



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 November 2021
EMA/HMPC/568018/2021
Human Medicines Division

Committee on Herbal Medicinal Products (HMPC)

Minutes for the meeting on 20-22 September 2021

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

20 September 2021, 10:00 – 17:00, virtual meeting

21 September 2021, 09:00 – 17:00, virtual meeting

22 September 2021, 09:00 – 16:00, virtual meeting

Disclaimers

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 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

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 20-22 September 2021 was adopted.

1.3. Adoption of the minutes

HMPC minutes for 05-07 July 2021 were adopted and will be published on the EMA website.

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 September 2021

Report: HMPC Chair

Action: For discussion

Document tabled: Overview

Outcome:

HMPC noted status of assessment work.

Rapporteurs were asked to inform secretariat and Chair on any changes before the first pre-mail (by 9 November 2021) to allow best adaptation of agenda and time-schedule.

2.1.2. Appointment of Rapporteurs and Peer-reviewers

None

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

2.2.1. Monograph on *Orthosiphonis folium* and supporting documents

Action: For adoption

Documents tabled: MO, AR, LoR, OoC; References: 37/46

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.

Advice regarding sufficient fluid intake particularly when linked to specific indications was removed from MO section 4.4 because more appropriate in section 4.2 (to be considered also for the template).

The proposed addition of a traditionally used homeopathic mother tincture in France was not agreed with reference to the homeopathic manufacturing and no data on posology and indication. Also, the posology for traditionally used powder capsules were double checked according to information from France. Some members suggested a shorter duration of use raising the need for earlier medical advice. However, it was referred to the documented use, comparison to other substances with analogous tradition and previous agreement. Minor changes were introduced in the AR.

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

None

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

2.4.1. Monograph on *Solidaginis virgaureae herba* 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 *Solidaginis virgaureae herba*.

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

After peer-review all information was deleted from the review report that was considered not to be linked to data potentially changing the content of the existing monograph.

The wording regarding available PhV data and risk of allergies was modified.

2.4.2. Monograph on *Urticae folium* and supporting documents - postponed

2.4.3. Monograph on *Urticae herba* and supporting documents - postponed

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

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

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

2.6.1. Monograph on *Centellae asiaticae herba* and supporting documents

Action: For adoption

Documents tabled: MO, AR, LoR; References: 13/142

Outcome:

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

The committee agreed to keep new clinical studies not linked to the traditional indication of the monograph in the AR. Members further discussed whether the possible signals from carcinogenicity and other toxicity studies may be cause for concern and need a closer assessment as regards their relevance for the traditional preparation, use and posology in the monograph.

2.6.2. Monograph on *Cisti cretici herba* and supporting documents - postponed

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

Action: For adoption

Documents tabled: Final revised PS, OoC, Questions to SWP, Response from SWP, Comments regarding SWP remarks

Outcome:

Final public statement and Overview of comments re-adopted by majority following modification upon suggestion from SWP.

HMPC secretariat to coordinate communication between Rapporteurs/ Chair with CHMP/SWP and CMDh regarding implementation for NAPs/CAPs containing estragole in active substance/ excipients before final publication.

4.2. Quality

4.2.1. Guideline on quality of herbal medicinal products/traditional herbal medicinal products

Action: For adoption

Documents tabled: Revised Guideline, OoC

Outcome:

Final revised guideline and overview of comments received during public consultation adopted by consensus.

HMPC secretariat in liaison with Rapporteur and QDG/QWP to coordinate adoption by CHMP and CVMP before final publication.

Minor remaining issues were discussed, and final modifications performed in the GL e.g. with regard to impurities. Additionally, some editorial improvements were introduced. Final gaps/adjustments have also to be completed in the OoC before editorial review and transfer to QWP and CHMP, CVMP.

The Chair thanked the Rapporteurs and small team of quality assessors for the finalisation using focused drafting meetings instead of regularly scheduled QDG meetings to finalise the drafts from 2018 which will be welcomed by industry and assessors alike.

4.2.2. Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products

Action: For adoption

Documents tabled: Revised Guideline, OoC

Outcome:

Final revised guideline and Overview of Comments received during public consultation adopted by majority.

HMPC secretariat in liaison with Rapporteur and QDG/QWP to coordinate adoption by CHMP and CVMP before final publication.

See 4.2.1.

4.2.3. Nitrosamines and Herbal MPs

Report: HMPC Chair

Action: For adoption

Documents tabled: CMDh practical guidance for Marketing Authorisation Holders, [Questions and answers for marketing authorisation holders/applicants](#)

Outcome:

Adoption postponed to **HMPC November** meeting. Rapporteur to update the version according to the discussion and based on comments.

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

Action: For discussion

Document tabled: Concept paper on the revision of GACP GL 2021

Outcome:

HMPC welcomed the first draft of the Concept paper on the revision of the GACP guideline. HMPC members invited to send **comments to the Rapporteur till 29th October**. Updated proposal to be presented at the **HMPC November** meeting for possible adoption.

Some suggestions were made to modify the wording and better match of the text with the subheadings.

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

Slovenia Presidency virtual meeting – 08-09 December 2021

Action: for discussion

Document tabled: Draft agenda

Outcome:

HMPC noted the draft agenda presented by the Slovenian delegate on the SRLM under the SI presidency which will be organised 8-9th December via video conference.

5.1.2. HMPC membership

Report: HMPC Chair

Action: For information

Outcome:

New membership:

- Luxembourg, Sven Back (member) as of 06 September 2021

End of membership:

- Norway, Steinar Madsen (member) as of 02 August 2021

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

Action: For discussion

Document tabled: Presentation

Outcome:

HMPC welcomed the presentation and clarification regarding the expected set-up for returning to face-to-face plenary meetings.

Following the survey outcome, discussion between EMA secretariat and Chair and latest developments, further updates on the arrangements for the November meeting will be given in time.

Some practical arrangements were discussed for the intended return to face-to-face during the pilot phase accepting the hybrid situation and acknowledging several uncertainty factors due to the pandemic situation and developments in NL and other MSs.

Post-meeting note: *Following the survey response, HMPC Chair and EMA secretariat agreed on 14 October to organise the plenary 22-24 November as face to face 'hybrid meeting' at the EMA premises/ WebEx even though about 50% of participants may still participate online.*

Due to the pandemic situation the committee was informed on 29 October 2021 that the meeting had to be organised as virtual meeting.

5.1.4. HMPC Rules of procedure - revision

Action: For adoption

Document tabled: HMPC Rules of Procedure

Outcome:

The revised HMPC Rules of Procedures were adopted by consensus.

HMPC heard the background of changes introduced for all committees due to the specific business continuity situation and had no objections.

Post-meeting note:

The European Commission and the EMA Management Board issued a favourable opinion on the revised Rules of Procedure (RoP) on 29 Sep and 7 Oct, respectively. The modified RoP have been published on the EMA website and came into force on 18 Oct 2021.

5.2. EMA Scientific Committees or CMDh-v

5.2.1. Scientific Coordination Board Meeting

Report: HMPC Chair

Action: For information

Documents tabled: Minutes 29 June 2021, Agenda 03 September 2021

Outcome:

HMPC noted topics discussed at the SciCo Board.

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 expert group meetings

Action: For information

Postponed

5.4.2. Coordination with the European Commission

Cannabis for medicinal use

Report: HMPC Chair

Action: For adoption

Documents tabled: Compilation of terms and definitions, EC request

Outcome:

Compilation of terms and definitions adopted by consensus for submission to the EC and possible publication on the EMA website for transparency reasons.

5.5. Cooperation with International Regulators

5.5.1. India — EC/EMA Joint Technical Working Group Ayurveda

Action: For discussion

Documents tabled: Agreed ToR, Presentation

Outcome:

HMPC noted the ToR and welcomed the presentation regarding establishment of India — EC/EMA Joint Technical Working Group Ayurveda. NL, CZ, DE members expressed first interest.

HMPC members are invited to submit their possible participation or leading role in the Expert group to the HMPC Secretariat **by 29th October 2021**.

EMA secretariat to clarify some technical modalities of future operation and participation for further discussion at the **HMPC November** meeting.

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) proposal on combinations of traditionally used herbal extracts based on monographs

Report: HMPC Chair

Action: For discussion

Outcome:

HMPC agreed to a hearing with AESGP at the November meeting (AESGP joining remotely).

HMPC noted proposal. A group of experts was formed to have a first evaluation and check of feasibility regarding the proposal on combinations.

This proposal should form one of the items for a first discussion.

Post-meeting note:

AESGP informed on 22/10/2021 to postpone the hearing to 2022.

5.7. Work plan

5.7.1. HMPC work plan 2021

Report: HMPC Chair, HMPC Vice Chair

Action: For information

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

Outcome:

HMPC noted the current status. Re-appointment of the Rapporteur for the revision of Pelargonii radix monograph is scheduled at the **HMPC November** meeting.

All remaining items will be scheduled for discussion or short update at the HMPC November meeting.

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

Report: Carmen Purdel

Action: For discussion

Documents tabled: Presentation, Report template

Outcome:

HMPC endorsed the proposal to supersede the HMPC Best practice guide for review and revision and to start revising the Review report and Assessment report templates. Next **discussion** scheduled at the **HMPC November** meeting.

It is considered as advantage and more user-friendly to directly put instructions into respective templates. The review report template is given priority because a lot of experiences were meanwhile gained with the more recent template. Reviews form the majority of current HMPC agenda items advocating to further streamline their outcomes.

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

Report: HMPC Chair

Action: For discussion

Outcome:

Postponed to **HMPC November** meeting.

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

Report: HMPC Vice Chair

Action: For discussion

Outcome:

HMPC noted the current ongoing discussions regarding workplan topic 1-3-2. Next **discussion** scheduled at the **HMPC November** meeting.

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

Report: Maria Helena Pinto Ferreira

Action: For discussion

Document tabled: Presentation

Outcome:

HMPC noted the current status of development of the discussion paper. HMPC secretariat to organise a **meeting in October**. Next discussion is scheduled at **HMPC November** meeting.

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

Report: HMPC Chair

Action: For discussion

Outcome:

Postponed to **HMPC November** meeting.

5.7.7. Training on assessment of applications for herbal medicinal products (2-1-2)

Report: HMPC Vice Chair

Action: For discussion

Document tabled: Presentation

Outcome:

HMPC welcomed update by the herbal steering group on the EU NTC training activities and on the last webinar on QRD Template for (T)HMP that took place on 15th July.

Experiences/feedback from the 3rd course 'QRD Template for (Traditional) Herbal Medicinal Products' were shared and timetable and content for plans on upcoming trainings presented. It is intended to continue the so far very successful project in 2022 and develop the curriculum further.

5.7.8. Preparation of HMPC work plan 2022

Report: HMPC Chair

Action: For discussion

Documents tabled: Template, HMPC 2021 WP report

Outcome:

HMPC members noted tracking table on status of 2021 projects and possible transfers to 2022.

For modified or new special projects for work plan 2022, template to be used. Proposals to be sent to the Chair and HMPC Secretariat by **5 October 2021** for consolidation and coordination within EMA.

For the core tasks monographs (Annex 1) and guidelines (Annex 2) HMPC secretariat to distribute first drafts for comments and discussion at the HMPC November 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 *Trigonellae foenugraeci semen* and supporting documents

Action: For discussion

Documents tabled: Draft MO, AR, LoR; References: 68/128

Outcome:

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

Timetable:

Documents to be sent to Peer-reviewer: **19 October 2021**

Peer-review documents to be sent to Rapporteur: **2 November 2021**

Final documents to be included latest in 2nd premail: **16 November 2021**

Only minor editorial changes were suggested for the monograph.

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 discussion

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

Outcome:

See 6.2.3

6.2.2. Public statement on *Foeniculi amari fructus aetheroleum* and supporting documents

Action: For discussion

Documents tabled: Draft PS, AR, LoR, Reader's Guidance, Comments from PL; References: 136/199

Outcome:

HMPC welcomed the first draft PS expressing serious concerns due to the high content of estragole. Next **discussion** scheduled at the **HMPC November** meeting.

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

Action: For discussion

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

Outcome:

Rapporteur to introduce changes in the monographs on *Foeniculi dulcis fructus* and *Foeniculi amari fructus* according to the discussion. Next **discussion** scheduled at the **HMPC November** meeting.

6.2.4. Monograph on Fumariae herba and supporting documents

Action: For 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. The indication was aligned with *Curcuma longa* monograph. Adolescents can be included in case of sufficient data that confirm traditional use. The duration of use should be aligned with other products to 2 weeks. Next **discussion** scheduled at the **HMPC November** meeting.

6.2.5. Monograph on Lavandulae aetheroleum and supporting documents - postponed

6.2.6. Monograph on Rosmarini aetheroleum and supporting documents

Action: For discussion

Document tabled: Draft MO; References: 11/00

Outcome:

Rapporteur to introduce changes in the MO and AR according to the discussion. Next **discussion** scheduled at the **HMPC November** meeting.

6.2.7. Monograph on Rosmarini folium and supporting documents

Action: For discussion

Document tabled: Draft MO; References: 11/00

Outcome:

See 6.2.6.

6.2.8. Monograph on Juniperi pseudo-fructus and supporting documents

Action: for discussion

Documents: Readers Guidance, Comments from PL; References: 00/00

Outcome:

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

If yes, following timetable to be respected:

Documents to be sent to Peer-reviewer: **19 October 2021**

Peer-review documents to be sent to Rapporteur: **2 November 2021**

Final documents to be included latest in 2nd premail: **16 November 2021**

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

6.3.1. Monograph on Arnicae flos and supporting documents

Action: For discussion

Document tabled: Review report; References 04/04

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. HMPC welcomed the proposal from SE to assess the PhV data that were detected during review procedure and could be assessed during the revision.

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

Timetable:

Documents to be sent to Peer-reviewer: **19 October 2021**

Peer-review documents to be sent to Rapporteur: **2 November 2021**

Final documents to be included latest in 2nd premail: **16 November 2021**

Anticipated changes in the monograph refer mainly to new products coming from the market overview and a few detected inconsistencies e.g. as regards posologies, duration of use to be adjusted in MO and AR. A couple of newly available studies will also be added to the AR. The PhV check was not yet performed but could be done with start of the revision.

6.3.2. Monograph on Camelliae sinensis non fermentatum folium and supporting documents

Action: For discussion

Document tabled: Presentation; References 00/00

Outcome:

Rapporteur to present first draft of the review report according to the discussion for **HMPC November** meeting.

6.3.3. Monograph on Cucurbitae semen and supporting documents

Action: For discussion

Document tabled: Review report; References 06/06

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 November** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **19 October 2021**

Peer-review documents to be sent to Rapporteur: **2 November 2021**

Final documents to be included latest in 2nd premail: **16 November 2021**

While newly available non-clinical and clinical data will be checked in detail for the November meeting, no relevant new information was identified from the market overview or other sources so far. It was agreed to keep the fatty oil as rather unique substance/preparation within the monograph on the seeds.

6.3.4. Monograph on Eucalypti aetheroleum and supporting documents - postponed

6.3.5. Monograph on Eucalypti folium and supporting documents - postponed

6.3.6. Monograph on Grindeliae herba and supporting documents

Action: For 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 November** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **19 October 2021**

Peer-review documents to be sent to Rapporteur: **2 November 2021**

Final documents to be included latest in 2nd premail: **16 November 2021**

6.3.7. Monograph on Hippocastani cortex and supporting documents

Action: For discussion

Documents tabled: Review report, Readers Guidance; References 14/15

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/update the review report based on the template and send for peer review before **possible adoption** at the **HMPC November** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **19 October 2021**

Peer-review documents to be sent to Rapporteur: **2 November 2021**

Final documents to be included latest in 2nd premail: **16 November 2021**

The Rapporteur highlighted 3 findings: a) a new product/preparation on the market in France, b) reconsideration of the wording for 'relief of symptoms of discomfort and heaviness of legs related to minor venous circulatory disturbances' vis-a-vis other comparably used substances and c) adjustment of information on specific preparations in the AR according to available literature. A majority of the committee, however, preferred not to revise the documents. Apart from a new product (only 27 years on the market) no substantial new information is available to justify minor adaptations/corrections in MO and AR.

6.3.8. Monograph on Juglandis folium and supporting documents

Action: For discussion

Document tabled: Presentation; References 00/00

Outcome:

Rapporteur to present first draft of the review report according to the discussion for **HMPC November** meeting.

A first short overview was given on findings of new information regarding market overview, scientific data, and quality standards (new Ph. Eur. monograph). After check of PhV data the report will be presented in November.

6.3.9. Monograph on Levistici radix and supporting documents

Action: For discussion

Document tabled: Review report; References 09/12

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 send for peer review before **adoption** at the **HMPC November** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **19 October 2021**

Peer-review documents to be sent to Rapporteur: **2 November 2021**

Final documents to be included latest in 2nd premail: **16 November 2021**

6.3.10. Monograph on Lichen islandicus and supporting documents

Action: For discussion

Document tabled: Review report; References 16/16

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 November** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **19 October 2021**

Peer-review documents to be sent to Rapporteur: **2 November 2021**

Final documents to be included latest in 2nd premail: **16 November 2021**

From the market overview (DE), slight differences in posology for the comminuted herbal substance (herbal tea) have been identified when compared with the approved monograph.

Although possible minor changes in dosage over 30 years in products or 'Standardzulassungen' were acknowledged, it was proposed to consider these deviations as minor. They may be mentioned in the review report (to be taken into account in addition to already available information in the existing AR). It was regarded as insufficient for a revision procedure unless a number of other minor issues could justify it.

6.3.11. Monograph on Marrubii herba and supporting documents

Action: For discussion

Document tabled: Review report; References 00/02

Outcome:

Postponed.

6.3.12. Monograph on Origani dictamni herba and supporting documents

Action: For discussion

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

Outcome:

Postponed.

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

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

Action: For discussion

Documents tabled: Draft PS, AR, LoR; References: 02/214

Outcome:

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

Timetable:

Documents to be sent to Peer-reviewer: **19 October 2021**

Peer-review documents to be sent to Rapporteur: **2 November 2021**

Final documents to be included latest in 2nd premail: **16 November 2021**

6.4.2. Monograph on *Taraxaci officinalis radix* and supporting documents

Action: For discussion

Documents tabled: Draft MO, AR, LoR; References: 78/85

Outcome:

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

Timetable:

Documents to be sent to Peer-reviewer: **19 October 2021**

Peer-review documents to be sent to Rapporteur: **2 November 2021**

Final documents to be included latest in 2nd premail: **16 November 2021**

6.4.3. 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 *Cnici benedicti herba* and supporting documents

Action: For discussion

Document tabled: Presentation; References: 07/04

Outcome:

HMPC welcomed the presentation on *Cnici benedicti herba*. Rapporteur to present first draft documents according to the discussion for **HMPC November** meeting.

Rapporteur to include available information already compiled (mainly from Poland) when the substance proposal was discussed and prioritised for monograph establishment.

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

Action: For discussion

Document tabled: Presentation; References: 07/00

Outcome:

Postponed.

7. Any other business

7.1. Topics for discussion

7.1.1. Working methodology of monograph establishment

Action: For discussion

Document tabled: Presentation

Outcome:

Postponed.

7.1.2. Changes to the Meeting Report format

Action: For discussion

Document tabled: Simplified HMPC public meeting report

Outcome:

HMPC endorsed the proposed changes to simplify the HMPC public meeting report format.

7.2. Documents for information

7.2.1. HMPC

Table of Decisions from HMPC meeting held on 05-07 July 2021

Overview of expertise of members HMPC and subgroups

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

[Abbreviations in HMPC agendas/minutes](#)

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

- Baden-Württemberg BPI programme - Panel discussion on the regulation on health claims
- Draft Agenda for the PCWP/HCPWP Joint meeting on the 21-22 September 2021
- Meeting Summary PCWP-HCPWP meeting 01-02 June 2021
- CxMP/EMA external representation: Revision of user manual: EMA/462963/2016; Template Request for meeting outside EMA premises: EMA/382651/2017

List of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 20-22 September 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	
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	
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	
Jacqueline Masterson	Alternate	Ireland	No restrictions applicable to this meeting	
Alessandro Assisi	Member	Italy	No interests declared	
Jurate Antanaviciene	Member	Lithuania	No interests declared	
Asta Kubiliene	Alternate	Lithuania	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Sven Back	Member	Luxembourg	No interests declared	
Everaldo Attard	Member	Malta	No interests declared	
Burt H Kroes	Member	Netherlands	No interests declared	
Hilda Kuin	Alternate	Netherlands	No interests declared	
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	
Ligia Elena Dutu	Alternate	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	
Karin Erika Svedlund	Member (Vice-Chair)	Sweden	No interests declared	
Gert Laekeman	Co-opted member	Belgium	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	
Pierre Duez	Expert – via WebEx*	Belgium	No interests declared	
Kristine Hvolby	Expert – via WebEx*	Denmark	No interests declared	
Friederike Stolte	Expert – via WebEx*	Germany	No interests declared	
Laura Galatti	Expert – via WebEx*	Italy	No interests declared	
Melanie Bald	Observer	EDQM	No interests declared	
A representative from the European Commission attended the meeting				
Meeting run with support from relevant EMA staff				

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