



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

07 July 2021
EMA/HMPC/300189/2021
Human Medicines Division

Committee on Herbal Medicinal Products (HMPC)

Minutes for the meeting on 3-5 May 2021

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

3 May 2021, 10:00 – 17:00, virtual meeting

4 May 2021, 09:00 – 17:00, virtual meeting

5 May 2021, 09:00 – 16:00, virtual meeting

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

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1. Introduction

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

The Chairperson opened the meeting by welcoming all participants. 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 3-5 May 2021.

Time schedule for 3-5 May 2021.

Outcome:

Agenda adopted.

Time schedule endorsed with minor modifications.

1.3. Adoption of the minutes

HMPC minutes for 1-3 March 2021.

Outcome:

Minutes adopted with minor modification (6.3.1).

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 May 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 July meeting according to the overview, Rapporteurs were asked to inform secretariat and Chair before the first pre-mail (by 21 June 2021) to allow best adaptation of agenda and time-schedule.

2.1.2. Appointment of Rapporteurs and Peer-reviewers

Report: HMPC Chair

Action: for adoption

New Rapporteur and Peer-Reviewer:

New substance for decision on prioritisation

- Tribuli terrestris herba

Documents: Presentation, Proposal (CZ), Summary of proposals

Outcome:

HMPC agreed by majority to add Tribuli terrestris herba to the HMPC work programme and start the assessment.

After validation, need and essential minimum data were considered available. The challenging therapeutic area/indication was not seen as obstacle for the possibility of an EU herbal monograph in reasonable time. HMPC secretariat will update tracking documents, announce the start of procedure in the public meeting report and publish a Call for data. Peer reviewer with preferably clinical expertise to be appointed at the **HMPC July meeting**.

Periodic reviews to start in 2021

- Juglandis folium

Change of rapporteurship

- Cisti cretici folium
- Fumariae herba
- Grindeliae herba
- Origani dictamni herba
- Paullinae semen
- Tiliae flos
- Centellae asiaticae herba
- Cinnamomi corticis aetheroleum
- Cinnamomi cortex
- Colae semen
- Menyanthes trifoliata folium
- Plantaginis lanceolatae folium

Outcome:

HMPC agreed on (re-)appointments according to adopted workplan 2021. HMPC secretariat will update the HMPC status overview.

Re-appointments were requested because of the end of mandate of the MLWP Chair, allowing again to act as Rapporteur.

Members were asked to check possible start for pending reviews for clarification on agenda scheduling and need for Rapporteur re-appointment as necessary at the HMPC July meeting (remaining from 2019, 2020 and those from 2021 with all Calls for data ending by June).

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

None

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 Colae semen and supporting documents

Action: for adoption

Document: Review report; References: 53/17

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 Colae semen.

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

New toxicological data were not considered relevant for the human situation and the respective wording changed in the report.

2.4.2. Monograph on Fumariae herba and supporting documents

Action: for adoption

Documents: Review report; References: 16/16

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 Fumariae herba.

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

Changes are anticipated particularly for monograph sections 2 and 4.2 according to information on marketed products / regulatory practice received.

2.4.3. Monograph on *Mate folium* and supporting documents

Action: for adoption

Document: Review report; References: 17/34

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 *Mate folium*.

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

Despite several new studies published and also a new Ph. Eur. monograph, there was no new information considered to change the actual content of the existing monograph.

2.4.4. Monograph on *Plantaginis lanceolatae folium* and supporting documents

Action: for adoption

Document: Review report; References: 09/09

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 *Plantaginis lanceolatae folium*.

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

Various types of new information and necessary updates in the monograph were detected potentially affecting monograph sections 2, 4.2, and 4.4.

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

Action: for adoption

Document: Review report; References: 30/22

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 *Violae tricoloris herba*.

The review report was adopted and will be published as addendum to the existing assessment report on the EMA website. Rapporteur to provide shortened version to the HMPC Secretariat.

The Ph. Eur. monograph (1855) for *Violae herba cum flore* in version 10.0 includes now only *Viola tricolor* L. and *Viola arvensis* Murray as confirmed botanical species. *Viola vulgaris* (Oborny) Koch is noted as a synonym for *Viola tricolor* L. Such minor change in the source plant taxonomy can be updated once a revision of the monograph package is indicated.

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

2.5.1. Monograph on *Menyanthes trifoliata* folium and supporting documents

Action: for adoption

Documents: MO, AR, LoR; References: 77/73

Outcome:

Minor amendments including changes in section 4.2 in the monograph were endorsed and final EU herbal monograph and supporting documents adopted by consensus. The Norwegian delegate expressed a favourable position.

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

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

Action: for adoption

Documents: PS, AR, LoR; References: 04/214

Outcome:

Draft Public statement and supporting documents adopted by consensus for 3 months public consultation. Minor clarification regarding inclusion of the Ph. Eur. reference in the list of references was endorsed.

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

Action: for adoption

Documents: MO, AR, LoR; References: 78/84

Outcome:

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

Members discussed particularly monograph section 4.4 and necessary warnings linked to gall bladder stimulation issues taking into account traditional indication, real data availability and also other somewhat comparable substances such as Curcuma.

Several minor improvements were performed in the AR.

2.6.3. Monograph on *Vaccinii macrocarpi* fructus and supporting documents

Action: for adoption

Documents: MO, AR, LoR, Readers Guidance; References: 197/313

Outcome:

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

Several corrections still had to be introduced in MO and AR. Details for correct reflection of the DER for the expressed juice were discussed. Particularly for further possible amendments in the AR it was referred to the preliminary supporting character (and disclaimer) for the draft and the opportunities after public consultation for the final version. Amendment of the table 4 including overview of the main non-clinical data/conclusions in the AR was endorsed.

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 toxic, unsaturated pyrrolizidine alkaloids (PAs) including recommendations regarding contamination with PAs

Action: for discussion

Documents: Draft PS, OoC, Comments from SWP

Outcome:

HMPC endorsed amended draft PS with implemented SWP comments.

Updated draft PS to be finalised in cooperation with EMA legal and RA department and to be presented at the **HMPC July** meeting for adoption.

4.2. Quality

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

Action: for discussion

Documents: [Draft Guideline](#), OoC, Presentation

Outcome:

HMPC discussed the status of progress on specification/quality GLs by quality experts. The outstanding open issues were presented and their implementation discussed.

HMPC secretariat to organise meeting of experts in May/June. Aim is to clarify remaining issues and to present both amended revised draft GLs for discussion/comments **at the HMPC July meeting**.

The committee noted a presentation from the Rapporteur. It was agreed that the expert group resolves remaining issues as far as possible before presenting draft revised GLs to the committee for comments and final open questions.

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 discussion

Documents: [Draft Guideline](#), OoC, Presentation

Outcome:

See 4.2.1.

4.2.3. [Nitrosamines and Herbal MPs](#)

Action: for discussion

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

Outcome:

HMPC Members and EMA secretariat invited to send further **comments for follow-up by 15 June** for an updated proposal to be presented for third discussion at **HMPC July** meeting.

4.2.4. [Change of assay methods in Ph. Eur. monographs](#)

Action: for discussion

Outcome:

HMPC noted the Rapporteur's draft proposal.

HMPC Members and EMA secretariat to send **comments by 15 June** for the Rapporteur to update proposal for follow-up discussion and possible adoption at **HMPC July** meeting.

Members discussed previous comments by SE and clarifications by EDQM that generally applicable conversion factors are not always possible. Usually this is product specific and may require performing both, the old and the new Ph. Eur. assay.

EU herbal MOs refer usually to the current applicable Ph. Eur. assay 'as amended' for the herbal substance that is not subject of HMPC assessment on safe use of the final product. Only for very few cases (monographs with a specified range of certain active markers e.g. HADs) it may become an issue for the individual products and relevant specification when referring to the EU monograph with a posology based on the old Ph. Eur. method.

Solution options at individual product level (NCA, MAHs) as well as Ph. Eur. and HMPC level will be further explored to find a future pragmatic approach.

4.3. Regulatory / Procedural

4.3.1. Regulatory Q&A on herbal medicinal products

Action: for adoption

Documents: Proposals for Q&A on use combination monographs; [Regulatory Q&A on herbal medicinal products](#)

Outcome:

HMPMC adopted the proposal for Q&A on the use of EU monographs on herbal tea combinations. The amended *Regulatory Q&A on Herbal Medicinal Products* (EMA/HMPC/345132/2010) will be published on EMA website.

No objections were raised to keep the previously applied principles in herbal tea combination monographs (limitation to maximum 4 herbal substances with minimum 10% proportion of each combi partner; limitation to herbal substances already assessed by HMPMC having the same indication as single substance). At the same time, it is explained that it does not exclude any somewhat deviating traditional tea combination from individual national product applications as justified.

One member suggested to soften the wording as regards national product application requirements; otherwise the Q&A was welcomed to be used as reference point for specifics in herbal tea combination assessment so far only explained in ARs or OoCs but not in standard procedures.

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 HMPMC

5.1.1. Strategic Review and Learning Meetings

Portugal Presidency virtual meeting – 17-18 March 2021

Report: A P Martins

Action: for information

Document: Minutes, Presentations

Outcome:

HMPMC welcomed the presentations and minutes from the discussions that took place during the SRLM under the Portuguese presidency in March.

HMPC noted the invitation and information by the Slovenian delegate on the SRLM under the SI presidency which will be organized 8-9th December via video conference.

A pre-announcement for a SRLM under the French presidency (14-15 April 2022) was welcomed.

5.1.2. HMPC membership

New membership:

- Austria, Peter Voitl (co-opted member) as of 3 May 2021
- Lithuania, Jūratė Antanavičienė (member) as of 4 March 2021
- Lithuania, Asta Kubilienė (alternate) as of 4 March 2021

End of membership:

- Lithuania, Rugilė Pilvinienė (member) as of 4 March 2021

5.1.3. Election of Co-opted member (Clinical pharmacology)

Report: HMPC Chair

Action: for adoption

Documents: Call for nominations dated 11 March 2021, [Procedure for the nomination and appointment of co-opted members of the CHMP, CVMP and HMPC](#), Candidature

Outcome:

Election took place in line with the HMPC Rules of procedure and the Procedure for co-opted members.

The Committee elected as new co-opted member with expertise in clinical pharmacology Maria da Graça Campos (PT) for a 3-year mandate starting 5 July 2021.

5.2. EMA Scientific Committees or CMDh-v

5.2.1. Scientific Coordination Board Meeting

Report: HMPC Chair

Action: for information

Documents: Agenda 28 April 2021

Outcome:

HMPC noted the agenda of the recent April meeting and information regarding the working group review project.

A short update was given on the overall status (no HMPC specifics had been discussed) of review agreed by HMA and MB, the upcoming implementation period (not expected to be finalised before beginning of 2022) and respective communication.

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: M Bald
Action: for information
Document: SoD
- EDQM TCM expert group meeting
Report: M Bald

Action: for information

Document: SoD

Outcome:

HMPC noted updates by the EDQM observer including highlights from the summaries of decisions for 13B and TCM meetings.

Members discussed briefly development of relevance including for finalised updated monographs (e.g. Solidago, Arnica, Echinacea) and activities regarding Cannabis or Centella, as well as discussions between all groups on reference/ specific requirements and voluntary vs mandatory testing for PAs applying the newly established general PA method.

5.4.2. Coordination with the European Commission

- Cannabis for medicinal use
Report: HMPC Chair

Action: for information

5.5. Cooperation with International Regulators

None

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

5.6.1. Stakeholder meeting (EUCOPE), 5 May 2021 - postponed

5.7. Work plan

5.7.1. HMPC work plan 2021

Report: HMPC Chair, HMPC Vice Chair

Action: for information

Documents: Work plan 2021, Annex 1, Annex 2

- PhV data and experiences in national assessments (National experiences)

Report: HMPC Vice Chair, R Länger

Action: for discussion

Documents: Proposed action for HMPC, Updated summary on national experiences with HMPC monographs and during MRP/DCP procedures; References: 29/29

Outcome:

HMPC welcomed the proposal for implementation: (1) Summary of national experiences with HMPC monographs and during MRP/DCP procedures will be updated at least once annually (cumulative). (2) Summary always available for all Rapporteurs to check at start of any review/assessment. (3) This check will be added to internal guidance documents (best practice guides) as standard step.

- PhV data and experiences in national assessments (PhV data)

Report: HMPC Vice Chair

Action: for adoption

Documents: Presentation

Outcome:

HMPC endorsed the proposal how to use available safety data from PhV tools. Templates and relevant documents to be updated. Endorsement of the point regarding EudraVigilance check as standard step in HMPC assessment postponed to **July meeting**.

HMPC agreed to have:

(1) Feedback from PSUSA standard step in HMPC assessment (if available)

(2) Establish a small group of PhV knowledgeable herbal assessors that can help out in case no possibility nationally for the Rapporteur to check PhV data

(3) Feedback from MRP/DCP procedures (see above, if available); periodically updated summary file available to all Rapporteurs

(4) Templates and relevant documents to be updated: Review/revision best practice guide and AR and Review report templates (all work plan topics 2021)

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

Report: HMPC Vice Chair, M H P Ferreira, M Petrikova

Action: for information

Document: Presentation

Outcome:

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

Rapporteurs evaluate MOs with paediatric indications as to what data was used as supportive. After review of all therapeutic areas, a discussion paper will be prepared with data requirements/possible extrapolation recommendations.

Areas reviewed so far: urinary tract and genital disorders, mental stress and mood disorders, sleep disorders and temporary insomnia, cough and cold, gastrointestinal disorders. The possible document category, preliminary findings on data used as supportive/consistent in assessment and areas that should be included into future guidance were already discussed by the group. Preliminary findings will be presented to HMPC members in July.

- Development of training on assessment of applications for herbal medicinal products

Report: HMPC Vice Chair, J Wiesner

Action: for discussion

Document: Presentations, Feedback report, Course description

Outcome:

HMPC welcomed update by the herbal steering group on the EU NTC training activities.

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

None

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

6.2.1. Monograph on *Agropyri repentis rhizoma* and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR, Readers Guidance; References: 74/67

Outcome:

HMPC endorsed the Rapporteur's position regarding inclusion of adolescents based on the product at German market.

Rapporteur to introduce changes in the monograph and AR according to the discussion for peer review and possible **adoption for public consultation** at the **HMPC July** meeting unless major issues detected during peer-review.

Timetable:

Documents to be sent to Peer-reviewer: **1 June 2021**

Peer-review documents to be sent to Rapporteur: **15 June 2021**

Final documents to be included latest in 2nd premail: **29 June 2021**

Posology and details in the AR such as publication date regarding German 'Standardzulassung' to be clarified between Rapporteur and DE member.

6.2.2. Monograph on *Foeniculi amari fructus* and supporting documents - postponed

6.2.3. Monograph on *Foeniculi amari fructus aetheroleum* and supporting documents - postponed

6.2.4. Monograph on *Foeniculi dulcis fructus* and supporting documents - postponed

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

Action: for discussion

Documents: Draft MO, AR, LoR; References: 15/15

Outcome:

Rapporteur to introduce changes in the MO and AR according to the discussion for **a 2nd discussion at the HMPC July** meeting.

Inclusion of warning due to one case report referring to lowering of the INR during treatment with vitamin K antagonists was not endorsed due to insufficient data (section 4.5 interactions). Likewise, the content of section 5.1 regarding glucose levels and assumed effect on diabetic patients was questioned as only based on weak non-clinical data.

6.2.6. Monograph on *Lavandulae aetheroleum* and supporting documents - postponed

6.2.7. Monograph on *Pelargonii radix* and supporting documents - postponed

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

6.3.1. Monograph on *Fucus vesiculosus* and supporting documents - postponed

6.3.2. Monograph on *Rosmarini aetheroleum* and supporting documents

Action: for discussion

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

Outcome:

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

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

Timetable:

Documents to be sent to Peer-reviewer: **1 June 2021**

Peer-review documents to be sent to Rapporteur: **15 June 2021**

Final documents to be included latest in 2nd premail: **29 June 2021**

6.3.3. Monograph on *Rosmarini folium* and supporting documents

Action: for discussion

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

Outcome:

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

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

Timetable:

Documents to be sent to Peer-reviewer: **1 June 2021**

Peer-review documents to be sent to Rapporteur: **15 June 2021**

Final documents to be included latest in 2nd premail: **29 June 2021**

6.3.4. Monograph on *Sabalis serrulatae fructus* and supporting documents

Action: for discussion

Document: Review report; References 40/37

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/shorten the review report and send for peer review/HMPC Secretariat comments before **adoption** at the **HMPC July** meeting.

Timetable:

Documents to be sent to Peer-reviewer/HMPC Secretariat: **1 June 2021**

Peer-review documents to be sent to Rapporteur: **15 June 2021**

Final documents to be included latest in 2nd premail: **29 June 2021**

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

Action: for discussion

Document: Review report, Readers Guidance; References 17/17

Outcome:

Rapporteur to introduce changes in the review report according to the discussion for a **5th discussion at the HMPC July** meeting.

Topics of discussion were relevance of possible cross sensitivities, the length of some information not relevant for the monograph in the review report, and the difference and data availability for *Virgaureae herba* vs. *Solidaginis herba*. For the latter, a potential new monograph was proposed by the Rapporteur if an interested party or NCA would provide relevant information on market relevance to the HMPC.

6.3.6. Monograph on *Urticae folium* and supporting documents

Action: for discussion

Document: Review report; References: 11/11

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/shorten the review report for peer review and **adoption** at the **HMPC July** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **1 June 2021**

Peer-review documents to be sent to Rapporteur: **15 June 2021**

Final documents to be included latest in 2nd premail: **29 June 2021**

Special warnings referring to a possible interaction between nettle leaf and antidiabetics were applied on products according to the market overview. However, it was concluded that there is no relevant safety data available in the references related to the warnings in the SmPC of products in Germany and a revision is not indicated for warnings and interactions in the monograph.

6.3.7. Monograph on *Urticae herba* and supporting documents

Action: for discussion

Document: Review report; References: 06/06

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. However, potential special warnings referring to a possible interaction between nettle leaf and antidiabetics were not endorsed (see 6.3.6).

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

Timetable:

Documents to be sent to Peer-reviewer: **1 June 2021**

Peer-review documents to be sent to Rapporteur: **15 June 2021**

Final documents to be included latest in 2nd premail: **29 June 2021**

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

None

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

6.5.1. Monograph on *Andrographidis paniculatae folium* and supporting documents

Action: for discussion

Documents: Presentation; References: 15/15

Outcome:

HMPC endorsed the Rapporteur's changed position that there is no sufficient new information available that could change the content of the PS from 2014, contrary to the review outcome and HMPC decision in May 2019. Adoption of the proposal to stop HMPC assessment of *Andrographis paniculatae folium* is scheduled for the **HMPC July** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **1 June 2021**

Peer-review documents to be sent to Rapporteur: **15 June 2021**

Final documents to be included latest in 2nd premail: **29 June 2021**

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

Action: for discussion

Documents: Draft MO, AR, LoR, Readers Guidance; References: 00/196

Outcome:

Rapporteur to introduce changes in the MO and AR according to the discussion (clarification on administration) for a **5th discussion** at the **HMPC July** meeting.

The proposal to get further information regarding administration in case of topical use including from UK, when part of the EU, was endorsed. Some members expressed concerns to establish the monograph based on the current data.

6.5.3. Monograph on *Cisti cretici folium* and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR, Readers Guidance, Botanical overview, Flora Iberica reference, Presentation; References: 00/86

Outcome:

HMPC endorsed Rapporteur's clarification on botanical name (*Cistus creticus*) and plant part (herba) to be used. Rapporteur to introduce changes in the MO and AR according to the discussion for a **12th discussion** at the **HMPC July** meeting.

6.5.4. Monograph on *Species digestivae* and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR, email communication; References: 00/21

Outcome:

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

Timetable:

Documents to be sent to Peer-reviewer: **1 June 2021**

Peer-review documents to be sent to Rapporteur: **15 June 2021**

Final documents to be included latest in 2nd premail: **29 June 2021**

The challenging tasks for the calculations to limit to 4 active substances while consequently recommending other substances as excipients (although often plausible use in the same indication as single substance) was discussed as regards traditional proportions of combination partners. Furthermore, the issue of old established combinations versus possible 'new combinations' based on the monograph and the issue of estragole in some substances were raised.

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 1-3 March 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)

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

None

7.2.4. Other

European Commission. Evaluation and revision of the general pharmaceutical legislation.
Ref. Ares(2021)2185074 - 29/03/2021

List of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 3-5 May 2021 meeting.

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Emiel Van Galen	Chair	Netherlands	No interests declared	
Reinhard Länger	Member	Austria	No interests declared	
Astrid Obmann	Alternate	Austria	No interests declared	
Patricia Bodart	Member	Belgium	No interests declared	
Ivan Kosalec	Member	Croatia	No interests declared	
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	
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	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Asta Kubiliene	Alternate	Lithuania	No interests declared	
Jane Murray	Alternate	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 Palomino	Member	Spain	No interests declared	
Karin Erika Svedlund	Member (Vice-Chair)	Sweden	No interests declared	
Malin Kyllikki Hobro Soderberg	Alternate	Sweden	No interests declared	
Peter Voitl	Co-opted member	Austria	No interests declared	
Gert Laekeman	Co-opted member	Belgium	No interests declared	
Heidi Foth	Co-opted member	Germany	No interests declared	
Maria Helena Pinto Ferreira	Co-opted member	Portugal	No interests declared	
Ulrich Rose	Observer	EDQM	No interests declared	
Melanie Bald	Observer	EDQM	No interests declared	
Barbara Toth*	Expert – via WebEx	Hungary	No interests declared	
Kristine Hvolby*	Expert – via WebEx	Denmark	No interests declared	
Friederike Stolte*	Expert – via WebEx	Germany	No interests declared	
A representative from the European Commission attended the meeting				

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
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Meeting run with the help of EMA staff

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