13 November 2024
EMA/CHMP/465101/2024
Human Medicines Division

Committee for medicinal products for human use (CHMP)

PROM[1] minutes for the meeting on 09 September 2024

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

09 September 2024, 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 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

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the PROM meeting to be held on 09 September 2024. 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 are also considered. See September 2024 PROM minutes.

1.2. Adoption of agenda

CHMP PROM adopted agenda for 09 September 2024 meeting

1.3. Adoption of the minutes

CHMP PROM Minutes of 09 September 2024 meeting will be adopted at the September 2024 CHMP plenary.

2. Quality Domain

2.1. Biologics Working Party (BWP)

Chair: Sean Barry

2.1.1. Nomination of new Biological Quality ESEC experts

Nomination of new experts to join the Biological Quality European Specialised Expert Community (ESEC).

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of the new members of the Biological Quality European Specialised Expert Community (ESEC).

2.1.2. Agenda and Minutes

- Minutes of the BWP meeting held remotely on 17-19 June 2024
- Agenda of the BWP meeting to be held remotely on 9-11 September 2024

Action: For information

The CHMP noted the agenda and minutes.

2.2. Quality Working Party (QWP)

Chair: Blanka Hirschlerova, Vice-Chairs: Marie-Hélène Sabinotto, Nicholas Lee

2.2.1. Agenda and Minutes

- Minutes of the QWP meeting held remotely on 17-18 June 2024
- Agenda of the QWP meeting to be held in person on 9-11 September 2024

Action: For information

The CHMP noted the agenda and minutes.

2.2.2. QWP consultation with Healthcare Professional Organisations on gravimetric filling in hospital pharmacies

The QWP has been discussing gravimetric filling (compounding) of liquid medicinal products and/or reconstituted medicinal products in hospital pharmacy settings.

Gravimetric compounding is compounding where the amount of liquid to be used or added is determined by weighing (instead of volumetric control) in the preparation for administration of medicinal products, e.g., the amount of solvent to be added, the amount of concentrate to be used for dilution, or the amount of dose to be filled out, but may also to be used in other processes.

A questionnaire has been sent from the QWP to the European Association of Hospital Pharmacists (EAHP) and to the European Society of Oncology Pharmacy (ESOP) with the aim to get a better understanding of the extent to which gravimetric filling is used across EU MSs to get an understanding from where hospital pharmacies obtain the information about the density of the liquids and if there is a need to provide this information (or other physical-chemical properties), for example in the SmPC. Responses have been requested by mid-September and will then be discussed at QWP, in consultation with other groups as needed (QRD, BWP, GMDP IWG).

Action: For information

The CHMP noted the questionnaire sent by QWP to the European Association of Hospital Pharmacists (EAHP) and to the European Society of Oncology Pharmacy (ESOP) with the aim to get a better understanding of the extent to which gravimetric filling is used across EU and where best from Hospital Pharmacists point of view to include any information on physical-chemical properties.

2.2.3. Guideline on quality and equivalence of locally applied, locally acting cutaneous products

The QWP has finalised the drafting of the above guideline. This is a new guideline (initially called "Guideline on quality and equivalence of topical products") which has evolved from the concept paper prepared in 2015. The purpose of developing this new guideline was to address Industry and Network needs for guidance with regard to topical cutaneous products. The guideline addresses the quality requirements of cutaneous products, containing new or known chemical active substances, throughout their marketing life. In addition, the guideline provides a framework to establish protocols for demonstrating therapeutic equivalence, suitable to the wide diversity of topical cutaneous products.

Public consultation of the first draft took place in H1 2019 following adoption by CHMP. The document was then put on hold due to the BCP which extended into the Covid-19 pandemic period. Upon gradual resuming of QWP normal activities it was prioritised and was further

developed consolidating firstly the comments from public consultation and later comments from QWP and MWP. It is noted that the drafting group comprised members of QWP and MWP (then PKWP). Input by the Biostatistics WP was also sought during the initial drafting. GCG has also completed their review.

Action: For adoption

The CHMP adopted the Guideline on quality and equivalence of locally applied, locally acting cutaneous products. The document will be published on the EMA website.

2.2.4. Nomination of new Chemical Quality ESEC experts

Nomination of new experts to join the Chemical Quality European Specialised Expert Community (ESEC).

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of the new members of the Chemical Quality European Specialised Expert Community (ESEC).

2.3. Biosimilar Medicinal Product Working Party (BMWP)

Chair: René Anour, Vice-Chair: Niklas Ekman

2.3.1. Agenda and Minutes

- Agenda and minutes of the BMWP meeting held remotely on 1 July 2024

Action: For information

The CHMP noted the agenda and minutes.

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)

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

3.1.1. Agenda and Minutes

- Minutes of the meeting held remotely on 18 and 19 June 2024
- Draft agenda of the meeting to be held remotely on 27 August and 11 September 2024

Action: For information

The CHMP noted the agenda and minutes.

3.1.2. Reply to CMDh questions to the NcWP

The CHMP adopted the reply to CMDh questions to the NcWP.

3.1.3. Reply to CMDh questions to NcWP

The CHMP adopted the reply to CMDh questions to NcWP.

3.1.4. Reminder call for nomination for new NcWP member

Following the departure of Fernando Mendez Hermida at the end of June 2024, the NcWP secretariat has launched in June a call for nomination for a new NcWP member. The deadline for nominations is 15 September 2024.

Action: For information

The CHMP noted the reminder for nomination for new NcWP member.

3.1.5. EFSA workshop for Biomarker Guidance

EMA drafted a brief statement summarising the points voiced by NcWP members regarding the development of a guideline on biomarkers by EFSA. The comments have been submitted to the food agency as part of the public consultation.

Action: for information

The CHMP noted the brief statement drafted by the EMA summarising the points voiced by NcWP members regarding the development of a guideline on biomarkers by EFSA.

3.1.6. Call for members for the Nitrosamine Safety Operational Expert Group

A call for members for the Nitrosamine Safety Operational Expert Group will be launched.

Action: for endorsement

The CHMP endorsed the call for members for the Nitrosamine Safety Operational Expert Group.

3.1.7. Publication of response to comments document of revised ERA guideline

The revised Environmental Risk Assessment (ERA) guideline was published in March this year and is in force since September this year. The revision process of the guideline included a public consultation. The responses to the comments received during this public consultation are now ready to be published.

Action: For information

The CHMP noted the responses to the comments received during the public consultation.

3.1.8. Nomination of Environmental Risk Assessment ESEC experts

Nomination of new experts to join the newly established Environmental Risk Assessment (ERA) European Specialised Expert Community (ESEC). The list of nominated experts comprises automatically nominated ESEC members meaning members of the NcWP and members of the ER-WP (vet) as well as experts nominated by committee members.

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of new experts to join the newly established Environmental Risk Assessment (ERA) European Specialised Expert Community (ESEC).

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

3.2.1. Call for nomination of CHMP/CVMP Joint 3Rs Working Party (3RsWP) members (deadline extended)

The two additional members of the 3RsWP will be experts' representatives of the human or veterinary areas and may also be members of the Non-Clinical Working Party (NCWP), Safety Working Party-Veterinary (SWP-V), Immunologicals Working Party-Veterinary (IWP), Biologics Working Party (BWP) and Efficacy Working Party-Veterinary (EWP-V), though this is not a requirement.

Action: For endorsement

The CHMP noted the extension of the deadline of the call for nomination of CHMP/CVMP Joint 3Rs Working Party (3RsWP) members.

4. Methodology Domain

4.1. Methodology Working Party (MWP)

Chair: Kit Roes, Vice-Chair: Kristin Karlsson

4.1.1. Agenda and Minutes

- Agenda and minutes of the virtual MWP meeting held on 20 June 2024

Action: For information

The CHMP noted the agenda and minutes.

4.1.2. Nomination of Methodology ESEC experts

Nomination of EMA staff and new experts to enter the Methodology European Specialised Expert Community (ESEC).

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of the new members of the Methodology European Specialised Expert Community (ESEC).

4.1.3. Reflection Paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle

Taking into account the comments received during public consultation phase, the RP has been finalised and presented to CHMP for adoption.

Expert: Gabriel Westman

Action: For adoption

The CHMP adopted the Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle. The document will be published on the EMA website.

4.1.4. Reflection paper on establishing efficacy based on single-arm trials submitted as pivotal evidence in a marketing authorisation application

Taking into account the comments received during public consultation phase, the RP has been finalised and presented to CHMP for adoption.

Expert: Kit Roes

Action: For adoption

The CHMP adopted the Reflection paper on establishing efficacy based on single-arm trials submitted as pivotal evidence in a marketing authorisation application. The document will be published on the EMA website.

5. Clinical Domain

5.1. Central Nervous System Working Party (CNSWP)

No topics

5.2. Cardiovascular Working Party (CVSWP)

No topics

5.3. Oncology Working Party (ONCWP)

Chair: Pierre Demolis, Vice-Chair: Olli Tenhunen

5.3.1. Work plan of the ONCWP

Work plan of the ONCWP for CHMP adoption to be released for public consultation.

ONCWP Chair: Piere Demolis

Action: For adoption

The CHMP adopted the Work plan of the ONCWP for public consultation.

5.4. Rheumatology and Immunology Working Party (RIWP)

Chair: Caroline Auriche Benichou, Vice-Chair: Karolina Törneke

5.4.1. Workplan of the RIWP

Work plan of the RIWP for CHMP adoption to be released for public consultation.

RIWP Chair: Caroline Auriche Benichou, RIWP Vice-Chair: Karolina Törneke

Action: For adoption

The CHMP adopted the Work plan of the RIWP for public consultation.

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 member

Nomination of new haematology ESEC member.

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of the new members of the haematology European Specialised Expert Community (ESEC).

5.7.2. Work plan of the HaemWP

Work plan of the HaemWP for CHMP adoption to be released for public consultation.

CHMP: Daniela Philadelphy

Action: For adoption

The CHMP adopted the Work plan of the HaemWP for public consultation.

5.7.3. Agenda and Minutes

- Final minutes for the Blood cluster meeting held virtually on 28 June 2024
- Draft agenda for the ad hoc blood cluster meeting to be held virtually on 27 August 2024

Action: For information

The CHMP noted the agenda and 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)

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

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

6.1.1. Agenda and Minutes

- Summary report of the Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties joint meeting to be held face-to-face on 27-28 February 2024
- Agenda of the Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties joint meeting held face-to-face on 02-03 July 2024
- Summary report of the Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties joint meeting to be held face-to-face on 02-03 July 2024

Action: For information

The CHMP noted the agenda and minutes.

6.1.2. CHMP early dialogue methodology with patient and healthcare professional organisations

An update of the early dialogue methodology will be presented. The updates are based on experience with patient and healthcare professional organisations and discussions with the CHMP core group and EMA legal team. In addition, a proposal has been made to the D210 assessment report template to reflect the input gathered from the organisations prior to D80.

Action: For endorsement

The CHMP noted the updates on the early dialogue methodology with patient and healthcare professional organisations, which includes a summary of the input to be completed by the patient and HCP organisations. In addition, CHMP endorsed the proposal on the D210 assessment report template to reflect the input gathered from the organisations prior to D80.

7. Harmonisation and consistency groups

7.1. International Council on Harmonisation (ICH)

7.1.1. ICH E6(R3) – Principles and Annex 1

The ICH Expert working group has completed its review and addressed any remaining issues from the public consultation and has started the final agency clearance process/caucus review. The draft was circulated end of August for any final comments for endorsement by the CHMP.

Experts: Lisbeth Bregnhøj, Gabriele Schwarz

Action: For adoption

The CHMP endorsed the ICH E6(R3) – Principles and Annex 1. The EWG will discuss any blocking comments and a final adoption is expected in December 2024.

7.1.2. ICH M11 Guideline, clinical study protocol template and technical specification

The ICH M11 Clinical Electronic Structured Harmonised Protocol Template provides comprehensive clinical protocol organization with standardized content with both required and optional components. The Technical Specification that are acceptable to all regulatory authorities of the ICH regions presents the conformance, cardinality, and other technical attributes that enable the interoperable electronic exchange of protocol content with a view to develop an open, non-proprietary standard to enable electronic exchange of clinical protocol information. The presentation will introduce the party review that will occur in September 2024.

Action: For information

The CHMP noted the progress and updates on the ICH M11 Guideline, clinical study protocol template and technical specification. In addition, CHMP noted the call to review the guideline, the scope and timelines for NCAs to provide input.

7.1.3. ICH guideline E21

The ICH guideline E21 is a new guideline that regards inclusion of pregnant and breastfeeding women in clinical trials. CHMP is consulted on key principles.

Action: For discussion

The CHMP noted the progress and updates on the ICH E21 on inclusion of pregnant and breastfeeding women in clinical trials. In addition, CHMP noted the call to review the guideline, the scope and timelines for NCAs to provide input by 11 October.

7.2. Guideline Consistency Group (GCG)

No topics

7.3. Summary of product characteristics Advisory Group

7.3.1. SmPC AG & VWP Q&A on SmPC information on coadministration of vaccines

To facilitate consistency in communicating information on coadministration of vaccines in SmPC, the SmPC AG and VWP have prepare a Q&A, which recommend that in the vast majority of cases section 4.5 of vaccine SmPCs should be confined to clear statements reflecting conclusions drawn from interaction studies, with simple recommendations made for allowing concomitant use, for avoiding concomitant use or stating that no interaction studies have been conducted.

Action: For endorsement

The CHMP endorsed the SmPC AG & VWP Q&A on SmPC information on coadministration of vaccines.

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: Ulla Wändel Liminga

Summary of recommendations and advice of PRAC meeting held on 02-05 September 2024.

Action: For information

The CHMP noted the summary of recommendations and advice.

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 in Teams and new tool for voting

Presentation and next steps.

Action: For information

The CHMP noted that CHMP meetings will be organised in Teams and a new tool for voting will be deployed. The EMA will further discuss and communicate to CHMP the timelines and timings for training and deployment.

9.2.3. GIREX - Group for Internal Rules on Extensions of Clock Stops

Proposal to reconvene GIREX

Action: For endorsement

The CHMP endorsed the proposal to reconvene GIREX 2024.

9.2.4. CHMP work plan 2024 – Status update

CHMP: Harald Enzmann

Action: For information

The CHMP noted the status update on the CHMP work plan 2024.

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 appointment of CHMP peer review for SA

10.1.2. Agenda and Table of Decisions

- Agenda from 02-05 September 2024 meeting held by Webex
- Draft Table of Decisions from 02-05 September 2024 meeting held by Webex

Action: For information

The CHMP noted the agenda and table of decisions.

10.2. Innovation Task Force

10.2.1. ITF meeting

10.2.2. ITF meeting

Meeting date: 16 September 2024

Action: For adoption

The CHMP endorsed the meeting.

10.2.3. ITF meeting

Meeting date: 25 September 2024

Action: For adoption

The CHMP endorsed the meeting.

10.3. Real-world evidence (including DARWIN EU) for regulatory decision making

Monthly touchpoint to explore emerging research questions at the time of pre-submission meetings and provide updates on the development of DARWIN EU, upcoming trainings and workshops and report on study requests received as well as planned/completed RWD studies. CHMP members will have an opportunity to raise RWD study proposals.

Action: For discussion

The CHMP noted the update Real-world evidence (including DARWIN EU) for regulatory decision making.

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. Pegfilgrastim - EMEA/H/C/006407

Treatment of neutropenia

Scope: Letter by the applicant requesting an extension to the clock stop to respond to the list of questions adopted in June 2024.

Action: For adoption

List of questions adopted on 27.06.2024

The CHMP did not agree to the request by the applicant for an extension to the clock stop to respond to the list of questions adopted in June 2024.

11.3. Filgrastim - EMEA/H/C/006400

For the reduction in the duration of neutropenia and the incidence of febrile neutropenia

Scope: Letter by the applicant requesting an extension to the clock stop to respond to the list of outstanding issues to be adopted in September 2024.

Action: For adoption

List of questions adopted on 25.04.2024

The CHMP agree to the request by the applicant for an extension to the clock stop to respond to the list of outstanding issues to be adopted in September 2024.

11.4. Spikevax - COVID-19 mRNA vaccine - EMEA/H/C/005791/II/0136

Moderna Biotech Spain S.L., Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Marie Louise Schougaard Christiansen Quality variation

Request for Supplementary Information adopted on 25.07.2024, 27.06.2024.

Positive Opinion adopted by consensus on 09.09.2024.

11.5. Ofev – Nintedanib - EMEA/H/C/003821/X/0057/G

Boehringer Ingelheim International GmbH;

Rapporteur: Finbarr Leacy, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: update on the procedure

Action: For discussion

List of Outstanding issues adopted on 25.07.2024. List of Questions adopted on 22.02.2024.

The CHMP noted the update on the procedure.

12. Any Other Business

12.1. Rapporteurships

Update.

Action: For information

The CHMP noted the update.

12.2. Health Threats and ETF Update

Action: For information

The CHMP noted the Health Threats and ETF updates.

12.3. 10 years review on the Post-Authorisation Studies

Presentation of the retrospective analysis conducted on all post-authorisation studies from September 2013 to September 2023.

Action: For discussion

The CHMP noted the presentation of the retrospective analysis conducted on all post-authorisation studies from September 2013 to September 2023.

12.4. EU Network Training Centre: supporting capacity and capability building in the EU Medicines Regulatory Network

The EU NTC recently celebrated 10 years in operation. To mark the occasion, we hosted an anniversary event at EMA on 30 May where we had the privilege to have the several Committee chairs and vice-chairs attending. In the margins of the event, we had the opportunity to discuss with some of them the possibility of having an agenda point at a future meeting of their committees to do some promotion around the EU NTC and raise awareness among Committee members. Also noting that CHMP, as well as other Committees, are undergoing elections for a new chair, we think it would be a good opportunity to remind colleagues about how the EU NTC supports capacity and capability building in the Network.

Action: For discussion

The CHMP noted the presentation from the EU Network Training Centre on supporting capacity and capability building in the EU Medicines Regulatory Network. In addition, the CHMP chair encouraged Committee members to promote the use of the EU NTC among their colleagues within their NCAs.

13. List of Participants

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Harald Enzmann	Chair	Germany	No interests declared	
Daniela Philadelphy	Member	Austria	No interests declared	
Christophe Focke	Member	Belgium	No restrictions applicable to this meeting	
Karin Janssen van Doorn	Alternate	Belgium	No interests declared	
Lyubina Racheva Todorova	Member	Bulgaria	No interests declared	
Margareta Bego	Member	Croatia	No interests declared	
Helena Panayiotopoulou	Member	Cyprus	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 discussion, final deliberations and voting on:	6.1.7. Esperoct - Turoctocog alfa pegol - EMEA/H/C/004883/II/0023
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	
Janet Koenig	Member	Germany	No interests declared	
Martin Mengel	Alternate	Germany	No interests declared	
Anastasia Mountaki	Alternate	Greece	No interests declared	
Robert Porszasz	Member	Hungary	No restrictions applicable to this meeting	
Beata Maria Jakline Ullrich	Alternate	Hungary	No interests declared	
Hrefna Gudmundsdottir	Member	Iceland	No interests declared	
Finbarr Leacy	Alternate	Ireland	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Maria Grazia Evandri	Alternate	Italy	No interests declared	
Elita Poplavska	Member	Latvia	No interests declared	
Martine Trauffler	Member	Luxembourg	No interests declared	
Alexandra Branchu	Alternate	Luxembourg	No participation in discussion, final deliberations and voting on:	5.1.2. Kevzara - Sarilumab - EMEA/H/C/004254/X/0043/G 6.1.5. Dupixent - Dupilumab - EMEA/H/C/004390/II/0081 6.1.6. Dupixent - Dupilumab - EMEA/H/C/004390/II/0083
Peter Mol	Member	Netherlands	No interests declared	
Patrick Vrijlandt	Alternate	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	
Grzegorz Cessak	Alternate	Poland	No interests declared	
Bruno Sepodes	Member (Vice-Chair)	Portugal	No interests declared	
Fatima Ventura	Alternate	Portugal	No restrictions applicable to this meeting	
Simona Badoi	Member	Romania	No interests declared	
Dana Gabriela Marin	Alternate	Romania	No interests declared	
Frantisek Drafi	Member	Slovakia	No interests declared	
Jana Klimasová	Alternate	Slovakia	No restrictions applicable to this meeting	
Andreja Kranjc	Alternate	Slovenia	No interests declared	
Antonio Gomez-Outes	Alternate	Spain	No interests declared	
Kristina Dunder	Member	Sweden	No interests declared	
Filip Josephson	Alternate	Sweden	No interests declared	
Bruno Delafont	Co-opted member	France	No interests declared	
Carla Torre	Co-opted member	Portugal	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Jan Mueller-Berghaus	Co-opted member	Germany	No interests declared	
Sol Ruiz	Co-opted member	Spain	No interests declared	
Deirdre Mannion	Expert	Denmark	No restrictions applicable to this meeting	
Sabine Mayrhofer	Expert	Germany	No interests declared	
Isabelle Puff	Expert	France	No interests declared	
Susanne Brendler-Schwaab	Expert	Germany	No interests declared	
Christian B. Roes	Expert	Netherlands	No restrictions applicable to this meeting	
Pierre Demolis	Expert	France	No interests declared	
Caroline Auriche-Benichou	Expert	France	No interests declared	
Gabriel Westman	Expert	Sweden	No interests declared	
Gabriele Schwarz	Expert	Germany	No interests declared	
Susan Uiterwaal	Expert	Netherlands	No interests declared	

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