welcomed the expansion of the OPEN scope and endorsed the process and products to be considered for the expansion. Whereas phase 1 of the OPEN pilot focused on COVID-19 vaccines and therapeutics, the phase 2 will expand to antimicrobial medicinal products, PRIME products, medicinal products responding to health threats or public health emergencies and to facilitate a cross regional collaborative assessment of CMC aspects. The new pilot foresees the identification of eligible products twice a year in collaboration with CHMP. A close collaboration with OPEN partners was envisaged, including sharing documents during the assessment phase and providing comments, but excluding a contribution to the CHMP conclusions during the final benefit-risk decision.

12.4. Call for membership of the CHMP drafting group on patient experience data

As a follow-up from the multistakeholder workshop on patient experience data in medicines development and regulatory decision-making that took place in September 2022, the outcomes defined that the Agency will elaborate a reflection paper to provide advice on the

best EU approach to generate and collect patient experience data. This action is also included in the CHMP workplan 2023 to be adopted this month.

We are therefore seeking a CHMP representative to take part in the drafting of the reflection paper. The work would take place in 2023, with the aim to have a draft of the paper circulated for public consultation by the end of the year.

Action: For discussion

The CHMP noted the call for membership of the CHMP drafting group on patient experience data. Nominations should be sent to the Agency by **17 February** 2023.

12.5. Update on collaboration with HTA-bodies

This topic is part of the CHMP Work Plan 2023.

Action: For information

The CHMP noted the update on collaboration with HTA-bodies. The CHMP was informed about the governance of the HTA cooperation under the new Regulation, including four CG subgroups. The secretariat for these groups will be provided by the European Commission. Furthermore, the Committee noted the planned EMA/EUnetHTA bilaterals with the closing event being scheduled for mid-September 2023.

12.6. CHMP strategic, review and learning meeting under the Swedish presidency of the Council of the European Union

Information on the SRLM under the Swedish presidency for the 1st part of 2023.

CHMP: Kristina Dunder

Action: For information

The CHMP noted the information on the SRLM under the Swedish presidency taking place 9-10 May 2023 in Uppsala, Sweden.

13. List of Participants

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda and for which restrictions apply
Harald Enzmann	Chair	Germany	No interests declared	
Daniela Philadelphly	Member	Austria	No interests declared	
Christian Gartner	Alternate	Austria	No interests declared	
Christophe Focke	Member	Belgium	No restrictions applicable to this meeting	
Karin Janssen van Doorn	Alternate	Belgium	No interests declared	
Margareta Bego	Member	Croatia	No interests declared	
Helena Panayiotopoulou	Member	Cyprus	No interests declared	
Ondřej Slanař	Member	Czechia	No restrictions applicable to this meeting	
Tomas Radimersky	Alternate	Czechia	No interests declared	
Aaron Sosa Mejia	Alternate	Denmark	No participation in final deliberations and voting on:	Wegovy - semaglutide - EMEA/H/C/005422/II/0009
Edward Laane	Alternate	Estonia	No restrictions applicable to this meeting	
Outi Mäki-Ikola	Member	Finland	No restrictions applicable to this meeting	
Johanna Lähteenvuo	Alternate	Finland	No interests declared	
Jean-Michel Race	Alternate	France	No interests declared	
Martina Weise	Member	Germany	No restrictions applicable to this meeting	
Janet Koenig	Alternate	Germany	No interests declared	
Konstantina Alexopoulou	Member	Greece	No interests declared	
Anastasia Mountaki	Alternate	Greece	No interests declared	
Robert Porszasz	Member	Hungary	No interests declared	
Beata Maria Jakline Ullrich	Alternate	Hungary	No interests declared	
Jayne Crowe	Member	Ireland	No interests declared	
Armando Genazzani	Member	Italy	No interests declared	
Elita Poplavska	Member	Latvia	No interests declared	
Vilma Petrikaite	Member	Lithuania	No interests declared	
Martine Trauffer	Member	Luxembourg	No interests declared	
John Joseph Borg	Member	Malta	No interests declared	
Johann Lodewijk Hillege	Member	Netherlands	No interests declared	
Ingrid Wang	Member	Norway	No interests declared	
Eva Skovlund	Alternate	Norway	No interests declared	
Ewa Balkowiec Iskra	Member	Poland	No interests declared	
Bruno Sepodes	Member (Vice-Chair)	Portugal	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda and for which restrictions apply
Fatima Ventura	Alternate	Portugal	No participation in final deliberations and voting on:	COVID-19 vaccines
Simona Badoi	Member	Romania	No interests declared	
Dana Gabriela Marin	Alternate	Romania	No interests declared	
Francisek Drafi	Member	Slovakia	No interests declared	
Kristina Nadrah	Member	Slovenia	No restrictions applicable to this meeting	
Nevenka Trsinar Brodt	Alternate	Slovenia	No interests declared	
Maria Concepcion Prieto Yerro	Member	Spain	No interests declared	
Kristina Dunder	Member	Sweden	No interests declared	
Filip Josephson	Alternate	Sweden	No interests declared	
Carla Torre	Co-opted member	Portugal	No interests declared	
Jan Mueller-Berghaus	Co-opted member	Germany	No interests declared	
Blanka Hirschlerova	Co-opted member	Czechia	No interests declared	
Susanne Høpner Rasmussen	Expert - via WebEx*	Denmark	No interests declared	
Deirdre Mannion	Expert - via WebEx*	Denmark	No restrictions applicable to this meeting	
Paolo Petracci	Expert - via WebEx*	France	No interests declared	
Paula Contreras Alarcón	Expert - via WebEx*	Spain	No participation in discussion, final deliberations and voting on:	epcoritamab - Orphan - EMEA/H/C/005985 upadacitinib - EMEA/H/C/004760/II/0027
Glenn Lastennet	Expert - via WebEx*	France	No interests declared	
Mette Tranholm	Expert - via WebEx*	Denmark	No interests declared	
Martina Perini	Expert - via WebEx*	Italy	No participation in discussion, final deliberations and voting on:	pegunigalsidase alfa - Orphan - EMEA/H/C/005618
Luca Santi	Expert - via WebEx*	Italy	No restrictions applicable to this meeting	
Michal Zwiewka	Expert - via WebEx*	Germany	No interests declared	
Zuzana Jedlickova	Expert - via WebEx*	Germany	No interests declared	
Katja Findeisen	Expert - via WebEx*	Germany	No restrictions applicable to this meeting	
Nathalie Morgensztejn	Expert - via WebEx*	France	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda and for which restrictions apply
Isabelle PUFF	Expert - via WebEx*	France	No interests declared	
Martin van Gils	Expert - via WebEx*	Netherlands	No interests declared	
Nora Cascante Estepa	Expert - via WebEx*	Germany	No interests declared	
Sabine Mayrhofer	Expert - via WebEx*	Germany	No interests declared	
Meeting run with support from relevant EMA staff.				

Experts were evaluated against the agenda topics or activities they participated in.