22 September 2021
EMA/HMPC/413456/2021
Human Medicines Division

Committee on Herbal Medicinal Products (HMPC)

Minutes for the meeting on 5-7 July 2021

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

5 July 2021, 10:00 – 17:00, virtual meeting

6 July 2021, 09:00 – 17:00, virtual meeting

7 July 2021, 09:00 – 16:00, virtual meeting

Disclaimers

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

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

Note on access to documents

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

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1. Introduction

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

The Chairperson opened this 100th 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 5-7 July 2021.

Time schedule for 5-7 July 2021.

Outcome:

Agenda adopted.

Time schedule endorsed.

1.3. Adoption of the minutes

HMPC minutes for 3-5 May 2021.

Outcome:

Minutes adopted.

2. EU herbal monographs and list entries for adoption

2.1. Status of HMPC/MLWP activities

2.1.1. Overview of HMPC/MLWP assessment work including the Rapporteurship distribution – Status in 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 September meeting according to the overview, Rapporteurs were asked to inform secretariat and Chair before the first pre-mail (by 6 September 2021) to allow best adaptation of agenda and time-schedule.

Following the end of Calls for data for all reviews on the work plan 2021, all substances will be added to the HMPC September agenda in line with procedure EMA/HMPC/124695/2011 Rev. 2.

2.1.2. Appointment of Rapporteurs and Peer-reviewers

Report: HMPC Chair

Action: for adoption

New Peer-Reviewer:

New assessments started in 2021

- Tribulus terrestris herba

Periodic reviews started in 2021

- Arnicae flos
- Camelliae sinensis non fermentatum folium
- Cichorii intybi radix
- Cucurbitae semen
- Curcumae xanthorrhizae rhizoma
- Eucalypti aetheroleum
- Eucalypti folium
- Fraxini folium
- Ginseng radix
- Grindeliae herba
- Hippocastani cortex
- Juglandis folium
- Levistici radix
- Lichen islandicus
- Liquiritiae radix
- Marrubii herba
- Origani dictamni herba
- Paulliniae semen
- Rhodiolae roseae rhizoma et radix

- Tiliae flos
- Urticae radix

Change of rapporteurship:

Periodic reviews started in 2020

- Fucus vesiculosus

Outcome:

HMPC agreed on new Peer reviewers according to adopted workplan 2021 and on change of Rapporteurship. HMPC secretariat will update the HMPC status overview.

2.1.3. Cancellation of assessment for Andrographidis paniculatae folium and supporting documents

Action: for adoption

Documents: Review reports, email communication, presentation, PS; References: 24/13

Outcome:

HMPC adopted by consensus 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. HMPC cancelled the assessment of Andrographidis paniculatae folium towards monograph establishment in line with procedure EMA/HMPC/84530/2010 Rev.2. HMPC tracking documents will be updated.

The new information available was considered by the Rapporteur as not coherent in terms of plant part, preparations specifics, marketed mono versus combi products and the allocation of respective available data to draw firm conclusions for a monograph.

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

2.3.1. Monograph on Agropyri repentis rhizoma and supporting documents

Action: for adoption

Documents: MO, AR, LoR; References: 77/86

Outcome:

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

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

2.4.1. Monograph on Rosmarini aetheroleum and supporting documents

Action: for adoption

Document: Review report; References: 05/05

Outcome:

HMPC agreed with Rapporteur's position to revise the monograph because new data were detected that require update and changes to the content of the monograph.

The HMPC decided by consensus to start the revision procedure and revise the monograph, assessment report and list of references on Rosmarini aetheroleum.

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

Aspects of the upcoming revision were discussed such as possible name changes according to new taxonomic reviews. Members reflected on the usefulness having one AR covering both, folium and aetheroleum since data allocation and safety aspects are quite different. While a common AR is currently planned to maintain, a clear distinction between essential oil versus leaf drug regarding applicability of data and conclusions was advocated.

2.4.2. Monograph on Rosmarini folium and supporting documents

Action: for adoption

Document: Review report; References: 08/08

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 Rosmarini folium.

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

2.4.3. Monograph on Sabalis serrulatae fructus and supporting documents

Action: for adoption

Documents: Review report, Readers guidance; References: 16/16

Outcome:

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

The HMPC decided by consensus not to revise the monograph, assessment report and list of references on Sabalis serrulatae fructus.

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

Despite some known national challenges to apply the current monograph for a wider range of preparations, members agreed that there is no essential new information on clinical efficacy or safety to change the current monograph. The general issue of extract comparability and particularly description parameters for superfluid CO_2 extracts should be dealt with separately by quality experts – potentially as a work plant topic for 2022 (see also 5.1.1).

2.4.4. Monograph on Urticae folium and supporting documents - postponed

2.4.5. Monograph on Urticae herba and supporting documents - postponed

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

None

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

2.6.1. Monograph on Species digestivae and supporting documents

Action: for adoption

Documents: MO, AR, LoR; References: 41/43

Outcome:

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

Some modifications had been performed mostly in the AR supporting the monograph.

The information regarding fennel was kept in line with the currently available monographs. In case estragole PS and fennel monographs under revision will change, it will be taken into account for the final monograph.

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

2.7.1. Monograph on Verbenae citriodorae folium and supporting documents

Action: for adoption

Documents: MO, Presentation; References: 31/35

Outcome:

HMPC endorsed Rapporteur's post finalisation changes by consensus after secretariats' review before publication. Section 4.2 in the monograph was aligned with the AR (posology details) and the herbal substance name was changed from Aloysiae citriodorae folium to Verbenae citriodorae folium to be in line with Ph. Eur.. HMPC tracking documents together with the website will be updated.

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 adoption

Documents: Draft PS, OoC, Comments from SWP

Outcome:

Final public statement on the use of herbal medicinal products containing toxic, unsaturated pyrrolizidine alkaloids (PAs) including recommendations regarding contamination with PAs adopted by majority (one divergent opinion).

Final changes referred mainly to reduction of detailed passages on food products, latest updates of references including the meanwhile finalised Chapter on PA analysis by the Ph. Eur., and improved wordings for the justification and final conclusions in section 3.

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

Action: for discussion

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

Outcome:

HMPC welcomed the SWP proposal for amendments. Consequences for implementation (products, monographs) before coordination with CMDh/CHMP were discussed. Specific proposals aiming for unambiguous regulatory guidance to be presented for adoption at **HMPC September** meeting.

4.2. Quality

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

Action: for discussion

Documents: Draft revised Guideline, OoC, Presentation

Outcome:

HMPC discussed the status of progress on specification/quality GL by quality experts. Consolidated draft guidelines agreed by quality experts. HMPC members invited to send **comments to the Rapporteurs till 27th August**. Updated proposal to be presented for possible adoption at **HMPC September** meeting.

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 revised 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 to send specific comments on proposed improved text **latest by 27th August** to the Rapporteur.

4.2.4. Change of assay methods in Ph. Eur. monographs

Action: for discussion

Outcome:

HMPC considered various versions of possible Q&A with focus on specific roles of HMPC, Ph. Eur, applicants and NCAs.

In view of very limited cases so far and the impossibility of concise Q&A encompassing all possible scenarios it was agreed to not publish a Q&A which could be disproportionate and wrongly suggest any role of EMA/HMPC regarding appliance of modernised Ph. Eur. assay methods beyond standard quality and declaration requirements.

It was agreed that a specific footnote will be inserted into Senna monographs with the next revision and into any other monograph it may apply to in future. The committee's general view is:

When new assay methods are introduced in Ph. Eur. monographs, it can in exceptional cases affect EU herbal monographs, where the posology is given in reference to a (group of) constituent calculated on the base of a previously applicable (Ph. Eur.) method.

The possibility for update of the EU herbal monograph depends on the fact whether a correlation factor between the old and the new assay method could be established, which could be applied to all concerned herbal preparations and herbal MPs.

In the case of such 'generally applicable' correlation factor established by EDQM the posologies in the monographs can be updated accordingly (e.g. revision of the monograph on *Aesculus hippocastanum*, semen).

In the case of no 'generally applicable' factor an update of the EU herbal monograph is not possible. Posologies referring to constituents with known therapeutic activity are based on clinical data. In case these constituents were characterised by the 'old' assay method it is up to the applicant for individual products to demonstrate compliance with the updated

quality requirements of Ph. Eur. and to bridge old with new posology when referring to bibliographic data, a reference product or the EU herbal monograph (e.g. by establishing a product specific correlation factor).

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 – 8-9 December 2021

Report: B Razinger

Action: for information

Outcome:

The Slovenian delegate confirmed the date of the virtual SRLM under the SI presidency and gave first thoughts what topics of HMPC relevance to be added to the programme (e.g. CO_2 extraction). Members were invited to contribute to the meeting.

5.1.2. HMPC membership

New membership:

- Portugal, Maria da Graça Ribeiro Campos (co-opted member) as of 5 July 2021

End of membership:

- Luxembourg, Clemence Varret (member) as of 1 July 2021
- Poland, Ewa Balkowiec Iskra (co-opted member) as of 3 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 29 June 2021, Minutes 28 April 2021

Outcome:

HMPC noted topics discussed at the Scientific Coordination 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 13A expert group meeting

Report: M Bald

Action: for information

Document: SoD

Outcome:

HMPC noted summaries of decisions for 13A meeting highlighted by the EDQM observer.

Monographs for Pharmeuropa or finalisation of relevance for the HMPC were mentioned including *Adhatoda*, *Eschscholzia*, *Vitis*, *Viola* as well as *Arnica*, *Arnica* tincture and *Sabal*.

Furthermore, it was shortly updated on discussions to which extent referring to the pyrrolizidine alkaloid (PA) assay methodology (validation criteria) in specific monographs as well as on the status of development for the various cannabis-related monographs.

5.4.2. Coordination with the European Commission

Cannabis for medicinal use

Report: HMPC Chair

Action: for information

Outcome:

HMPC noted current status of work on draft compilation of terms and definitions. Rapporteur to introduce changes in modified draft based on comments provided by EMA legal/RA/SEC for follow up with EMA secretariat and EC and final adjustments before possible adoption at the **HMPC September** meeting.

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

None

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

Outcome:

HMPC noted the status of work on all work plan topics and agreed to schedule all topics for further update by topic leads at **HMPC September meeting**.

For required support such as meeting organisation or required documents topic leads can contact the secretariat.

- PhV data and experiences in national assessments

  Report: HMPC Vice Chair

  Action: for information

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

  Report: HMPC Vice Chair, J Wiesner

  Action: for information

  Documents: EU NTC June 2021 newsletter, Presentations

  Outcome:

  HMPC welcomed update by the herbal steering group on the EU NTC training activities. The training course 'The QRD template for (traditional) herbal medicinal products' scheduled for July 15th.

  For preparation of further training courses the steering group will meet beginning of September.

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 Orthosiphonis folium and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR, OoC; References: 40/46

Outcome:

HMPC discussed comments received during public consultation and endorsed Rapporteur's view that no substantial changes will be included in the draft monograph. Rapporteur to finalise the draft documents for peer review and **adoption** at the **HMPC September** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **17 August 2021**

Peer-review documents to be sent to Rapporteur: **31 August 2021**

Final documents to be included latest in 2nd premail: **14 September 2021**

Comments suggested additional preparations for the revised monograph. The Committee discussed the acceptance of mother tinctures in the past; however, independent of a previous status as homeopathic product, the Rapporteur confirmed that essential information on herbal preparation and specified use according to TU requirements of Directive 2001/83/EC is missing in this case and no references were provided by IPs. For the use of the powder, not only the French market situation but also the Spanish and Belgian products should be taken into account and AR and OoC adapted accordingly.

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: Draft MO, AR, Reader's Guidance; References: 00/00

Outcome:

See 6.2.3

6.2.2. Monograph on Foeniculi amari fructus aetheroleum and supporting documents

Action: for discussion

Documents: Draft MO, AR, Reader's Guidance; References: 00/00

Outcome:

See 6.2.3

6.2.3. Monograph on Foeniculi dulcis fructus and supporting documents

Action: for discussion

Documents: Draft MO, AR, Reader's Guidance; References: 00/00

Outcome:

Rapporteur to introduce changes in the monographs on Foeniculi dulcis fructus and Foeniculi amari fructus considering the outcome of the presented PS on estragole (see 4.1.2). Rapporteur to consider the withdrawal of the monograph for Foeniculi amari fructus aetheroleum due to safety concerns based on the high content of estragole. Next **discussion** scheduled at the **HMPC September** meeting.

6.2.4. Monograph on Fumariae herba and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR; References: 33/69

Outcome:

Rapp to align the indication with *Curcuma longa* monograph and introduce changes in the MO and AR according to the discussion for **a 2nd discussion at the HMPC September** meeting.

6.2.5. Monograph on Juniperi pseudo-fructus and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR, Readers Guidance; References: 18/64

Outcome:

Rapporteur to introduce changes in the MO and AR according to the discussion for peer review and for **possible adoption for public consultation** at the **HMPC September** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **17 August 2021**

Peer-review documents to be sent to Rapporteur: **31 August 2021**

Final documents to be included latest in 2nd premail: **14 September 2021**

The Rapporteur highlighted changes such as the name according to Ph. Eur. (pseudo-fructus to galbulus), consideration of a mean weight for berries without reference but based on data by the PL member, and modification in the tea posology. Deletions were performed in MO sections 4.5 and 5.1 because of insufficient clinical evidence for any interaction with vitamin K antagonists or influence on glucose levels in diabetes. Available weak data are maintained in the AR.

6.2.6. Monograph on Lavandulae aetheroleum and supporting documents

Action: for discussion

Document: Reader's Guidance; References: 08/08

Outcome:

Rapporteur to prepare AR with respect to discussion on indication and usage of clinical studies to have a more concise **3rd discussion** at the **HMPC September** meeting.

The Rapporteur presented 3 issues for discussion. Review of EU herbal monographs and list entries in preparation for decision on revision

6.2.7. Monograph on Arnicae flos and supporting documents - postponed

6.2.8. Monograph on Camelliae sinensis non fermentatum folium and supporting documents - postponed

6.2.9. Monograph on Cichorii intybi radix and supporting documents - postponed

6.2.10. Monograph on Cucurbitae semen and supporting documents

Action: for discussion

Documents: Review report, Presentation; References 00/00

Outcome:

Rapporteur to introduce changes in the review report according to the discussion for **a 2nd discussion at the HMPC September** meeting.

6.2.11. Monograph on Curcumae xanthorrhizae rhizoma and supporting documents - postponed

6.2.12. Monograph on Fucus vesiculosus and supporting documents - postponed

6.2.13. Monograph on Hippocastani cortex and supporting documents

Action: for discussion

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

Outcome:

Rapporteur to introduce changes in the review report according to the discussion for **a 2nd discussion at the HMPC September** meeting.

While the Rapporteur had not found substantial new information compared to the initial assessment, he questioned the plausible effect of Hippocastani cortex particularly when used orally in the same indication as Hippocastani semen despite the lack of aescin.

The content in coumarins such as aesculin and fraxin with possible quick, local anti-inflammatory activity, as well as other polyphenols with a weak astringent or eventually gastro-protective effects are unlikely having a systemic effect on the venous system after oral use, because of lack of aescin. Others emphasised that chemical composition/ pre-clinical data considerations are not sufficient to superpose the documented tradition of use of products on the market, even though the science behind is weak and it may have been transferred from Hippocastani semen.

Some information was given on the product status in France, but also products in Spain and elsewhere should be taken into account.

6.2.14. Monograph on Solidaginis virgaureae herba and supporting documents

Action: for discussion

Document: Review report; References 14/14

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 before **adoption** at the **HMPC September** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **17 August 2021**

Peer-review documents to be sent to Rapporteur: **31 August 2021**

Final documents to be included latest in 2nd premail: **14 September 2021**

It was agreed that during peer review it is focused beside possible shortening of the report (details not relevant for the decision on revision) on cross allergy risks (including latex) arising not only from *Solidago* but other species of the Asteraceae family. While it may not really justify additional information beyond the already included contraindication (Hypersensitivity to the active substance or to plants of the Asteraceae family) in the *Solidago* monograph, another general public statement under consideration of existing public statements on allergenic potencies may be considered.

6.2.15. Monograph on Zingiberis rhizoma and supporting documents

Action: for discussion

Documents: Review report, Readers Guidance; References: 137/100

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 September** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **17 August 2021**

Peer-review documents to be sent to Rapporteur: **31 August 2021**

Final documents to be included latest in 2nd premail: **14 September 2021**

The Rapporteur proposed a revision; in particular, there is data on herbal substances/preparations with 30/15 years of TU with a new indication. In addition, MO sections 4.4, 4.5 and 4.8 should be updated with information of safety issues. Members were asked to provide to the Rapporteur any available information related to hypersensitivity reactions and the possible risk of bleeding events with the concomitant use of anticoagulants.

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

6.3.1. Monograph on Salviae mitiorrhizae radix et rhizoma and supporting documents

Action: for discussion

Documents: Draft PS, AR, LoR; References: 00/89

Outcome:

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

Timetable:

Documents to be sent to Peer-reviewer: **17 August 2021**

Peer-review documents to be sent to Rapporteur: **31 August 2021**

Final documents to be included latest in 2nd premail: **14 September 2021**

The Committee discussed briefly the signalling function of such assessment outcome when at European level even for some herbal substances that already have a national registration still no monograph can be generated to facilitate national registrations.

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

6.4.1. Monograph on Centellae asiaticae herba and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR, Readers Guidance; References: 00/140

Outcome:

Rapporteur to introduce changes in the MO and AR according to the discussion for peer review and for **adoption for public consultation** at the **HMPC September** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **17 August 2021**

Peer-review documents to be sent to Rapporteur: **31 August 2021**

Final documents to be included latest in 2nd premail: **14 September 2021**

The Rapporteur proposed a partially generic wording for the posology in MO section 4.2. More precise information on the infusion preparation is not available although the amount of comminuted substance is known. Furthermore, changes in the AR were presented and clinical safety data discussed such as on cognitive impairment, psoriasis and generalised anxiety disorders as regards their relevance for the use included in the MO.

6.4.2. Monograph on Cisti cretici folium and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR, Readers Guidance; References: 00/67

Outcome:

Rapporteur to introduce changes in the MO and AR according to the discussion for peer review and for **possible adoption for public consultation** at the **HMPC September** meeting. HMPC endorsed the change of herbal substance name Cisti cretici folium to Cisti cretici herba. HMPC tracking documents together with the website will be updated.

Timetable:

Documents to be sent to Peer-reviewer: **17 August 2021**

Peer-review documents to be sent to Rapporteur: **31 August 2021**

Final documents to be included latest in 2nd premail: **14 September 2021**

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 3-5 May 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

- Meeting Summary PCWP-HCPWP meeting 3-4 March 2021
- Agenda - PCWP-HCPWP Joint meeting 1-2 June 2021
- GPT Position Statement Extrapolation Phytomedicine 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 5-7 July 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	Czechia	No restrictions applicable to this meeting	
Marie Heroutova	Alternate	Czechia	No interests declared	
Maria Paile Hyvarinen	Member	Finland	No interests declared	
Sari Koski	Alternate	Finland	No interests declared	
An Le	Member	France	No interests declared	
Jacqueline Wiesner	Member	Germany	No interests declared	
Susanne Flemisch	Alternate	Germany	No interests declared	
Ioanna Chinou	Member	Greece	No interests declared	
Stavroula Mamoucha	Alternate	Greece	No interests declared	
Zsuzsanna Bíróné Dr Sándor	Member	Hungary	No interests declared	
Jacqueline Masterson	Alternate	Ireland	No restrictions applicable to this meeting	
Alessandro Assisi	Member	Italy	No interests declared	
Baiba Jansone	Member	Latvia	No interests declared	
Jurate Antanaviciene	Member	Lithuania	No interests declared	
Everaldo Attard	Member	Malta	No interests declared	
Burt H Kroes	Member	Netherlands	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Hilda Kuin	Alternate	Netherlands	No interests declared	
Wojciech Dymowski	Member	Poland	No interests declared	
Ana Paula Martins	Member	Portugal	No interests declared	
Carmen Purdel	Member	Romania	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	
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	
Pierre Duez	Expert – via WebEx*	Belgium	No interests declared	
Kristine Hvolby	Expert – via WebEx*	Denmark	No interests declared	
Melanie Bald	Observer	EDQM	No interests declared	
Meeting run with the help of EMA staff				

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