26 March 2018
EMA/HMPC/146940/2018 - **FINAL**
Inspections, Human Medicines Pharmacovigilance & Committees Division

# Committee on Herbal Medicinal Products (HMPC)

## Minutes for the meeting on 29-30 January 2018

Chair: Marisa Delbò Vice-Chair: Emiel Van Galen

29 January 2018, 14:00 – 19:00, 2F

30 January 2018, 09:00 – 13:00, 2F

### Health and safety information

In accordance with the Agency's health and safety policy, delegates are briefed on health, safety and emergency information and procedures prior to the start of the meeting.

### Disclaimers

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

Of note, the minutes are 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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# Table of contents

# 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 agenda 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.

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 (i.e. 22 or more members were present in the room).

*End of memberships:*

Gioacchino Calapai (Italy); his membership terminated on 28 November 2017

Per Claeson (Sweden); his membership terminated on 15 January 2018

*New memberships:*

Erika Svedlund, member (Sweden); her membership started on 20 January 2018

Katarzyna Tomaszewska, alternate (Poland); her membership started on 14 December 2017

## 1.2. Adoption of agenda

HMPC agenda for 29-30 January 2018

Time schedule for 29-30 January 2018

**Outcome:**
Agenda adopted.

## 1.3. Adoption of the minutes

HMPC minutes for 20-21 November 2017

**Outcome:**
Minutes adopted.

# 2. European Union herbal monographs and list entries

## 2.1. Report on MLWP activities

### 2.1.1. MLWP Mandate and Rules of Procedure - revision

**Action:** for adoption
Document: Revised mandate/ RoP Rev. 4

### 2.1.2. MLWP work plan 2018

Report: MLWP Chair
Work plan 2018
**Action:** for adoption
Documents: MLWP work plan 2018, list of monographs due for review

**Outcome:**
Adopted with minor amendments. 5 public statements to be put under systematic review with call for data. It was agreed to add a note like for all committees to explain that the work plan is subject to the business continuity plan of the Agency, which can include the number and duration of face to face meetings in 2018.

Some substances (new assessments) were moved from 2.1 (monograph finalisation) to 2.2 (drafts for public consultation) taking into account current status and realistic timelines until end of 2018.

For other substances for review/revision it was requested to double-check some Peer-reviewers.

HMPC secretariat to publish the work plan on the EMA website.

### 2.1.3. New substances proposed for HMPC assessment

Report: MLWP Chair, E. v. Galen
**Action:** for discussion
Document: inventory, presentation, proposals for HMPC assessment received: Aloysiae folium (Lippia citriodora), Combination: Rehmannia 6, Combination: Species pectorals, Ecliptae prostatae herba, Herniariea herba (in combination), Menyanthes trifoliatae folium (in combination), Pueraria lobatae radix, Salvia miltiorrhizae rhizoma, Siegesbeckia orientalis herba, Tribuli terrestris herba and proposal NL regarding public statements

**Outcome:**
HMPC decided the start of assessment for 4 new substances: Herniariae herba (in combination), Verbenae citriodorae folium (Aloysiae folium), Menyanthidis trifoliatae folium (in combination) and Salvia miltiorrhizae radix et rhizoma. Accordingly amendments were included in the MLWP work plan 2018 (see 2.1.2).

For five public statements that are older than 5 years it was agreed to start the review procedure in analogy to the procedure for existing monographs. Calls for data will be published. The procedure can be cancelled and existing public statements and supporting documents remain as they are if no new relevant data is submitted by Interested Parties or identified by the Rapporteur.

HMPC secretariat accordingly to adapt the HMPC priority list and MLWP work plan for publication.

***Post-meeting note:*** *Calls for data for new substances and substances agreed for review will be published in 3 waves to allow compilation by Interested Parties.*

## 2.1.4. Appointment of Rapporteurs and Peer-reviewers

Changes of Rapporteurs for Monograph revision

Filipendulae ulmariae flos – New rapporteur
Filipendulae ulmariae herba – New rapporteur
Bursae pastoris herba – New rapporteur
Foeniculi amari fructus – New co-rapporteur
Foeniculi amari fructus aetheroleum – New co-rapporteur
Foeniculi dulcis fructus – New co-rapporteur
Phaseoli fructus (sine semine) – New rapporteur

Appointment of new Rapporteurs for new substances adopted for start HMPC assessment (only if added to HMPC priority list for assessment), see 2.1.3 (10 proposals in total, 4 proposed by MLWP for start 2018).

**Outcome:**
Endorsed.
It was agreed that the new Swedish HMPC/MLWP member takes over the Rapporteurships from the previous Swedish member.
***Post meeting note:*** *During MLWP it was considered that the same transfers apply to the peer reviewer positions.*

Rapporteurs/ Peer-Reviewers were appointed for new substances added to the HMPC priority list and MLWP work plan (see 2.1.3):
Herniariae herba
Verbenae citriodorae folium
Menyanthidis trifoliatae folium
Salvia miltiorrhiza radix et rhizoma

## 2.1.5. Election of MLWP Chair

Report: HMPC Chair
**Action:** for adoption
Document: Call for candidates from 11 January 2018

**Outcome:**
I. Chinou was re-elected as MLWP Chair for a fourth 3-year mandate starting on 30 January 2018.

## 2.1.6. Appointment of new MLWP member

Report: HMPC Chair
**Action:** for adoption
Document: Call for nominations from 04 January 2018, nominations

**Outcome:**

The HMPC was reminded of the call for nomination for a new MLWP member following the resignation of J Viguet Poupelloz. With the recent departure of P. Claeson, a second place in the MLWP became vacant. It was agreed that the sought expertise is the same for both member positions. B. Tóth and E. Svedlund were appointed as new MLWP members.

### 2.1.7. Report from the MLWP November 2017 meeting

Report: MLWP Chair
**Action:** for information
Document: Draft minutes for the MLWP meeting on 20-23 November 2017

The HMPC noted the report by the MLWP Chair based on the draft minutes.

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

### 2.2.1. Monograph on Uvae ursi folium

**Action**: for adoption
Documents: MO, AR, LoR, OoC; References: 111/111; see also 6.1.5

**Outcome:**
Final revised monograph and supporting documents adopted by consensus. The Norwegian delegate expressed a favourable position.

The members discussed the indication and agreed by majority to amend the indication from treatment to relief of symptoms. This minor change was considered as editorial and therefore not requiring a public consultation.

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

### 2.3.1. Monograph on Rusci aculeati rhizoma and supporting documents

**Action**: for adoption

Documents: Draft MO, AR, LoR; References: 10/57

**Outcome:**
Draft revised monograph with a minor change and supporting documents adopted by consensus for 3 months public consultation.

### 2.3.2. Monograph on Hyperici herba and supporting documents

**Action**: for adoption
Documents: Draft MO (TU), AR, LoR; References: 236/236

**Outcome:**
Draft revised monograph (TU) with a change in 4.1. and supporting documents adopted by majority for 3 months public consultation.

The HMPC discussed if the indication “for the supportive treatment of nervous restlessness and sleep disorders.” should be reworded to “stress”. There was no absolute majority supporting the change. HMPC endorsed the MLWP recommendation that in contrast to TU

monograph, the WEU monograph should not be revised currently as no new relevant data are available.

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

None

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

#### 2.5.1. Monograph on Cisti cretici folium and supporting documents – postponed to March 2018

## 3. Referral procedures

None

## 4. Guidelines and guidance documents

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

None

### 4.2. Quality

None

### 4.3. Regulatory

None

### 4.4. Report on HMPC Drafting Groups activities

#### 4.4.1. Quality DG

Report: QDG Chair

- Meeting report from Q DG virtual meeting held on 07 Dec 2017
  **Action:** for adoption
  Document: Meeting report
- Meeting report from Q DG face-to-face meeting held on 14-15 Dec 2017
  **Action:** for adoption
  Document: Meeting report
- Draft agenda for the Q DG face-to-face meeting to be held 22 Feb 2018
  **Action:** for information
  Document: Draft agenda
- Work Plan 2018
  **Action:** for adoption
  Documents: Draft work plan; QDG 2018 meeting dates

**Outcome:**
The Q DG Chair highlighted items discussed at the two meetings in December, especially the progress on the work on the guidelines. A view on AESGP proposals for Simplification of Variations for Herbal Medicinal Products is being drafted and will be brought to HMPC in March. The meeting reports from both meetings were adopted. Updates were given by the Q DG Chair on the forthcoming meeting (face-to-face) in February.

The Q DG Chair presented the work plan 2018 with specific focus to finalise the revision of the two main guidelines. The Work Plan 2018 was adopted.

### 4.4.2. ORGAM DG

Report: ORGAM DG Chair

- Meeting report from ORGAM virtual meeting held on 05 Dec 2017
  **Action:** for adoption
  Document: Meeting report from ORGAM DG meeting held on 05 Dec 2017
- Agenda
  **Action:** for information
  Document: Draft agenda for the ORGAM DG meeting to be held on 20 Feb 2018
- Work Plan 2018
  **Action:** for adoption
  Documents: Draft work plan; ORGAM DG 2018 meeting dates

**Outcome:**
Meeting report was adopted. Updates were given by the ORGAM Chair on the forthcoming meeting (virtual) in February.

The ORGAM Chair presented the work plan.

No rapporteurs were identified for three topics of the draft work plan (Procedure on management of proposals submitted by interested parties, Guideline on documentation to be submitted for inclusion into Community list and Template for proposal to HMPC for assessment to establish herbal monograph/list entry) and therefore it was agreed to delete these topics from the work plan.

Under point 2.3 A. Le was appointed as Rapporteur for the first procedure and W. Knoess was appointed for the other three procedures. It was agreed that the procedures should be reviewed and a concept on how to proceed should be developed. Members were invited to provide comments. The concepts will be discussed at ORGAM.

The Work Plan 2018 was adopted with amendments.

The ORGAM Chair asked for more members of HMPC or MLWP for the drafting group to allow drafting activities in 2018 as outlined in the work plan.

# 5. Organisational, regulatory and methodological matters

## 5.1. Mandate and organisation of the HMPC

### 5.1.1. Strategic Review and Learning Meetings

Report: HMPC Chair, HMPC Vice-chair
Estonia Presidency meeting – Bucharest, 11-12 Oct 2017 – follow up

**Action:** for discussion
Documents: presentations; Follow-up discussion paper

**Outcome:**

The Rapporteur presented the document with proposals for decisions to improve the performance and output of HMPC and MLWP in 2018.

There was a discussion on options for an amended meeting schedule to make HMPC/MLWP outcome and interaction more efficient; furthermore taken into consideration the business continuity situation created by Brexit and the EMA relocation.

HMPC agreed to try to use drafting groups and/or TCs to finalise discussions over the next 2 years to compensate a cut in MLWP meetings during the business continuity situation. Crucial topics can be finalised in the HMPC plenary based on good quality documents prepared by MLWP.

A disclaimer is added to the relevant work plans that the document is based on the current meeting schedule but can be subject to change considering business continuity provisions.

EMA management will inform the committee about the revised schedule of the HMPC-MLWP meetings in 2018-2019. Future discussion on organisation of HMPC/MLWP beyond that period will also take place at later stage.

### 5.1.2. Election of Co-opted member

Report: HMPC Chair
**Action:** for adoption
Documents: Expertise of HMPC members; Call for nominations from 04 Jan 2018

**Outcome:**
HMPC discussed whether it should continue to seek a fifth co-opted member or whether to reduce the number of co-opted members to four. It was agreed to continue seeking a co-opted member to the HMPC with clinical expertise (clinical pharmacologist/ clinical assessor). A third and final call for expression of interest should be sent by the Secretariat. It was agreed to inform relevant other EMA committees about the call for expression of interest.

## 5.2. Coordination with EMA Scientific Committees or CMDh-v

### 5.2.1. Scientific Coordination Board Meeting

Report: HMPC Chair
**Action:** for information
Documents: Agenda 11 Dec 2017

The report was noted.

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

### 5.3.1. Ethanol used as an excipient in medicinal products for human use

Action: for discussion

Documents: Ethanol PIL comparison, Q&A, email dated 11 January 2018

**Outcome:**
Comments on the distributed documents have been received from one Member State and further comments should be sent to the Coopted Member for non-clinical pharmacology, who volunteered to summarise them by 8th February for feedback to SWP.

## 5.4. Cooperation within the EU regulatory network

### 5.4.1. Coordination with the European Commission

- Update on List entries
  **Action**: for information

- Update on workshop "Complementary and alternative therapies for patients today and tomorrow" held at EP, Brussels, 16 October 2017
  **Action**: for information
  Document: summary report, REFIT Platform Opinion on the submission by businesses on the THMP Directive

  **Outcome:**
  The EC informed the group about the adoption of 2 list entries which will be published soon. The Secretariat will be informed, once published, to update the website. Information will also be provided to Member States.

  The summary report on the workshop "Complementary and alternative therapies for patients today and tomorrow" was tabled for information.

### 5.4.2. Coordination with European Pharmacopoeia

- EDQM 13A expert group meeting to be held on 6-7 March 2018
  Report: M. Bald (EDQM)
  **Action:** for information

- EDQM 13B expert group meeting held on 23-24 Jan 2018
  Report: M. Bald (EDQM)
  **Action:** for information
  Document: Draft agenda

- EDQM TCM expert group meeting to be held on 24-25 January 2018
  Report: M. Bald (EDQM)
  **Action:** for information
  Document: Draft agenda

- EDQM PA working party
  Report: M. Bald (EDQM)

  **Outcome:**
  HMPC noted SoDs and updates on 13A, 13B, TCM and PA expert groups given by the EDQM representative.

### 5.4.3. Coordination with EFSA

- Safety assessment of hydroxyanthracene derivatives - update
  Report: J. Wiesner, L. Anderson
  **Action:** for discussion
  Document: email communication, comments, EFSA draft opinion

- Safety assessment of green tea - update
  Report: C.Purdel, G.Laekeman
  **Action:** for discussion
  Document: email communication, EFSA draft opinion, draft comments

  **Outcome:**
  HMPC endorsed the expert opinion on the safety assessment of hydroxyanthracene derivatives by Linda Anderson and Jacqueline Wiesner as mandated in the November meeting, which have been provided to EFSA on 24 January 2018.

  Following the release of the EFSA draft opinion on the safety assessment of green tea, the HMPC comments drafted by Carmen Purdel can be further elaborated. Carmen Purdel will compile further comments. These will be circulated to the group for adoption via written procedure to keep the deadline for comments.

## 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. Requests by Interested Parties

- Requests for hearing by EUROCAM
  Report: HMPC Chair
  **Action:** for discussion
  Documents: email communication

- Request for IP status by ECHAMP
  Report: HMPC Chair
  **Action:** for discussion
  Documents: Request dated 18 Jan 2018

  **Outcome:**
  Postponed.

### 5.6.2. Question on HMPC assessment and national monograph use

Report: HMPC Chair
**Action:** for discussion
Document: Request dated 21 December 2017, Draft HMPC response

**Outcome:**
The HMPC discussed a query from a company and the draft response prepared by the EMA. The answers to questions 1-3 were agreed. EMA was asked to draft an answer to question 4

on the basis of the explanation of the Hedera Rapporteur. It was considered to check old PhV information and whether such information is public. The amended draft agreed by Rapporteur and Chair will be circulated for endorsement by HMPC.

## 5.7. Work plan

### 5.7.1. HMPC work plan 2017

- Report: HMPC Chair
  **Action:** for discussion
  Document: Work plan 2017 – implementation status
- Project 2.1.1. Patients involvement in assessment work
  Report: S. Bager
  **Action:** for discussion
  Documents: Presentation

  **Outcome:**
  A presentation was given.

  The HMPC agreed to summary and proposal for follow-up. Draft monographs going for public consultation will be notified to patient representatives for the possibility for written comments. In case of major issues identified Patient representative also can be invited to MLWP/HMPC meetings if appropriate.
- Project 2.1.2. Coordination on safety assessments of herbal constituents - postponed
  Report: H. Foth
- Project 2.1.3. Cooperation with Academia - postponed
  Report: MLWP Chair

### 5.7.2. HMPC work plan 2018

- Report: HMPC Chair
  **Action:** for adoption
  Documents: Draft Work plan 2018

  **Outcome:**
  HMPC work plan 2018 was adopted with amendments.

  The Committee discussed work plan topics in detail, modified as necessary and confirmed /added topic leads and project participants.

  HMPC took note of the disclaimer added to all committee work plans to explain that the work plan is based on the current meeting schedule but can be subject to the business continuity plan of the Agency, which can include changes to the number and duration of meetings in 2018.

  An activity to organise a hearing with Interested parties to exchange information on the utility of HMPC was deleted from the work plan due to the business continuity plan of the Agency. The aim is to include this topic with specified scope and objectives in the HMPC work plan again once the EMA has settled in the new location.

## 5.8. Planning and reporting

None

## 5.9. Legislation and regulatory affairs

### 5.9.1. Evidence on the period of traditional use

Report: E. V. Galen
**Action:** for discussion
Documents: Request to EC, draft response Jan 2017; presentations

**Outcome:**
Following questions sent to the EC in 2017 on the validity of information from Overseas Countries and Territories (OCTs) for the demonstration of traditional use, the EC representative presented answers to the raised questions:

1. Only EEA and EU MS count within EU. OCTs are excluded. Specific national agreements would be needed to consider it as part of EU and the acquis communautaire would need to have been applied.

2. 15 years of traditional use does not need to be immediately before the submission of the application. A case by case decision is needed.

The EC will provide the answers in writing for potential addition to the Regulatory Q&A on herbal products at the EMA website.

### 5.9.2. Letter to the HMPC regarding data protection and substance prioritisation

Report: HMPC Chair
**Action:** for information
Document: Letter dated 28 Sept 2017, EMA response dated 22 Jan 2018

**Outcome:**
The HMPC discussed a response to a letter regarding data protection and substance prioritisation drafted by the EMA. The response was adopted by consensus. EMA will sign and send out the letter.

# 6. Any other business

### 6.1.1. Questions from NCAs on Public statement on pyrrolizidine alkaloid contaminations

Report: H. Foth
**Action:** for discussion
Documents: Response to questions from BE & NL received in May 2017; Literature

**Outcome:**
Postponed.

### 6.1.2. Follow up on HMPC 2017 assessors training

Report: Q DG Chair
**Action:** for discussion

Documents: agenda, presentations

**Outcome:**
Updates were given by the Q DG Chair on the HMPC 2017 assessors training.

Positive feedback has been received from all involved parties.

The Q DG Chair suggested possible follow-up activities as regards quality assurance, further to be discussed at Q DG before a proposal is brought to HMPC. Regarding pyrrolizidine alkaloids it was emphasized that the transition as announced in the 2016 public statement on contamination will end in 2019 and a realistic follow-up should be prepared. A new topic lead comprising quality and safety aspects needs to be identified.

### 6.1.3. Saccharomyces cerevisiae CBS 5926

Rapporteur: HMPC Chair
**Action**: for discussion
Documents: draft letter; table status in MS

**Outcome:**
Further comments have been received on the latest draft of the letter to the EC to clarify the classification of *Saccharomyces cerevisiae*. The comments have been incorporated in the letter and the revised letter was adopted and will be sent to the EC.

### 6.1.4. User manual on CxMP/EMA external representation

**Action**: for discussion
Documents: Presentation; User manual

**Outcome:**
HMPC noted the presentation on Committee/WP/SAG members and experts representing CxMP or EMA at external meetings.

### 6.1.5. Submission and use of confidential data for HMPC assessment work

**Action**: for discussion
Documents: information received during public consultations, legal view

**Outcome:**
The EMA explained that consent of the owner of unpublished data has to be given in order to use it for the development/revision of monographs. In case of requests for access to documents of such data held by the EMA, the owner has to be consulted before release. Consent could be requested from the owner before taking the data into account.

### 6.1.6. Preparedness for UK's withdrawal from the EU – postponed

## 6.2. Documents for information

### 6.2.1. HMPC

Table of Decisions from HMPC meeting held on 20-21 November 2017

Overview of expertise of members HMPC and subgroups

Meeting report from HMPC meeting held on 20-21 November 2017

Overview of status of HMPC assessment work – priority list

Inventory of herbal substances for assessment work

Abbreviations in HMPC agendas/minutes

Common names of herbal substances in all languages

### 6.2.2. MLWP

- Overview of status of HMPC/MLWP assessment work
- Draft agenda of MLWP meeting to be held on 30 January-1 February 2018

### 6.2.3. ARSP

- English template
- English summaries for publication:
  - Hederae helicis folium
  - Meliloti herba
  - Ribis nigri folium

No objections were raised on the ARSP before publication.

### 6.2.4. Feedback on national experiences with HMPC monographs and guidelines

Rapporteur: R. Laenger, A. Assisi

- draft template
- summary feedback, examples feedback received: Cytisine (PL), Harpagophytum (SE)

### 6.2.5. New PhV information on herbal substances relevant for HMPC assessment

Rapporteur: Z. Birone-Sandor

- summary of available PSURs

### 6.2.6. Other

- PCWP/HCPWP meetings:
  - Meeting summary of the PCWP meeting with all eligible organisations held on 22 November 2017 (EMA/757232/2017): for information
- Article on Allergy-like immediate reactions with herbal medicines in children: A retrospective study using data from VigiBase®
- Anticipated PMDA/MHLW Recommendations for Regulatory Action
- Communication by Prof. Dr. Wenjun Zou (Chengdu University of Traditional Chinese Medicine) dated 26 January 2018
- EU herbal monographs, list entries and public statements post adoption: for information
  - Publication delays 2016/2017 updates
  - Remaining publication delays:

- Allii sativi bulbus
- Pistacia lentiscus (mastix)

# List of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 29-30 January 2018 meeting.

| Name | Role | Member State or affiliation | Outcome restriction following evaluation of e-DoI | Topics on agenda for which restrictions apply |
|---|---|---|---|---|
| Marisa Delbò | Chair | Italy | No interests declared | |
| Reinhard Länger | Member | Austria | No interests declared | |
| Heidi Neef | Member | Belgium | No interests declared | |
| Gert Laekeman | Co-opted member | Belgium | No interests declared | |
| Elena Mustakerova | Member | Bulgaria | No interests declared | |
| Ivan Kosalec | Member | Croatia | No restrictions applicable to this meeting | |
| Marie Heroutova | Member | Czech Republic | No interests declared | |
| Markéta Příhodová | Alternate | Czech Republic | No interests declared | |
| Steffen Bager | Member | Denmark | No restrictions applicable to this meeting | |
| Eeva Sofia Leinonen | Member | Finland | No interests declared | |
| An Le | Member | France | No interests declared | |
| Werner Knoess | Expert | Germany | No interests declared | |
| Ioanna Chinou | Member | Greece | No interests declared | |
| Zoi Karampourmpouni | Alternate | Greece | No interests declared | |
| Zsuzsanna Bíróné Dr Sándor | Member | Hungary | No interests declared | |
| Una Mockler | Member | Ireland | No restrictions applicable to this meeting | |
| Anna Maria Serrilli | Member | Italy | No interests declared | |
| Baiba Jansone | Member | Latvia | No interests declared | |
| Bruch Marcel | Alternate | Lithuania | No interests declared | |
| Everaldo Attard | Member | Malta | No interests declared | |
| Emiel Van Galen | Member | Netherlands | No interests declared | |
| Burt H Kroes | Alternate | Netherlands | No interests declared | |
| Steinar Madsen | Alternate | Norway | No interests declared | |
| Wojciech Dymowski | Member | Poland | No interests declared | |
| Ana Paula Martins | Alternate | Portugal | No interests declared | |
| Maria Helena Pinto Ferreira | Member | Portugal | No interests declared | |
| Carmen Purdel | Member | Romania | No interests declared | |
| Samo Kreft | Member | Slovenia | No interests declared | |
| Adela Núñez Velázquez | Member | Spain | No interests declared | |
| Karin Erika | Member | Sweden | No interests declared | |

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|---|---|---|---|---|
| Svedlund | | | | |
| Malin Kyllikki Hobro Soderberg | Alternate | Sweden | No interests declared | |
| Linda Anderson | Member | United Kingdom | No interests declared | |
| Sue Harris | Alternate | United Kingdom | No interests declared | |
| Melanie Bald | Observer (via TC) | EDQM | No interests declared | |
| Isabelle Holmquist | EC Representative | European Commission | Full involvement | |