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SCIENCE MEDICINES HEALTH

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Human Medicines Division

Committee on Herbal Medicinal Products (HMPC)

Final Minutes for the meeting on 16-18 November 2020

Chair: E. van Galen, Vice-Chair: E. Svedlund

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

Of note, this set of minutes is a working document primarily designed for HMPC members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned in the 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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1. Introduction

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 table of decisions of the current meeting, the Committee Secretariat announced that no restriction in the involvement of meeting participants in upcoming discussions was identified.

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 with regard to topics on the agenda.

Discussions, deliberations and voting took place in line with the relevant provisions of the Rules of Procedure.

New membership:

- Netherlands, Hilda Kuin (alternate) as of 12 November 2020

1.2. Adoption of agenda

HMPC agenda for 16-18 November 2020 was adopted.

Time schedule for 16-18 November 2020 was endorsed.

1.3. Adoption of the minutes

HMPC minutes for 21-23 September 2020 were adopted and will be published on the EMA website.

2. EU herbal monographs and list entries for adoption

2.1. Status of HMPC/MLWP activities

2.1.1. Overview of HMPC/MLWP assessment work including the Rapporteurship distribution – Status in November 2020

Report: HMPC Chair

Action: for discussion

Document: Overview

Outcome:

HMPC noted status of assessment work.

In case of postponement of topics scheduled for the HMPC January meeting according to the overview, Rapporteurs were asked to inform secretariat and Chair before the first pre-mail to allow best adaptation of agenda and time-schedule.

2.1.2. Appointment of Rapporteurs and Peer-reviewers

None

2.2. Revised EU herbal monographs and list entries for final adoption

None

2.3. Revised EU herbal monographs and list entries for public consultation

None

2.4. Reviewed EU herbal monographs and list entries for decision on revision

2.4.1. Monograph on *Agropyri repentis rhizoma* and supporting documents

Action: for adoption

Documents: Review report; References: 67/02

Outcome:

Adoption postponed.

Discrepancies regarding daily dose and preparation of a herbal tea (decoction/infusion) were discussed. Document to be finalised according to the discussion for possible adoption at the **HMPC January** meeting.

2.4.2. Monograph on *Carvi aetheroleum* and supporting documents

Action: for adoption

Documents: Review report; References: 17/15

Outcome:

HMPC agreed with Rapporteur's position that no monograph revision is needed because no new data of relevance were detected that would change the content of the monograph.

The HMPC decided by consensus not to revise the monograph, assessment report and list of references on *Carvi aetheroleum*.

The review report was adopted and will be published as addendum to the existing assessment report on the EMA website.

2.4.3. Monograph on *Carvi fructus* and supporting documents

Action: for adoption

Documents: Review report; References: 17/15

Outcome:

HMPC agreed with Rapporteur's position that no monograph revision is needed because no new data of relevance were detected that would change the content of the monograph.

The HMPC decided by consensus not to revise the monograph, assessment report and list of references on Carvi fructus.

The review report was adopted and will be published as addendum to the existing assessment report on the EMA website.

2.4.4. Monograph on Caryophylli floris aetheroleum and supporting documents

Action: for adoption

Documents: Review report; References: 05/05

Outcome:

HMPC agreed with Rapporteur's position that no monograph revision is needed because no new data of relevance were detected that would change the content of the monograph.

The HMPC decided by consensus not to revise the monograph, assessment report and list of references on Caryophylli floris aetheroleum.

The review report was adopted and will be published as addendum to the existing assessment report on the EMA website.

2.4.5. Monograph on Chamomillae romanae flos and supporting documents

Action: for adoption

Documents: Review report; References: 31/38

Outcome:

HMPC agreed with Rapporteur's position that no monograph revision is needed because no new data of relevance were detected that would change the content of the monograph.

The HMPC decided by consensus not to revise the monograph, assessment report and list of references on Chamomillae romanae flos.

The review report was adopted and will be published as addendum to the existing assessment report on the EMA website.

2.4.6. Monograph on Lavandulae aetheroleum and supporting documents

Action: for adoption

Documents: Review report, Readers guidance; References: 43/198

Outcome:

HMPC agreed with Rapporteur's position to revise the monograph because new data were detected that require update and changes to the content of the monograph.

The HMPC decided by consensus to start the revision procedure and revise the monograph, assessment report and list of references on Lavandulae aetheroleum.

The review report was adopted and HMPC tracking documents will be updated.

2.4.7. Monograph on Lavandulae flos and supporting documents

Action: for adoption

Documents: Review report; References: 00/00

Outcome:

HMPC agreed with Rapporteur's position that no monograph revision is needed because no new data of relevance were detected that would change the content of the monograph.

The HMPC decided by consensus not to revise the monograph, assessment report and list of references on Lavandulae flos.

The review report was adopted and will be published as addendum to the existing assessment report on the EMA website.

2.4.8. Monograph on Solani dulcamarae stipites and supporting documents

Action: for adoption

Documents: Review report; References: 00/00

Outcome:

HMPC agreed with Rapporteur's position that no monograph revision is needed because no new data of relevance were detected that would change the content of the monograph.

The HMPC decided by consensus not to revise the monograph, assessment report and list of references on Solani dulcamarae stipites.

The review report was adopted and will be published as addendum to the existing assessment report on the EMA website.

2.5. EU herbal monographs, list entries and public statements for final adoption

2.5.1. Monograph on Species amarae and supporting documents

Rapporteur: C Purdel; Peer-reviewer: A Assisi

Action: for adoption

Documents: MO, AR, LoR, OoC; References: 10/13

Outcome:

Final EU herbal monograph and supporting documents adopted by majority vote (20 out of 21). The Norwegian delegate expressed a favourable position.

Divergent opinion: Wojciech Dymowski

The amendment of 'Regulatory questions and answers on herbal medicinal products' such as a question how to use EU herbal monographs on combinations will be prepared for discussion at next plenary meeting by the Rapporteurs of species amarae and species sedativae.

Divergent opinion referred to concerns with inclusion of HMPC monographs that the proposed combination monograph refers to and in contrary exclusion of the herbal substances where the HMPC monograph does not exist.

2.5.2. Monograph on Species sedativae and supporting documents

Rapporteur: S Flemisch; Peer-reviewer: R Länger

Action: for adoption

Documents: MO, AR, LoR, OoC, Reader's guidance; References: 35/23

Outcome:

Final EU herbal monograph and supporting documents adopted by majority vote (20 out of 22). The Norwegian delegate expressed a favourable position.

Divergent opinion: Wojciech Dymowski, Zsuzsanna Biró-Sándor

The amendment of 'Regulatory questions and answers on herbal medicinal products' such as a question how to use EU herbal monographs on combinations will be prepared for discussion at next plenary meeting by the Rapporteurs of species amarae and species sedativae.

Divergent opinion referred to concerns with omitting herbal substances where evidence of safe long-standing use is fulfilled.

2.6. EU herbal monographs, list entries and public statements for adoption for release for public consultation

2.6.1. Monograph on *Saccharomyces cerevisiae* CBS 5926 and supporting documents

Action: for adoption

Documents for adoption: MO, LoR, AR; References: 2/214

Documents for discussion: Draft PS, presentation, email correspondence

Outcome:

Adoption postponed.

No majority was found to support the release for public consultation (13 out of 22 votes). The Norwegian delegate expressed a favourable position. The draft MO currently covers both WEU and TU.

Members expressed their concerns regarding the current version of the MO and the Rapporteur was asked to prepare a PS containing an appropriate justification for finalisation of assessment and explanation why a monograph is not established in line with HMPC procedures.

2.7. EU herbal monographs, list entries and public statements - post finalisation

None

3. Referral procedures

None

4. Guidelines and guidance documents

4.1. Non-clinical/clinical safety and efficacy and multidisciplinary

4.1.1. Public statement on the use of herbal medicinal products containing estragole

Action: for adoption

Documents: PS, OoC

Outcome:

Final public statement on the use of herbal medicinal products containing estragole adopted by consensus.

HMPC agreed to initiate the communication between CHMP/SWP and CMDh before final publication.

4.2. Quality

None

4.3. Regulatory / Procedural

None

4.4. Report on HMPC Drafting Groups activities

4.4.1. Quality DG

None

4.4.2. ORGAM DG

None

5. Organisational, regulatory and methodological matters

5.1. Mandate and organisation of the HMPC

5.1.1. Strategic Review and Learning Meetings

Germany Presidency meeting – September 2020

Action: for information

Document: Summary of discussions

Outcome:

HMPC welcomed the summary of discussions that took place during the SRLM under the German presidency in September.

5.1.2. Election of Co-opted member (paediatrics)

Report: HMPC Chair

Action: for discussion

Documents: Call for nominations, [Procedure for the nomination and appointment of co-opted members of the CHMP, CVMP and HMPC](#), Expertise of HMPC members

Outcome:

Election postponed. No candidates were nominated by HMPC members.
The need for a paediatric expert was re-confirmed.

Post-meeting note:

The election will be scheduled for the HMPC March meeting to allow more time for consultation of the paediatric network. A third call for nomination will be sent out by the HMPC secretariat.

5.1.3. Elections of Co-opted members (Experimental/non-clinical pharmacology and General and family medicine)

Report: HMPC Chair

Action: for adoption

Documents: Call for nominations, [Procedure for the nomination and appointment of co-opted members of the CHMP, CVMP and HMPC](#), Expertise of HMPC members, Candidatures

Outcome:

Election took place in line with the HMPC Rules of procedure.

Gert Laekeman was elected as HMPC co-opted member for experimental/non-clinical pharmacology with a renewed 3-year mandate starting 24 November 2020.

Maria Helena Pinto Ferreira was elected as HMPC co-opted member for general and family medicine with a renewed 3-year mandate starting 24 November 2020.

5.2. EMA Scientific Committees or CMDh-v

5.2.1. Scientific Coordination Board Meeting

Report: HMPC Chair

Action: for discussion

Documents: Final agenda 19 October 2020; Draft Minutes 19 October 2020; Presentation (HMPC Chair)

Outcome:

HMPC noted topics discussed at the Scientific Coordination Board in October and the current progress of Review Group on Working parties and Drafting groups presented by HMPC Chair.

5.3. Coordination with EMA Working Parties/Working Groups/Drafting Groups

None

5.4. Cooperation within the EU regulatory network

5.4.1. Coordination with European Pharmacopoeia

- EDQM 13A expert group meeting
Report: M Bald
Action: for information
Documents: SoD, Senna fruit dry extract, Senna leaf
- EDQM 13B expert group meeting
Report: M Bald
Action: for information
Document: SoD
- EDQM TCM expert group meeting
Report: M Bald
Action: for information
Document: SoD
- EDQM PA working party meeting
Report: R Laenger
Action: for information
Documents: Draft Method (Contaminant pyrrolizidine alkaloids (2.8.26.)), Comments from HMPC

Outcome:

HMPC noted summaries of decisions for 13A, 13B and TCM meetings highlighted by the EDQM observer and changes in PA draft method in line with comments received from HMPC.

5.4.2. Coordination with the European Commission

- Cannabis for medicinal use
Report: HMPC Chair
Action: for discussion

5.5. Cooperation with International Regulators

None

5.6. Contacts of the HMPC with external parties and interaction with the Interested Parties to the Committee

5.6.1. Stakeholder meeting (AESGP), 18 November 2020

Report: HMPC Chair

Action: for discussion

Documents: Agenda, List of participants, Presentations

Outcome:

AESGP discussed with HMPC 3 topics of relevance. A hearing report will be drafted separately for publication at the EMA website.

The Committee received some new information with regard to HMPC guidance concerning herbal products containing pyrrolizidine alkaloids. Updates were given and views exchanged regarding the alignment of EU herbal monographs with Ph. Eur.

5.7. Work plan

5.7.1. HMPC work plan 2020

Report: HMPC Chair, HMPC Vice Chair

Action: for discussion

Document: Work plan 2020, Annex 1, Annex 2 – current status November 2020

- Activity area 1-3-1: Implementation of a modified procedure for EU herbal monograph establishment and maintenance

Report: HMPC Vice Chair, HMPC Chair

Action: for discussion

Documents: Presentations, Draft HMPC Plenary Best Practice guide with annexed Reader's Guidance template

Outcome:

A survey that will be circulated to HMPC members and experts to improve the usage of PhV data in HMPC review reports was presented by the project lead. Results of the survey to be presented in **HMPC January** meeting.

The updated Best practice guide with annexed reader's guidance was presented by the project lead. Final adoption is scheduled for the **HMPC January** meeting.

- Activity area 1-3-2: Forward planning and prioritisation

Report: HMPC Vice Chair, HMPC Chair

Action: for information

Documents: Proposals from MSs

Outcome:

HMPC welcomed the received proposals for assessment to establish EU herbal monograph from six MSs. A summary of validated proposals for discussion and informed decision on prioritisation will be scheduled for the **HMPC January meeting**.

- Activity area 2-1-3: Use of PhV, non-clinical and real-world data for HMPC relevant safety assessments

Report: HMPC Vice Chair

Action: for discussion

Document: Presentation

Outcome:

HMPC welcomed presentation by the steering group on the general principles for contraindications and warnings. The ongoing discussion on principles for extrapolation of

data in paediatric population and the status of the contraindication in children under 2 years of age in the MO on *Hedera helix* were presented.

- Activity area 2-2-1: Development of training on assessment of applications for herbal medicinal products
Report: HMPC Vice Chair
Action: for discussion
Document: Presentation

Outcome:

HMPC welcomed presentation by the steering group on the development of training for 2021. HMPC Secretariat to contact EDQM representative for possible cooperation on training.

5.7.2. Draft HMPC work plan 2021

Report: HMPC Chair, HMPC Vice Chair

Action: for discussion

Documents: Draft Work plan 2021, Annex 1, Annex 2

Outcome:

HMPC secretariat to circulate a draft workplan to HMPC members for comments and identification of new topics or topic leaders and project contributors before final adoption at the HMPC January meeting.

5.8. Planning and reporting

None

5.9. Legislation and regulatory affairs

None

5.10. Questions from members

None

6. EU herbal monographs and list entries in preparation

6.1. Revision of EU herbal monographs and list entries in preparation for adoption after public consultation

6.1.1. Monograph on *Hyperici herba* and supporting documents

Action: for discussion

Documents: Draft MO-TU, AR, LoR, OoC, Reader's guidance; References: 03/822

Outcome:

Rapporteur to introduce changes in the monograph according to the discussion for **a 6th discussion at the HMPC January** meeting.

HMPC endorsed the combined AR and MO for TU and WEU. Rapporteur to align both parts taking into account all comments received during the plenary meeting regarding consistency (e.g. section 4.4 or 4.8). The newly combined draft revised monograph with all aligned changes will require procedural adaptations.

6.2. Revision of EU herbal monographs and list entries in preparation for public consultation

6.2.1. Monograph on *Orthosiphonis folium* and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR, Reader's guidance; References: 00/53

Outcome:

HMPC endorsed the Rapporteur's position that information in the MO regarding reduced fluid intake was shifted to section 4.3 to be in line with other monographs.

Rapporteur to finalise the documents for peer review and **adoption for public consultation** at the **HMPC January** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **4 December 2020**

Peer-review documents to be sent to Rapporteur: **16 December 2020**

Final documents to be included latest in 2nd premail: **5 January 2021**

6.2.2. Monograph on *Trigonellae foenugraeci semen* and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR; References: 05/99

Outcome:

Rapporteur to introduce changes in the MO with regard to the Polish product for **a 4th discussion at the HMPC January** meeting. The information regarding French market overview should be taken into account once received from the French delegate.

6.3. Review of EU herbal monographs and list entries in preparation for decision on revision

6.3.1. Monograph on *Cinnamomi corticis aetheroleum* and supporting documents

Action: for discussion

Documents: Review report; References: 00/02

Outcome:

HMPC noted the Rapporteur's position that there is no new information available that could change the content of the monograph. However, Rapporteur to consider that overall assessment of new data is still needed in order to make a final conclusion.

Rapporteur to modify the review report according to the discussion for **2nd discussion** at the **HMPC January** meeting.

6.3.2. Monograph on Cinnamomi cortex and supporting documents

Action: for discussion

Documents: Review report; References: 00/12

Outcome:

Rapporteur to consider that overall assessment of new data is still needed in order to make a final conclusion and to modify the review report according to the discussion for **2nd discussion** at the **HMPC January** meeting.

6.3.3. Monograph on Colae semen and supporting documents

Action: for discussion

Documents: Review report; References: 53/53

Outcome:

HMPC toxicologist expressed the willingness to support the Rapporteur with the assessment of toxicological data. Rapporteur to modify the review report according to the discussion for **4th discussion** at the **HMPC January** meeting.

6.3.4. Monograph on Fucus vesiculosus and supporting documents - postponed

Outcome:

Postponed.

6.3.5. Monograph on Fumariae herba and supporting documents

Action: for discussion

Documents: Review report, presentation; References: 00/16

Outcome:

Rapporteur to modify the review report according to the discussion regarding posology for single and daily dose with regard to the amount of water (and their possible merging) for **2nd discussion** at the **HMPC January** meeting.

The consistency as regards the products on the market should be double-checked.

6.3.6. Monograph on Mate folium and supporting documents

Action: for discussion

Document: Review report; References: 00/34

Outcome:

HMPC endorsed the Rapporteur's position that only new information available that could change the content of the monograph is reference to the new Ph. Eur. monograph. HMPC secretariat to clarify for next meeting if minor adjustment of the existing MO beside acknowledgement in the addendum of the AR is beneficial.

6.3.7. [Monograph on Plantaginis lanceolatae folium and supporting documents - postponed](#)

Outcome:

Postponed.

6.3.8. [Monograph on Rosmarini aetheroleum and supporting documents - postponed](#)

Outcome:

Postponed.

6.3.9. [Monograph on Rosmarini folium and supporting documents - postponed](#)

Outcome:

Postponed.

6.3.10. [Monograph on Solidaginis virgaureae herba and supporting documents - postponed](#)

Outcome:

Postponed.

6.3.11. [Monograph on Urticae folium and supporting documents - postponed](#)

Outcome:

Postponed.

6.3.12. [Monograph on Urticae herba and supporting documents - postponed](#)

Outcome:

Postponed.

6.3.13. [Monograph on Violae tricoloris herba and supporting documents](#)

Action: for discussion

Documents: Review report, Presentation; References: 28/29

Outcome:

HMPC endorsed the Rapporteur's position that the only change in the content of the monograph is an update of the name of the source plants for the herbal substance according to the current Ph. Eur. monograph. HMPC secretariat to clarify for next meeting if

minor adjustment of the existing MO beside acknowledgement in the addendum of the AR is beneficial.

6.3.14. Monograph on Zingiberis rhizoma and supporting documents - postponed

Outcome:

Postponed.

6.3.15. Monograph on Sabalis serrulatae fructus and supporting documents

Action: for discussion

Documents: Reader's guidance; References: 48/00

Outcome:

Rapporteur to modify the review report according to the discussion regarding market overview for **2nd discussion** at the **HMPC January** meeting.

6.4. EU herbal monographs and list entries in preparation for adoption after public consultation

6.4.1. Monograph on Aloysiae citriodoraе folium and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR; References: 00/31

Outcome:

No comments received during public consultation. Rapporteur to finalise the draft documents for peer review and **adoption** at the **HMPC January** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **4 December 2020**

Peer-review documents to be sent to Rapporteur: **16 December 2020**

Final documents to be included latest in 2nd premail: **5 January 2021**

6.5. EU herbal monographs and list entries in preparation for adoption for release for public consultation

6.5.1. Monograph on Andrographidis paniculatae folium and supporting documents

Action: for discussion

Documents: Summary of problems; References: 00/00

Outcome:

HMPC noted the Rapporteur's position that no monograph can be established based on current available data. HMPC secretariat to clarify next steps with the Rapporteur and Chair before the **HMPC January** meeting taking into account the existing PS and the review outcome and HMPC decision from May 2019 when new data had been identified to start the assessment procedure for monograph establishment.

6.5.2. Monograph on Centellae asiaticae herba and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR; References: 00/216

Outcome:

Rapporteur to introduce changes in the MO and AR according to the discussion for a **3rd discussion** at the **HMPC January meeting**.

6.5.3. Monograph on Cisti cretici folium and supporting documents - postponed

Outcome:

Postponed.

6.5.4. Monograph on Hyperici herba and supporting documents

Action: for discussion

Documents: MO-WEU

Outcome:

See 6.1.1.

6.5.5. Monograph on Salviae miltiorrhizae radix et rhizoma and supporting documents

Action: for discussion

Documents: Draft PS, AR, LoR; References: 00/90

Outcome:

HMPC noted that there are no sufficient data to establish a monograph. Rapporteur to finalise the draft documents according to the discussion for peer review and for a **4th discussion** or possible **adoption for public consultation** at the **HMPC January** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **4 December 2020**

Peer-review documents to be sent to Rapporteur: **16 December 2020**

Final documents to be included latest in 2nd premail: **5 January 2021**

6.5.6. Monograph on Species digestivae or species stomachicae and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR; References: 00/20

Outcome:

Rapporteur to introduce changes in the MO regarding the preclinical safety data currently mentioned in section 4.6. for **an 8th discussion at the HMPC January** meeting, where

more information on the ongoing discussion with SWP (see 4.1.1.) might be available and where discussion on associated draft MO on bitter and sweet fennel is awaited.

6.5.7. Monograph on *Taraxaci officinalis radix* and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR, Reader's guidance; References: 00/99

Outcome:

Rapporteur to finalise the draft documents for peer review and for a **3rd discussion** or possible **adoption for public consultation** at the **HMPC January** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **4 December 2020**

Peer-review documents to be sent to Rapporteur: **16 December 2020**

Final documents to be included latest in 2nd premail: **5 January 2021**

6.5.8. Monograph on *Vaccinii macrocarpi fructus* and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR, Reader's guidance; References: 459/260

Outcome:

Some members emphasised the limitations of data and expressed having concerns regarding indication or preparations included in the monograph/assessment report.

Rapporteur and Peer-reviewer to finalise the draft monograph for a **10th discussion** or possible **adoption** at the **HMPC January** meeting

7. Any other business

7.1. Topics for discussion

None

7.2. Documents for information

7.2.1. HMPC

Table of Decisions from HMPC meeting held on 21-23 September 2020

Overview of expertise of members HMPC and subgroups

[Inventory of herbal substances for assessment work](#)

[Abbreviations in HMPC agendas/minutes](#)

Common names of herbal substances in all languages

Final Monograph Overview

7.2.2. ARSP

- English template
- English summaries for publication
 - Millefolii herba

7.2.3. EU herbal monographs, list entries and public statements – on hold

None

7.2.4. Other

- HMPC meeting dates 2022-2024

List of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 16-18 November 2020 meeting.

| Name | Role | Member state or affiliation | Outcome restriction following evaluation of e-DoI | Topics on agenda for which restrictions apply |
|----------------------------|-----------|-----------------------------|---|---|
| Emiel Van Galen | Chair | Netherlands | No interests declared | |
| Reinhard Länger | Member | Austria | No interests declared | |
| Patricia Bodart | Member | Belgium | No interests declared | |
| Ivan Kosalec | Member | Croatia | No restrictions applicable to this meeting | |
| Darko Trumbetic | Alternate | Croatia | No interests declared | |
| Maria Yiannitsarou | Alternate | Cyprus | No interests declared | |
| Markéta Příhodová | Member | Czech Republic | No restrictions applicable to this meeting | |
| Marie Heroutova | Alternate | Czech Republic | No interests declared | |
| Steffen Bager | Member | Denmark | No restrictions applicable to this meeting | |
| Maria Paile Hyvarinen | Member | Finland | No interests declared | |
| Sari Koski | Alternate | Finland | No interests declared | |
| An Le | Member | France | No interests declared | |
| Jacqueline Wiesner | Member | Germany | No interests declared | |
| Susanne Flemisch | Alternate | Germany | No interests declared | |
| Ioanna Chinou | Member | Greece | No interests declared | |
| Stavroula Mamoucha | Alternate | Greece | No interests declared | |
| Zsuzsanna Biróné Dr Sándor | Member | Hungary | No interests declared | |
| Alessandro Assisi | Member | Italy | No interests declared | |
| Baiba Jansone | Member | Latvia | No interests declared | |
| Clemence Varret | Alternate | Luxembourg | No interests declared | |
| Everaldo Attard | Member | Malta | No interests declared | |
| Burt H Kroes | Member | Netherlands | No interests declared | |

| Name | Role | Member state or affiliation | Outcome restriction following evaluation of e-DoI | Topics on agenda for which restrictions apply |
|--|---------------------|------------------------------------|--|--|
| Hilda Kuin | Alternate | Netherlands | No interests declared | |
| Steinar Madsen | Member | Norway | No interests declared | |
| Gro Anita Fossum | Alternate | Norway | No interests declared | |
| Wojciech Dymowski | Member | Poland | No interests declared | |
| Ana Paula Martins | Member | Portugal | No interests declared | |
| Carmen Purdel | Member | Romania | No interests declared | |
| Ligia Elena Dutu | Alternate | Romania | No interests declared | |
| Milan Nagy | Alternate | Slovakia | No interests declared | |
| Barbara Razinger | Member | Slovenia | No interests declared | |
| Cristina Martinez Garcia | Alternate | Spain | No interests declared | |
| Karin Erika Svedlund | Member (Vice-Chair) | Sweden | No interests declared | |
| Barbara Toth | Expert | Hungary | No interests declared | |
| Gert Laekeman | Co-opted member | Belgium | No interests declared | |
| Heidi Foth | Co-opted member | Germany | No interests declared | |
| Maria Helena Pinto Ferreira | Co-opted member | Portugal | No interests declared | |
| Melanie Bald | Observer | EDQM | No interests declared | |
| Olga Palomino | Expert | Spain | No interests declared | |
| Pierre Duez | Expert | Belgium | No interests declared | |
| Meeting run with the help of EMA staff | | | | |