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SCIENCE MEDICINES HEALTH

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Human Medicines Division

## Committee on Herbal Medicinal Products (HMPC)

### Minutes for the meeting on 28-30 March 2022

Chair: Emiel Van Galen, Vice-Chair: Karin Erika Svedlund

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

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## 1. Introduction

### 1.1. Welcome and declarations of interest of members, alternates and experts

The Chairperson opened the meeting by welcoming all participants. The meeting was held remotely.

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 (see list of participants).

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 line with the relevant provisions of the Rules of Procedure.

### 1.2. Adoption of agenda

HMPC agenda for 28-30 March 2022.

**Outcome:**

Agenda and time scheduled adopted.

### 1.3. Adoption of the minutes

HMPC minutes for 24-26 January 2022.

**Outcome:**

Minutes adopted.

Minor changes were introduced in the HMPC minutes for 24-26 January 2022.

## 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 March 2022

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Report: HMPC Chair

**Action:** For discussion

Document tabled: Overview (new format)

**Outcome:**

HMPC noted the new format for status of assessment work.

In case of postponement of topics scheduled for the HMPC May meeting according to the overview, Rapporteurs were asked to inform secretariat and Chair before the first pre-mail (by 03 May 2022) to allow best adaptation of agenda and time-schedule.

### 2.1.2. Appointment of Rapporteurs and Peer-reviewers

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None

### 2.1.3. Cross-monographs harmonisation for EU monographs with information that adequate fluid intake is required during treatment and related warning or contraindication concerning the use in patients under a reduced fluid intake

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Report: HMPC Vice-Chair

**Action:** For adoption

Document tabled: Proposal from the rapporteurs; Overview concerned monographs 2022

Related to: 2.2.1, 2.3.4, 2.7.1

**Outcome:**

The HMPC endorsed the recommendations from the group, which looked at all EU monographs with the indication '*THMP to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary complaints*'. At the next revision of the monographs concerned, the Rapporteur should introduce the following statements:

- in section 4.2 'Posology and method of administration' under the subheading 'Method of administration': 'To ensure an increase of the amount of urine, adequate fluid intake is required during treatment (see section 4.4. Special warnings and precautions for use)
- in section 4.4 "Because adequate fluid intake is required during treatment (see section 4.2. Posology and method of administration), <plant, plant part> is not recommended for patients with conditions where reduced fluid intake is advised by a medical doctor'.

It was clarified that the introduction of these statements is relevant for the following monographs:

- when the Rapporteur had found traditional use data pointing to this requirement to increase the amount of fluid intake, AND
- when the monograph includes herbal preparations other than herbal tea preparations.

### 2.1.4. Tracking of number of available references in HMPC agendas & minutes

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**Action:** For information

**Outcome:**

The HMPC endorsed the secretariat's proposal to track, in HMPC agendas & minutes, the number of references available at EMA (i.e., provided by the Rapporteur to EMA secretariat) in support of packages (EU herbal monographs, list entries, public statements) only when tabled for final adoption (initial assessment, first and subsequent revisions).

The tracking at intermediate stages is very time consuming and often does not reflect the final status.

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

### 2.2.1. Monograph on *Agropyri repentis rhizoma* and supporting documents

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**Action:** For adoption

Documents tabled: MO, AR, LoR, Readers Guidance; References: 76/84

**Outcome:**

The monograph was amended to implement the recommendations endorsed by the HMPC as a result of the cross-monographs harmonisation exercise carried out previously (see point 2.1.3). The HMPC secretariat was asked to amend the AR accordingly.

Final revised EU herbal monograph and supporting documents adopted by consensus. The Norwegian delegate expressed a favourable position.

### 2.2.2. Monograph on *Centellae asiaticae herba* and supporting documents

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**Action:** For adoption

Documents tabled: MO, AR, LoR; References: 100/137

**Outcome:**

No comments were received during the public consultation, thus the HMPC was invited to adopt the documents that had been released on EMA website for public consultation. The Rapporteur was invited to submit to the secretariat the missing references (see 2.1.4).

Final revised EU herbal monograph and supporting documents adopted by consensus. The Norwegian delegate expressed a favourable position.

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

### 2.3.1. Monograph on *Foeniculi amari fructus* and supporting documents

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**Action:** For adoption

Documents tabled: MO, AR, LoR, Reader's Guidance

**Outcome:**

Adoption postponed.

HMPC discussed the recommendations in the [CMDh press release](#) against the wording of the [HMPC public statement on HMPs containing estragole](#), and the impact on the monograph's revision (see also 5.2.3). There was an agreement that the concerns are most prominent with the fennel oil given its high content of estragole and that, for herbal teas, the extraction process reduces the amount of estragole. HMPC had agreed to recommend 'guidance values' in the public statement (PS) rather than 'limits'. Some members pointed to the expectation that, when revising the monographs, HMPC would respect the set 'guidance values' in the posology adopted for the herbal preparations. Other members were concerned that the posology would no longer reflect the TU data/evidence that support the recommended uses; they pointed to the known variability of estragole concentration depending on the variety and geographical origin as well as to the long history of safe use

of fennel in Europe. In relation to the 'guidance values', the HMPC PS states that 'the consideration of **a guidance value**, which has been calculated according to the ICH guideline M7, **is regarded as a helpful tool for statements e.g. on sensitive patient groups, acceptance of estragole containing excipients or also on the duration of use or acceptable daily doses**'. The CMDh press release reads: 'MAHs/RHs of medicinal products containing plants or their preparations which contain estragole, **either as active substance or excipient**, should check whether their medicinal products **comply with this guidance value**'. In order to release the revised monograph on Foeniculi amari fructus for public consultation, it is important that a decision is taken on whether the posology in the monograph must comply with the PS.

Rapporteur to modify the draft monograph and assessment report according to the discussion and comments from Peer-reviewer for **possible adoption** for release for public consultation at the **HMPC May** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **19 April 2022**

Peer-review documents to be sent to Rapporteur: **29 April 2022**

Final documents to be included latest in 2nd premail: **10 May 2022**

### 2.3.2. [Monograph on Foeniculi dulcis fructus and supporting documents](#)

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**Action:** For adoption

Documents tabled: MO, AR, LoR, Reader's Guidance

**Outcome:**

Adoption postponed (see 2.3.1).

Rapporteur to modify the draft monograph and assessment report according to the discussion and comments from Peer-reviewer for **possible adoption** for release for public consultation at the **HMPC May** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **19 April 2022**

Peer-review documents to be sent to Rapporteur: **29 April 2022**

Final documents to be included latest in 2nd premail: **10 May 2022**

### 2.3.3. [Monograph on Fumariae herba and supporting documents](#)

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**Action:** For adoption

Documents tabled: MO, AR, LoR, Readers Guidance

**Outcome:**

Adoption postponed.

Rapporteur to modify the draft monograph and assessment report according to the discussion (in particular, to integrate the outcome of searches in pharmacovigilance databases) and comments from Peer-reviewer for **possible adoption** for release for public consultation at the **HMPC May** meeting.



The Rapporteur was invited to ensure consistency between the monograph and the AR with regard to:

- the use in children and adolescents;
- the decision to include a warning in section 4.4 (*'Due to possible stimulation on bile secretion, Fumariae herba is not recommended in case of obstruction of the bile duct, cholangitis, liver disease, gallstones and any other biliary diseases'*) for consistency with the monograph on Curcumae longae rhizoma.

The Rapporteur pointed to the HMPC decision, when revising the monograph on Cynarae folium in 2018, to have a contraindication in section 4.3, i.e. *'Obstruction of bile duct, cholangitis, liver disease, gallstones and any other biliary disorders that require medical supervision and advice.'* HMPC invited the Rapporteur to ascertain the evidence on the influence on bile flow to justify the inclusion of a warning as opposed to a contraindication.

Timetable:

Documents to be sent to Peer-reviewer: **19 April 2022**

Peer-review documents to be sent to Rapporteur: **29 April 2022**

Final documents to be included latest in 2nd premail: **10 May 2022**

#### 2.3.4. Monograph on Juniperi pseudo-fructus and supporting documents

**Action:** For adoption

Documents tabled: MO, AR, LoR, Readers Guidance, Annex

**Outcome:**

Adoption postponed.

The HMPC endorsed the Rapporteur's proposal to treat the annex on the weight of juniper berries as a reference to be added in the list of bibliographic references (the monograph no longer covers the use of the cone berries; however, the scientific work is to be acknowledged). The Rapporteur was invited to:

- spell out fully 'single dose' and 'daily dose' (instead of SD and DD) having in mind greater clarity for readers;
- add missing standard statements from the monograph template;
- ensure consistency between the monograph and the AR in relation to the statements agreed upon following the cross-monographs harmonisation discussed under point 2.1.3.

Rapporteur to modify the draft monograph and assessment report according to the discussion and comments from Peer-reviewer for **possible adoption** for release for public consultation at the **HMPC May** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **19 April 2022**

Peer-review documents to be sent to Rapporteur: **29 April 2022**

Final documents to be included latest in 2nd premail: **10 May 2022**

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

### 2.4.1. Monograph on Arnicae flos and supporting documents

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**Action:** For adoption

Document tabled: Review report

**Outcome:**

The HMPC noted the large number of registered THMPs. The French member clarified that the product used as impregnated dressing for the 'local treatment of ecchymosis and subcutaneous haematoma' is no longer marketed (was on the market as of 1976, not 1982). For historical reasons, former declaration of tinctures was against the solvent, thus some old records refer to DSR – drug solvent ratio (1:5 or 1:10); it was remarked that DSR tend to be superior to DER – drug extract ratio.

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 Arnicae flos. The Rapporteur indicated that the revised draft monograph and supporting documents will be presented at the September or November HMPC meeting.

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

### 2.4.2. Monograph on Frangulae cortex and supporting documents

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**Action:** For adoption

Document tabled: Review report

**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 Frangulae cortex.

The review report was adopted (with amended sentence '*Overall, the results of the two in vivo studies do not trigger an unscheduled revision of the monograph since **results of the Comet assays on aloe-emodin revealed no, or inconclusive, genotoxic effects***') and will be published as addendum to the existing assessment report on the EMA website.

### 2.4.3. Monograph on Hippocastani cortex and supporting documents

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**Action:** For adoption

Document tabled: Review report

**Outcome:**

The HMPC discussed the modifications proposed by the Rapporteur, pointing to the need for consistency in the way the Committee handles the integration of the posology approved for THMPs registered after the establishment of the monograph (new posology is added; it is

not substituted to the posology found in the monograph). The HMPC Chair enquired about developments in the field of markers like esculin. Members were invited to provide the Rapporteur with any additional information on horse-chestnut bark products on their market.

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 Hippocastani cortex.

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

#### 2.4.4. Monograph on Juglandis folium and supporting documents

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**Action:** For adoption

Document tabled: Review report

**Outcome:**

Adoption postponed.

Rapporteur to modify the review report according to the discussion and possible comments from peer-reviewer for **possible adoption** at the **HMPC May** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **19 April 2022**

Peer-review documents to be sent to Rapporteur: **29 April 2022**

Final documents to be included latest in 2nd premail: **10 May 2022**

#### 2.4.5. Monograph on Liquiritiae radix and supporting documents

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**Action:** For adoption

Document tabled: Review report, Readers Guidance

**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 Liquiritiae radix.

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

#### 2.4.6. Monograph on Paullinae semen and supporting documents

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**Action:** For adoption

Document tabled: Review report

**Outcome:**

Adoption postponed.

Rapporteur to modify the review report (in particular, to integrate the outcome of searches in pharmacovigilance databases) according to the discussion and possible comments from peer-reviewer for **possible adoption** at the **HMPC May** meeting.

Timetable: Documents to be sent to Peer-reviewer: **19 April 2022**

Peer-review documents to be sent to Rapporteur: **29 April 2022**

Final documents to be included latest in 2nd premail: **10 May 2022**

#### 2.4.7. Monograph on Rhamni purshianae cortex and supporting documents

**Action:** For adoption

Document tabled: Review report

**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 Rhamni purshianae cortex.

The review report was adopted (with amended sentence '*Overall, the results of the two in vivo studies do not trigger an unscheduled revision of the monograph since **results of the Comet assays on aloe-emodin revealed no, or inconclusive, genotoxic effects***') and will be published as addendum to the existing assessment report on the EMA website.

#### 2.4.8. Monograph on Rhei radix and supporting documents

**Action:** For adoption

Document tabled: Review report

**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 Rhei radix.

The review report was adopted (with amended sentence '*Overall, the results of the two in vivo studies do not trigger an unscheduled revision of the monograph since **results of the Comet assays on aloe-emodin revealed no, or inconclusive, genotoxic effects***') and will be published as addendum to the existing assessment report on the EMA website.

#### 2.4.9. Monograph on Urticae radix and supporting documents - postponed

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

#### 2.5.1. Public statement on Salviae mitiorrhizae radix et rhizoma and supporting documents

**Action:** For adoption

Documents tabled: PS, AR, LoR; References: 67/89

**Outcome:**

Final public statement and supporting documents adopted by majority vote (25 out of 26). Divergent opinion: Burt Kroes (Netherlands). The Norwegian delegate expressed a favourable position.

### 2.5.2. Monograph on *Species digestivae* and supporting documents

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**Action:** For adoption

Documents tabled: MO, AR, LoR, Combinations table; References: 37/42

**Outcome:**

Final EU herbal monograph and supporting documents adopted by majority vote (24 out of 25). Divergent opinion: Wojciech Dymowski (Poland). The Norwegian delegate expressed a favourable position.

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

None

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

### 2.7.1. Monograph on *Taraxaci officinalis radix* and supporting documents

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**Action:** For adoption

Documents tabled: MO, AR; References: 91/91

**Outcome:**

The HMPC Chair reminded members that comments had been raised by the HMPC secretariat. The new Rapporteur confirmed that the documents were now amended according to these comments.

The Polish member signalled that the method of preparation of the expressed juice (DER 1:1) [herbal preparation b) in the monograph; in the AR, referred to as 'Taraxaci radices succus stabilised'] is inadequately described in both the monograph and the AR. According to the Polish tradition, the fresh roots are not boiled in ethanol but subjected to a steam of ethanol.

As the package had been formally adopted in November 2021, the HMPC considered that it was not necessary to proceed with a new vote. In liaison with the new Rapporteur, the HMPC secretariat was asked to bring the monograph in line with the conclusions reached under point 2.1.3, i.e., to include the 2 statements on adequate fluid intake in sections 4.2 and 4.4 and to amend accordingly the relevant sections in the AR. Minor changes were introduced in the AR. HMPC secretariat to take care of the publication of the amended package.

### 3. Referral procedures

None

### 4. Guidelines and guidance documents

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

##### 4.1.1. Guideline on Assessment of genotoxicity of herbal substances/preparations (EMA/HMPC/107079/2007) for public consultation

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**Action:** For adoption

Document tabled: Concept paper on the revision of the guideline

**Outcome:**

Adoption postponed.

HMPC members were invited to send comments in writing to the Rapporteurs in order to inform the Rapporteurs of their position vis-a-vis the option currently described in the concept paper. The HMPC Chair stressed that members, having heard the distinct views on the matter at stake, should communicate their position ahead of the next meeting to the Rapporteurs, in order to guide them towards the majority view.

Rapporteurs to modify the concept paper according to the discussion and comments from members for **possible adoption** for release for public consultation at the **HMPC May** meeting.

#### 4.2. Quality

##### 4.2.1. Guideline on Good Agricultural and Collection Practice (GACP) of starting materials of herbal origin

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**Action:** For information

Document tabled: [Concept paper on the revision of the Guideline](#)

**Outcome:**

HMPC noted the publication of the concept paper on the revision of the guideline on GACP. It was agreed that:

- the small drafting group would compile the comments received from interested parties;
- the review of the comments would take place in joint meetings between the small drafting group and the core-quality group.

#### 4.3. Regulatory / Procedural

None

## 4.4. Report on HMPC Drafting Groups activities

### 4.4.1. Quality DG

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None

### 4.4.2. ORGAM DG

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None

## 5. Organisational, regulatory and methodological matters

### 5.1. Mandate and organisation of the HMPC

#### 5.1.1. Strategic Review and Learning Meetings (SRLM)

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- French Presidency virtual meeting – 14 April 2022

Report: An Le

**Action:** For information

Document tabled: Draft agenda

**Outcome:**

HMPC noted the meeting's draft agenda presented by the French delegate. HMPC members and alternates willing to participate virtually in the meeting should register themselves (see invitation sent on 23 March 2022).

The dates for the next SRLM in 2023 during the Swedish presidency of the Council of the European Union were announced: the meeting will be offered virtually to participants, from Uppsala, on 18-19 April 2023.

- Slovenian Presidency virtual meeting – 08-09 December 2022

Report: Barbara Razinger

**Action:** For information

Document tabled: Follow-up plan

**Outcome:**

HMPC agreed to keep updating this document after the SRLM organised by France (with the suggestion to add and complete a column entitled 'Status').

#### 5.1.2. HMPC membership

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- Data protection notice

**Action:** For information

Documents tabled: Data protection notice - list of CXMP members alternates contacts in MMD (EMA/67519/2022), Presentation, HMPC contact list

**Outcome:**

HMPC noted the data protection notice (DPN) for the processing of the contact details of the members/alternates of the EMA's scientific Committees. The HMPC endorsed the availability in MMD of the tabled 'HMPC contact list', which includes the members' and alternates' name, affiliation and e-mail address. The DPN refers to the 'Data Controller' that is EMA as an organisational entity. Each EU institution or body has a 'Data Protection Officer' (DPO), who ensures, in an independent manner, the internal application of Regulation (EU) 2018/1725.

- Revision of the procedure for nomination and appointment of co-opted members

**Action:** For discussion

Documents tabled: Revised procedure (EMA/747064/2021 Rev.2), Presentation

**Outcome:**

HMPC endorsed the revision of the 'Procedure for the nomination and appointment of co-opted members of the CHMP, CVMP and HMPC'. The HMPC took note of the changes introduced in the document, including an alignment with the Committees' Rules of Procedure regarding voting and the definition of majority and the introduction of a reference to EMA policy on handling of competing interests.

- Membership update

Report: HMPC Chair

**Action:** For information

**Outcome:**

Re-nominated members:

- Hungary, Rita Németh (alternate) as of 04 April 2022
- Slovakia, Miroslava Petrikova (member) as of 21 April 2022
- Croatia, Ivan Kosalec (member) as of 30 June 2022
- Croatia, Darko Trumbetic (alternate) as of 30 June 2022
- Austria, Astrid Obmann (alternate) as of 19 July 2022
- Slovenia, Barbara Razinger (member) as of 27 June 2022
- Belgium, Patricia Bodart (member) as of 22 May 2022
- Portugal, Eva Mendes (alternate) as of 22 June 2022

End of membership:

- Bulgaria, Valentin Kotev (alternate) as of 25 February 2022
- Germany, Heidi Foth (Co-opted member) as of 7 July 2022

### 5.1.3. Pilot – Relaunch of face-to-face Scientific Committee Meetings

---

**Action:** For information

Document tabled: Presentation

**Outcome:**



HMPC noted the Agency's initiative to relaunch face-to-face meetings at the beginning of May 2022, in a hybrid set-up (in-person and remotely) and for every other scientific Committee meeting. HMPC Chair had expressed strong disappointment with the decision that HMPC would only meet at EMA premises in July, whilst all other Committees would meet in May or June. HMPC was informed that, in addition to the one planned in July, the HMPC secretariat was now exploring the possibility to organise such a face-to-face HMPC plenary already in May, with members attending in-person whilst alternates & experts would connect remotely. The test carried out in the selected room revealed no connectivity problems. In terms of number of in-person participants, the HMPC was informed about the limited room capacity due to Covid-19 measures still in place. HMPC members were invited to indicate potential availability to travel to EMA in May. HMPC secretariat to inform the HMPC as soon as an EMA Management decision is available.

*Post-meeting note: EMA management approved on 12 April 2022 the organisation of an in-person HMPC meeting in May.*

## 5.2. EMA Scientific Committees or CMDh-v

### 5.2.1. Scientific Coordination Board Meeting

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Report: HMPC Chair

**Action:** For information

Documents tabled: Minutes 31 January 2022, Draft Agenda 25 April 2022

**Outcome:**

HMPC noted topics discussed in January and on agenda for discussion in April at the Scientific Coordination Board. The HMPC Chair indicated that he would seek to add, to the agenda of the April meeting, a discussion on the integration of the HMPC former Quality Drafting Group in the new EMA model for Working Parties and Drafting Groups (see 5.7.2) and to report at the May meeting.

### 5.2.2. Coordination with QRD and CMDh – Update on Herbal specifics for QRD template ([CMDh/349/2016, Rev.0 - EMA/HMPC/770889/2014](#))

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**Action:** For discussion

Documents tabled: Addendum to the QRD templates, Readers Guidance

**Outcome:**

HMPC noted the progress achieved in the preparation of the addendum to the QRD templates. The Rapporteur presented the topics for discussion/input. HMPC members, especially those with practical experience of regulatory procedures and the use of QRD templates at NCA level, were invited to provide feedback and/or proposals to the Rapporteur on the issues highlighted in the Readers Guidance.

Rapporteur to modify the draft addendum according to the comments already received and expected additional contributions, for discussion at the next meeting.

### 5.2.3. Coordination with CMDh – List of estragole-containing plants

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**Action:** For discussion

Documents tabled: List of estragole-containing plants, [Public statement on the use of herbal medicinal products containing estragole](#) (EMA/HMPC/137212/2005 Rev.1) published on 01 March 2022, [Report from the CMDh meeting held on 22-23 February](#)

**Outcome:**

HMPC noted the publication of the public statement on the use of herbal medicinal products containing estragole and was made aware of the comments raised by CMDh on the list of estragole-containing plants that had been transmitted to them prior to the January 2022 HMPC meeting (the data as presented did not allow a straight forward search in national medicines databases; uncertainty about 'active substance' versus 'excipient' status; unspecified amount of estragole when the original source of information had not been assessed by HMPC).

Rapporteurs were thanked for having compiled the list under short deadlines. They were invited to identify a priority list of plants/plant parts with the highest level of estragole and used as active substance (for which the safety concerns are the most prominent) for discussion at the next meeting and transmission to CMDh.

HMPC Chair and Vice-chair to further discuss the concerns raised by the Chair and some members about the wording of the CMDh press release (see also 2.3.1).

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

#### 5.3.1. Nomination of HMPC representative (and alternate) for Patients and Consumers Working Party (PCWP) and for Healthcare Professionals Working Party (HCPWP)

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Report: HMPC Chair

**Action:** For discussion

Documents tabled: Email correspondence dated 09 March 2022

**Outcome:**

HMPC to identify members for nomination as HMPC representative (and alternate) for PCWP and HCPWP.

Current HMPC representatives in PCWP and in HCPWP are S. Bager, G. Laekeman and A. Le (see: <https://www.ema.europa.eu/en/committees/working-parties-other-groups/chmp/patients-consumers-working-party> <https://www.ema.europa.eu/en/committees/working-parties-other-groups/chmp/healthcare-professionals-working-party>).

S. Bager indicated that he no longer wishes to be HMPC representative in these groups. O. Palomino and A. Le expressed interest. HMPC secretariat to organise a meeting with them and the HMPC Chair and Vice-chair.

*Post-meeting note: nomination of HMPC representatives/alternates for the PCWP and HCPWP new mandate as follows:*

- PCWP: Representative: An Le; Alternate: Olga Maria Palomino

- HCPWP: Representative: Olga Maria Palomino; Alternate: An Le

## 5.4. Cooperation within the EU regulatory network

### 5.4.1. Coordination with European Pharmacopoeia

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- EDQM 13A expert group meeting

Report: Melanie Bald

**Action:** For information

Document tabled: SoD

- EDQM TCM expert group meeting

Report: Melanie Bald

**Action:** For information

Document tabled: SoD

**Outcome:**

The HMPC welcomed Bruno Spieldenner, new Head for the 'Chemically defined substances, Finished Products, General chapters & Herbals' Division within the European Pharmacopoeia Department (EPD) at EDQM.

HMPC noted summaries of decisions highlighted by the EDQM observer, in particular:

- ongoing work on the Ph. Eur. monograph on bitter fennel (method for the quantitative determination of estragole);

- in the Ph. Eur. Chapter 2.8.2 Foreign Matter, the requirements for other foreign matter have been further specified to include '*any other unwanted matter (e.g. glass, metal, plastic)*';

- the addition of cranberry juice to the work programme of the EDQM 13A expert group.

HMPC also noted the announcement for the 2022 EDQM Conference to mark the launch of 11th Edition European Pharmacopoeia, scheduled for 19-21 September 2022, which unfortunately coincides with the HMPC plenary.

The work of the TCM group was commented upon. In that context, it was clarified that some methods of processing according to the Chinese pharmacopoeia, like 'stir frying', 'calcining' and 'torrefication', that are unknown for the Ph. Eur., have been published for information only.

### 5.4.2. Coordination with the European Commission

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- Revision of EU pharmaceutical legislation (human)

Report: HMPC Chair

**Action:** For information

**Outcome:**

- Collaboration with EC on the feasibility to establish an EU herbal monograph for Cannabis flos

Report: HMPC Chair

**Action:** For information

Documents tabled: Email correspondence dated 24 February 2022

**Outcome:**

HMPC noted planned steps towards the preparation of a draft Questions & Answers document to be released with a call for data from interested parties. A first draft is being prepared by a drafting group and will be presented to the HMPC at its May meeting. The HMPC secretariat was invited to further liaise with the Eur. Com. with a view to identifying the new Commission representative in the Committee. Feedback is still expected from the Commission on the compilation of cannabis-related terms and definitions (see [https://www.ema.europa.eu/en/documents/minutes/minutes-hmpc-20-22-september-2021-meeting\\_en.pdf](https://www.ema.europa.eu/en/documents/minutes/minutes-hmpc-20-22-september-2021-meeting_en.pdf)).

*Post-meeting note: DG SANTE confirmed their approval for EMA to proceed with the publication of the compilation that was transmitted on 20 December 2021. The compilation is published under a new subsection of 'Guidance documents' at:*

*<https://www.ema.europa.eu/en/human-regulatory/herbal-products/herbal-medicines-regulatory-scientific-support>*

## 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. Association of the European Self-Medication Industry (AESGP) – hearing on 18 May 2022

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Report: HMPC Chair

**Action:** For discussion

Documents tabled: AESGP Proposal on combinations of traditionally used herbal extracts based on monographs

Related to: 5.1.3.

**Outcome:**

HMPC endorsed the proposal to have a virtual hearing of AESGP at the HMPC May meeting for discussion on AESGP's proposal about combinations of traditionally used herbal extracts based on monographs.

HMPC agreed to reconvene the drafting group on combinations and organise a preparatory meeting, ahead of the hearing, with the support of the HMPC secretariat.

## 5.7. Work plan and related activities

### 5.7.1. HMPC work plan 2022

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Report: HMPC Chair

**Action:** For information

Document tabled: HMPC Work plan, Annex 1, Annex 2

**Outcome:**

HMPC noted the publication of the HMPC work plan 2022.

### 5.7.2. New EMA model for Working Parties and Drafting Groups

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- Call for nominations for CHMP working parties

Report: HMPC Chair

**Action:** For discussion

Documents tabled: Email correspondence dated 02 March 2022

- Call for nomination for an expert in non-clinical working party (NCWP)

Report: HMPC Chair

**Action:** For discussion

Documents tabled: Email correspondence dated 15 March 2022

**Outcome:**

HMPC discussed the invitation to nominate an expert to become a full member of the NCWP, having specific expertise in non-clinical assessment of herbal medicinal products but also with a broader expertise in the non-clinical safety assessment of human medicinal products. The HMPC was alerted to the implications of such membership, including the expectation to spend 25% of work time to the NCWP activities.

An alternative would be to identify a member (either NCA-nominated or co-opted), an alternate or an expert (academic or from an NCA) with expertise in non-clinical assessment of herbal medicinal products, who could attend NCWP meetings on an ad hoc basis and ensure the liaison between HMPC and NCWP when guidelines under preparation by the HMPC would be shared with the NCWP for input/coordination.

HMPC secretariat was invited to support the organisation of a meeting between the HMPC Chair, Vice-chair, interested delegates and EMA staff members with a view to answering the call, as no nomination could take place during the meeting.

*Post-meeting note: Jacqueline Wiesner has been nominated as the HMPC expert designated to liaise with the Non-Clinical Working Party.*

### 5.7.3. Quality domain governance and draft multiannual work plan

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Report: Carmen Purdel, HMPC Chair; Expert: Kristine Hvolby

**Action:** For discussion

Document tabled: Ad-hoc Quality Group Minutes 22 February 2022

**Outcome:**

HMPC noted the progress achieved by the ad-hoc quality group. Next meeting scheduled for 21 April.

### 5.7.4. Improved use of data source for HMPC relevant safety assessment

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- Review report template

Report: HMPC Vice-chair, Carmen Purdel

**Action:** For discussion

Documents tabled: Review report template

**Outcome:**

HMPC endorsed the changes that were integrated into the revised draft 'review report template' following comments received from members.

Rapporteurs to modify the template according to the discussion and possible additional written comments from members for discussion at the next meeting. See also point raised under 6.3.3.

- Use of MedDRA terminology and classification system in Assessment Reports

Report: HMPC Vice-chair

**Action:** For discussion

Documents tabled: External query received by EMA on Oenotherae oleum

**Outcome:**

HMPC acknowledged the issues raised in an external query received by EMA on Oenotherae oleum, in particular:

- the choice of terms included in section 4.8 Undesirable effects of monographs vis-à-vis standards for adverse events terminology (use of MedDRA terminology and classification system). The content of monographs' section 4.8 tends to stem from TU sources such as old textbooks and terms may no longer correspond to modern medical terminology used to classify adverse event information associated with the use of pharmaceuticals;
- the traceability of information on adverse events found in Assessment Reports.

HMPC agreed to reflect on these issues, whilst remarking that monographs are not expected to substitute for SmPCs in MA/TUR applications.

#### 5.7.5. Evaluation of data from paediatric clinical practice for the safe use of herbal substances in children - postponed

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Report: Peter Voithl, Miroslava Petriková

#### 5.7.6. Development of training on assessment of applications for herbal medicinal products

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Report: HMPC Vice-chair, Carmen Purdel, Burt Kroes

**Action:** For discussion

Documents tabled: Course description, Presentation

**Outcome:**

HMPC noted the progress achieved in the development of a new part of the Herbal Curriculum: training on the CTD format and the use of herbal monographs. The training will be delivered by Carmen Purdel and Burt Kroes and is scheduled for July 2022. HMPC members were invited to send comments on the slides by 20 April 2022.

### 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 - postponed

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

6.2.1. Monograph on Foeniculi amari fructus aetheroleum and supporting documents

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**Action:** For 8<sup>th</sup> discussion

Documents tabled: Draft PS, Presentation, Reader's Guidance

**Outcome:**

Rapporteur to modify the draft public statement and supporting documents according to the discussion and possible additional comments from peer-reviewer and from HMPC members.

The question of the communication to EFSA of HMPC's position on risks associated with the amount of estragole was raised and will be discussed at the May meeting.

Rapporteur to prepare an assessment report supporting the public statement on Foeniculi amari fructus aetheroleum for peer-review and for **possible adoption** for release for public consultation at the **HMPC May** meeting.

Timetable: Documents to be sent to Peer-reviewer: **19 April 2022**

Peer-review documents to be sent to Rapporteur: **29 April 2022**

Final documents to be included latest in 2nd premail: **10 May 2022**

6.2.2. Monograph on Lavandulae aetheroleum and supporting documents – postponed

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6.2.3. Monograph on Pelargonii radix and supporting documents

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**Action:** For 1<sup>st</sup> discussion

Documents tabled: Reader's Guidance, Presentation

**Outcome:**

Rapporteur presented different elements to be taken into consideration for the revision. Rapporteur to prepare a draft revised assessment report according to the discussion and expected input as agreed during the meeting. HMPC members were invited to send comments to the Rapporteur.

Next **discussion** scheduled at the **HMPC May** meeting.

#### 6.2.4. Monograph on *Plantaginis lanceolatae folium* and supporting documents – postponed

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#### 6.2.5. Monograph on *Rosmarini aetheroleum* and supporting documents

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**Action:** For 4<sup>th</sup> discussion

Documents tabled: Draft MO, AR, Reader's Guidance

**Outcome:**

HMPC rediscussed the current absence from the market of THMP containing rosemary essential oil for oral use (from responses of HMPC members to the market overview). As discussed in January, HMPC maintains regulatory consistency (TU evidence had been found and remain valid); thus, removing the oral use from the monograph must be justified. Some members wondered if safety concerns explain the fact that there are not any registered products for that particular use and indication. Rapporteur was invited to further look into this issue: if the oral use is to be removed from the monograph, this must be justified by arguments other than the absence of marketed products.

Rapporteur to introduce changes in the draft monograph and assessment report according to the discussion and to send the package to the peer-reviewer. HMPC members were invited to send to the Rapporteur any information in relation to the above-mentioned issue.

Next **discussion** scheduled at the **HMPC May** meeting.

#### 6.2.6. Monograph on *Rosmarini folium* and supporting documents

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**Action:** For 4<sup>th</sup> discussion

Documents tabled: Draft MO, AR

**Outcome:**

Rapporteur to introduce changes in the draft monograph and assessment report according to the discussion and possible additional comments from peer-reviewer and HMPC members.

Next **discussion** scheduled at the **HMPC May** meeting.

#### 6.2.7. Monograph on *Zingiberis rhizoma* and supporting documents

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**Action:** For 1<sup>st</sup> discussion

Documents tabled: Reader's Guidance, References

**Outcome:**

Rapporteur to continue the ongoing references search and revision of the assessment report according to the discussion and possible additional references and comments from peer-reviewer and HMPC members.

Next **discussion** scheduled at the **HMPC May** meeting.



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

#### 6.3.1. Monograph on *Camelliae sinensis non fermentatum folium* and supporting documents

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**Action:** For 4<sup>th</sup> discussion

Document tabled: Review report, Readers Guidance

**Outcome:**

Postponed.

#### 6.3.2. Monograph on *Curcumae xanthorrhizae rhizoma* and supporting documents

---

**Action:** For 1<sup>st</sup> discussion

Documents tabled: Review report

**Outcome:**

The Rapporteur presented the review report and pointed to the slight difference in the wording of the therapeutic indication approved for *Curcumae longae rhizoma* (*traditional herbal medicinal product used for the relief of digestive disturbances, such as feelings of fullness, slow digestion and flatulence*) and that for *Curcumae xanthorrhizae rhizoma* (*traditional herbal medicinal product used for symptomatic treatment of digestive disturbances, such as feelings of fullness, slow digestion and flatulence*). The HMPC considered that this does not justify a revision to align the therapeutic indications in both monographs. The Rapporteur also referred to the change in the name from *Curcuma xanthorrhiza* into *Curcuma zanthorhizza* and several method changes in the Ph. Eur. monograph.

HMPC endorsed the Rapporteur's position that there is no new information available that could change the content of the monograph.

Rapporteur to finalise the review report and send for peer review before **adoption** at the **HMPC May** meeting.

Timetable: Documents to be sent to Peer-reviewer: **19 April 2022**

Peer-review documents to be sent to Rapporteur: **29 April 2022**

Final documents to be included latest in 2nd premail: **10 May 2022**

#### 6.3.3. Monograph on *Ginseng radix* and supporting documents

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**Action:** For 3<sup>rd</sup> discussion

Document tabled: Review report

**Outcome:**

HMPC endorsed the Rapporteur's position that there is relevant new information available that could change the content of the monograph and therefore a revision of the complete package is advocated.

Rapporteur to finalise the review report and send for peer review before **adoption** at the **HMPC May** meeting.

Timetable: Documents to be sent to Peer-reviewer: **19 April 2022**

Peer-review documents to be sent to Rapporteur: **29 April 2022**

Final documents to be included latest in 2nd premail: **10 May 2022**

The HMPC noted that the list of references supporting the proposed revision was not included in the review report and discussed this in the context of the ongoing revision of the review report template (see point 5.7.4). It will be specified in the template that the list of references may be omitted when the review report's content clearly points to the need for revision.

#### 6.3.4. Monograph on *Tiliae flos* and supporting documents

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**Action:** For 1<sup>st</sup> discussion

Documents tabled: Review report, Presentation

**Outcome:**

The HMPC discussed the references identified by the Rapporteur. Although references related to research in phytochemical composition of HMPs are not expected to be mentioned in review reports, the Rapporteur pointed to references on novel alkaloid compounds isolated from lime flowers and on tests conducted to assess their spasmodic activity. Some members found it interesting to include them in the report as the indirect cholinergic activity of these alkaloids might explain some aspects of the traditional use of lime flowers accepted in the monograph. The relevance of these findings was questioned by others, illustrating the difficulty in finding the right balance between documenting essential findings from academia and restricting the review exercise to the HMPC needs from a regulatory perspective. A consistent approach in the handling of publications identified during the review is desired, to avoid request for justifications as to why publications are selected and others not.

Rapporteur to modify the review report according to the discussion and possible additional comments from peer-reviewer and HMPC members.

Next **discussion** scheduled at the **HMPC May** meeting.

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

#### 6.4.1. Monograph on *Vaccinii macrocarpi fructus* and supporting documents

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**Action:** For 2<sup>nd</sup> discussion

Documents tabled: Draft MO, AR, LoR, OoC

**Outcome:**

HMPC discussed the complexity of the assessment of all comments received during the public consultation and supported the HMPC Chair proposal to assist the current Rapporteur and Peer-reviewer with setting up a multi-expert team of experienced assessors. New drafts are expected for the HMPC July meeting.

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

### 6.5.1. Monograph on Cisti cretici herba and supporting documents – postponed

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### 6.5.2. Monograph on Hyperici herba/Cimicifugae rhizoma and supporting documents

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**Action:** For 2<sup>nd</sup> discussion

Documents tabled: Presentation

**Outcome:**

Postponed.

### 6.5.3. Monograph on Tribuli terrestris herba and supporting documents

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**Action:** For 1<sup>st</sup> discussion

Document tabled: Presentation

**Outcome:**

The first discussion was postponed; however, HMPC confirmed that the Rapporteur can exclude references without a clear description of the herbal preparations (unclear plant part).

## 7. Any other business

### 7.1. Topics for discussion

None

### 7.2. Documents for information

#### 7.2.1. HMPC

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Table of Decisions from HMPC meeting held on 24-26 January 2022

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

HMPC plenary Best Practice Guide with annexed Reader's Guidance template

#### 7.2.2. Assessment Report Summary for the Public (ARSP)

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None

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

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None

### 7.2.4. Other

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- Meeting Summary – PCWP-HCPWP meeting with all eligible organisations - 24 November 2021
- Agenda - PCWP-HCPWP Joint meeting – 02-03 March 2022
- Human Medicines Highlights 2021
- Veterinary Medicines Highlights 2021
- Response to External query received by EMA on TU of *Vitis vinifera* L., folium

### List of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 28-30 March 2022 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	
Astrid Obmann	Alternate	Austria	No interests declared	
Patricia Bodart	Member	Belgium	No interests declared	
Gert Laekeman	Co-opted member	Belgium	No interests declared	
Darko Trumbetic	Alternate	Croatia	No interests declared	
Maria Yiannitsarou	Alternate	Cyprus	No interests declared	
Marie Heroutova	Alternate	Czechia	No interests declared	
Markéta Přihodová	Member	Czechia	No restrictions applicable to this meeting	
Steffen Bager	Member	Denmark	No restrictions applicable to this meeting	
Kristine Hvolby	Expert	Denmark	No interests declared	
Sari Koski	Alternate	Finland	No interests declared	
Maria Paile Hyvarinen	Member	Finland	No interests declared	
An Le	Member	France	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Susanne Flemisch	Alternate	Germany	No interests declared	
Heidi Foth	Co-opted member	Germany	No interests declared	
Jacqueline Wiesner	Member	Germany	No interests declared	
Stavroula Mamoucha	Alternate	Greece	No interests declared	
Zsuzsanna Biróné Dr Sándor	Member	Hungary	No interests declared	
Sarah Kellaghan	Member	Ireland	No interests declared	
Jacqueline Masterson	Alternate	Ireland	No interests declared	
Alessandro Assisi	Member	Italy	No interests declared	
Baiba Jansone	Member	Latvia	No interests declared	
Jurate Antanaviciene	Member	Lithuania	No interests declared	
Asta Kubiliene	Alternate	Lithuania	No interests declared	
Sven Back	Member	Luxembourg	No interests declared	
Everaldo Attard	Member	Malta	No interests declared	
Burt H Kroes	Member	Netherlands	No interests declared	
Hilda Kuin	Alternate	Netherlands	No interests declared	
Marianne Loiten Dalhus	Alternate	Norway	No interests declared	
Gro Anita Fossum	Member	Norway	No interests declared	
Wojciech Dymowski	Member	Poland	No interests declared	
Maria da Graca Ribeiro Campos	Co-opted member	Portugal	No interests declared	
Ana Paula Martins	Member	Portugal	No interests declared	
Ligia Elena Dutu	Alternate	Romania	No interests declared	
Carmen Purdel	Member	Romania	No interests declared	
Olga Teresa Esteban	Alternate	Spain	No interests declared	
Olga Maria Palomino	Member	Spain	No interests declared	
Malin Kyllikki Hobro Soderberg	Alternate	Sweden	No interests declared	
Charlotta Lofberg	Expert*	Sweden	No restrictions applicable to this meeting	
Karin Erika Svedlund	Member (Vice-	Sweden	No interests	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
	Chair)		declared	
Melanie Bald	Observer	EDQM	No interests declared	
Bruno Spieldenner	Expert*	EDQM	No interests declared	
Meeting run with support from relevant EMA staff				

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