16 January 2023
EMA/CHMP/22030/2023
Human Medicines Division

Committee for medicinal products for human use (CHMP)

PROM[1] minutes for the meeting on 16 January 2023

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

16 January 2023, 09:00–16:00, 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 PReparatory and Organisational Matters (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

The CHMP adopted the PROM agenda for 16 January 2023 meeting.

1.3. Adoption of the minutes

CHMP PROM Minutes of 16 January 2023 meeting will be adopted at the January 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

BWP Chair Sol Ruiz's last term will expire in February 2023. A call of nomination for a new BWP Chair was launched during December 2022 PROM meeting. Nominations should be sent to the Agency by **10 February 2023**. Candidates are kindly asked to submit a brief CV in support of their candidature together with a cover letter highlighting their expertise.

The election will take place at the February 2023 CHMP plenary meeting.

Action: For information

The CHMP noted the call for nomination for a BWP Chair and upcoming election.

2.1.2. Nomination of new alternate

Nomination of new BWP alternate to replace Grzegorz Kontny representing Poland.

Action: For endorsement

CHMP endorsed the nomination of BWP alternate Paweł Pawłowski to replace Grzegorz Kontny representing Poland.

2.1.3. Nomination of new member and alternate

Nomination of new BWP member and BWP alternate to replace member Heidi Meyer and alternate Matthias Renner representing Germany.

Action: For endorsement

The CHMP endorsed Nomination of new BWP member Elena Grabski and BWP alternate Sonja Matt to replace member Heidi Meyer and alternate Matthias Renner representing Germany.

2.1.4. BWP Workplan 2023

The workplan has been agreed by the BWP and is presented to the CHMP for adoption.

Action: For adoption

The CHMP adopted the BWP workplan.

2.1.5. Agenda and Minutes

- Draft agenda of the 16-18 January 2023 meeting to be held via Webex
- Final minutes of the 3-4 November 2022 meeting held via Webex

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. Call for nomination for the QWP Chair

QWP Chair Blanka Hirschlerova's first term will expire in February 2023. A new call of nomination for a QWP chair was launched during December 2022 PROM meeting. The election is scheduled at the January 2023 CHMP Plenary meeting.

Nominations received

Action: For information

The CHMP noted the call for nomination for a QWP Chair and upcoming election.

2.2.2. QWP Core Team Agenda & Minutes

- Final agenda and minutes for QWP-CT meeting held by teleconference on 7 December 2022

Action: For information

The CHMP noted the agenda and minutes.

2.3. Biosimilar Medicinal Product Working Party (BMWP)

Vice-Chair: Niklas Ekman

2.3.1. Call for nominations for BMWP members

Call for nominations for members of the BMWP following the stepping down of 4 members. The BMWP will welcome candidates with expertise primarily in quality (1 candidate) and clinical assessment of biosimilars including PK aspects (3 candidates).

Nominations should be sent to the Agency by **10 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. CHMP was also informed that a call for BMWP chair will be launched in the near future.

2.4. 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

- Final minutes of NcWP meeting with EMA and industry stakeholders held on 4 October 2022
- Draft minutes for the NcWP meeting held virtually on 6-7 December 2022
- Draft agenda for the NcWP meeting to be held virtually on 18 January 2023

Action: For information

The CHMP noted the agenda and minutes.

3.1.2. Non-clinical domain workplan – priorities 2023

The 3-year workplan including priorities for 2023 was endorsed by the NcWP on 7 December 2022.

Action: For adoption

The CHMP adopted the Non-clinical domain workplan and the priorities for 2023.

3.1.3. CMDh questions to NcWP on new nitrosamines

The CMDh requests that the NcWP determines the acceptable intake for

- N-nitroso-atomoxetine - With regards to N-nitroso-atomoxetine, the CMDh also puts the following question forward to the NcWP: Is the life-long intake (AI) of 573 ng/day Nitrosoatomoxetin for Strattera (atomoxetin HCl) as proposed by the MAH acceptable?
- N-nitroso-atenolol (to be added to the group of beta-blockers for which the AI has already been requested)
- N-nitroso-desmethyl-tripelennamine
- N-nitroso-p-chloro-benzylamino-pyridine and N-nitroso-desmethyl-chloropyramine

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

Additional question:

- For N-nitroso-desmethylazithromycin, the CMDh requests the NcWP to confirm that N-nitroso-desmethylazithromycin can be seen as non-mutagenic and consequently can be controlled as non-mutagenic impurity in accordance with ICH Q3A/B.

Action: For adoption

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

3.1.4. NcWP recommendations for implementing SEND data in the European regulatory review

The Clinical Data Interchange Standards Consortium (CDISC), a non-profit organisation, developed the Standard for Exchange of Nonclinical Data (SEND) to harmonise the way pharmaceutical companies and contract research organisations (CROs) could submit electronic data to Regulatory Agencies. In 2020 a working group consisting of few NCAs was formed with the goal of evaluating the potential benefits and limitations of implementing SEND visualisation in the regulatory review process. The outcome of the pilot phase has been discussed at the NCWP and the group has made some recommendations to EMA. Peter van Meer, member of the NcWP and topic lead for the pilot project, will present the main conclusions from this project together with the recommendations from the NcWP to EMA.

NcWP expert: Peter van Meer

Action: For discussion

The CHMP endorsed the NcWP recommendations for implementing SEND data in the European regulatory review. CHMP enquired what would be the impact on SEND of the new law approved from the US senate regarding the replacement of animals to support the

licensing of new medicinal product. Peter van Meer clarified that available guidelines already provide opportunities such as new approach methodologies to replace animals studies. This process of replacement, will probably take many years and no drastic changes in the pre-clinical testing are expected in the nearby future. CHMP enquired also on the resources and the type of software needed. It was clarified that there are different softwares available to be evaluated and that certain level of investment will be needed. However implicit efficiency gains in assessment are expected.

3.1.5. New nomination in the ERA Drafting Group

Nomination of an additional expert for the drafting group for the revision of the Guideline on Environmental Risk Assessment (ERA) of medicinal products for human use (EMEA/CHMP/SWP/4447/00 Rev. 1).

Action: For endorsement

The CHMP endorsed the nomination of Arne Hein as additional expert in the ERA Drafting Group.

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

Chairs: Sonja Beken, Sarah Adler-Flindt

3.2.1. Non-clinical domain workplan – priorities 2023

The 3-year workplan including priorities for 2023 was endorsed by the 3Rs Working Party on 23 November 2022 (see 3.1.2).

Action: For adoption

The CHMP adopted the non-clinical domain workplan and the priorities for 2023.

4. Methodology Domain

4.1. Methodology Working Party (MWP)

Chairs: Kit Roes, Kristin Karlsson

4.1.1. Call for Nominations for Modelling and Simulation Operational Expert Groups

Launch of Call for Nominations to Biostatistics and Modelling and Simulation Operational Expert Groups.

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

Action: For endorsement

The CHMP noted the call for nominations for the Modelling and Simulation Operational Expert Groups. CHMP requested for a document with further information on the group (e.g. scope, expertise needed).

4.1.2. Agenda and minutes

- Final Agenda & minutes for MWP meeting held by teleconference on 08 December 2022

Action: For information

The CHMP noted the agenda and minutes.

4.2. Biostatistics Operational Expert Group (BOEG)

No topics

4.3. Modelling and Simulation Operational Expert Group (MSOEG)

No topics

4.4. 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)

Chairs: Alar Irs, Patrick Vrijlandt

5.2.1. Paediatric Addendum on the guidelines on clinical investigation of medicinal products for the treatment and prophylaxis of venous thromboembolic disease

This is an addendum to the Guideline on clinical investigation of medicinal products for the treatment of venous thromboembolic disease (EMA/CHMP/41230/2015) [1] and the two guidelines for prophylaxis of venous thromboembolism (VTE) in surgical (EMA/CHMP/325170/2012 Rev.2) [2] and non-surgical adult patients (EMA/CPMP/EWP/6235/04 Rev. 1) [3] and should be read in conjunction with these guidelines. This addendum includes guidance on paediatric clinical medicine development, highlighting paediatric specific issues and differences from the treatment and prophylaxis of venous thromboembolism in adults.

Action: For adoption

The CHMP adopted paediatric addendum on the guidelines on clinical investigation of medicinal products for the treatment and prophylaxis of venous thromboembolic disease and the Overview of External Comments for this Guideline.

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 the experts to enter the Oncology European Specialised Expert Community (ESEC).

Action: For endorsement

The CHMP endorsed the nomination of Zuzana Jedlickova (PEI), Riitta Niittyvuopio (FIMEA) and Anna Sundlöv as Oncology ESEC experts.

5.3.2. Upcoming MAA in Oncology

Presentation of the upcoming MAA in Oncology for 2023 based on the business pipeline data to identify specific need for additional Oncology ESEC experts and topics for upcoming webinars.

Action: For discussion

The CHMP noted the presentation of the upcoming MAA in Oncology for 2023.

5.4. Rheumatology and Immunology Working Party (RIWP)

No topics

5.5. Infectious Disease Working Party (IDWP)

Chair: Maria Jesus Fernandez Cortizo, Vice Chair: Maja Sommerfelt Grønvold

5.5.1. IDWP Work Plan

The Infectious Disease Working Party work plan was endorsed by IDWP on 10 January 2023.

IDWP Chair & Vice-Chair: Maria Jesus Fernandez Cortizo, Maja Sommerfelt Grønvold

Action: For adoption

The CHMP adopted the IDWP Work Plan.

5.6. Vaccines Working Party (VWP)

Chair: Mair Powell

5.6.1. Guideline on Clinical evaluation of new vaccines (EMEA/CHMP/VWP/164653/2005)

This guideline is for final adoption after public consultation and GCG review.

VWP Chair: Mair Powell

Action: For adoption

The CHMP adopted the Guideline on Clinical evaluation of new vaccines. The CHMP noted that the Annex to the guideline on clinical evaluation of new vaccines: summary of product characteristics requirements will be superseded with the updated Guideline.

5.7. Haematology Working Party (HaemWP)

Chair: Daniela Philadelphy

5.7.1. Minutes

- Draft minutes of the Blood cluster held by teleconference on 04 November 2022

Action: For information

The CHMP noted the minutes.

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)

No topics

7. Harmonisation and consistency groups

7.1. International Council on Harmonisation (ICH)

7.1.1. ICH M13 - Bioequivalence for orally administered immediate-release (IR) solid oral dosage forms (Step 2b)

Following ICH sign-off, this document is proposed for CHMP's endorsement and to be subsequently released for a 4-months public consultation period.

Action: For adoption

The CHMP adopted the ICH M13 - Bioequivalence for orally administered immediate-release (IR) solid oral dosage forms.

7.1.2. ICH Q9(R1) – Quality risk management (Step 5)

Following ICH sign-off of this final revised guideline, this document is proposed for CHMP's endorsement and to be subsequently published with an enforcement date 6 months after publication.

Action: For adoption

The CHMP adopted the ICH Q9(R1) – Quality risk management.

7.1.3. ICH S1B(R1) – Addendum to testing for carcinogenicity for pharmaceuticals

Following CHMP adoption of the revised ICH S1B(R1) in September 2022, and in preparation for its enforcement in March 2023, SAWP and NCWP are likely to be approached by Applicant's seeking to receive agreement for not performing a 2-year rat carcinogenicity study, as the new guideline allows under specific cases. A dedicated workflow for SA/PA procedures, including a consultation of NCWP by default is proposed.

Action: For information

The CHMP noted the ICH S1B(R1) – Addendum to testing for carcinogenicity for pharmaceuticals and supported the proposed implementation actions for SAWP-NCWP.

7.2. Guideline Consistency Group (GCG)

Chair: Kristina Dunder

7.2.1. Reader's Guidance for GCG review

A short Reader's Guidance has been prepared by the GCG, which the authors of documents are to provide at the start of the GCG review in order to facilitate the review process.

Chair: Kristina Dunder

Action: For information

The CHMP noted Reader's Guidance for the start of a GCG review.

7.3. Summary of product characteristics Advisory Group

7.3.1. Information on immunogenicity in the SmPC

Overview on the information of immunogenicity in the SmPC and proposals for consistency following learnings proposal in 2022.

Action: For discussion

The CHMP noted the overview on the information of immunogenicity in the SmPC and proposals for consistency following learnings proposal in 2022. To complete information on existing guidance, reference was made to core SmPCs on Factor VIII and IX.

CHMP confirmed existing recommendations on how to present unintended immunogenicity with identified effect as per the SmPC guideline, and welcomed an inclusion of a subsection "Immunogenicity" under "Pharmacodynamic effect" in section 5.1 to present supportive data or include a standard statement when no effect is identified (along the lines proposed in the presentation). In case there is an identified effect impacting efficacy it was noted that information should be defined on a case-by-case basis, with warning to be presented in 4.4 and posology recommendation in 4.2 (with cross-references as appropriate).

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 28 November - 03 December 2022.

Action: For information

The CHMP noted the summary of recommendations and advice.

8.2.2. Call for joint CHMP/PDCO members

The paediatric legislation foresees 5 joint CHMP/PDCO members and alternates to be appointed by CHMP into PDCO. CHMP is asked to express interest to step into a joint CHMP/PDCO membership position for the next 3-year term.

Action: For information

The CHMP noted the call for joint CHMP/PDCO members.

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 Co-rapporteur critique

Update and proposal to the CHMP.

Action: For information

The CHMP noted the update of the Co-rapporteur critique and the proposal to the CHMP.

9.2.3. Practical working instructions for Multinational assessment Teams (MNATs)

5-year update of guidance.

CHMP: Outi Mäki-Ikola

Action: For discussion

The CHMP noted the practical working instructions for Multinational assessment Teams (MNATs).

9.2.4. CHMP Co-opted membership

The CHMP co-opted member position of Christian Gartner became vacant as he was nominated as the new CHMP alternate representing Austria. The CHMP should decide on whether a new co-opted member should be appointed and if so, on the required specific complementary scientific expertise. Afterwards a call for nominations will be launched.

Action: For discussion

The CHMP noted the CHMP Co-opted membership. CHMP recommended to discuss on the expertise as part of the upcoming January CHMP plenary meeting.

9.2.5. CHMP Work Plan 2023

Following changes in CHMP Lead for topic CHMP workplan 2023 - Strengthening the assessment of Companion Diagnostics in the Work-plan, re-adoption of the CHMP Work Plan for 2023 from the version adopted during December 2022 plenary meeting. Members are encouraged to volunteer as contributors for this activity by contacting EMA.

Action: For information

The CHMP noted changes in CHMP lead and additional CHMP contributors for the CHMP work plan for 2023 adopted during December plenary meeting.

10. Product development support

10.1. Scientific Advice Working Party (SAWP)

Chair: Paolo Foggi

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 09-12 January 2023 meeting held face-to-face

- Draft Table of Decisions from 09-12 January 2023 meeting held face-to-face

Action: For information

The CHMP noted the agenda and the table of decisions.

10.1.3. SAWP mandate revision

SAWP mandate revision 17 to be adopted at PROM on 13 February 2023.

Action: For information

The CHMP noted the SAWP mandate revision.

10.1.4. SAWP composition re-nomination

Call for expression of interest to propose names for the SAWP members and associated alternates to be appointed by the CHMP to be launched on 16 January 2023.

Please send your nominations to the Agency by **15 February 2023** EOB.

Action: For information

The CHMP noted the SAWP composition re-nomination.

10.2. Innovation Task Force

10.2.1. ITF meeting

Meeting date: 26 January 2023

Action: For adoption

The CHMP endorsed the meeting.

10.2.2. ITF meeting

Meeting date: 3 February 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. Buvidal - buprenorphine - EMEA/H/C/004651/II/0017

Camurus AB

Rapporteur: Finbarr Leacy, Co-Rapporteur: Agnes Gyurasics, PRAC Rapporteur: Tiphaine Vaillant

Scope: "To add the new therapeutic indication of treatment of moderate to severe chronic pain in patients with opioid dependence. As a consequence, sections 4.1, 4.2, 4.5, 5.1 and 6.6 of the SmPC and sections 1, 3 and Instruction for use of the PL are updated accordingly. The updated RMP version 2.1 has also been submitted."

Letter by the applicant requesting an extension to the clock stop to respond to the request for supplementary information adopted in June 2022.

Action: For adoption

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the request for supplementary information adopted in June 2022.

12. Any Other Business

12.1. Rapporteurships

Update

Action: For information

CHMP noted the update.

12.2. Diabetes Drafting Group - Guideline on clinical investigation of medicinal products in the treatment or prevention of diabetes mellitus - (CPMP/EWP/1080/00)

Update on the Guideline on clinical investigation of medicinal products in the treatment or prevention of diabetes mellitus (CPMP/EWP/1080/00) further to the comments received at the public consultation.

CHMP: Kristina Dunder

Action: For adoption

The CHMP adopted the proposed approach related to the indication in the Guideline on clinical investigation of medicinal products in the treatment or prevention of diabetes mellitus. It was clarified that the changes in the guideline are not to be applied retroactively.

12.3. CHMP communications to EMA's stakeholders

Overview of CHMP communications and process flow.

Action: For information

The CHMP noted the overview of CHMP communications and process flow.

12.4. Q&A "Is the monitoring of bioequivalence clinical trials mandatory?"

Q&A "Is the monitoring of bioequivalence clinical trials mandatory?" published on EMA corporate website – Q&A: Good clinical practice (GCP) | European Medicines Agency (europa.eu) please refer to B.16. A further clarification document: *Assessment of the adequacy of monitoring information in bioequivalence clinical trials* drafted.

CHMP: Jayne Crowe

Action: For adoption

The CHMP adopted the Q&A "Is the monitoring of bioequivalence clinical trials mandatory?" to be published on EMA corporate website.

12.5. Nomination of CHMP representative for ENCePP Steering Group 2021-2023

Nomination of CHMP representative in the ENCePP Steering Group (SG) for the period 2021-2023 to replace Johann Lodewijk Hillege as current CHMP representative

Action: For endorsement

The CHMP appointed Carla Torre as CHMP representative in the ENCePP Steering Group (SG) for the remaining period of the current 2021-2023 mandate.

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 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	
Margareta Bego	Member	Croatia	No interests declared	
Selma Arapovic Dzakula	Alternate	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	
Thalia Marie Estrup Blicher	Member	Denmark	No interests declared	
Aaron Sosa Mejia	Alternate	Denmark	No participation in final deliberations and voting on:	CHMP draft Plenary Agenda: 4.3.1. Esperoct - turoctocog alfa pegol - EMEA/H/C/004883/X/0016
Alar Irs	Member	Estonia	No restrictions applicable to this meeting	
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	
Alexandre Moreau	Member	France	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	
Anastasia Mountaki	Alternate	Greece	No interests declared	
Robert Porszasz	Member	Hungary	No interests declared	
Beata Maria Jakline Ullrich	Alternate	Hungary	No interests declared	
Hrefna Gudmundsdottir	Member	Iceland	No interests declared	
Jayne Crowe	Member	Ireland	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda and for which restrictions apply
Armando Genazzani	Member	Italy	No interests declared	
Maria Grazia Evandri	Alternate	Italy	No interests declared	
Vilma Petrikaite	Member	Lithuania	No interests declared	
Silvijus Abramavicius	Alternate	Lithuania	No restrictions applicable to this meeting	
Martine Trauffler	Member	Luxembourg	No interests declared	
Alexandra Branchu	Alternate	Luxembourg	No participation in discussion, final deliberations and voting on:	CHMP draft plenary meeting Agenda: 5.1.1. Dupixent - dupilumab - EMEA/H/C/004390/II/0060
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	
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	
Nevenka Trsinar Brodt	Alternate	Slovenia	No interests declared	
Maria Concepcion Prieto Yerro	Member	Spain	No interests declared	
Blanca Garcia-Ochoa	Alternate	Spain	No interests declared	
Kristina Dunder	Member	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	
Vincent Gazin	Expert - via WebEx*	France	No interests declared	
Sabine Mayrhofer	Expert - via WebEx*	Germany	No interests declared	
Nora Cascante Estepa	Expert - via WebEx*	Germany	No interests declared	
Maria Jesus Fernández Cortizo	Expert - via WebEx*	Spain	No interests declared	
Maja Sommerfelt Grønvold	Expert - via WebEx*	Norway	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda and for which restrictions apply
Deirdre Mannion	Expert - via WebEx*	Denmark	No restrictions applicable to this meeting	
Maria Victoria Tudanca Pacios	Expert - via WebEx*	Spain	No restrictions applicable to this meeting	
Susanne Brendler-Schwaab	Expert - via WebEx*	Germany	No interests declared	
Theis Moeslund Jensen	Expert - via WebEx*	Denmark	No restrictions applicable to this meeting	
Antonio Gomez-Outes	Expert - via WebEx*	Spain	No interests declared	
Martina Perini	Expert - via WebEx*	Italy	No restrictions applicable to this meeting	
Luca Santi	Expert - via WebEx*	Italy	No restrictions applicable to this meeting	
Peter Theunissen	Expert - via WebEx*	Netherlands	No interests declared	
Mair Powell	Expert - via WebEx*	Ireland	No interests declared	
A representative from the European Commission attended the meeting				
Meeting run with support from relevant EMA staff				

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