12 June 2023
EMA/CHMP/266883/2023
Human Medicines Division

Committee for medicinal products for human use (CHMP)

PROM[1] minutes for the meeting on 12 June 2023

Vice-Chair: Bruno Sepodes

12 June 2023, 09:00–11:00, 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.

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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

CHMP adopted the PROM agenda for the 12 June 2023 meeting

1.3. Adoption of the minutes

CHMP PROM Minutes of 12 June 2023 meeting will be adopted at the June 2023 CHMP plenary.

2. Quality Domain

2.1. Biologics Working Party (BWP)

Chair: Sean Barry, Vice-Chair: Francesca Luciani

2.1.1. Concept Paper on the development of a Guideline on the quality aspects of mRNA vaccines

Concept paper for adoption by CHMP for 3-month public consultation.

Action: For adoption

The CHMP adopted the Concept Paper on the development of a Guideline on the quality aspects of mRNA vaccines for a 3-month public consultation.

2.1.2. Agenda and Minutes

- Draft agenda for the BWP meeting to be held face-to-face on 12-14 June 2023
- Final minutes for the BWP meeting held virtually on 15-17 May 2023

Action: for information

The CHMP noted the agenda and minutes.

2.1.3. Nominations of BWP members

Following the call for nominations launched in April, the BWP selection panel has recommended the new BWP members to be endorsed by CHMP at the June plenary meeting.

The proposed list of BWP members is tabled for information.

Action: For information

The CHMP noted the nominations of BWP members. The BWP members will be endorsed at the June CHMP plenary meeting.

2.2. Quality Working Party (QWP)

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

2.2.1. QWP response to the proposal of the European Pharmacopoeia Commission on the revision of the general monograph Pharmaceutical Preparations (2619)

QWP response to EDQM on their proposal to revise the general monograph Pharmaceutical Preparations (2619).

Chair: Blanka Hirschlerova

Action: For information

The CHMP noted the QWP response to the proposal of the European Pharmacopoeia Commission on the revision of the general monograph Pharmaceutical Preparations (2619).

2.2.2. Agenda and Minutes

- Final agenda and minutes for QWP-CT meeting held virtually on 17 May 2023

Action: For information

The CHMP noted the agenda and minutes.

2.2.3. Nominations of QWP members

Following the call for nominations launched in April, the QWP selection panel has recommended the new QWP members to be endorsed by CHMP at the June plenary meeting.

The proposed list of QWP members is tabled for information.

Action: For information

The CHMP noted the nominations of QWP members. The QWP members will be endorsed at the June CHMP plenary meeting.

2.3. Biosimilar Medicinal Product Working Party (BMWP)

Chair: vacant, Vice-Chair: Niklas Ekman

2.3.1. Nominations of BMWP members

Following the call for nominations launched in April, the BMWP selection panel has recommended the new BMWP members to be endorsed by CHMP at the June plenary meeting.

The proposed list of BMWP members is tabled for information.

Action: For information

The CHMP noted the nominations of BMWP members. The BMWP members will be endorsed at the June CHMP plenary meeting.

2.4. Quality Innovation Group (QIG)

Chair: Marcel Hoefnagel

2.4.1. Published report from the first Quality Innovation Group Listen and Learn Focus Group (LLFG)

The QIG organised the first Listen and Learn Focus Group (LLFG) meeting on 13 March 2023 focusing on two of its priority topics for 2023, namely continuous manufacturing (CM) of biologicals or end-to-end CM (all product classes) and decentralised manufacturing (DM). The report from the first Listen and Learn Focus Group has now been published.

Action: For information

The CHMP noted the published report from the first Quality Innovation Group Listen and Learn Focus Group (LLFG).

2.5. Formulation Expert Group (FEG)

No topics

3. Non-Clinical Domain

3.1. Non-Clinical Working Party (NcWP)

Chair: Susanne Brendler-Schwaab, Vice-Chair: Karen van Malderen

3.1.1. Agenda and Minutes

- Draft minutes for the NcWP meeting held virtually on 16-17 May 2023
- Draft agenda for the NcWP meeting to be held face-to-face on 13-14 June 2023

- Agenda of NcWP/NS OEG meeting with Industry stakeholders

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-sotalol
- N-nitroso-levofloxacin

The CMDh further request that the NcWP re-evaluates the acceptable intake for **N-nitroso-dabigatran** based on newly available information.

Action: For adoption

The CHMP endorsed the CMDh questions to NcWP on new nitrosamines.

3.1.3. Call for nominations of new NcWP member

Following the departure of Louise Bang-Lauritsen at the end of April 2023 the NcWP is launching a call for nomination of a new member.

Action: For information

The CHMP noted the call for nominations of new NcWP member.

3.1.4. Nomination of Non-clinical and New Approach Methodologies ESEC experts

Nomination by NcWP of the experts to enter the Non-clinical and New Approach Methodologies (NAMs) European Specialised Expert Community (ESEC).

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination by NcWP of the experts to enter the Non-clinical and New Approach Methodologies (NAMs) ESEC.

3.1.5. EMA response to MAH on mutagenic impurity CMIC in Tenofovir disoproxil containing medicinal products

After CMDh and CHMP consulted NcWP on the potential mutagenicity of CMIC in 2022, EMA and CMDh have sent a letter in March 2023 requesting MAHs of Tenofovir disoproxil containing products to tighten the limit of CMIC according to ICH M7(R2) guideline. EMA has now received a response from a MAH providing arguments for not supporting the new request and limit of 50ppm. EMA (RA and legal colleagues) with the support of the NcWP have prepared a draft response.

NcWP Chair: Susane-Brendler Schwaab

Action: For information

The CHMP noted the EMA response to the MAH on mutagenic impurity CMIC in tenofovir disoproxil containing medicinal products.

3.1.6. Request for external representation

Karen van Malderen (NcWP Vice-Chair) is proposed as EMA representative to the Annual Meeting of The American College of Toxicology, to be held face-to-face in Orlando, Florida. The meeting will take place in November 2023 and the session to which Karen can contribute is dedicated to the course on ICH S11 since Karen has been involved in the drafting and implementation of the ICH S11 guideline.

Action: For endorsement

The CHMP endorsed the request of Karen van Malderen (NcWP Vice-Chair) to represent EMA at the Annual Meeting of The American College of Toxicology, to be held face-to-face in Orlando, Florida.

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

Chair: Sonja Beken, Vice-Chair: Sarah Adler-Flindt

3.2.1. Agenda and Minutes

- Minutes of the 3RsWP stakeholder and core group meetings held on 28 Feb and 01 March 2023
- Agenda of the 3RsWP meeting held virtually on 11 May 2023

Action: For information

The CHMP noted the agenda and minutes.

3.2.2. Publication of the report of the 3RsWP Public Session held as part of the February stakeholder meeting

On 28 February 2023, the newly established Joint CHMP/CVMP 3Rs Working Party (3RsWP) hosted a virtual public session to present the 3RsWP work plan and priorities for 2023. Stakeholders were given an opportunity to comment and provide their views on the working party's activities. This report provides a summary of the topics discussed during the public session, including the input received from the stakeholders during the interactive SLIDO session.

Link to event page: 3Rs Working Party (3RsWP) plenary meeting - Public session on the 2023 work plan

Action: For information

The CHMP noted the publication of the report of the 3RsWP Public Session held as part of the February stakeholder meeting.

3.2.3. Proposal for 3RsWP chair to attend two external meetings

- **2nd MPS (microphysiological systems) World Summit, including the CAAT T4 satellite workshop**: Proposal to have Sonja Beken, chair of the 3RsWP, attend representing CHMP/EMA. Involvement to include opening remarks, including an update on the activities of the 3RsWP, and participation in a session entitled "Biology-Inspired Microphysiological System Approaches to Advance Patient Benefit and Animal Welfare". The satellite workshop will take place on 23 and 24 June 2023 and the main summit will take place on 26-30 June, both in Berlin. Sonja Beken to attend in person. These topics are in line with the 3-year workplan of the non-clinical domain which has been endorsed by the domain governance and CHMP.
- **DIA 2023 Global Annual Meeting:** Proposal to have Sonja Beken, chair of the 3RsWP, attend representing CHMP/EMA. Involvement to include participation in a session on new approach methodologies (NAMs), giving regulatory perspective and update on activities of the 3RsWP in in relation to NAMs. The hybrid meeting will take place on 26 June in Boston. Sonja Beken to attend virtually. This topic is in line with the 3-year workplan of the non-clinical domain which has been endorsed by the domain governance and CHMP.

Action: For endorsement

The CHMP endorsed the proposal for Sonja Beken to attend the 2nd MPS (microphysiological systems) World Summit, including the CAAT T4 satellite workshop representing CHMP/EMA and to attend the DIA 2023 Global Annual Meeting representing CHMP/EMA.

3.2.4. Mandate objectives and rules of procedure for the Batch Release Testing Operational Experts Group (BRT OEG)

Presentation of the mandate of the Batch Release Testing Operational Experts Group (BRT OEG).

Action: For endorsement

The CHMP endorsed the mandate of the Batch Release Testing Operational Experts Group.

3.2.5. Call for nominations - Batch Release Testing OEG

The Batch Release Testing Operational Experts Group (BRT OEG) is mandated to review protocols related to the quality control and batch release testing of human and (mainly) veterinary medicinal products authorised via the centralised procedure between 1996 and 2013, with a view to promote and implement 3Rs-compliant testing methods within these processes as far as possible. This is a continuation of the activity initiated by the Joint CVMP/CHMP ad-hoc Expert Group on the application of the 3Rs (JEG 3Rs) and Joint CVMP/CHMP Working Group on the application of the 3Rs (J3RsWG) during the existence of these groups between 2011 and 2019, and is in line with the EMA Regulatory Science Strategy to 2025 which aims to promote in silico methodology (e.g. modelling), novel in vitro assays and systematic reviews to reduce animal use, particularly in toxicology/ epidemiology and batch control. Thus, the BRT OEG will support the operational work of the CHMP and CVMP regarding the identification and promotion of opportunities for the implementation of 3Rs approaches within quality control and batch release testing processes for centrally authorised human and veterinary medicines.

CHMP Committee members are invited to nominate experts with special knowledge and experience and/or strong interest in the area of: batch release testing of human and veterinary medicines, especially regarding biologicals/immunologicals/vaccines and botulinum neurotoxin products; alternative 3Rs-compliant testing models used or potentially suitable for the batch release and quality control testing of human and veterinary medicinal products; qualification and/or validation (incl. product-specific validation) and regulatory acceptance of 3Rs-compliant testing methods (e.g. performance standards, reference compounds); 3Rs principles implemented in in vivo studies, i.e. reduction and refinement, including statistical expertise.

Experts should be part of the European Regulatory Network (e.g. assessors working for a NCA, members of the different WPs or experts from academia in institutions/universities with relevant expertise for the BRT OEG).

Action: for information

The CHMP noted the call for nominations.

4. Methodology Domain

4.1. Methodology Working Party (MWP)

Chairs: Kit Roes, Kristin Karlsson

4.1.1. Agenda and minutes

- Final Agenda and Minutes for MWP meeting held in hybrid mode on 4 and 5 May 2023

Action: For information

The CHMP noted the agenda and minutes.

4.1.2. Nomination of Methodology ESEC experts

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

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination by MWP of the experts to enter the Methodology European Specialised Expert Community (ESEC).

4.2. Pharmacokinetics Working Party (PKWP)

No topics

5. Clinical Domain

5.1. Central Nervous System Working Party (CNSWP)

No topics

5.2. Cardiovascular Working Party (CVSWP)

Chair: Alar Irs, Vice-Chair: Patrick Vrijlandt

5.2.1. Agenda and Minutes

- Final Agenda and Minutes for CVS WP meeting held via teleconference on 1 June 2023

Action: For information

The CHMP noted the agenda and minutes.

5.2.2. Concept Paper on the need for revision of the Paediatric addendum to the guideline on clinical investigation of medicinal products for the treatment of pulmonary arterial hypertension (EMA/144703/2023)

Concept paper for adoption by CHMP for 3-month public consultation.

Experts: Clemens Mittmann, Patrick Vrijlandt

Action: For adoption

The CHMP adopted the Concept Paper on the need for revision of the Paediatric addendum to the guideline on clinical investigation of medicinal products for the treatment of pulmonary arterial hypertension (EMA/144703/2023) for 3-month public consultation.

5.2.3. Guideline on clinical investigation of medicinal products in the treatment or prevention of diabetes mellitus Rev. 2

Final Guideline.

Action: For adoption

The topic was postponed to the main plenary agenda and will be discussed during the June CHMP meeting.

5.3. Oncology Working Party (ONCWP)

Chair: Pierre Demolis, Vice-Chair: Olli Tenhunen

5.3.1. Nomination of oncology ESEC experts

Nomination by Oncology WP of experts to enter the Oncology European Specialised Expert Community (ESEC).

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination by Oncology WP of experts to enter the Oncology European Specialised Expert Community (ESEC).

5.4. Rheumatology and Immunology Working Party (RIWP)

No topics

5.5. Infectious Disease Working Party (IDWP)

No topics

5.6. Vaccines Working Party (VWP)

No topics

5.7. Haematology Working Party (HaemWP)

Chair: Daniela Philadelphy

5.7.1. Nomination of haematology ESEC experts

Nomination by Haematology WP of experts to enter the Haematology European Specialised Expert Community (ESEC).

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination by Haematology WP of experts to enter the Haematology European Specialised Expert Community (ESEC).

5.7.2. Agenda Blood cluster meeting

- Draft Agenda of the Blood cluster meeting to be held via teleconference on 23 June 2023

Action: For information

The CHMP noted the agenda.

5.7.3. Agenda FDA/HC/EMA meeting

- Ad hoc FDA/HC/EMA meeting to be held via teleconference on 14 June 2023

Action: For information

The CHMP noted the agenda of the FDA/HC/EMA meeting.

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: Marko Korenjak (ELPA)

HCPWP: Co-chair: Rosa Giuliani (ESMO)

6.1.1. CHMP Question to HCPWP

CHMP questions to HCPWP on SmPC guidance section 5.1.

Action: For adoption

Following-up on the discussions during the Swedish SRLM on the guidance document on the information to be included in section 5.1 "Pharmacodynamic properties" of the SmPC, which also includes description of clinical trials, and given that HCP are the primary users of the SmPC, the CHMP has drafted a LoQ to consult the HCP WP on a few specific aspects.

Members were invited to send comments for further discussion on the CHMP June plenary.

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

Chair: Kristina Dunder

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 5-8 June 2023.

Action: For information

The CHMP noted the summary of recommendations and advice.

8.2.2. Draft Scientific advice from EMA/CVMP under Article 107(6) of Regulation (EU) 2019/6 for the establishment of a list of antimicrobials which shall not be used in

accordance with Articles 112, 113 and 114 of the same Regulation or which shall only be used in accordance with these articles subject to certain conditions

Action: For information

The CHMP noted the Draft Scientific advice from EMA/CVMP under Article 107(6) of Regulation (EU) 2019/6 for the establishment of a list of antimicrobials.

9. Regulatory/Organisational matters

9.1. Regulatory Issues/new legislation

No topics

9.2. CHMP organisation/templates

9.2.1. CHMP learnings

Collection, discussion and recording of CHMP learnings.

CHMP: Outi Mäki-Ikola

Action: For discussion

The CHMP endorsed the proposed learnings.

9.2.2. CHMP meetings

Alternating face-to-face and virtual meetings.

Action: For discussion

The topic is postponed to the main plenary agenda and will be discussed during the June CHMP meeting.

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 5-8 June 2023 meeting held by Webex
- Draft Table of Decisions from 5-8 June 2023 meeting held by Webex

Action: For information

The CHMP noted the agenda and the table of decisions.

10.1.3. Call for interest for nomination of a replacement SAWP member

Call for interest for nomination of a replacement SAWP member following departure of Peter Mol.

Required areas of expertise: cardiovascular medicine, endocrinology/diabetes/metabolic diseases, oncology and haematology.

The new SAWP member and his/her alternate starting date will immediately follow their nomination by the CHMP PROM (10 July 2023).

Action: For information

The CHMP noted the call for interest for nomination of a replacement SAWP member.

10.2. Innovation Task Force

10.2.1. ITF meeting

Meeting date: 15 June 2023

Action: For adoption

The CHMP endorsed the meeting.

10.2.2. ITF meeting

Meeting date: 27 June 2023

Action: For adoption

The CHMP endorsed the meeting.

10.2.3. ITF meeting

Meeting date: 7 July 2023

Action: For adoption

The CHMP endorsed the meeting.

11. Product related topics

11.1. Preview CHMP Plenary

CHMP: Bruno Sepodes

Action: For information

The CHMP Vice-Chair flagged some procedures on the agenda of the upcoming plenary.

11.2. Preparation of oncology product-related discussions

Action: For discussion

The topic was postponed to the main plenary agenda and will be discussed during the June CHMP meeting.

12. Any Other Business

12.1. Rapporteurships

Update.

Action: For information

The CHMP noted the update.

12.2. EU Network Training Centre: annual planning cycle and rollout of Learning & Development Toolkit

EMA will remind the CHMP about the various EU NTC curricula and the importance of the annual planning cycle exercise for each of them. In this context, EMA will introduce the newly developed Learning & Development (L&D) Toolkit, an interactive guide to support the work of the EU NTC curriculum steering groups. The CHMP will also be informed of the fact that the EU NTC Training Steering Group co-chairs will provide an update on the status of the various EU NTC training curricula to HMA.

Action: For discussion

The CHMP noted the various EU NTC curricula and the importance of the annual planning cycle exercise for each of them. Furthermore, the CHMP expressed their full support to the EU NTC to reinforce capacity and capability within the EU Network and to ensure the sustainability of the system.

12.3. Call for expression of interest for specialists in chemical, radiological and/or nuclear medical countermeasures to support Emergency Task Force (ETF) activities

A call for expression of interest is open seeking specialists in chemical, radiological and/or nuclear medical countermeasures who may or may not belong to NCAs. Such experts are expected to contribute to the activities of the ETF on an ad hoc basis in the capacity of additional experts to the ETF.

Action: For information

The CHMP noted the Call for expression of interest for specialists in chemical, radiological and/or nuclear medical countermeasures to support Emergency Task Force (ETF) activities.

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
Bruno Sepodes	Vice-Chair; deputising for the Chair	Portugal	No interests declared	
Daniela Philadelphy	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	
Selma Arapovic Dzakula	Alternate	Croatia	No interests declared	
Emilia Mavrokordatou	Alternate	Cyprus	No participation in final deliberations and voting on:	COVID-19 vaccines
Tomas Radimersky	Member	Czechia	No interests declared	
Petr Vrbata	Alternate	Czechia	No interests declared	
Thalia Marie Estrup Blicher	Member	Denmark	No interests declared	
Aaron Sosa Mejia	Alternate	Denmark	No participation in final deliberations and voting on:	Refixia - nonacog beta pegol - EMEA/H/C/004178/II/0032
Outi Mäki-Ikola	Member	Finland	No restrictions applicable to this meeting	
Johanna Lähteenvuo	Alternate	Finland	No interests declared	
Martina Weise	Member	Germany	No restrictions applicable to this meeting	
Janet Koenig	Alternate	Germany	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	
Maria Grazia Evandri	Alternate	Italy	No interests declared	
Elita Poplavska	Member	Latvia	No interests declared	
Vilma Petrikaite	Member	Lithuania	No interests declared	
Martine Trauffler	Member	Luxembourg	No interests declared	
Alexandra Branchu	Alternate	Luxembourg	No participation in discussion, final deliberations and voting on:	Praluent - alirocumab - EMEA/H/C/003882/II/0078
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	

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	
Frantisek Drafi	Member	Slovakia	No interests declared	
Dorota Distlerova	Alternate	Slovakia	No interests declared	
Andreja Kranjc	Alternate	Slovenia	No interests declared	
Maria Concepcion Prieto Yerro	Member	Spain	No interests declared	
Carolina Prieto Fernandez	Alternate	Spain	No interests declared	
Kristina Dunder	Member	Sweden	No interests declared	
Bruno Delafont	Co-opted member	France	No participation in discussion, final deliberations and voting on:	Imjudo - tremelimumab - EMEA/H/C/006016/II/0001
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	
Sol Ruiz	Co-opted member	Spain	No interests declared	
Vincent Gazin	Expert	France	No interests declared	
Susanne Brendler-Schwaab	Expert	Germany	No interests declared	
Martijn van Gils	Expert	Netherlands	No interests declared	
Sabine Mayrhofer	Expert	Germany	No interests declared	
Paolo Petracci	Expert	France	No interests declared	
Clemens Mittmann	Expert	Germany	No interests declared	
Tina Soon Engraff	Expert	Norway	No interests declared	
Line Praest Lauridsen	Expert	Denmark	No restrictions applicable to this meeting	
Luca Santi	Expert	Italy	No restrictions applicable to this meeting	
Martina Perini	Expert	Italy	No restrictions applicable to this meeting	
Maria Victoria Tudanca Pacios	Expert	Spain	No restrictions applicable to this meeting	
Patrick Vrijlandt	Expert	Netherlands	No interests declared	
Meeting run with support from relevant EMA staff.				

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