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SCIENCE MEDICINES HEALTH

26 January 2021  
EMA/HMPC/734733/2021  
Human Medicines Division

## Committee on Herbal Medicinal Products (HMPC)

### Minutes for the meeting on 22-24 November 2021

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

22 November 2021, 10:00 – 17:00, virtual meeting

23 November 2021, 09:00 – 17:00, virtual meeting

24 November 2021, 09:00 – 16:00, virtual meeting

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Some of the information contained in this set 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 set of 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 ongoing 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

The Chairperson opened the meeting by welcoming all participants. Due to the current coronavirus (COVID-19) outbreak, and the associated EMA Business Continuity Plan (BCP), 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.

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.

### 1.2. Adoption of agenda

HMPC agenda for 22-24 November 2021.

**Outcome:**

Agenda adopted.

### 1.3. Adoption of the minutes

HMPC minutes for 20-22 September 2021.

**Outcome:**

Minutes adopted.

## 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 2021

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Report: HMPC Chair

**Action:** For discussion

Document tabled: 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 (by 11 January 2022) to allow best adaptation of agenda and time-schedule.

## 2.1.2. Appointment of Rapporteurs and Peer-reviewers

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### **New Rapporteur-New Peer Reviewer**

Unscheduled reviews to consider specific new data to start in 2021

#### **1<sup>st</sup> step (planned adoption January 2022)**

- Aloes folii succus siccatus
- Sennae folium
- Sennae fructus

#### **2<sup>nd</sup> step – (possible adoption March 2022)**

- Frangulae cortex
- Rhamni purshianae cortex
- Rhei radix

#### **Change of rapporteurship:**

Revision (started in 2020)

- Pelargonii radix

#### **Outcome:**

HMPC agreed on new Rapporteurs and Peer reviewers for unscheduled review to start in 2021 and on a change of rapporteurship. HMPC secretariat will update the HMPC status overview.

For the Pelargonium revision the previous Rapporteur kindly agreed to transfer all information available and as possible also assist further.

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

### 2.2.1. Monograph on *Trigonellae foenugraeci semen* and supporting documents

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**Action:** For adoption

Documents tabled: MO, AR, LoR; References: 67/130

#### **Outcome:**

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

Missing references to be provided before publication.

Minor inconsistencies regarding posology between monograph and AR as well as regards template standard wordings for herbal tea preparations were requested from the secretariat to be sorted with Rapporteur and PR during editorial review before publication.

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

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

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**Action:** For adoption

Documents tabled: MO, AR, LoR, Readers Guidance; References: 20/66

**Outcome:**

Adoption postponed.

Rapporteur to modify the draft MO and AR according to the discussion and comments from SE for **possible adoption** at the **HMPC January** meeting. PL member to provide report regarding posology measurements.

Remaining issues in MO and AR that were raised during early peer review were re-discussed, but not all found sufficiently implemented in the documents to agree on a draft version for public consultation (incl. references and appropriate quotation, advice on reduced fluid intake as well as warnings and adverse events in MO sections 4.2 vs 4.4, 4.8, some adjustment in the AR sections 2 and 6).

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

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

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### 2.4.2. Monograph on Cucurbitae semen and supporting documents

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**Action:** For adoption

Document tabled: Review report; References 06/06

**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 Cucurbitae semen.

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 Grindeliae herba and supporting documents

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**Action:** For adoption

Document tabled: Review report; References 07/07

**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 *Grindeliae herba*.

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 *Hippocastani cortex* and supporting documents

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**Action:** For adoption

Document tabled: Review report; References 15/12

**Outcome:**

Adoption postponed.

Rapporteur to modify the review report according to the discussion for **possible adoption** at the **HMPC January** meeting

The status of a product on the Spanish market should be double-checked as it may fulfil 30 years documented traditional use. Together with minor items for re-consideration/correction mentioned during the discussion at the HMPC September meeting, Rapporteur with the support of the Peer-reviewer should reconsider the conclusions on the availability of new information and need for monograph revision. It may include short statements on relevance of new literature detected and listed in the review report.

#### 2.4.5. Monograph on *Levistici radix* and supporting documents

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**Action:** For adoption

Document tabled: Review report; References 09/11

**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 *Levistici radix*.

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

The Rapporteur confirmed that neither new scientific literature nor new PhV data of concern were found.

#### 2.4.6. Monograph on *Lichen islandicus* and supporting documents

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**Action:** For adoption

Documents tabled: Review report, Reference for discussion; References 17/16

**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 *Lichen islandicus*



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

Minor changes in the posology for the comminuted herbal substance (herbal tea) in the history of German 'Standardzulassungen' had been identified but found comparable and not justifying alone a revision of the monograph.

#### 2.4.7. Monograph on *Urticae folium* and supporting documents

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**Action:** For adoption

Document tabled: Review report; References 04/04

**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 January** meeting.

HMPC re-confirmed their agreement to the proposal of the Rapporteur that there are no new data from the market, PhV or scientific databases that cause any need to update the monograph. Some improvements have been introduced after peer review in evaluation of clinical safety data as regards their shortcomings and relevance. The Rapporteur was asked for a final polishing /shortening before adoption.

#### 2.4.8. Monograph on *Urticae herba* and supporting documents

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**Action:** For adoption

Document tabled: Review report; References 05/05

**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 *Urticae herba*.

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

Revision is recommended because of a new herbal preparation with 30/15 years of TU identified in Poland. Although the expressed juice (1:1) from the fresh herb which is already included in the MO (Herbal preparation C), the posology differs substantially.

The Rapporteur was asked to consider editorial improvements in the evaluation of new clinical studies (not leading to changes in the monograph) when adding to the AR during the revision procedure.

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

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**Action:** For adoption

Documents tabled: Review report, Readers Guidance; References: 10/10

**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 *Zingiberis rhizoma*.

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

The rapporteur proposed revision mainly because of safety information included in the SmPC of marketed products on interactions with anticoagulantia and an increased risk of bleeding events.

Different views were expressed with regard to new data on the use during pregnancy. Additional safety data on pregnant women using ginger has been published since the first version of the AR. The risks of using ginger during pregnancy have been evaluated by several institutes and authorities with inconsistent conclusions. While the Rapporteur proposes to keep the conclusion in MO section 4.6 (as a precautionary measure it is preferable to avoid the use during pregnancy), other members considered an indication for pregnant women as an option for a revised MO with reference to newly available data and a product approved in one MS (WEU).

Such discussion may include seeking advice from other committees/experts during the revision. Also, the Rapporteurs' proposal to add *Zingiberis rhizoma* to the EURD-list should be discussed during the revision when a revised AR summarising all data is available.

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

### 2.5.1. Public statement on *Saccharomyces cerevisiae* CBS 5926 and supporting documents

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**Action:** For adoption

Documents tabled: PS, AR, LoR; References: 219/214

**Outcome:**

Final PS and supporting documents adopted by consensus (27 out of 27). The Norwegian delegate expressed a favourable position.

### 2.5.2. Public statement on *Salviae miltiorrhizae radix et rhizoma* and supporting documents

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**Action:** For adoption

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

**Outcome:**

Adoption postponed.

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

Some improvements on presentations/interpretation of available information and wordings in the AR had been suggested taking into account that products containing *Salviae miltiorrhizae* have already been registered as THMP in the EU. The HMPC PS and AR may

discuss what essential public data were considered missing and not available to conclude on a monograph, but should not rule out possibilities for TU registration in EU MSs.

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

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**Action:** For adoption

Documents tabled: MO, AR, LoR; References: 93/84

**Outcome:**

Final EU herbal monograph and supporting documents adopted by majority vote (25 out of 26). The Norwegian delegate expressed a favourable position.

Divergent opinion: Sarah Kellaghan

The committee discussed indications, necessary warnings in comparison to other comparable monographs.

The divergent view based on general concerns regarding the safe use in the indications "temporary loss of appetite" and "increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary complaints." plus specific concerns on the dosing in children and adolescents above 12 years of age.

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

### 2.6.1. Monograph on *Cisti cretici herba* and supporting documents

---

**Action:** For adoption

Documents tabled: MO, AR, LoR, Readers Guidance, Comments from Peer Review; References: 03/66

**Outcome:**

Adoption postponed.

Rapporteur to modify the documents according to the discussion and possible comments from peer-reviewer. Rapporteur is asked to inform HMPC secretariat and Chair before the first pre-mail (by 11 January 2022) if the documents are ready for **possible adoption** at the **HMPC January** meeting or should be scheduled for **next discussion**.

## 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

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**Action:** for discussion

Documents tabled: Final revised PS, OoC, Question to SWP, Response from SWP, CMDh feedback

**Outcome:**

HMPC discussed the CMDh feedback regarding PS implementation for NAPs/CAPs containing estragole in active substance/excipients. List of potential plants containing estragole to be prepared by DE Rapporteur and NL member by **3<sup>rd</sup> December** and circulated to CMDh. The communication between Rapporteurs/ Chair with CMDh and CHMP will follow. The committee agreed to inform EFSA on this issue again following previous coordination and receipt of data during earlier stages of the PS.

#### 4.1.2. Guideline on Assessment of genotoxicity of herbal substances/preparations (EMA/HMPC/107079/2007)

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**Action:** For discussion

Document tabled: Email communication

**Outcome:**

Rapporteurs to present first general views on revision of the guideline at SRLM in December. Draft concept paper on revision to be discussed at January meeting.

Some possible aspects on new documents/ new approaches to be taken into consideration for the revision were already mentioned. The Chair emphasised that the concept paper is only the kick-off to get also views from Interested parties on the sketched revision; while the content as such should only be discussed when revising the GL.

### 4.2. Quality

#### 4.2.1. Nitrosamines and Herbal MPs

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**Action:** For adoption

**Outcome:**

Final Q&A on nitrosamines and HMPs adopted by consensus. HMPC secretariat to coordinate communication between Rapporteurs and CMDh regarding final publication in the CMDh practical guidance.

Although it was acknowledged that there might be herbal specific root causes not found in other MPs, it was agreed not to elaborate on these from a general perspective. There is no specific knowledge available and the area too complex that theoretical assumptions could be supported by specific data to allow currently any conclusions and an informed risk assessment. The example of tobacco was discussed.

After CMDh approval and publication HMPC may consider taking up this point in herbal specific quality guidance (such as Q&A revision in 2022).

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

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**Action:** For adoption

Documents tabled: Concept paper on the revision, Comments from SE

**Outcome:**

HMPC adopted by consensus the Concept paper on the revision of Guideline on GACP of starting materials of herbal origin.

Members agreed on the need to revise the GL from 2005. The scope of the GL including for veterinary products was discussed and should be carefully considered for the revised GL during the revision in line with GMP Annex 7 and other relevant guidance documents as well as possible coordination with Inspectors WP.

#### 4.2.3. Q&A on Elemental impurities - evaluation in herbal medicinal products

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Report: HMPC Chair

**Action:** For discussion

Document tabled: Draft Q&A on Elemental impurities for addition to [Herbal Quality Q&A](#)

**Outcome:**

HMPC agreed to the draft Q&A on Elemental impurities. Rapporteur to update the draft according to discussion for further follow up on the quality Q&A in line with the work plan 2021.

The committee welcomed the draft Q&A as a first step to revise the Herbal Quality Q&A (see also 5.7.2)

### 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

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- Slovenian Presidency virtual meeting – 08-09 December 2021

**Action:** For information

Document tabled: Draft agenda

- Czech Republic Presidency meeting 2022 - cancelled

**Action:** For information

Document tabled: Email correspondence

**Outcome:**

HMPC noted the draft agenda presented by the Slovenian delegate on the SRLM under the SI presidency and the information regarding cancellation of the SRLM under CZ presidency (second half 2022).

Members /alternates who received invitations were asked to register by 2<sup>nd</sup> December on the Slovenian SRLM website. Agenda and presentations will be made available. It was informed that the agenda is full and only the final section will be without external participants to be able to discuss confidential items.

Members were asked to consider any initiatives e.g. via HMA to perform an HMPC SRLM under the Czech presidency.

#### 5.1.2. HMPC membership

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Report: HMPC Chair

**Action:** For information

**Outcome:**

New membership:

- Bulgaria, Valentin Kotev (alternate) as of 08 October 2021
- Spain, Olga Teresa Esteban (alternate) as of 08 October 2021

End of membership:

- Bulgaria, Dafna Marinkeva (alternate) as of 28 September 2021
- Spain, Cristina Martinez Garcia (alternate) as of 05 October 2021

### 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 03 September 2021, Minutes 18 October 2021, Agenda 03 December 2021, Email communication, Presentation

**Outcome:**

HMPC noted topics discussed at the SciCo Board.

### 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: Discussion paper, Email communication

**Outcome:**

HMPC endorsed rapporteur's proposal to reduce the addendum to the content that is specific for (traditional) herbal medicinal products. Afterwards no monitoring of the regular QRD is required.

Rapporteur to liaise with AT CMDh colleagues or SK CMDh/HMPC colleague to prepare document for discussion at the **HMPC January** meeting.

Options for the most appropriate format were discussed taking into account more frequent updates of the standard template and less frequent specifics from a herbal perspective. Use by assessors but also ease of updates/ publications were considered.

### 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](#)

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- EDQM 13A expert group meeting  
Report: Melanie Bald  
**Action:** For information  
Document tabled: SoD
- EDQM 13B 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:**

HMPC noted summaries of decisions for the latest 13A, 13B and TCM meetings as well as monographs new /revised monographs in the pipeline that could be of relevance for the HMPC as highlighted by the EDQM observer.

e.g. Cannabis extractum siccum (3068), Cannabis extractum spissum (3069), Cannabis flos (3028); Centellae asiaticae herba (1498), Juglandis folium (2946), Uncariae tomentosae cortex (2530), Rhodiola rosea radix et rhizoma (2893) – all 13B, Anisi aetheroleum (0804), Foeniculi amari fructus (0824), Rhei radix (0291) – all 13A

HMPC re-confirmed the proposal to start a monograph for Vaccinii macrocarpi fructus as already requested in 2017.

#### 5.4.2. Coordination with the European Commission

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None

### 5.5. Cooperation with International Regulators

#### 5.5.1. India – EC/EMA Joint Technical Working Group Ayurveda

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**Action:** For discussion

Documents tabled: Terms of references, Presentation

**Outcome:**

HMPC welcomed the presentation regarding establishment of India– EC/EMA Joint Technical Working Group Ayurveda. HMPC members who responded already are invited to submit their short job description to the HMPC Secretariat by **3<sup>rd</sup> December 2021**.

HMPC welcomed and endorsed update:

HMPC participants: Emiel van Galen, Burt Kroes, Markéta Přihodová and Jacqueline Wiesner; EMA participant and contact point, EDQM participant (Commission agreement); no participant from Commission identified so far. The group is expected to work remotely via electronic means. Depending on progress made, in exceptional cases, the possibility of future f-2-f meeting(s) could be explored.

#### 5.5.2. IRCH – WHO 13th annual virtual meeting

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Report: HMPC Chair

**Action:** For information

Documents tabled: Communication EMA/HMPC representation, Draft Agenda

**Outcome:**

HMPC noted draft Agenda for IRCH-WHO 13<sup>th</sup> annual meeting.

Appointment of HMPC Chair as IRCH focal point for HMPC representation (beside HMPC scientific lead for EMA) was agreed via written procedure in October, because the information on the annual meeting came after the September meeting. It was referred to EMA standard procedure as regards EMA/committee representation as distributed in September.

Several members indicated to participate on behalf of their NCAs.



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

None

## 5.7. Work plan

### 5.7.1. HMPC work plan 2021

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Report: HMPC Chair, HMPC Vice Chair

**Action:** For discussion

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

The status of implementation as indicated by the traffic light system was noted. Achievements, delays and necessary transfers were discussed (see also 5.7.2).

- Update the HMPC Review and Revision Best Practice Guides, HMPC Assessment Report and Review Report templates (Annex 2, 2-3)

Report: Nicoleta Carmen Purdel

**Outcome:**

HMPC noted the current status and discussed necessary continuation in 2022.

A first draft with modifications in the review template is currently under discussion. Several proposals are discussed to streamline input by various Rapporteurs and harmonise the understanding via clear instructions.

- Working methodology adaptations for herbal MO and GL establishment and maintenance (1-3-1)

Report: HMPC Chair

**Outcome:**

HMPC noted the current status and discussed necessary continuation in 2022.

- PhV data and experiences in national assessments (1-3-2)

Report: HMPC Vice Chair

**Outcome:**

HMPC noted the current status and discussed necessary continuation in 2022.

- Use of real-world data and requirements for the safe use of herbal substances in children (1-3-3)

Report: Maria Helena Pinto Ferreira

**Outcome:**

HMPC noted the current status and discussed necessary continuation in 2022.

The topic lead thanked the SK colleagues for their thorough analysis so far, first draft of a discussion paper and the questionnaire sent out. More detailed information will be provided during the SRLM presidency meeting. The topic will continue in 2022 with planned involvement of the HMPC co-opted member for paediatrics.

- Forward planning and prioritisation (1-3-4)

Report: HMPC Chair

**Outcome:**

HMPC noted the current status and discussed necessary continuation in 2022.

### 5.7.2. Preparation of HMPC work plan 2022

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Report: HMPC Chair, Carmen Purdel

**Action:** For discussion

Documents tabled: Draft Work plan 2022, Draft Annex 1, Draft Annex 2, Quality domain governance and draft multiannual work plan

**Outcome:**

HMPC noted the current ongoing discussions on draft work plan 2022.

HMPC secretariat to circulate an advanced draft to HMPC members for comments and identification of new topics, topic leads and project contributors before final adoption at the HMPC January meeting.

As there were few proposals received, HMPC members discussed the Chairs/secretariats draft one by one and introduced modifications. Further polishing, finetuning and appointments should be prepared for adoption in January.

Since there are currently no new monograph assessments foreseen for 2022, members were asked to submit proposals (template will be distributed again).

The HMPC heard also a report from the HMPC representative in the quality domain implementation group who will follow up with quality assessors e.g. as regards a modified 3-year work plan. General clarification on the 2022 prospects for re-activation of HMPC subgroups was requested and proposed to invite EMA project leads for the 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 *Agropyri repentis rhizoma* and supporting documents

---

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

Documents tabled: Draft MO, AR, LoR; References: 77/84

**Outcome:**

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

Timetable:

Documents to be sent to Peer-reviewer: **21 December 2021**

Peer-review documents to be sent to Rapporteur: **4 January 2022**

Final documents to be included latest in 2nd premail: **18 January 2022**

While no comments were received during public consultation a few editorial improvements particularly in section 4.2 of the monograph were requested (e.g. DER). The committee also discussed here the appropriateness of contraindication, warnings and advice linked to the posology as regards the use as diuretic and necessary recommendations on fluid intake. It should be carefully checked in consistency with other monographs and agreed between Rapporteur and Peer-reviewer before final adoption.

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

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

Documents tabled: Draft MO, AR, LoR, OoC, Reader's Guidance; References: 238/823

**Outcome:**

Rapporteur to introduce changes in the monograph according to the discussion. Next **discussion** scheduled at the **HMPC January** meeting.

The Rapporteur presented the overview of comments received during public consultation and subsequent changes drafted in the MO (sections 4.1, 4.2, 4.3, 4.5, 4.6, 4.9, 5.1, 5.2, 5.3).

Four main issues were proposed for discussion: (1) WEU pharmacokinetic interactions: differentiation between extracts with hyperforin below 1 mg daily dose and extracts with higher hyperforin exposure based on the reference Zahner et al. (2019). (2) Shift of coumarin type anticoagulants from contraindications to interactions in line with the wording of the SmPCs of coumarin type anticoagulants. (3) Fertility and 5.3: Proposal to go back to the former wording in view of publications indicating negative effects as well as indicating safety. (4) Overdose: differentiation between herbal tea and other herbal preparations.

Members mostly commented on the hyperforin issue: the strength/relevance of available data for safety/efficacy and regulatory consequences. Some concerns were expressed towards the distinction according to hyperforin content of extracts in the monograph.

The Chair acknowledged the tremendous work by the Rapporteur and importance of the monograph - also reflected by the number of comments received. He announced to go through all items one by one at the HMPC January meeting using trend votes and work with majorities in order to take steps forward for finalisation of the revision.

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

### 6.2.1. Monograph on Fumariae herba and supporting documents

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

Documents tabled: Draft MO, AR, LoR, Reader's Guidance; References: 47/69

**Outcome:**

Rapporteur to introduce changes in the MO and AR according to the discussion and further clarify with SE (comments regarding contraindication), Peer-reviewer, Chair and HMPC Secretariat if **adoption for public consultation** is possible at the **HMPC January** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **21 December 2021**

Peer-review documents to be sent to Rapporteur: **4 January 2022**

Final documents to be included latest in 2<sup>nd</sup> premail: **18 January 2022**

### 6.2.2. Monograph on Lavandulae aetheroleum and supporting documents

---

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

Documents tabled: Draft MO, AR, LoR, Reader's Guidance; References: 83/126

**Outcome:**

Postponed.

### 6.2.3. Monograph on Plantaginis lanceolatae folium and supporting documents - Postponed

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### 6.2.4. Monograph on Rosmarini aetheroleum and supporting documents

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

Documents tabled: Draft MO, AR; References: 11/00

**Outcome:**

Rapporteur to introduce changes in the MO and AR according to the discussion. Rapporteur's proposal to keep the warning regarding cardiac and renal insufficiency was agreed. Next **discussion** scheduled at the **HMPC January** meeting.

### 6.2.5. Monograph on Rosmarini folium and supporting documents

---

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

Documents tabled: Draft MO, AR; References: 11/00

**Outcome:**

Rapporteur to introduce changes in the MO and AR according to the discussion.  
Rapporteur's proposal to keep the warning regarding cardiac and renal insufficiency was agreed. Next **discussion** scheduled at the **HMPC January** 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

---

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

Document tabled: Presentation; References 01/04

**Outcome:**

HMPC endorsed the preliminary Rapporteur's position that the new information available could change the content of the monograph, however, potential scientific and legal concerns may advocate for not adding new data and not revising the MO. Rapporteur to present first draft of the review report according to the **discussion** at **HMPC January** meeting.

#### 6.3.2. Monograph on *Cichorii intybi radix* and supporting documents

---

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

Document tabled: Review report; References 00/00

**Outcome:**

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 January** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **21 December 2021**

Peer-review documents to be sent to Rapporteur: **4 January 2022**

Final documents to be included latest in 2<sup>nd</sup> premail: **18 January 2022**

Although the check of PhV data still needs to be performed it is not expected that major safety issues will be detected for this substance.

#### 6.3.3. Monograph on *Eucalypti aetheroleum* and supporting documents

---

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

Document tabled: Review report; References 00/19

**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 January** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **21 December 2021**

Peer-review documents to be sent to Rapporteur: **4 January 2022**

Final documents to be included latest in 2nd premail: **18 January 2022**

The need for revision of the monographs was largely based on the market overview and necessary adjustments of inconsistencies as regards posology. While there are also several new non-clinical and clinical data as well as PhV data, these were initially not considered leading to any changes in the assessment or monograph.

#### 6.3.4. Monograph on Eucalypti folium and supporting documents

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

Document tabled: Review report; References 00/06

**Outcome:**

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 January** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **21 December 2021**

Peer-review documents to be sent to Rapporteur: **4 January 2022**

Final documents to be included latest in 2nd premail: **18 January 2022**

In contrast to the essential oil, for Eucalyptus leaf no data were detected likely to change the existing monograph. New non-clinical and clinical safety data as well as efficacy data and PhV data were not considered to provide anything substantially new.

#### 6.3.5. Monograph on Fraxini folium and supporting documents

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

Document tabled: Review report; References 08/04

**Outcome:**

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 January** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **21 December 2021**

Peer-review documents to be sent to Rapporteur: **4 January 2022**

Final documents to be included latest in 2nd premail: **18 January 2022**

#### 6.3.6. Monograph on Fucus vesiculosus and supporting documents

---

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

Documents tabled: Review report, Presentation; References 00/00

**Outcome:**

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 January** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **21 December 2021**

Peer-review documents to be sent to Rapporteur: **4 January 2022**

Final documents to be included latest in 2nd premail: **18 January 2022**

#### 6.3.7. Monograph on Ginseng radix and supporting documents

---

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

Document tabled: Readers Guidance; References 00/00

**Outcome:**

Rapporteur to present first draft of the review report according to the discussion at **HMPC January** meeting.

The Rapporteur summarised first findings. (1) From the market feedback by some MSs some clarifications are required to conclude on the relevance for the monograph. (2) Eudravigilance data are available to higher extent as usual; however, when looking into the often imprecise data for most products no causalities can usually be derived, or adverse effects are already known. (3) From many new publications relevant clinical and safety data were filtered and further scrutiny will be applied and included in the review report to draw conclusions for the need to revise AR and MO.

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

---

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

Document tabled: Review report; References 00/00

**Outcome:**

Rapporteur to introduce changes in the review report according to the discussion for a **3<sup>rd</sup> discussion at the HMPC January** meeting.

The Rapporteur presented the new information obtained. From the market overview some inconsistencies in posologies vis-a-vis the existing monograph were detected that may be taken into account when discussing the need for update/ revision. It was recommended to shorten the overview on PhV data as well as new clinical and safety data in the report.

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

---

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

Document tabled: Review report; References 00/64

**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 introduce changes in the review report according to the discussion for a **2<sup>nd</sup> discussion at the HMPC January** meeting.

Several reasons for update were identified such as new posology and interaction data. A general request regarding the wording for enzyme inhibition vs induction was suggested that would also apply to other monographs and maybe added to the MO template.

### 6.3.10. Monograph on Marrubii herba and supporting documents

---

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

Document tabled: Review report; References 00/02

**Outcome:**

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 January** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **21 December 2021**

Peer-review documents to be sent to Rapporteur: **4 January 2022**

Final documents to be included latest in 2nd premail: **18 January 2022**

### 6.3.11. Monograph on Origani dictamni herba and supporting documents

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

Documents tabled: Review report, Presentation; References 00/10

**Outcome:**

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 January** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **21 December 2021**

Peer-review documents to be sent to Rapporteur: **4 January 2022**

Final documents to be included latest in 2nd premail: **18 January 2022**



### 6.3.12. Monograph on Paulliniae semen and supporting documents

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

Document tabled: Review report; References 00/17

**Outcome:**

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 January** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **21 December 2021**

Peer-review documents to be sent to Rapporteur: **4 January 2022**

Final documents to be included latest in 2nd premail: **18 January 2022**

### 6.3.13. Monograph on Rhodiolae roseae rhizoma et radix and supporting documents

---

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

Documents tabled: Review report, Readers Guidance; References 13/14

**Outcome:**

Rapporteur to introduce changes in the review report according to the discussion for a **2<sup>nd</sup> discussion at the HMPC January** meeting. Members with corresponding products on the market invited to send information to the Rapporteur regarding adverse events mentioned in section 4.8.

Relevant new information was provided by interested parties and also detected in scientific databases. New clinical and safety data may lead to changes in the monograph.

A modification of the therapeutic indication was proposed by IPs that will require a more detailed evaluation of data on traditional use and from clinical studies during a revision of the package.

### 6.3.14. Monograph on Tiliae flos and supporting documents - Postponed

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### 6.3.15. Monograph on Urticae radix and supporting documents

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

Document tabled: Review report; References 04/04

**Outcome:**

Postponed.

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

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

---

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

Documents tabled: Draft MO, AR, LoR; References: 42/42

**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: **21 December 2021**

Peer-review documents to be sent to Rapporteur: **4 January 2022**

Final documents to be included latest in 2<sup>nd</sup> premail: **18 January 2022**

Rapporteur and Peer-reviewer to check consistency of table in MO with the AR after editorial changes for public consultation. According to previous decision in July, any wording regarding estragole in AR and MO should be checked for the final because some changes have meanwhile been introduced into the estragole PS.

If primarily the draft revisions of fennel monographs need to be ready (potentially adapted posology), it should be discussed whether the combination MO can be finalised or should be put on hold.

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

---

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

Documents tabled: Readers Guidance, OoC; References: 197/00

**Outcome:**

Rapporteur to introduce changes in the AR and MO according to the discussion for **a 2<sup>nd</sup> discussion at the HMPC January** meeting.

Upon SE support to the Rapporteur the OoC was compiled and a reader's guidance summary provided. Five IPs had provided comments and 8 main issues for discussion were listed. They refer to (a) reference to pharmacopoeial standards in absence of Ph. Eur., (b) the inclusion of an extract registered in several EU MS but left out from the HMPC draft MO plus linked documentation and posology proposals, (c) addition of new data after data lock stop in 2019, (d) brand names in the AR, and (e) proposals for modification of the indication.

While the HMPC discussed (a) and re-confirmed that a Ph. Eur monograph for Cranberry as already proposed in 2017 would be very welcome (see also 5.4.1), other items will need detailed informed discussion based on the OoC and national views.

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

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

---

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

Document tabled: Presentation; References: 07/00

**Outcome:**

Rapporteur to prepare first draft documents according to the discussion for the **HMPC January** meeting. Members with corresponding products on the market invited to send information to the Rapporteur. Rapporteur to doublecheck the DE product on the market since several changes in the composition were implemented.

HMPC discussed first findings on products on the market (old WEU, more recent WEU and TU) as well as available clinical studies specifically for the combinations vis-a-vis single substance use data.

## 7. Any other business

### 7.1. Topics for discussion

#### 7.1.1. Working methodology of monograph establishment

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**Action:** For discussion

Document tabled: Presentation

**Outcome:**

HMPC noted the presentation on working methodology regarding literature references and common names.

Previously agreed policies as regards availability of references for (1) committee discussions and (2) for archiving at EMA with the final adoption were presented. New experiences from specifics during review and revision procedures – particularly dealing with references from the first assessment were listed for possible further discussions and new agreements.

#### 7.1.2. Public statement on the use of herbal medicinal products containing toxic, unsaturated pyrrolizidine alkaloids (PAs) including recommendations regarding contamination with PAs - post finalisation

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**Action:** For discussion

Documents tabled: PS, Email communication from AT

**Outcome:**

HMPC endorsed the minor editorial correction in PS that will be republished.

The number of decimals after the comma had caused misleading interpretations for implementation by MAHs.

Furthermore, justifications for rounding up or down was briefly explained by the Rapporteur.

For other requests regarding issues with the implementation of the PS, the Chair asked members to send precise proposals or questions to the HMPC. Otherwise it is proposed to discuss this topic from a general review and learning perspective at a presidency meeting.

## **7.2. Documents for information**

### **7.2.1. HMPC**

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Table of Decisions from HMPC meeting held on 20-22 September 2021

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 joint meeting on 21 and 22 September 2021
- Agenda Meeting with civil society representatives in EMA scientific committees 01 October 2021
- Draft Agenda - Annual PCWP-HCPWP joint meeting with all Eligible Organisations on 24 November 2021

## List of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 22-24 November 2021 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	
Darko Trumbetic	Alternate	Croatia	No interests declared	
Antri Kouroufexi	Member	Cyprus	No interests declared	
Markéta Příhodová	Member	Czechia	No restrictions applicable to this meeting	
Marie Heroutova	Alternate	Czechia	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	
Sarah Kellaghan	Member	Ireland	No interests declared	
Alessandro Assisi	Member	Italy	No interests declared	
Jurate Antanaviciene	Member	Lithuania	No interests declared	
Asta Kubiliene	Alternate	Lithuania	No interests declared	
Sven Back	Member	Luxembourg	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	
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	
Miroslava Petrikova	Member	Slovakia	No interests declared	
Milan Nagy	Alternate	Slovakia	No interests declared	
Barbara Razinger	Member	Slovenia	No interests declared	
Olga Maria Palomino	Member	Spain	No interests declared	
Olga Teresa Esteban	Alternate	Spain	No interests declared	
Karin Erika Svedlund	Member (Vice-Chair)	Sweden	No interests declared	
Peter Voithl	Co-opted member	Austria	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	
Maria da Graca Ribeiro Campos	Co-opted member	Portugal	No interests declared	
Melanie Bald	Observer	EDQM	No interests declared	
Stina Wallin Ottoson	Observer	Sweden	No interests declared	
Stefanie Bodemann	Expert	Germany	No interests declared	
Kristine Hvolby	Expert	Denmark	No interests declared	
Priscilla Schoondermark	Expert	Netherlands	No interests declared	
Roland Froetschl	Expert	Germany	No interests declared	
Meeting run with support from relevant EMA staff				

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