



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

13 June 2022  
EMA/CHMP/584121/2022  
Human Medicines Division

## Committee for medicinal products for human use (CHMP) PROM<sup>1</sup> minutes for the meeting on 13 June 2022

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

13 June 2022, 09:00–13:00, virtual meeting/room 08-A

### 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).

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<sup>1</sup> 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.



## Table of contents

<b>1.</b>	<b>Agenda and Minutes</b>	<b>4</b>
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
<b>2.</b>	<b>Non-therapeutic-area-specific working parties</b>	<b>4</b>
2.1.	Patients and Consumers Working Party (PCWP) Healthcare Professionals Working Party (HCPWP) .....	4
2.2.	Biologics Working Party (BWP) .....	4
2.3.	Quality Working Party (QWP) .....	4
2.4.	Non-clinical Working Party (NcWP) .....	5
2.5.	Biosimilar Medicinal Product Working Party (BMWP) .....	6
2.6.	Methodology Working Party (MWP).....	6
2.7.	Pharmacogenomics Working Party (PGWP).....	6
2.8.	Pharmacokinetics Working Party (PKWP).....	6
<b>3.</b>	<b>Therapeutic-area-specific working parties and SAGs</b>	<b>7</b>
3.1.	Haematology Working Party (HaemWP) .....	7
3.2.	Central Nervous System Working Party (CNSWP) .....	8
3.3.	Cardiovascular Working Party (CVSWP) .....	8
3.4.	Infectious Diseases Working Party (IDWP) .....	8
3.5.	Oncology Working Party (ONCWP) .....	8
3.6.	Rheumatology/Immunology Working Party (RIWP) .....	8
3.7.	Vaccines Working Party (VWP).....	8
3.8.	Scientific Advisory Groups (SAGs) .....	8
<b>4.</b>	<b>Drafting groups</b>	<b>8</b>
4.1.	Excipients Drafting Group.....	8
4.2.	Gastroenterology Drafting Group (GDG) .....	9
4.3.	Geriatric Expert Group (GEG).....	9
4.4.	Radiopharmaceuticals Drafting Group (RadDG).....	9
4.5.	Respiratory Drafting Group (RDG) .....	9
4.6.	Diabetes Drafting Group .....	9
<b>5.</b>	<b>Harmonisation and consistency groups</b>	<b>9</b>
5.1.	International Council on Harmonisation (ICH) .....	9
5.2.	Guideline Consistency Group (GCG).....	10
5.3.	Summary of product characteristics Advisory Group .....	10

<b>6.</b>	<b>Joint groups and collaboration with other Scientific committees</b>	<b>10</b>
6.1.	Joint CVMP/CHMP ad-hoc expert group on the application of the 3Rs (replacement, reduction and refinement) in the regulatory testing of medicinal products (J 3RsWG) .....	10
6.2.	Joint CHMP/CVMP/CMDh/CMDv Working Group on Active Substance Master File Procedures (ASMF WG) .....	10
6.3.	Collaboration with other Scientific committees .....	10
<b>7.</b>	<b>Regulatory/Organisational matters</b>	<b>11</b>
7.1.	Regulatory Issues/new legislation .....	11
7.2.	CHMP organisation/templates .....	11
<b>8.</b>	<b>Product development support</b>	<b>12</b>
8.1.	Scientific Advice Working Party (SAWP).....	12
8.2.	Innovation Task Force .....	12
<b>9.</b>	<b>Product related topics</b>	<b>13</b>
9.1.	Preview CHMP Plenary.....	13
<b>10.</b>	<b>Any Other Business</b>	<b>13</b>
10.1.	Rapporteurships .....	13
10.2.	A workshop of the ESC Cardiovascular Round Table; "Real World Evidence" .....	13
10.3.	EMA study on the impact of RWE in applicants' submissions .....	13
10.4.	EMA funded registry-based study on Spinal muscular atrophy .....	13
<b>11.</b>	<b>List of Participants</b>	<b>15</b>

## 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 as well as the draft agenda of the plenary meeting, the Committee Secretariat announced the restricted involvement of some Committee members, alternates and experts for concerned agenda topics.

Participants 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. Restrictions applicable to this meeting are captured in the List of participants included in the minutes.

### 1.2. Adoption of agenda

The CHMP adopted the PROM agenda for 13 June 2022 meeting.

### 1.3. Adoption of the minutes

CHMP PROM Minutes of 13 June 2022 meeting will be adopted at the June CHMP plenary.

## 2. Non-therapeutic-area-specific working parties

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

No topics

### 2.2. Biologics Working Party (BWP)

Chairs: Sol Ruiz, Sean Barry

#### 2.2.1. Agenda and minutes

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- Draft agenda of BWP meeting to be held virtually on 13-15 June 2022
- Final minutes of BWP meeting held virtually on 11-13 April 2022

**Action:** For information

The CHMP noted the agenda and the minutes.

### 2.3. Quality Working Party (QWP)

Chair: Blanka Hirschlerova

### 2.3.1. Agenda and minutes

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- Final Agenda and minutes for QWP-CT meeting held by teleconference on 11 May 2022

**Action:** For information

The CHMP noted the agenda and the minutes.

### 2.3.2. Removal or replacement of Titanium Dioxide Q&A

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Proposal for adoption of EMA's Quality Working Party (QWP) Questions and Answers to provide technical and procedural guidance to replace/remove titanium dioxide (TiO<sub>2</sub>) in medicines.

**Action:** For adoption

The CHMP adopted EMA's Quality Working Party (QWP) Questions and Answers to provide technical and procedural guidance to replace/remove titanium dioxide (TiO<sub>2</sub>) in medicines.

## 2.4. Non-clinical Working Party (NcWP)

Chairs: Susanne Brendler-Schwaab, Karen van Malderen

### 2.4.1. Minutes

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- Draft minutes for NcWP meeting held virtually on 10-11 May 2022

**Action:** For information

The CHMP noted the minutes.

### 2.4.2. Launch of the Nitrosamines Safety Operational Experts Group (NS OEG)

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The SWP nitrosamines expert group has been converted into the Nitrosamines Safety Operational Expert group (NS OEG). The NcWP is seeking endorsement of the group and the experts.

**Action:** For endorsement

The CHMP endorsed the Launch of the Nitrosamines Safety Operational Experts Group (NS OEG) as well as the list of experts proposed.

### 2.4.3. NcWP position on new nitrosamine nitrosoduloxetine

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NcWP position on the acceptable intake (AI) for nitrosoduloxetine based on lifetime daily exposure including information on the points of departure and methodology used.

**Action:** For adoption

The CHMP adopted the NcWP position on new nitrosamine nitrosoduloxetine.

#### 2.4.4. CMDh question to NcWP on new nitrosamines N-nitrosoparoxetine

CMDh question to the NcWP to determine the acceptable intake for N-nitrosoparoxetine based on lifetime daily exposure including information on the points of departure and methodology used.

**Action:** For adoption

The CHMP adopted the CMDh question to NcWP on new nitrosamines N-nitrosoparoxetine.

### 2.5. **Biosimilar Medicinal Product Working Party (BMWP)**

No topics

### 2.6. **Methodology Working Party (MWP)**

Chairs: Christian Roes, Kristin Karlsson

#### 2.6.1. Agenda and minutes

- Final Agenda & minutes for QWP-CT meeting held by teleconference on 10 and 24 May 2022

**Action:** For information

The CHMP noted the agenda and the minutes.

#### 2.6.2. Nominations for additional expertise for Methodology Working Party

CHMP is presented with nominations for additional expertise for MWP.

The recent call for nominations included a general call for expertise in Real World Evidence. Nominations were received in the area of Artificial Intelligence, the Information Technology side of Data Science, and several other applicants indicated they had such expertise. However:

- No candidates appear to have specific expertise in pharmacoepidemiology;
- Some candidates did not give sufficient granularity in their answers to be able to ascertain whether they had the required expertise.

Following reopening of call of nominations experts are proposed.

**Action:** For endorsement

The CHMP endorsed Carla Torre, Olaf Klungel, and Stine Hasling as members of the Methodology Working Party.

### 2.7. **Pharmacogenomics Working Party (PGWP)**

No topics

### 2.8. **Pharmacokinetics Working Party (PKWP)**

Chair: Carolien Versantvoort

### 2.8.1. Product-specific guidelines

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The public consultation on the following product-specific guidelines finished on 31 March 2022. No comments were received, and it is therefore proposed that the published drafts will also be the final versions.

Final product-specific guidelines for publication:

- Enzalutamide soft capsule 40 mg and film-coated tablet 40 & 80 mg product-specific bioequivalence guidance (EMA/CHMP/371467/2021)
- Ibrutinib hard capsules 140 mg and film-coated tablet 140, 280, 420 & 560 mg product-specific bioequivalence guidance (EMA/CHMP/371445/2021)
- Olaparib film-coated tablet 100 & 150 mg product specific bioequivalence guidance (EMA/CHMP/371470/2021)
- Ursodeoxycholic acid capsule 250 mg, film-coated tablet 150, 300, 450, 500 & 600 mg and suspension 50 mg/ml (250 mg/5 ml) product-specific bioequivalence guidance (EMA/CHMP/559890/2021)

**Action:** For adoption

The CHMP adopted the above specified product-specific guidelines.

## 3. Therapeutic-area-specific working parties and SAGs

### 3.1. Haematology Working Party (HaemWP)

Chair(s): Vacant

#### 3.1.1. Minutes

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- Final minutes for the Blood cluster meeting held by teleconference on 18 March 2022

**Action:** For information

The CHMP noted the minutes.

#### 3.1.2. Election of HAEMWP chair

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- Election of HAEMP chair following the implementation of the new Working Parties Operating Model (WOM).

**Action:** For adoption

The CHMP elected Daniela Philadelphy as HAEMWP chair.

#### 3.1.3. Agenda of the annual meeting with PPTA and IPFA

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- Agenda of the annual meeting with PPTA and IPFA held on 7 June 2022

**Action:** For information

The CHMP noted the agenda.

### **3.2. Central Nervous System Working Party (CNSWP)**

No topics

### **3.3. Cardiovascular Working Party (CVSWP)**

No topics

### **3.4. Infectious Diseases Working Party (IDWP)**

No topics

### **3.5. Oncology Working Party (ONCWP)**

Chairs: Pierre Demolis, Sigrid Klaar

#### **3.5.1. Agenda and minutes**

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- Final Agenda for ONCWP meeting held by teleconference on 20 May 2022
- Final minutes for ONCWP meeting held by teleconference on 22 April 2022

**Action:** For information

The CHMP noted the agenda and the minutes.

#### **3.5.2. Nomination of Oncology ESEC experts**

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

**Action:** For endorsement

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

### **3.6. Rheumatology/Immunology Working Party (RIWP)**

No topics

### **3.7. Vaccines Working Party (VWP)**

No topics

### **3.8. Scientific Advisory Groups (SAGs)**

No topics

## **4. Drafting groups**

### **4.1. Excipients Drafting Group**

No topics



## 4.2. Gastroenterology Drafting Group (GDG)

No topics

## 4.3. Geriatric Expert Group (GEG)

No topics

## 4.4. Radiopharmaceuticals Drafting Group (RadDG)

No topics

## 4.5. Respiratory Drafting Group (RDG)

No topics

## 4.6. Diabetes Drafting Group

No topics

# 5. Harmonisation and consistency groups

## 5.1. International Council on Harmonisation (ICH)

### 5.1.1. Call for expression of interest to the upcoming ICH M15

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A call for expression of interest for appointment of two experts to represent CHMP/EMA/EC in the newly formed ICH M15 working group, working on a new guideline on General Principles of Model-Informed Drug Development, was launched via the Methodology WP with deadline on 25 May. The two expert nominations are now brought for CHMP endorsement.

**Action:** For adoption

The CHMP adopted the nomination of Kristin Karlsson and Flora Musuamba Tshinanu as, respectively, topic lead and deputy topic lead for the development of the new guideline on General Principles of Model-Informed Drug Development.

### 5.1.2. Call for expression of interest to the upcoming revision of the ICH Q1 series/ICHQ5C

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A call for expression of interest for appointment of two experts to represent CHMP/EMA/EC in the newly formed ICH Q1/Q5C working group, working on a new guideline on revision of the stability guideline series, was launched via the Quality and Biologics WPs with deadline on 27<sup>th</sup> May. The two expert nominations are now brought for CHMP endorsement.

**Action:** For adoption

The CHMP adopted the nomination of Greger Abrahamsen as topic lead and Sandrine Chiappini as deputy topic lead for the upcoming revision of the ICH Q1 stability guideline series series/ICH Q5C.

## 5.2. Guideline Consistency Group (GCG)

Chair: TBC

### 5.2.1. Nomination of new members of GCG

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Nominations received of new GCG members.

**Action:** For endorsement

The CHMP endorsed the nomination of Maria Grazia Evandri, Andre Elferink, Elita Poplavska and Janet Koenig as new members of GCG.

### 5.2.2. Call for expression of interest for a Chair of the GCG

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Following the end of mandate of Arantxa Sancho as Chair of GCG on 25 July 2021, a call for expression of interest for appointment for a Chair of the GCG is launched. The Chair should be appointed from the current members. Nominations should be sent to the Agency by **4 July 2022**. 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 expression of interest for a Chair of the GCG.

## 5.3. Summary of product characteristics Advisory Group

No topics

## 6. Joint groups and collaboration with other Scientific committees

### 6.1. Joint CVMP/CHMP ad-hoc expert group on the application of the 3Rs (replacement, reduction and refinement) in the regulatory testing of medicinal products (J 3RsWG)

No topics

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

No topics

### 6.3. Collaboration with other Scientific committees

#### 6.3.1. PRAC report to CHMP

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Chair: Sabine Straus

Summary of recommendations and advice of PRAC meeting held on 7-10 June 2022.

**Action:** For information

The CHMP noted the summary of recommendations and advice.

## 7. Regulatory/Organisational matters

### 7.1. Regulatory Issues/new legislation

#### 7.1.1. Procedural guidance for variation for variant update to COVID-19 vaccines - Revision

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Revision of the procedural guidance for variation for variant update to COVID-19 vaccines, regarding naming of variant strain qualifiers for COVID-19 vaccines based on NRG proposal.

**Action:** For adoption

The CHMP adopted the proposed revision of the Procedural guidance for variant strain(s) update to vaccines intended for protection against Human coronavirus.

#### 7.1.2. Finalisation of the Companion Diagnostics (CDx) consultation procedure

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Further to public consultation on the draft version published in December 2021, the EMA guidance on the CDx consultation has been updated and is now final. The CHMP/CAT AR CDx template as well as the application forms for both initial and follow-up procedures have also been updated.

**Action:** For adoption

This topic was postponed and expected to be covered during the June CHMP plenary meeting.

### 7.2. CHMP organisation/templates

#### 7.2.1. CHMP learnings

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Collection, discussion and recording of CHMP learnings.

CHMP: Outi Mäki-Ikola

**Action:** For discussion

CHMP endorsed the learnings. In addition, the CHMP discussed the need to re-assess the learnings process and a group was formed to initiate a review of such process.

#### 7.2.2. Call for nominations for CHMP co-opted members

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- At the May 2022 CHMP PROM meeting the Committee agreed that a co-opted member should be appointed in the following area of expertise: **Medical Statistics**. 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.

Elections will take place at the June CHMP Plenary meeting.

- At the May 2022 CHMP PROM meeting the Committee agreed that a co-opted member should be appointed in the following area of expertise: **Quality and safety (biological), with expertise in advanced therapies (gene, cell and tissue**

**therapies**). 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.

Elections will take place at the July CHMP Plenary meeting.

**Action:** For information

CHMP noted the nomination(s) received for the position of a co-opted member in the area of expertise **Medical Statistics** by the deadline.

In addition, the CHMP noted the call for nominations for a CHMP co-opted member in the area of Quality and safety (biological), with expertise in advanced therapies (gene, cell and tissue therapies).

## 8. Product development support

### 8.1. Scientific Advice Working Party (SAWP)

Chair: Paolo Foggi

#### 8.1.1. Agenda and Table of Decisions

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- Agenda from 07-10 June 2022 meeting held by Webex
- Draft Table of Decisions from 07-10 June 2022 meeting held by Webex

**Action:** For information

The CHMP noted the agenda and the table of decisions.

#### 8.1.2. Appointment of CHMP peer review for SA

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**Action:** For information

CHMP noted the appointment of CHMP peer review for Scientific Advice.

### 8.2. Innovation Task Force

#### 8.2.1. ITF meeting

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Meeting date: 20 June 2022

**Action:** For adoption

The CHMP endorsed the meeting.

#### 8.2.2. ITF meeting

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Meeting date: 21 June 2022

**Action:** For adoption

The CHMP endorsed the meeting.

## 9. Product related topics

### 9.1. Preview CHMP Plenary

CHMP: Harald Enzmann

**Action:** For information

The CHMP Chair flagged some procedures on the agenda of the upcoming plenary. COVID-19 ongoing and upcoming procedures

List of currently ongoing and upcoming (imminently, i.e. expected within the next 2 months) applications for COVID-19 vaccines and therapeutics.

**Action:** For information

The CHMP noted the COVID-19 ongoing and upcoming procedures.

## 10. Any Other Business

### 10.1. Rapporteurships

List of rapporteurships.

**Action:** For information

The CHMP noted the update of the list of rapporteurships.

### 10.2. A workshop of the ESC Cardiovascular Round Table; "Real World Evidence"

Draft Agenda and List of participants from the EMA working parties.

**Action:** For adoption

The CHMP noted the draft agenda and List of participants from the EMA working parties on the workshop of the ESC Cardiovascular Round Table; "Real World Evidence.

### 10.3. EMA study on the impact of RWE in applicants' submissions

Presentation highlighting the study results and reflections.

**Action:** For information

The CHMP noted the presentation highlighting the study results and reflections of the EMA study on the impact of RWE in applicants' submissions. CHMP noted that this work is being conducted as part of the CHMP Workplan 2022. CHMP raised a recommendation to describe use cases where RWE was adequate for decision making but also the situations where it was not adequate or supportive of decision making.

### 10.4. EMA funded registry-based study on Spinal muscular atrophy

Presentation highlighting the study objectives and timelines.

**Action:** For information

The CHMP noted the study objectives and timelines on the EMA funded registry-based study on Spinal muscular atrophy.

## 11. 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	Alternate	Austria	No interests declared	
Christophe Focke	Member	Belgium	No restrictions applicable to this meeting	
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 restrictions applicable to this meeting	
Aaron Sosa Mejia	Alternate	Denmark	No restrictions applicable to this meeting	
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	
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	
Konstantina Alexopoulou	Member	Greece	No interests declared	
Robert Porszasz	Member	Hungary	No interests declared	
Agnes Gyurasics	Alternate	Hungary	No interests declared	
Jayne Crowe	Member	Ireland	No interests declared	
Armando Genazzani	Member	Italy	No interests declared	
Maria Grazia Evandri	Alternate	Italy	No interests declared	
Elita Poplavska	Member	Latvia	No interests declared	
Romaldas Mačiulaitis	Member	Lithuania	No participation in final deliberations and voting on:	COVID-19 vaccines
Martine Trauffer	Member	Luxembourg	No interests declared	
John Joseph Borg	Member	Malta	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda and for which restrictions apply
Johann Lodewijk Hillege	Member	Netherlands	No interests declared	
Paula Boudewina van Hennik	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	
Fatima Ventura	Alternate	Portugal	No participation in final deliberations and voting on:	COVID-19 vaccines
Dana Gabriela Marin	Alternate	Romania	No interests declared	
Francisek Drafi	Member	Slovakia	No interests declared	
Dorota Distlerova	Alternate	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	
Christian Gartner	Co-opted member	Austria	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	
Deirdre Mannion	Expert - via WebEx*	Denmark	No restrictions applicable to this meeting	
Anne Hasle Buur	Expert - via WebEx*	Denmark	No interests declared	
Paula Contreras Alarcón	Expert - via WebEx*	Spain	No part in discussions, final deliberations and voting on:	5.1.16. Rinvoq - upadacitinib - EMEA/H/C/004760/II/0016
Maria Victoria Tudanca Pacios	Expert - via WebEx*	Spain	No restrictions applicable to this meeting	
Mas Parra Paloma	Expert - via WebEx*	Spain	No restrictions applicable to this meeting	
Luca Santi	Expert - via WebEx*	Italy	No restrictions applicable to this meeting	



Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda and for which restrictions apply
Martina Perini	Expert - via WebEx*	Italy	No part in discussions, final deliberations and voting on:	3.3.5. pegunigalsidase alfa - Orphan - EMEA/H/C/005618  4.1.1. Procysbi - mercaptamine - Orphan - EMEA/H/C/002465/X/0035
Meeting run with the help of EMA staff				

\*Experts were evaluated against the product(s) they have been invited to talk about.