



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

3 March 2021  
EMA/HMPC/62722/2021  
Human Medicines Division

## Committee on Herbal Medicinal Products (HMPC)

### Minutes for the meeting on 11-13 January 2021

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

11 January 2021, 10:00 – 17:00, virtual meeting

12 January 2021, 09:00 – 17:00, virtual meeting

13 January 2021, 09:00 – 16:00, virtual meeting

#### Disclaimers

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

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

#### Note on access to documents

Some documents mentioned in the minutes cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).

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## 1. Introduction

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

In accordance with the Agency's policy on handling of declarations of interests of scientific Committees' members and experts, based on the declarations of interest submitted by the Committee members, alternates and experts and based on the topics in the agenda of the current meeting, the Committee Secretariat announced that no restriction in the involvement of meeting participants in upcoming discussions was identified.

Participants in this meeting were asked to declare any changes, omissions or errors to their declared interests and/or additional restrictions concerning the matters for discussion. No new or additional interests or restrictions were declared with regards to topics on the agenda.

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.

New membership:

- Ireland, Sarah Kellaghan (member) as of 01 December 2020
- Denmark, Rahat Nazmi (alternate) as of 07 December 2020

### Adoption of agenda

HMPC agenda for 11-13 January 2021.

Time schedule for 11-13 January 2021.

**Outcome:**

Agenda adopted.

Time schedule endorsed with minor modifications.

### Adoption of the minutes

HMPC minutes for 16-18 November 2020.

**Outcome:**

Minutes adopted.

Topic 7.1.1 added.

## 2. EU herbal monographs and list entries for adoption

### Status of HMPC/MLWP activities

#### 2.1.1. Overview of HMPC/MLWP assessment work including the Rapporteurship distribution – Status in January 2021

---

Report: HMPC Chair

**Action:** for discussion

Document: Overview

**Outcome:**

HMPC noted status of assessment work.

In case of postponement of topics scheduled for the HMPC March meeting according to the overview, Rapporteurs were asked to inform secretariat and Chair before the first pre-mail (by 15 February 2021) to allow best adaptation of agenda and time-schedule.

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

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Report: HMPC Chair

**Action:** for adoption

**New Rapporteur-New Peer Reviewer** (see also 5.7.2):

New assessments to start in 2021 (see also 5.7.1, activity area 1-3-2)

- Cnici benedicti herba  
Documents: Proposal (PL), Supporting literature, Summary of proposals
- Cimicifugae rhizoma/ Hyperici herba  
Documents: Proposal (AT), Summary of proposals
- Tribulus terrestris herba  
Documents: Proposal (CZ), Summary of proposals

**Outcome:**

HMPC agreed to add Cnici benedicti herba and the combination Cimicifugae rhizoma/ Hyperici herba to the HMPC work programme based on validated proposals using a modified template.

Decision on Tribulus terrestris herba (appropriateness of indication) as well as Rapp./PR appointment postponed to the **HMPC March meeting**.

Sufficient information had been provided to confirm a need/ potential benefit of an EU harmonised opinion as well as the likelihood of an outcome 'monograph' due to available data on strength/posology including from products in more than one MS. No obstacles were identified arising from composition or indication. Only for Tribulus, members were asked to check whether there are major concerns regarding the intended medicinal use that may not justify the start of the procedure.

Other 7 proposals will be re-checked once sufficient information is provided using a new template (see also 5.7.1). It was further proposed to start the assessment procedure for Cannabis flos but referred to a specific point on the HMPC work plan 2021.

Periodic reviews to start in 2021

**Monographs/LEs adopted in 2012**

- Cucurbitae semen
- Fraxini folium
- Grindeliae herba
- Hippocastani cortex

- Levistici radix
- Liquiritiae radix
- Rhodiolae roseae rhizoma et radix
- Tiliae flos
- Urticae radix

#### **Monographs/LEs adopted in 2013**

- Camelliae sinensis non fermentatum folium
- Cichorii intybi radix
- Eucalypti folium
- Juglandis folium
- Marrubii herba
- Origani dictamni herba
- Paullinae semen

#### **Monographs/LEs adopted in 2014**

- Arnicae flos
- Curcumae xanthorrhizae rhizoma
- Eucalypti aetheroleum
- Ginseng radix
- Lichen islandicus

#### **Outcome:**

HMPC agreed to start for 21 substances the periodic review procedure.

HMPC secretariat will update the HMPC status overview, announce the start of procedures in the public meeting report and publish Calls for data (in several waves to ease the response by Interested parties). Peer reviewers and remaining Rapporteurs to be appointed at the **HMPC March meeting**.

New HMPC members/ alternates and those without any Rapporteurship/Peer review so far were invited to consider takeover of some reviews in order to distribute assessment work more evenly. While each monograph needs an HMPC Rapporteur, Rapporteurs are free to involve experts from the EMA expert database as required (NCA, academia, including from HMPC subgroups).

## **Revised EU herbal monographs and list entries for final adoption**

None

## **Revised EU herbal monographs and list entries for public consultation**

### **2.1.3. Monograph on Orthosiphonis folium and supporting documents**

---

**Action:** for adoption

Documents: MO, AR, LoR, Reader's guidance; References: 09/46

#### **Outcome:**

Revised EU herbal monograph and supporting documents adopted by consensus for 3 months public consultation.

Some changes and comments were discussed. The contraindication was questioned by some members and an additional explanation proposed for the Assessment report.

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

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

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**Action:** for adoption

Documents: Review report, Review of doses of herbal teas infusion or decoction;  
References: 67/02

**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 majority to start the revision procedure and revise the monograph, assessment report and list of references on *Agropyri repentis rhizoma*.

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

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

### 2.1.5. Monograph on *Aloysiae citriodoraefolium* and supporting documents

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**Action:** for adoption

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

**Outcome:**

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

Rapporteur to provide all full text references before publication of the final documents.

Final minor modifications were introduced in monograph section 4.2 and the assessment report. Consistency of the herbal substance name (*Aloysia* instead of older synonyms *Verbena* and *Lippia*) was advocated for all documents where possible.

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

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

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**Action:** for adoption

Document for adoption: PS

Documents for discussion: LoR, AR; References: 2/214

**Outcome:**

Adoption postponed.



Final modifications to be introduced in the PS. HMPC secretariat to organise a meeting in February (Rapporteur, PR, Chair, quality experts and EMA support) for finalisation of PS taking into account the different views. Final PS to be presented at the **HMPC March** meeting.

Several members proposed changes to the modified content of the PS as well as the supporting AR.

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

---

**Action:** for adoption

Documents: PS, AR, LoR; References: 00/89; SE comments

**Outcome:**

PS and supporting documents adopted by majority for 3 months public consultation. Members discussed some passages in the AR as well as the scope and outcome of the European assessment regarding preparations and required evidence vis-a-vis existing national TUR.

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

---

**Action:** for adoption

Documents: MO, AR, LoR, Reader's guidance; References: 75/99

**Outcome:**

Adoption postponed.

Rapporteur to finalise the draft MO and AR according to the discussion and possible comments from DE, SE for **adoption for public consultation** at the **HMPC March** meeting.

Some adjustments were requested for an unusual preparation in monograph section 2 as well as some sections in the Assessment report.

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

None

## 3. Referral procedures

None

## 4. Guidelines and guidance documents

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

- 4.1.1. Public statement on the use of herbal medicinal products containing toxic, unsaturated pyrrolizidine alkaloids (PAs) including recommendations regarding contamination of herbal MPs with PAs (EMA/HMPC/893108/2011 Rev. 1)
- 

**Action:** for discussion

Documents: Draft PS, OoC

**Outcome:**

HMPC noted comments from IPs and first responses by the Rapporteur as well as topics identified for more detailed discussion and agreement.

Coordination with SWP to be initiated before next discussion at the **HMPC March meeting** aiming for final adoption latest in May (end of transition period).

Comments were received on quality control/contamination aspects (e.g. skip testing, essential oils, literature on structure-dependent potencies, testing substance vs final product) as well as on risk assessment (e.g. model use and uncertainty factors in relation to the EFSA-applied BMDL10 and other factors such as life time exposure to food derived PAs vs short term use of MPs; use in children; cutaneous use).

### Quality

- 4.1.2. Guideline on quality of herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/201116/2005 Rev. 3)
- 

**Action:** for information

Documents: Draft revised Guideline, OoC, email correspondence, AT comments

**Outcome:**

HMPC welcomed the Rapporteur's update on status of finalisation. Even though the OoC is largely finalised and minor changes will be introduced into the revised GL, finalisation of the guideline was put on hold and parallel finalisation of the specification guideline (4.2.2) proposed.

- 4.1.3. Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/162241/2005 Rev. 3)
- 

**Action:** for information

Document: [Draft Guideline](#)

**Outcome:**

See 4.2.1.

## Regulatory / Procedural

### 4.1.4. HMPC Plenary Best Practice Guide

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**Action:** for adoption

Document: HMPC Plenary Best Practice guide with annexed Reader's Guidance template

**Outcome:**

HMPC Plenary Best Practice guide was adopted by majority. HMPC Chair welcomed the guide as opportunity for improvement of current practice and encouraged to follow it aiming for more efficient use of plenary time for all participants.

### 4.1.5. Regulatory Q&A on herbal medicinal products – update

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**Action:** for discussion

Documents: New additional Q&A on use of combination monographs; [Regulatory Q&A on herbal medicinal products](#)

**Outcome:**

HMPC noted the proposal for new additional Q&A on use of combination monographs by Rapporteurs. Members are invited to send comments till **1st February**. Updated proposal to be presented for possible adoption at **HMPC March** meeting.

## Report on HMPC Drafting Groups activities

### 4.1.6. Quality DG

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None

### 4.1.7. ORGAM DG

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None

## 5. Organisational, regulatory and methodological matters

### Mandate and organisation of the HMPC

#### 5.1.1. Strategic Review and Learning Meetings

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- Portugal Presidency meeting – March 2021

Report: A P Martins

**Action:** for information

Document: Topics for the Agenda

- Slovenia Presidency meeting – November 2021

Report: B Razinger

**Action:** for information

Document: Cancellation of SRLM

**Outcome:**

Postponed.

## EMA Scientific Committees or CMDh-v

### 5.1.2. Scientific Coordination Board Meeting

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Report: HMPC Chair

**Action:** for discussion

Documents: Final Agenda 30 November 2020, Draft Agenda 14 December 2020, Presentation from HMPC Chair

**Outcome:**

HMPC noted topics discussed at the SciCo Board and focused in its discussion on the current progress of Review Group on Working parties and Drafting groups following a presentation by the HMPC Chair.

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

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

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**Action:** for discussion

Documents: Questions to SWP, Final PS, OoC

**Outcome:**

HMPC Secretariat to liaise with the Rapporteurs and Chair to a) verify the need for clarification on guidance for different age groups in the HMPC PS and b) to distribute modified questions to members till **1st February**. Members are invited to send comments till **15th February**. Final questions to be adopted at **HMPC March** meeting.

## Cooperation within the EU regulatory network

### 5.1.4. Coordination with European Pharmacopoeia

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- Joint EDQM-EMA forum

**Action:** for information

Document: Draft minutes

**Outcome:**

HMPC noted the minutes from EDQM EMA forum and discussed the options/limitations regarding a requested alignment of Ph. Eur. and EU herbal monographs as relevant in some cases after change of analytical methods by EDQM.

The different functions of Ph. Eur. monograph vs. EU herbal monographs including update practice and feasibility as well as the availability of conversion factors from old to new analytical methods were discussed. Once again, members saw limited room for the HMPC to

solve this issue of regulatory practice at EMA monograph level (apart from possible re-confirming footnotes as appropriate) but referred to EDQM for assay methods and quality standards and NCAs for individual products in national procedures.

#### 5.1.5. Coordination with the European Commission

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- Cannabis for medicinal use

Report: HMPC Chair

**Action:** for discussion

### Cooperation with International Regulators

#### 5.1.6. IRCH – WHO 12th annual virtual meeting

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Report: HMPC Chair

**Action:** for information

Documents: Report, Agenda, Participants list

**Outcome:**

Postponed.

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

#### 5.1.7. AESGP

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Report: HMPC Chair

**Action:** for adoption

Document: Summary of hearing held on 18 November 2020

**Outcome:**

Postponed.

#### 5.1.8. EUCOPE

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- Hearing to be held in March 2021

Report: HMPC Chair

**Action:** for discussion

Document: Request for hearing

- Digital Conference on the European Health Economy

Report: HMPC Chair

**Action:** for information

Documents: Questions on BW Event Session on Health claims; List of participants

**Outcome:**

Postponed.

## Work plan

### 5.1.9. HMPC work plan 2020

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Report: HMPC Chair, HMPC Vice Chair

**Action:** for discussion

Documents: Work plan 2020, Annex 1, Annex 2

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

Report: HMPC Vice Chair

**Action:** for discussion

Document: PhV survey results

**Outcome:**

HMPC noted the presented results from PhV survey between MSs. Topic lead to liaise with HMPC secretariat and conclude on options for use of PhV data for HMPC assessment including cooperation with PRAC where necessary. Next steps to be discussed at SRLM in Portugal and **HMPC March** meeting.

Difficulties in cooperation with national PhV experts in some MSs were discussed.

According to pilot tests on various elements of PhV tools and data availability since 2017 project participants to summarise a pragmatic implementation proposal for use of safety relevant PhV data to keep monograph assessment work up-to-date.

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

Report: HMPC Vice Chair

**Action:** for discussion

Documents: Summary of proposals, Draft New Template - Proposals for assessment by HMPC

**Outcome:**

HMPC welcomed the draft new template for proposals for assessment. HMPC secretariat to organise meeting of experts in February to finalise the proposal for possible adoption at **HMPC March** meeting.

The new template should be used to collect and verify information on need/benefit and essential data availability for an informed decision by HMPC for additions to the HMPC work programme.

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

Report: HMPC Vice Chair, J Wiesner, M Petrikova

**Action:** for discussion

Document: Presentation

**Outcome:**

HMPC welcomed presentation by the steering group on the status of the contraindication in children under 2 years of age in the MO on *Hedera helix*. The implementation of the change

from contraindication to warnings and communication with PRAC to be realised during scheduled review in 2022.

The principles for extrapolation of data in the paediatric population to be presented at the **HMPC March** meeting.

- Activity area 2-2-1: Development of training on assessment of applications for herbal medicinal products  
Report: HMPC Vice Chair, C Purdel

**Action:** for discussion

Documents: Presentations; Course description template

**Outcome:**

HMPC welcomed presentation by the steering group updating about the next steps.

Members are invited to send comments on the presentation for the training course till **1st February**.

**Post-meeting note:**

*After finalisation of the presentation the 2nd herbal curriculum training is scheduled for February 23rd 2021. For registration to the webinar "Introduction to herbal medicinal product applications" go to the EU NTC Learning Management System platform (for details separate information email provided to all members).*

#### 5.1.10. Draft HMPC work plan 2021

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Report: HMPC Chair, HMPC Vice Chair

**Action:** for adoption

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

**Outcome:**

HMPC work plan including Annex 1 and Annex 2 adopted with modifications and added project leads and participants. HMPC Rapporteurs not yet appointed for topics on the work plan (e.g. guidelines included in Annex 2) to be appointed at **HMPC March** meeting because limited resources, the ongoing review of subgroups and BCP-related constraints may not allow start of all guideline activities.

## Planning and reporting

#### 5.1.11. Big Data Training Signpost

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**Action:** for discussion

Document: Presentation

**Outcome:**

Postponed.

#### 5.1.12. Introduction of new Executive Director Emer Cooke

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**Action:** for discussion

Document: Oral Presentation

**Outcome:**

HMPC welcomed the introductory presentation of EMA Executive Director Emer Cooke.

## Legislation and regulatory affairs

None

## Questions from members

### 5.1.13. Nitrosamines and Herbal MPs

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**Action:** for discussion

Documents: CMDh practical guidance for Marketing Authorisation Holders; Question from AT

**Outcome:**

HMPC identified possibility for a more specific harmonised information as regards herbal products. Rapporteur to draft a brief proposal for Q&A on nitrosamines and HMPs for **next discussion** at **HMPC March** meeting. Other quality experts are invited to send comments/proposals to the Rapporteur.

Specific implementation challenges from EMA/CMDh Q&A and general guidance documents for nitrosamines were identified for herbal MPs - also reflected by questions from companies to NCAs and EMA. Herbal specific harmonised considerations will first be discussed by HMPC before finding an appropriate place in the general EMA information / guidance.

## 6. EU herbal monographs and list entries in preparation

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

None

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

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

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**Action:** for discussion

Document: See 6.2.3; References: 00/00

**Outcome:**

See 6.2.3

#### 6.1.2. Monograph on *Foeniculi amari fructus aetheroleum* and supporting documents

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**Action:** for discussion

Document: See 6.2.3.; References: 00/00



**Outcome:**

See 6.2.3

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### 6.1.3. Monograph on *Foeniculi dulcis fructus* and supporting documents

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**Action:** for discussion

Document: Presentation; References: 00/00

**Outcome:**

HMPC noted the Rapporteur's presentation. Questions raised by the Rapporteur in connection to the HMPC PS on estragole (see also 5.3.1 to be discussed at the **HMPC March meeting**).

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### 6.1.4. Monograph on *Hyperici herba* and supporting documents

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**Action:** for discussion

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

**Outcome:**

HMPC endorsed the updated combined AR and MO for TU and WEU based on previous comments. Members expressing their proposals for section 4.4. and 4.6 of the MO are invited to send them to the Rapporteur. Rapporteur to finalise the documents for peer review and **adoption for public consultation** at the **HMPC March** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **26 January 2021**

Peer-review documents to be sent to Rapporteur: **9 February 2021**

Final documents to be included latest in 2nd premail: **23 February 2021**

Members discussed alignment between WEU and TU regarding monograph sections 4.6 and 5.3 as well as the fine-tuning of the wording for TU indication 4 related to sleep. Also experiences from the PSUSA discussion vis-a-vis harmonisation of SmPCs were raised.

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### 6.1.5. Monograph on *Juniperi pseudo-fructus* and supporting documents - postponed

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### 6.1.6. Monograph on *Lavandulae aetheroleum* and supporting documents - postponed

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### 6.1.7. Monograph on *Pelargonii radix* and supporting documents - postponed

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### 6.1.8. Monograph on *Sabalii serrulatae fructus* and supporting documents

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**Action:** for discussion

Document: Reader's guidance

**Outcome:**

HMPC noted Rapporteur's proposal for further action. Rapporteur to prepare the review report according to the discussion for **2nd discussion** at the **HMPC March** meeting.

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

**Action:** for discussion

Documents: Draft MO, AR, LoR; References: 08/100

**Outcome:**

HMPC endorsed the Rapporteur's position that amended information in the AR lead to update of section 4.2. in the MO. Rapporteur to finalise the documents for peer review and **adoption for public consultation** at the **HMPC March** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **26 January 2021**

Peer-review documents to be sent to Rapporteur: **9 February 2021**

Final documents to be included latest in 2nd premail: **23 February 2021**

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

#### 6.1.10. Monograph on *Cinnamomi corticis aetheroleum* and supporting documents

**Action:** for discussion

Document: 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 shorten to the relevant information for peer review and **adoption** at the **HMPC March** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **26 January 2021**

Peer-review documents to be sent to Rapporteur: **9 February 2021**

Final documents to be included latest in 2nd premail: **23 February 2021**

#### 6.1.11. Monograph on *Cinnamomi cortex* and supporting documents

**Action:** for discussion

Document: Review report; References: 00/12

**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 shorten to the relevant information for peer review and **adoption** at the **HMPC March** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **26 January 2021**

Peer-review documents to be sent to Rapporteur: **9 February 2021**

Final documents to be included latest in 2nd premail: **23 February 2021**

#### 6.1.12. Monograph on Colae semen and supporting documents - postponed

#### 6.1.13. Monograph on Fucus vesiculosus and supporting documents - postponed

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

**Action:** for discussion

Documents: Review report, Reader's guidance, Presentation; References: 00/16

**Outcome:**

Rapporteur to modify the review report according to the discussion (clear proposal for a revision) for **3rd discussion** at the **HMPC March** meeting.

#### 6.1.15. Monograph on Mate folium and supporting documents

**Action:** for discussion

Documents: Review report, email correspondence; References: 00/34

**Outcome:**

Postponed.

#### 6.1.16. Monograph on Plantaginis lanceolatae folium and supporting documents

**Action:** for discussion

Document: Review report; References: 00/09

**Outcome:**

Postponed.

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

**Action:** for discussion

Documents: Review report, Presentation; References: 05/05

**Outcome:**

Postponed.

**6.1.18. Monograph on Rosmarini folium and supporting documents**

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**Action:** for discussion

Documents: Review report, Presentation; References: 08/08

**Outcome:**

Postponed.

**6.1.19. Monograph on Solidaginis virgaureae herba and supporting documents**

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**Action:** for discussion

Document: Review report; References: 33/19

**Outcome:**

Postponed.

**6.1.20. Monograph on Urticae folium and supporting documents**

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**Action:** for discussion

Document: Review report; References: 08/11

**Outcome:**

Postponed.

**6.1.21. Monograph on Urticae herba and supporting documents**

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**Action:** for discussion

Document: Review report; References: 07/06

**Outcome:**

Postponed.

**6.1.22. Monograph on Violae tricoloris herba and supporting documents**

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**Action:** for discussion

Documents: Review report, email correspondence; References: 28/25

**Outcome:**

Postponed.

**6.1.23. Monograph on Zingiberis rhizoma and supporting documents**

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**Action:** for discussion

Document: Presentation

**Outcome:**

Postponed.

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

None

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

### 6.1.24. Monograph on *Andrographidis paniculatae folium* and supporting documents - postponed

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

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**Action:** for discussion

Documents: Draft MO, AR, LoR, Reader's guidance; References: 00/216

**Outcome:**

Rapporteur to introduce changes in the AR to contain only information with respect to herbal preparation included in the MO. The current posology and the way of use to be adjusted in line with other monographs where impregnated dressings are used, as well as section 5.3 according to the discussion for a **4th discussion** at the **HMPC March meeting**.

### 6.1.26. Monograph on *Cisti cretici folium* and supporting documents

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**Action:** for discussion

Documents: Draft MO, AR, LoR, Presentation; References: 00/50

**Outcome:**

Rapporteur to circulate new market overview and to prepare updated MO and AR for a possible **10th discussion** at the **HMPC March meeting**.

### 6.1.27. Monograph on *Species digestivae* or *species stomachicae* and supporting documents

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**Action:** for discussion

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

**Outcome:**

HMPC endorsed the Rapporteur's position that no change in section 4.6 is required. Rapporteur of fennel mono-monographs to inform the Rapporteur on changes potentially relevant for the combination monograph.

Rapporteur to finalise the draft MO and AR according to the discussion for peer review and **adoption for public consultation** at the **HMPC March** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **26 January 2021**

Peer-review documents to be sent to Rapporteur: **9 February 2021**

Final documents to be included latest in 2nd premail: **23 February 2021**

#### 6.1.28. [Monograph on Vaccinii macrocarpi fructus and supporting documents](#)

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**Action:** for discussion

Documents: Draft MO, AR, LoR; References: 475/249

**Outcome:**

Rapporteur to finalise the draft MO and AR according to the discussion and possible comments from BE, DE, SE for peer review and **adoption for public consultation** at the **HMPC March** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **26 January 2021**

Peer-review documents to be sent to Rapporteur: **9 February 2021**

Final documents to be included latest in 2nd premail: **23 February 2021**

## 7. Any other business

### Topics for discussion

#### 7.1.1. [Update on PSUSA Menthae piperitae aetheroleum](#)

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**Action:** for discussion

HMPC noted short information regarding PRAC discussion on necessary warnings in SmPC for products containing Menthae piperitae aetheroleum. Further clarification will be provided at the **HMPC March meeting** to determine follow-up and need for coordination in view of the corresponding EU herbal monograph.

### Documents for information

#### 7.1.2. [HMPC](#)

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Table of Decisions from HMPC meeting held on 16-18 November 2020

Overview of expertise of members HMPC and subgroups

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

[Abbreviations in HMPC agendas/minutes](#)

Common names of herbal substances in all languages

Final Monograph Overview

### 7.1.3. ARSP

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- English template
- English summaries for publication
  - Species amarae
  - Species sedativae

No objections were raised before publication of the finalised summaries on the EMA website.

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

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None

### 7.1.5. Other

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## List of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 11-13 January 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	
Patricia Bodart	Member	Belgium	No interests declared	
Ivan Kosalec	Member	Croatia	No restrictions applicable to this meeting	
Darko Trumbetic	Alternate	Croatia	No interests declared	
Antri Kouroufexi	Member	Cyprus	No interests declared	
Markéta Příhodová	Member	Czech Republic	No restrictions applicable to this meeting	
Marie Heroutova	Alternate	Czech Republic	No interests declared	
Steffen Bager	Member	Denmark	No restrictions applicable to this meeting	
Rahat Nazmi	Alternate	Denmark	No interests declared	
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	
Everaldo Attard	Member	Malta	No interests declared	
Burt H Kroes	Member	Netherlands	No interests declared	



<b>Name</b>	<b>Role</b>	<b>Member state or affiliation</b>	<b>Outcome restriction following evaluation of e-DoI</b>	<b>Topics on agenda for which restrictions apply</b>
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	
Adela Núñez Velázquez	Member	Spain	No interests declared	
Cristina Martinez Garcia	Alternate	Spain	No interests declared	
Karin Erika Svedlund	Member (Vice-Chair)	Sweden	No interests declared	
Malin Kyllikki Hobro Soderberg	Alternate	Sweden	No interests declared	
Gert Laekeman	Co-opted member	Belgium	No interests declared	
Maria Helena Pinto Ferreira	Co-opted member	Portugal	No interests declared	
Melanie Bald	Observer	EDQM	No interests declared	
Olga Palomino	Expert	Spain	No interests declared	
Ewa Widy Tyszkiewicz	Expert	Poland	No interests declared	
Pierre Duez	Expert	Belgium	No interests declared	
Barbara Toth	Expert	Hungary	No interests declared	
Meeting run with the help of EMA staff				