



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 January 2022
EMA/HMPC/82262/2022
Human Medicines Division

Committee on Herbal Medicinal Products (HMPC)

Minutes for the meeting on 24-26 January 2022

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

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 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/729522/2016).

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

An agency of the European Union



Table of contents

1.	Introduction	5
1.1.	Welcome and declarations of interest of members, alternates and experts	5
1.2.	Adoption of agenda.....	5
1.3.	Adoption of the minutes	5
2.	EU herbal monographs and list entries for adoption	5
2.1.	Status of HMPC/MLWP activities	5
2.1.1.	Overview of HMPC/MLWP assessment work including the Rapporteurship distribution – Status in January 2022.....	5
2.1.2.	Appointment of Rapporteurs and Peer-reviewers	6
2.1.3.	New substances for assessment	7
2.2.	Revised EU herbal monographs and list entries for final adoption	7
2.2.1.	Monograph on Agropyri repentis rhizoma and supporting documents	7
2.3.	Revised EU herbal monographs and list entries for public consultation	8
2.3.1.	Monograph on Fumariae herba and supporting documents - Postponed	8
2.3.2.	Monograph on Juniperi pseudo-fructus and supporting documents	8
2.4.	Reviewed EU herbal monographs and list entries for decision on revision.....	9
2.4.1.	Monograph on Aloes folii succus siccatus and supporting documents	9
2.4.2.	Monograph on Arnicae flos and supporting documents - Postponed	9
2.4.3.	Monograph on Cichorii intybi radix and supporting documents.....	9
2.4.4.	Monograph on Eucalypti aetheroleum and supporting documents.....	9
2.4.5.	Monograph on Eucalypti folium and supporting documents	10
2.4.6.	Monograph on Fraxini folium and supporting documents.....	10
2.4.7.	Monograph on Fucus vesiculosus and supporting documents	10
2.4.8.	Monograph on Hippocastani cortex and supporting documents	11
2.4.9.	Monograph on Marrubii herba and supporting documents	11
2.4.10.	Monograph on Origani dictamni herba and supporting documents.....	11
2.4.11.	Monograph on Paullinae semen and supporting documents - Postponed.....	12
2.4.12.	Monograph on Rhodiolae roseae rhizoma et radix and supporting documents	12
2.4.13.	Monograph on Sennae folium and supporting documents.....	12
2.4.14.	Monograph on Sennae fructus and supporting documents.....	12
2.4.15.	Monograph on Urticae folium and supporting documents	13
2.5.	EU herbal monographs, list entries and public statements for final adoption	13
2.5.1.	Public statement on Salviae mitiorrhizae radix et rhizoma and supporting documents	13
2.5.2.	Monograph on Species digestivae and supporting documents	14
2.6.	EU herbal monographs, list entries and public statements for adoption for release for public consultation	14
2.7.	EU herbal monographs, list entries and public statements - post finalisation	14
2.7.1.	Monograph on Taraxaci officinalis radix and supporting documents	14

3.	Referral procedures	15
4.	Guidelines and guidance documents	15
4.1.	Non-clinical/clinical safety and efficacy and multidisciplinary	15
4.1.1.	Guideline on Assessment of genotoxicity of herbal substances/preparations (EMA/HMPC/107079/2007)	15
4.2.	Quality	15
4.2.1.	Guideline on Good Agricultural and Collection Practice (GACP) of starting materials of herbal origin - Postponed	15
4.3.	Regulatory / Procedural	15
4.4.	Report on HMPC Drafting Groups activities	15
4.4.1.	Quality DG	15
4.4.2.	ORGAM DG	15
5.	Organisational, regulatory and methodological matters	16
5.1.	Mandate and organisation of the HMPC	16
5.1.1.	Strategic Review and Learning Meetings	16
5.1.2.	HMPC membership	16
5.2.	EMA Scientific Committees or CMDh-v	17
5.2.1.	Scientific Coordination Board Meeting	17
5.2.2.	Coordination with QRD and CMDh – Update on Herbal specifics for QRD template (CMDh/349/2016, Rev.0 - EMA/HMPC/770889/2014) - Postponed	17
5.3.	Coordination with EMA Working Parties/Working Groups/Drafting Groups	17
5.4.	Cooperation within the EU regulatory network	17
5.4.1.	Coordination with European Pharmacopoeia	17
5.4.2.	Coordination with the European Commission	17
5.5.	Cooperation with International Regulators	17
5.5.1.	WHO – International Regulatory Cooperation for Herbal medicines (IRCH) Network 13th annual virtual meeting	17
5.6.	Contacts of the HMPC with external parties and interaction with the Interested Parties to the Committee	18
5.6.1.	Association of the European Self-Medication Industry (AESGP) – hearing in March 2022	18
5.7.	Work plan	18
5.7.1.	HMPC work plan 2022	18
5.7.2.	Review of Working parties and Drafting groups	19
5.7.3.	Quality domain governance and draft multiannual work plan	19
5.8.	Planning and reporting	20
5.9.	Legislation and regulatory affairs	20
5.10.	Questions from members	20
6.	EU herbal monographs and list entries in preparation	20
6.1.	Revision of EU herbal monographs and list entries in preparation for adoption after public consultation	20

6.1.1.	Monograph on Hyperici herba and supporting documents.....	20
6.2.	Revision of EU herbal monographs and list entries in preparation for public consultation.....	21
6.2.1.	Monograph on Foeniculi amari fructus and supporting documents.....	21
6.2.2.	Monograph on Foeniculi amari fructus aetheroleum and supporting documents	21
6.2.3.	Monograph on Foeniculi dulcis fructus and supporting documents.....	21
6.2.4.	Monograph on Lavandulae aetheroleum and supporting documents	21
6.2.5.	Monograph on Pelargonii radix and supporting documents – Postponed	22
6.2.6.	Monograph on Plantaginis lanceolatae folium and supporting documents – Postponed	22
6.2.7.	Monograph on Rosmarini aetheroleum and supporting documents	22
6.2.8.	Monograph on Rosmarini folium and supporting documents	23
6.3.	Review of EU herbal monographs and list entries in preparation for decision on revision	23
6.3.1.	Monograph on Camelliae sinensis non fermentatum folium and supporting documents	23
6.3.2.	Monograph on Curcumae xanthorrhizae rhizoma and supporting documents - Postponed..	23
6.3.3.	Monograph on Ginseng radix and supporting documents.....	23
6.3.4.	Monograph on Juglandis folium and supporting documents	24
6.3.5.	Monograph on Liquiritiae radix and supporting documents	24
6.3.6.	Monograph on Tiliae flos and supporting documents - Postponed.....	24
6.3.7.	Monograph on Urticae radix and supporting documents.....	24
6.4.	EU herbal monographs and list entries in preparation for adoption after public consultation.....	25
6.4.1.	Monograph on Vaccinii macrocarpi fructus and supporting documents - Postponed.....	25
6.5.	EU herbal monographs and list entries in preparation for adoption for release for public consultation	25
6.5.1.	Monograph on Cisti cretici herba and supporting documents – Postponed	25
6.5.2.	Monograph on Cnici benedicti herba and supporting documents.....	25
6.5.3.	Monograph on Hyperici herba/Cimicifugae rhizoma and supporting documents – Postponed	25
6.5.4.	Monograph on Tribuli terrestris herba and supporting documents	25
7.	Any other business	26
7.1.	Topics for discussion	26
7.2.	Documents for information.....	26
7.2.1.	HMPC.....	26
7.2.2.	Assessment Report Summary for the Public (ARSP)	26
7.2.3.	EU herbal monographs, list entries and public statements – on hold.....	26
7.2.4.	Other	26
List of participants		27

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 (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 24-26 January 2022.

Outcome:

Agenda adopted.

Some constraints related to the late circulation of documents for discussion at the next meeting were highlighted, namely in those cases that require a more detailed discussion internally in each Member State.

1.3. Adoption of the minutes

HMPC minutes for 22-24 November 2021.

Outcome:

Minutes adopted.

Minor changes were introduced in the HMPC minutes for 22-24 November 2021.

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 January 2022

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 March meeting according to the overview, Rapporteurs were asked to inform secretariat and Chair before the first pre-mail (by 15 March 2022) to allow best adaptation of agenda and time-schedule.

2.1.2. Appointment of Rapporteurs and Peer-reviewers

New Rapporteur-New Peer Reviewer

Unscheduled reviews to consider specific new data:

2nd step – (planned adoption March 2022)

- Frangulae cortex
- Rhamni purshianae cortex
- Rhei radix

Periodic reviews to start in 2022:

Monographs/LEs adopted in 2014

- Melaleucae aetheroleum
- Ononidis radix
- Rosae flos
- Rubi idaei folium
- Sisymbrii officinalis herba

Monographs/LEs adopted in 2015

- Agrimoniae herba
- Capsici fructus
- Epilobii herba
- Eschscholziae herba
- Ginkgo folium
- Matricariae flos
- Myrtilli fructus siccus
- Myrtilli fructus recens
- Pilosellae herba cum radice
- Symphyti radix

Monographs/LEs adopted in 2016

- Crataegi folium cum flore
- Helichrysi flos

- Origani majoranae herba
- Polygoni avicularis herba
- Pruni africanae cortex
- Ricini oleum
- Sideritis herba

Outcome:

HMPC agreed on new Rapporteurs and Peer reviewers for unscheduled review to consider specific new data and for periodic reviews to start in 2022.

HMPC secretariat will update the HMPC status overview.

It was noted that Rapporteurships tend to be taken by the same delegates and the Chair invited the most recently appointed members and alternates to take up Peer-review positions, which provide an opportunity to develop knowledge of HMPC assessment practice.

2.1.3. [New substances for assessment](#)

Report: HMPC Chair

Action: For discussion

Documents tabled: Email communication, Template for new proposals

Outcome:

HMPC acknowledged email sent out with the template for new proposals.

The Chair invited members to propose new substances and combinations for assessment, reminding them that making a suggestion does not imply taking the Rapporteurship.

2.2. [Revised EU herbal monographs and list entries for final adoption](#)

2.2.1. [Monograph on Agropyri repentis rhizoma and supporting documents](#)

Action: For adoption

Documents tabled: MO, AR, LoR, Readers Guidance; References: 78/84

Outcome:

Adoption postponed given the need for harmonisation across all 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'. These monographs have, either as a warning or as a contra-indication, a statement addressing the use in patients with conditions where a reduced fluid intake is recommended (e.g. severe cardiac or renal disease). The Committee was reminded that such a statement relates to the mode of action i.e. 'flushing of the urinary tract' and had not been added due to safety concerns about the medicinal products. Some members were of the view that contraindications must be substantiated by real evidence and that a warning is better suited to alert patients. The need for a warning was questioned given that the labelling of diuretic medicines does not contain any such CI or warning about fluid intake. Such a warning would also need to be considered vis-à-vis the recommendation about fluid intake to achieve an increased urine volume in section 4.2

under 'Method of administration', («*To ensure an increase of the amount of urine, adequate fluid intake is required during treatment*» as in the juniper berry monograph or «**Appropriate fluid intake is required during treatment to ensure adequate amount of the urine**»).

The wording for a warning in section 4.4. was discussed having regard to the framework for THMPs i.e. use without medical supervision but in the expectation that patients will not themselves decide to be subject to a reduced fluid intake but upon instruction from a HCP. Different wordings were proposed («*in conditions where a reduced fluid intake is recommended, the use of this medicinal product **should be avoided***» or «*in conditions where a reduced fluid intake has been medically advised, the use of this medicinal product **is not recommended***»).

HMPC endorsed the Vice-Chair proposal that all Rapporteurs should meet (ad hoc online discussion) to specifically discuss and agree on this point in advance of the March meeting. HMPC secretariat to support this virtual meeting in cooperation with Vice-Chair.

Rapporteur to modify the draft monograph and assessment report according to the discussion and possible additional comments from peer-reviewer and HMPC members, for **possible adoption** at the **HMPC March** meeting.

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

2.3.1. Monograph on *Fumariae herba* and supporting documents - Postponed

2.3.2. Monograph on *Juniperi pseudo-fructus* and supporting documents

Action: For adoption

Documents tabled: MO, AR, LoR, Readers Guidance, PL Comments; References: 43/76

Outcome:

Adoption postponed.

The Rapporteur presented the changes introduced in the documents to consider the decisions taken in September 2021 after the review of the package on *Orthosiphonis folium*. As the monograph no longer includes the use of the cone berries, all references to the use of the "herbal substance" should be removed in the different sections.

Rapporteur to modify the draft monograph and assessment report according to the discussion and comments from peer-reviewer (also according to the outcome of the ad hoc discussion on 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 – see 2.2.1) for **possible adoption** at the **HMPC March** meeting.

HMPC agreed to keep the data on the weight of the juniper berries in a report separate from the AR, that could be accessed upon request.

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

2.4.1. Monograph on *Aloes folii succus siccatus* and supporting documents

Action: For adoption

Document tabled: Review report; References 03/04

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 Unscheduled Review includes now recent studies. However, the HMPC Vice-Chair stressed that it should be made clear that no full bibliographic search has been conducted (as it is normally done for scheduled reviews) and that this unscheduled review focused on assessing findings from non-clinical toxicology studies.

The HMPC decided by majority vote (26 out of 27) not to revise the monograph, assessment report and list of references on *Aloes folii succus siccatus*. Divergent opinion: Polish member.

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

2.4.2. Monograph on *Arnicae flos* and supporting documents - Postponed

2.4.3. Monograph on *Cichorii intybi radix* and supporting documents

Action: For adoption

Document tabled: Review report; References 00/00

Outcome:

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

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

The review report (pending modifications agreed at the meeting) was adopted and will be published as addendum to the existing assessment report on the EMA website.

2.4.4. Monograph on *Eucalypti aetheroleum* and supporting documents

Action: For adoption

Document tabled: Review report; References 19/19

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 *Eucalypti aetheroleum*.

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

Revision of the monograph is recommended to include a range for the oral daily dose with an upper limit of 600 mg. At present, the monograph's posology reads 'Single dose: 100-200 mg, 2 to 5 times a day'. However, the traditional use (supported by the Commission monograph, Blumenthal et al. 1998) referred to a daily dose for oral use of 0.3 to 0.6 g essential oil. Also considering the products on the market, the Committee agreed that the monograph should include, for the oral use, a daily dose of 200-600 mg essential oil.

2.4.5. Monograph on *Eucalypti folium* and supporting documents

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 *Eucalypti folium*.

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

2.4.6. Monograph on *Fraxini folium* and supporting documents

Action: For adoption

Document tabled: Review report; References 05/05

Outcome:

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

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

The review report (pending modifications agreed at the meeting) was adopted and will be published as addendum to the existing assessment report on the EMA website. See also general discussion on the review report template under 5.7.1.

2.4.7. Monograph on *Fucus vesiculosus* and supporting documents

Action: For adoption

Documents tabled: Review report; References 13/13

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 *Fucus vesiculosus*.

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

2.4.8. Monograph on Hippocastani cortex and supporting documents

Action: For adoption

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

Outcome:

Adoption postponed.

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

The HMPC endorsed the Rapporteur's position in favour of a revision of the monograph. To facilitate the understanding of the evidence of long-standing use for the herbal preparation, the Rapporteur was invited to prepare a table for discussion at the March meeting and ultimately for inclusion in section 2.3 of the revised AR (see page 10 of the AR template: https://www.ema.europa.eu/en/documents/template-form/template-assessment-report-development-european-union-herbal-monographs-european-union-list-entries_en.pdf). The HMPC discussed the need for regulatory consistency in its scientific opinions on herbal preparations included in adopted monographs, in the knowledge that marketed products are subject to slight variations by manufacturers.

2.4.9. Monograph on Marrubii herba and supporting documents

Action: For adoption

Document tabled: Review report; References 02/02

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 *Marrubii herba*.

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

2.4.10. Monograph on Origani dictamni herba and supporting documents

Action: For adoption

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

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 *Origani dictamni herba*.

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

2.4.11. Monograph on *Paulliniae semen* and supporting documents - Postponed

2.4.12. Monograph on *Rhodiolae roseae rhizoma et radix* and supporting documents

Action: For adoption

Documents tabled: Review report; References 14/14

Outcome:

HMPC agreed with Rapporteur's position to revise the package because new data were detected that need assessment, in support of potential changes to the content of the monograph:

- reports of adverse events in published literature and in the EudraVigilance database for possible inclusion in section 4.8 'Undesirable effects'
- possible rewording for the therapeutic indication (upon analysis of a proposal by interested parties).

The HMPC decided by consensus to start the revision procedure and revise the monograph, assessment report and list of references on *Rhodiolae roseae rhizoma*.

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

2.4.13. Monograph on *Sennae folium* and supporting documents

Action: For adoption

Document tabled: Review report; References 02/02

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 Unscheduled Review includes now recent studies. However, the HMPC Vice-Chair stressed that it should be made clear that no full bibliographic search has been conducted (as it is normally done for scheduled reviews) and that this unscheduled review focused on assessing findings from non-clinical toxicology studies.

The HMPC decided by majority vote (26 out of 27) not to revise the monograph, assessment report and list of references on *Sennae folium*. Divergent opinion: Polish member.

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

2.4.14. Monograph on *Sennae fructus* and supporting documents

Action: For adoption

Document tabled: Review report; References 02/02

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 Unscheduled Review includes now recent studies. However, the HMPC Vice-Chair stressed that it should be made clear that no full bibliographic search has been conducted (as it is normally done for scheduled reviews) and that this unscheduled review focused on assessing findings from non-clinical toxicology studies.

The HMPC decided by majority vote (26 out of 27) not to revise the monograph, assessment report and list of references on *Sennae fructus*. Divergent opinion: Polish member.

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

2.4.15. Monograph on *Urticae folium* and supporting documents

Action: For adoption

Document tabled: Review report; References 04/04

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 *Urticae folium*.

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

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

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

Action: For adoption

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

Outcome:

Adoption postponed.

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

The Rapporteur was invited to reword the conclusion of section 2.3 with a view to clarifying it is the absence of data in the public domain that prevents the HMPC to establish a monograph (instead of «*No monograph could be established, as no preparation fulfils the requirements for traditional or well-established use*»).

2.5.2. Monograph on Species digestivae and supporting documents

Action: For adoption

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

Outcome:

Adoption postponed.

Rapporteur to modify the draft monograph and assessment report according to the discussion and possible additional comments from peer-reviewer and HMPC members, for **possible adoption** at the **HMPC March** meeting.

The Rapporteur was invited to update the wording in section 5.3 of the monograph for the subparts '*Combinations containing Anisi fructus*' and '*Combinations containing Foeniculi fructus*'. The HMPC supported the HMPC Vice-Chair proposal to introduce a reference to the revised Public statement on the use of herbal medicinal products containing estragole (EMA/HMPC/137212/2005 Rev1) [instead of the statements «*The genotoxic risk related to estragole is not considered to be relevant in the specified conditions of use (short term use in adolescents, adults and elderly) due to the small amount present in herbal infusions prepared from aniseed*» and «*The genotoxic risk related to estragole is not considered to be relevant in the specified conditions of use due to the small amount present in herbal infusions prepared from fennel*» respectively], in order to allow NCAs, in registration application procedures, to request that the amount of estragole be specified in the given product (same approach as that taken for thujone).

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

Action: For adoption

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

Outcome:

Adoption postponed.

Peer-reviewer/Secretariat to modify the draft monograph and assessment report according to the discussion and possible comments from HMPC members (also according to the outcome of the ad hoc discussion on 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 – see 2.2.1), for **possible adoption** at the **HMPC March** meeting.

The Peer-reviewer had identified three discrepancies between the monograph and the assessment report (single dose for the comminuted herbal substance for decoction; need to ascertain the therapeutic indications for the herbal preparations c), d) and e); the warning

in section 4.4. about use in patients with a condition where reduced fluid intake is recommended – see also agenda point 2.2.1).

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)

Action: For discussion

Document tabled: Draft concept paper

Outcome:

HMPC discussed the draft concept paper on revision of the guideline. HMPC Chair invited the members and alternates to submit additional inputs to the Rapporteur, for possible adoption for release for public consultation at the **HMPC March** meeting.

It was highlighted that the guideline on assessment of genotoxicity needs to integrate the requirements to address DNA-directed as well as non-DNA-directed cellular events that may increase genomic instability. The proposed revision also includes extending the scope of the guideline to herbal medicinal products for veterinary use. Such extension of the scope would require coordination with relevant CVMP Working Parties. The Rapporteur suggested discussing with veterinary colleagues and inform the HMPC.

4.2. Quality

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

4.3. Regulatory / Procedural

None

4.4. Report on HMPC Drafting Groups activities

4.4.1. Quality DG

None

4.4.2. ORGAM DG

None

5. Organisational, regulatory and methodological matters

5.1. Mandate and organisation of the HMPC

5.1.1. Strategic Review and Learning Meetings

- Slovenian Presidency virtual meeting – 08-09 December 2021

Report: Barbara Razinger

Action: For information

Document tabled: Agenda, Presentations, Follow up plan

- French Presidency virtual meeting – 14 April 2022

Report: An Le

Action: For information

Document tabled: Draft agenda

Outcome:

HMPC noted the follow up plan presented by the Slovenian delegate and Vice-Chair, and draft agenda presented by the French delegate. HMPC members and alternates willing to contribute to the topics on the agenda for the 14 April meeting should contact An Le directly.

It was noted that proposals resulting from Slovenian Presidency are still open for inputs and some of them qualify for further development during the French Presidency. It was suggested to rename the session no. 4 "Essential oils as therapeutic tools to avoid bacterial resistance" in the draft agenda for the French Presidency virtual meeting.

5.1.2. HMPC membership

Report: HMPC Chair

Action: For information

Outcome:

New membership:

- Norway, Marianne Løiten Dalhus (alternate) as of 07 January 2022

Renomination:

- Romania, Nicoleta Carmen Purdel (member) as of 25 February 2022

Swap of roles:

- Norway, Gro Anita Fossum (alternate to member) as of 07 January 2022

End of membership:

- Slovakia, Milan Nagy (alternate) as of 15 December 2021
- Maja Leon Grzymkowska (EC Representative)

5.2. EMA Scientific Committees or CMDh-v

5.2.1. Scientific Coordination Board Meeting

Report: HMPC Chair

Action: For information

Documents tabled: Minutes 03 December 2021, Agenda 31 January 2022

Outcome:

HMPC noted topics discussed in December and on agenda for discussion in January at the Scientific Coordination 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) - Postponed

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

None

5.4. Cooperation within the EU regulatory network

5.4.1. Coordination with European Pharmacopoeia

- EDQM 13B expert group meeting

Report: Melanie Bald

Action: For information

Document tabled: SoD

- New assay method for Rhei radix

Report: Melanie Bald

Action: For discussion

Document tabled: Email communication

Outcome:

HMPC noted summaries of decisions highlighted by the EDQM observer.

5.4.2. Coordination with the European Commission

Revision of EU pharmaceutical legislation (human) Report: HMPC Chair

Action: For information

5.5. Cooperation with International Regulators

5.5.1. WHO – International Regulatory Cooperation for Herbal medicines (IRCH) Network 13th annual virtual meeting

Report: HMPC Chair

Action: For information

Documents tabled: Agenda

Outcome:

HMPC noted topics discussed at the WHO - IRCH 13th annual virtual meeting, held on 24-26 November 2021.

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 in March 2022

Report: HMPC Chair

Action: For discussion

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

Outcome:

HMPC noted communication with the AESGP regarding a proposal on combinations of traditionally used herbal extracts based on monographs.

HMPC considered that a face-to-face meeting with AESGP would be preferable, with the hearing initially planned for March being rescheduled for May or July, depending on the conditions of access to EMA building. The hearing agenda will include AESGP's proposal. *Post-meeting note: AESGP hearing scheduled for 18 May (tentatively).*

5.7. Work plan

5.7.1. HMPC work plan 2022

Report: HMPC Chair

Action: For adoption

Documents tabled: Draft Work plan 2022, Draft Annex 1, Draft Annex 2

- Topic 1-3-1 'Improved use of data source for HMPC relevant safety assessment' – adapt respective templates

Report: Nicoleta Carmen Purdel

Action: For discussion

Documents tabled: Review report template

The Committee discussed the revised 'Review report template' that includes guidance for Rapporteurs, especially concerning the selection of scientific publications to be reported after the scientific literature search. The recommendation is that in general, data on the phytochemical composition and analytical data on the herbal substance/herbal preparations, non-clinical pharmacological data and pharmacokinetic data should not be presented in the Review report, unless they could trigger a revision of the monograph. To those members, who see value in updating the AR with findings of new publications also when they come to support (reinforce) the monograph's content, the HMPC Chair pointed to the scarce resources

at the HMPC disposal and thus the regulatory approach to select data on a 'need to know' basis rather than on a 'nice to know' basis.

- Topic 2-1-1 'Collaboration with EC on the feasibility to establish a EU Herbal Monograph for Cannabis flos' (specific Q&A for basic information; specific Call for data)

Report: HMPC Chair, Ana Paula Martins

Action: For discussion

Documents tabled: Presentation

Outcome:

HMPC adopted the work plan 2022 by consensus.

Concerning the involvement of HMPC members, alternates and experts into the different activities:

- Heidi Foth, Wojciech Dymowski and Sarah Kellaghan (expert, Ireland) volunteered to contribute to Topic 1-3-3 'Evaluation of a harmonised approach for the use of monographs in procedures for combination products';
- Ioanna Chinou volunteered to contribute to Topic 2-1-1 'Collaboration with EC on the feasibility to establish a EU Herbal Monograph for Cannabis flos';
- Stefanie Bodemann (expert, Germany) and Susanne Flemisch volunteered to contribute to Topic 2-2-1 'Implementation of new architecture for WP/DG'.

HMPC Chair invited more members and alternates to volunteer -or to nominate experts- to participate:

- in the topics listed in the work plan 2022
- in the topics listed in the Annex 1 (EU herbal monographs/list entries)
- in the topics listed in the Annex 2 (Guidance and procedural documents).

Deadline: 21 February 2022.

5.7.2. Review of Working parties and Drafting groups

Report: HMPC Chair; Expert: Kristine Hvolby

Action: For discussion

Documents tabled: Presentation

Outcome:

HMPC noted the methodology and timelines for the implementation of the new model for working parties and drafting groups. Background information on the new model can be found in the published minutes from the Management Board meetings held in December 2020 and March 2021.

5.7.3. Quality domain governance and draft multiannual work plan

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

Action: For discussion

Documents tabled: Consolidated 3-year work plan, Proposal from the HMPC Chair

Outcome:

HMPC noted topics on consolidated 3-year work plan.

HMPC Chair invited members and alternates to volunteer -or to nominate experts- to join the ad-hoc core group working on quality guidelines. Deadline: 21 February 2022.

HMPC secretariat to suggest a few dates for 2022.

Post-meeting note:

- Knut Almgren (expert, Sweden) volunteered to join the core group.

- Olga Maria Palomino (member, Spain)

5.8. Planning and reporting

None

5.9. Legislation and regulatory affairs

None

5.10. Questions from members

None

6. EU herbal monographs and list entries in preparation**6.1. Revision of EU herbal monographs and list entries in preparation for adoption after public consultation****6.1.1. Monograph on Hyperici herba and supporting documents**

Action: For 9th discussion

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

Outcome:

HMPC noted possible scenarios based on comments received during public consultation; an orientation vote took place to inform the Rapporteur about which option would likely be supported by a majority.

Rapporteur to modify 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 March** meeting.

The Rapporteur presented 3 possible approaches based on the comments received during public consultation in relation the content of hyperforin and the findings from the interaction study by Zahner et al 2019 & PRAC conclusions. In a trend vote, most members supported a revision of the monograph to include, as a separate/additional herbal preparation, the dry extract with a low level of hyperforin.

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

6.2.1. Monograph on *Foeniculi amari fructus* and supporting documents

Action: For 7th discussion

Documents tabled: Draft MO, AR, LoR, Reader's Guidance; References: 136/199

Outcome:

Rapporteur to modify the draft monograph and assessment report according to the discussion and possible additional comments from peer-reviewer and HMPC members, for possible adoption for release for public consultation at the **HMPC March** meeting.

The need to update the wording in section 5.3 of monograph regarding estragole genotoxic risk was emphasised, including a reference to the revised public statement on the use of herbal medicinal products containing estragole (EMA/HMPC/137212/2005 Rev1). See 2.5.2.

6.2.2. Monograph on *Foeniculi amari fructus aetheroleum* and supporting documents

Action: For 7th discussion

Documents tabled: Draft PS, Presentation, Reader's Guidance; References: 136/199

Outcome:

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

The Rapporteur was invited to reflect on possibly establishing 2 distinct AR, one supporting the monographs and one supporting the PS.

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

6.2.3. Monograph on *Foeniculi dulcis fructus* and supporting documents

Action: For 7th discussion

Documents tabled: Draft MO, AR, LoR, Reader's Guidance; References: 136/199

Outcome:

Rapporteur to modify the draft monograph and assessment report according to the discussion and possible additional comments from peer-reviewer and HMPC members, for possible adoption for release for public consultation at the **HMPC March** meeting.

The need to update the wording in section 5.3 of monograph regarding estragole genotoxic risk was emphasised, including a reference to the revised public statement on the use of herbal medicinal products containing estragole (EMA/HMPC/137212/2005 Rev1). See 2.5.2.

6.2.4. Monograph on *Lavandulae aetheroleum* and supporting documents

Action: For 3rd discussion

Documents tabled: Draft MO, AR, LoR, Reader's Guidance; References: 92/129

Outcome:

Rapporteur to modify 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 March** meeting.

The HMPC discussed a few issues raised by the Rapporteur. In relation to the use as bath additive, the HMPC discussed the need for regulatory consistency and the fact there are no products containing lavender oil registered for use as bath additive, for relief of mild symptoms of mental stress and exhaustion and to aid sleep. The Rapporteur was invited to work towards having a distinctive AR on *Lavandulae flos* and one on the essential oil.

6.2.5. Monograph on *Pelargonii radix* and supporting documents – Postponed

6.2.6. Monograph on *Plantaginis lanceolatae folium* and supporting documents – Postponed

6.2.7. Monograph on *Rosmarini aetheroleum* and supporting documents

Action: For 3rd discussion

Documents tabled: Draft MO, AR; References: 13/13

Outcome:

Rapporteur to modify 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 March** meeting.

The Rapporteur presented the revised monograph and AR. The currently published AR supports the oral use of the essential oil and the proposed posology:

'Pharmacopée Française - Préparation Officinale, 1980: Oral use - Spasmolytic - Essential oil = 3 to 4 drops, 3-4 times/day [...]

Blumenthal, The Complete German Commission E Monographs, 1998: Oral use – Dyspeptic complaints - Daily dose 10-20 drops essential oil; equivalent preparations

Ed. Note: The essential oil dosage appears excessive and possibly unsafe. A more reasonable dosage for internal use would be 2 drops (1 ml).'

The disappearance of medicinal products for oral use in the indication *'symptomatic relief of dyspepsia and mild spasmodic disorders of the gastrointestinal tract'* from the market is not a justification to remove the oral use of the essential oil from the monograph. Having in mind regulatory consistency, removing a certain use from a given monograph must be justified e.g. by new/emerging evidence of safety concerns. The HMPC also discussed the warnings in section 4.4, especially the warning *'If there is inflammation of the skin or subcutaneous induration, ulcers, sudden swelling of one or both legs particularly associated with redness and heat, cardiac or renal insufficiency, or a sudden sharp pain in the leg when at rest, a doctor should be consulted'* which stems from the SmPC from a THMP approved after a DCP. In November 2021, the Rapporteur's proposal to keep the warning regarding cardiac and renal insufficiency had been agreed. After discussion, the HMPC endorsed the proposal that would draft with the Rapporteur a rationale justifying the HMPC position not to include *'cardiac and renal insufficiency'* in the warning. As the therapeutic indications are

identical in the monographs on rosemary oil and on rosemary leaf, this aspect is relevant to both monographs.

6.2.8. Monograph on Rosmarini folium and supporting documents

Action: For 3rd discussion

Documents tabled: Draft MO, AR; References: 13/13

Outcome:

Rapporteur to modify 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 March** meeting.

See 6.2.7.

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 3rd discussion

Document tabled: Review report, Readers Guidance; References 13/26

Outcome:

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 March** meeting.

The Rapporteur presented the status of assessment of the new data identified after the literature search. Verification of the list of references against the publications cited in EFSA's scientific opinion on the safety of green tea catechins is ongoing. The Rapporteur was invited to describe carefully, in the review report, the selected filters that led to the exclusion of publications, given the high number of new references resulting from the search. Findings not relevant to the herbal preparations described in the monograph can be excluded.

6.3.2. Monograph on Curcumae xanthorrhizae rhizoma and supporting documents - Postponed

6.3.3. Monograph on Ginseng radix and supporting documents

Action: For 2nd discussion

Document tabled: Readers Guidance; References 00/00

Outcome:

Rapporteur to present first draft of the review report for discussion at **HMPC March** meeting.

The Rapporteur presented the status of assessment of the new data identified after the literature search. HMPC confirmed that it can be highlighted in the review report that not all references have been fully assessed yet. It is sufficient for the review report to include a justification in favour of the revision of the monograph, based on the preliminary findings (regulatory activity /results from the market overview), for HMPC decision. When the revision is initiated, the review report is not published.

6.3.4. Monograph on Juglandis folium and supporting documents

Action: For 3rd discussion

Document tabled: Review report; References 00/13

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 according to the discussion for peer review and for **adoption** at the **HMPC March** meeting.

Timetable: Documents to be sent to Peer-reviewer: **22 February 2021**

Peer-review documents to be sent to Rapporteur: **8 March 2022**

Final documents to be included latest in 2nd premail: **22 March 2022**

6.3.5. Monograph on Liquiritiae radix and supporting documents

Action: For 2nd discussion

Document tabled: Review report, Readers Guidance; References 00/29

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 review of the complete package is advocated.

Rapporteur to finalise the review report according to the discussion for peer review and for **adoption** at the **HMPC March** meeting.

Timetable: Documents to be sent to Peer-reviewer: **22 February 2021**

Peer-review documents to be sent to Rapporteur: **8 March 2022**

Final documents to be included latest in 2nd premail: **22 March 2022**

6.3.6. Monograph on Tiliae flos and supporting documents - Postponed

6.3.7. Monograph on Urticae radix and supporting documents

Action: For 1st discussion

Document tabled: Review report; References 04/04

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 according to the discussion for peer review and for **adoption** at the **HMPC March** meeting.

Timetable: Documents to be sent to Peer-reviewer: **22 February 2021**

Peer-review documents to be sent to Rapporteur: **8 March 2022**

Final documents to be included latest in 2nd premail: **22 March 2022**

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 - Postponed

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

6.5.2. Monograph on Cnici benedicti herba and supporting documents

Action: For 2nd discussion

Document tabled: Draft MO, LoR, Presentation; References: 07/16

Outcome:

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

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

The Rapporteur presented the available evidence that appears to support the establishment of a draft monograph on Cnici benedicti herba, in particular bibliographic evidence from the Austrian and Polish pharmacopoeias and information about products on the market in Poland since 1993.

6.5.3. Monograph on Hyperici herba/Cimicifugae rhizoma and supporting documents – Postponed

6.5.4. Monograph on Tribuli terrestris herba and supporting documents

Action: For 1st discussion

Document tabled: Presentation; References: 00/00

Outcome:

Discussion postponed and scheduled at the **HMPC March** meeting.

7. Any other business

7.1. Topics for discussion

None

7.2. Documents for information

7.2.1. HMPC

Table of Decisions from HMPC meeting held on 22-24 November 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)

None

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

None

7.2.4. Other

- Compilation terms and definitions for cannabis derived MPs; EC comments and response
- PA Database evaluation 2021
- Schrenk *et al.* Novel Insights into Pyrrolizidine Alkaloid Toxicity and Implications for Risk Assessment: Occurrence, Genotoxicity, Toxicokinetics, Risk Assessment–A Workshop Report. *Planta Medica* 2021
- Update on BAH PA database received by Barbara Steinhoff
- Estragole-containing plants

List of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 24-26 January 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	
Ivan Kosalec	Member	Croatia	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	
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	
Jacqueline Masterson	Alternate	Ireland	No interests declared	
Alessandro Assisi	Member	Italy	No interests declared	
Jurate Antanaviciene	Member	Lithuania	No interests declared	
Sven Back	Member	Luxembourg	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Everaldo Attard	Member	Malta	No interests declared	
Burt H Kroes	Member	Netherlands	No interests declared	
Hilda Kuin	Alternate	Netherlands	No interests declared	
Gro Anita Fossum	Alternate	Norway	No interests declared	
Marianne Løiten Dalhus	Alternate	Norway	No interests declared	
Wojciech Dymowski	Member	Poland	No interests declared	
Ana Paula Martins	Member	Portugal	No interests declared	
Carmen Purdel	Member	Romania	No interests declared	
Ligia Elena Dutu	Alternate	Romania	No interests declared	
Miroslava Petrikova	Member	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	
Malin Kyllikki Hobro Soderberg	Alternate	Sweden	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	
Pierre Duez	Expert	Belgium	No interests declared	
Kristine Hvolby	Expert	Denmark	No interests declared	
Meeting run with support from relevant EMA staff				

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