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SCIENCE MEDICINES HEALTH

19 July 2023  
EMA/HMPC/345565/2023  
Human Medicines Division

## Committee on Herbal Medicinal Products (HMPC)

### Minutes for the meeting on 17-19 July 2023

Chair: Emiel Van Galen

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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.

#### **Note on access to documents**

Some documents mentioned in the set of minutes cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to 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/729522/2016).

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## 1. Introduction

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

The Chair opened the meeting by welcoming all participants. 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 meeting, the Committee Secretariat announced that no restriction in the involvement of meeting participants for agenda topics was identified (see list of participants).

Participants were asked to declare any changes, omissions or errors to their declared interests concerning the matters for discussion. No new or additional competing interests 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](#). All decisions taken at this meeting were made in the presence of a quorum of members. All decisions, recommendations and advice were agreed by consensus, unless otherwise specified.

The Chair welcomed the new and re-nominated members and thanked the departing member for her contribution to the Committee.

### 1.2. Adoption of agenda

HMPC agenda for 17-19 July 2023.

**Action:** For adoption

**Outcome:**

Agenda and time schedule adopted.

### 1.3. Adoption of the minutes

HMPC minutes for 10-12 May 2023.

**Action:** For adoption

**Outcome:**

Minutes adopted with minor changes introduced prior to the start of meeting (a typo was amended during the meeting).

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

### 2.1. Status of HMPC activities

#### 2.1.1. Overview of HMPC assessment work including the Rapporteurship distribution – Status in May 2023

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Report: HMPC Chair

**Action:** For discussion

Document tabled: Overview

**Outcome:**

HMPC noted the status of assessment work.

In case of postponement of topics scheduled for the HMPC September 2023 meeting according to the overview, Rapporteurs were asked to inform secretariat and Chair before the first pre-mail (by 05 September 2023) 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**

None

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

### 2.3.1. Monograph on *Plantaginis lanceolatae folium* and supporting documents

**Action:** For adoption

Documents tabled: MO, AR, LoR, Reader's Guidance

**Outcome:**

Adoption postponed upon request by the Peer reviewer.

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

**Action:** For adoption

Documents tabled: MO, AR, LoR, Reader's Guidance

**Outcome:**

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

The Rapporteur summarised changes during peer review included in the MO (deletion of the subheading 'children, adolescents' in section 4.2 as requested in the last HMPC meeting) and in the AR (non-clinical part: shift of the majority of the studies to 'secondary pharmacology' and remaining studies in primary pharmacology summarised in table 4; clinical part: addition of table 5 with the main conclusions on the clinical studies).

It was highlighted that common names are differently approached in various languages. While the English common name is 'Arctic root', the precise plant part of the herbal substance is 'rhizoma et radix'. Members may therefore check for the final revised MO whether they give the traditional common name in their language (often 'root' or 'rhizome' only), or they prefer to translate the more accurate Latin substance name. Final amendments in the AR as proposed by the Peer reviewer were suggested to be taken up after public consultation.

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

### 2.4.1. Monograph on *Capsici fructus* and supporting documents

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**Action:** For adoption

Document tabled: Review report, References 30/4

**Outcome:**

HMPC agreed with Rapporteur's position that no EU herbal 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 *Capsici fructus*.

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

The Rapporteur pointed out that after discussion in May he received additional information on lower-dose Capsaicin products marketed in the MSs such as those previously reported in the AR from the Spanish market. However, after a thorough check for none of them all requirements were found coherently fulfilled regarding strength, different traditional indication, posology and 30 years medicinal TU. Therefore, no preparation was included in the TU part of the MO.

### 2.4.2. Monograph on *Melaleuca aetheroleum* and supporting documents

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**Action:** For adoption

Document tabled: Review report, References 0/5

**Outcome:**

HMPC agreed with Rapporteur's position that no EU herbal 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 *Melaleuca aetheroleum*.

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

Listed full text references supporting the decision to be provided before publication.

The Rapporteur emphasised that the use of tea tree oil during pregnancy and lactation is not recommended (MO section 4.6. fertility, pregnancy and lactation) and although the information about oromucosal absorption is not known, it is expected that when used as a gargle, the exposure is lower than from oral use. This is not considered to trigger a revision at present but that could be relevant for the next review when further information is available, e.g. for inclusion of further information in MO section 5.3. preclinical safety data. The reference for calculation of a human equivalence value was discussed to allow bridging the posology according to the EU herbal monograph with some safety concerns derived from a rat study in accordance with OECD TG414 (European Chemicals Agency, 2021) resulting in a NOAEL value for maternal toxicity and developmental of 20 mg/kg bw/day. While CHMP/SWP/28367 Rev 01 gives in general the basis to use allometric factors, the actual

factor can only be taken from the *Guideline for Estimating the Maximum Safe Starting Dose in Initial Clinical Trials for Therapeutics in Adult Healthy Volunteers* (FDA, 2005), which will be quoted correctly in the addendum to explain how the human equivalent dose of 3.22 mg/kg for safety assurance in relation to MO and LE has been calculated.

#### 2.4.3. **Monograph on *Origani majoranae herba* and supporting documents**

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**Action:** For adoption

Document tabled: Review report, References 0/6

**Outcome:**

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

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

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

Listed full text references supporting the decision to be provided before publication.

The Rapporteur considered no revision required because there are no new products on the market and no new scientific data related to non-clinical and clinical safety or clinical efficacy which could trigger a revision.

A minor editorial change in MO section 4.2. posology and method of administration was proposed (positioning of bullet point "b").

#### 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 *Cisti cretici herba* and supporting documents - postponed**

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#### 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. Guideline on the assessment of genotoxicity of herbal substances/preparations (EMA/HMPC/107079/2007) - postponed
- 

### 4.2. Quality

- 4.2.1. Guideline on good agricultural and collection practice (GACP) of starting materials of herbal origin (EMA/HMPC/246816/2005)
- 

**Action:** For discussion

Document tabled: Draft revised guideline

**Outcome:**

HMPC noted remaining issues presented by the Rapporteur after comments received from the Quality DG and re-discussions.

HMPC members were invited to provide comments.

Timetable:

Members to send comments to the Rapporteur latest by 31 August;

Meeting of GACP group first week of September;

Discussion at QDG second week of September;

Clean consolidated version to be provided for HMPC plenary 3rd week September for adoption and possible transfer for coordination with inspectors group before public consultation.

- 4.2.2. Q&A on quality of herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/41500/2010)
- 

**Action:** For discussion

Document tabled: Draft revised Q&A (Rev.7)

**Outcome:**

A revised version of the herbal quality Q&A was presented highlighting newly added questions, modifications in remaining questions and also those questions that were deleted as meanwhile addressed in main revised quality guidelines.

HMPC Members were invited to provide comments on the content before **possible adoption** at the **HMPC September 2023** meeting (layout/format and subheadings to be updated after content agreement).

The Rapporteur highlighted that a Q&A regarding nitrosamines in herbal products has not been included as already included in the specific CMDh Q&A.

It was encouraged to submit comments to the Rapporteur ideally before end of August in order to allow final amendments and discussions beginning September at QDG in preparation of adoption at HMPC.

#### 4.2.3. [Concept paper on the development of a Reflection Paper on modern manufacturing techniques used for herbal preparations \(EMA/HMPC/885124/2022\)](#)

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**Action:** For adoption

Document tabled: Draft Concept paper

**Outcome:**

Concept paper adopted by consensus for publication.

The Rapporteur highlighted the changes introduced, e.g. use of the wording “modern” instead of “new” manufacturing techniques given that some technologies are not that recent but used for years already although mostly in areas outside herbal MPs such as the food industry. Comparability of extracts obtained with new technologies with each other and with conventional solvent extracts are a main reason to start the dialogue with industry. It is envisaged that the proposed reflection paper could support pharmaceutical industry in the development and application of modern manufacturing techniques for herbal preparations. HMPC members suggested some additional editorial changes.

### 4.3. **Regulatory / Procedural**

#### 4.3.1. [Procedure for the preparation of Monographs/List Entries](#)

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**Action:** For discussion

Document tabled: Draft Procedure for the preparation of MO and LE

**Outcome:**

The Rapporteur highlighted the aspects added. The timing of the submission of draft divergent opinions for final packages for better transparency before final adoption was discussed and may be reworded. Other open issues regarding relationship to established SOPs, quotation of unpublished guidance documents and necessary granularity of the procedural steps and flow chart to be sorted by the secretariat.

Next **discussion** or **possible adoption** scheduled at the **HMPC September 2023** meeting.

#### 4.3.2. [Questions & Answers on the EU framework for \(traditional\) herbal medicinal products, including those from a 'non-European' tradition \(EMA/HMPC/402684/2013\)](#)

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Report: HMPC Chair

**Action:** For discussion

Document tabled: Draft revised Q&A (Rev. 1)

**Outcome:**

The Q&A had been modified following input from EMA and committee members. New Q/As added and those proposed to be updated were presented, and some suggestions were made to improve the answers' wording. HMPC members were invited to review the document and provide additional comments (by mid-August) for **possible adoption** scheduled at the **HMPC September 2023** meeting.

## 4.4. Report on HMPC Drafting Groups activities

### 4.4.1. ORGAM DG

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None

### 4.4.2. Quality DG

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Report: Nicoleta Carmen Purdel

**Action:** For information

Document tabled: Minutes

**Outcome:**

The HMPC noted a report from the QDG activities including the activities regarding guidance documents (see 4.2.1., 4.2.2. and 4.2.3.) and the new NTC training to be developed (see 5.7.1). Moreover, it was highlighted that the herbal Quality DG will have to review their three-year work plan by September 2023 to feed into planning for the quality domain (QWP) currently established.

HMPC heard a report on the progress with the implementation of the quality domain. It was welcomed that the Herbal QDG Chair was appointed as member of QWP also to serve as link to HMPC. Otherwise HMPC is not foreseen to be part of any domain governance and that after QWP and BWP establishment from September onwards the renewed setup of the Herbal QDG (mandate, work plan integration into Q domain) is planned. The proposal to discuss the topic at the Spanish SRLM beginning October was welcomed.

## 5. Organisational, regulatory and methodological matters

### 5.1. Mandate and organisation of the HMPC

#### 5.1.1. Strategic Review and Learning Meetings (SRLM)

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- HMPC SRLM Follow up plan - status July 2023

Report: HMPC Chair

**Action:** For information

Document tabled: Follow-up plan

**Outcome:**

The HMPC Chair presented the latest status of the SRLM follow up plan and highlighted that some topics are only foreseen for 2024 (e.g. get a better view on 'traditional HMP' for animals, as part of implementation of Veterinary Regulation; increase HMPC involvement in EMA initiatives e.g. the next EMA Regulatory Science Strategy).

- Spanish Presidency meeting – 09-10 October 2023

Report: Olga Palomino

**Action:** For discussion

Document tabled: Draft Agenda

**Outcome:**

The draft agenda for the next SRLM organised by the Spanish Presidency of the Council of the European Union on 09-10 October 2023 was presented. Some comments regarding content and organisational aspects were made and a modified draft will be circulated after further consultation with Chairs and secretariat. The HMPC Chair and members welcomed the organisation of a face-to-face meeting allowing socialising and discussions in between in times of mostly 'virtual' interactions.

### 5.1.2. HMPC membership

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Report: HMPC Chair

**Action:** For information

**Outcome:**

Re-nominated members:

- Sweden, Malin Kyllikki Hobro Soderberg (alternate) as of 15 May 2023
- Finland, Maria Paile Hyvarinen (member) as of 21 June 2023
- Greece, Ioanna Chinou (member) as of 9 June 2023
- Greece, Stavroula Mamoucha (alternate) as of 9 June 2023

End of membership:

- Lithuania, Greta Budukeviciute (member) as of 21 June 2023

New member:

- Lithuania, Gabriele Balciunaite Murziene (member) as of 21 June 2023

### 5.1.3. Call for Co-opted members (Experimental/non-clinical pharmacology and General/family medicine)

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Report: HMPC Chair

**Action:** For discussion

Documents: [Procedure for the nomination and appointment of co-opted members of the CHMP, CVMP and HMPC](#), Expertise of HMPC members, presentation

**Outcome:**

HMPC noted next steps regarding the nomination and appointment of co-opted members, taking into account that two mandates are about to expire on 23/11/2023. The 2 areas of expertise were discussed but no decision taken yet to confirm or to change so that calls could be sent for possible election in September to avoid any gaps later.

Some members highlighted new areas of expertise may be considered to complement those available to HMPC (e.g. RWD/RWE or pharmacoepidemiologist). The importance to maintain practical physician experience related to general medicinal practice was also emphasised as well as the relevance of paediatric expertise.

## 5.2. EMA Scientific Committees or CMDh-v

### 5.2.1. Scientific Coordination Board Meeting

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Report: HMPC Chair

**Action:** For information

Documents tabled: Agenda 26 June 2023, Minutes 03 March 2023

**Outcome:**

Postponed.

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

None

### 5.4. Cooperation within the EU regulatory network

#### 5.4.1. Coordination with European Pharmacopoeia

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- EDQM 13A expert group meeting

Report: Melanie Bald

**Action:** For information

Document tabled: SoD

**Outcome:**

The HMPC noted the summary of decisions from the June 2023 13A group meeting (next meeting in October 2023) and highlighted monographs for publication in Pharmeuropa or those for adoption by the Commission and publication in Ph. Eur.

The EDQM observer responded to questions regarding the Cannabis flos monograph (adopted by the Commission in June 2023; the text would be published in January 2024 in supplement 11.5 of the Ph. Eur.), Cranberry (clarification regarding the starting material for monograph establishment needed), the proposal for a general method for the determination of toxic compounds (pulegone, estragole and thujone), and discussions on currently revised herbal substances containing estragole.

- Certificate of suitability (CEP)

Report: HMPC Chair

Action: For information

**Outcome:**

The HMPC Chair summarised the agenda of the Steering Committee Meeting of the Certification Procedure held on 29 June 2023, and highlighted the specific topic on herbal CEPs and control of pyrrolizidine alkaloids as a good example of possible and collaborative work between HMPC and the CEP Steering Committee to address issues arising from the CEP procedures for herbal assessors.

### 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. Association of the European Self-Medication Industry (AESGP) – request for a hearing in November 2023

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Report: HMPC Chair

**Action:** For discussion

Document tabled: Email communication

**Outcome:**

Postponed.

## 5.7. Work plan and related activities

### 5.7.1. HMPC work plan 2023

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Report: HMPC Chair

**Action:** For discussion

Documents tabled: Work plan 2023, Annex 1, Annex 2 – current status

**Outcome:**

The HMPC members noted current status of projects, monographs and guidelines.

- (1.3.1) Evaluation of data from paediatric clinical practice for the safe use of herbal substances in children

(See also topic 7.1.2)

**Action:** For discussion

**Outcome:**

HMPC welcomed the draft RP on data requirements for the use of (T)HMPs in children/adolescents.

HMPC members were invited to send **comments by 11 August 2023** particularly focussing on scope, the draft annex under development (TU proposed age limits per therapeutic area) and a chapter on active data generation using RWE/RWD in order to prepare a mature draft for possible agreement at the September HMPC before stepping into coordination with PDCO.

- (1.3.2) Harmonise the approach for the use of EU herbal monographs in the assessment of combination products

Document tabled: Draft survey

**Action:** For discussion

**Outcome:**

HMPC discussed a proposal for a survey on combination products.

A modified draft survey to be prepared for possible agreement at the HMPC September meeting to be fit for purpose i.e. to establish a short list of few justified candidates for HMPC assessment taking into account existing templates and an appropriate expenditure for data collection and analysis.

The high amount of combination products in some MSs was raised. There is limited gain expected when collecting data on all combinations because combi-monographs have been proven to be challenging when attempting to list precisely all marketed combinations even for 2 substances. Furthermore, some combinations with often more than 2 plants are specific for just one product for which a monograph may not be seen as the ideal harmonisation tool. It should be therefore looked at a few targeted proposals where NCAs

reckon a monograph could be useful taking into account experiences from previous surveys and the existing template for substantiated assessment proposals (addressing also combinations).

- (2.1.1) HMPC position on the role of EU herbal monographs and assessment reports in relationship to borderline issues

Document tabled: Draft Q&A

**Action:** For discussion

**Outcome:**

The HMPC noted six questions for Q&As to be developed reflecting the HMPC view on the role of EU herbal monographs and assessment reports with respect to borderline issues. Appropriate formats and legal/regulatory scope of HMPC tasks vis-a-vis other institutions and borderline groups were discussed.

HMPC members were invited to submit comments to the Rapporteurs over the next 2/3 weeks in order to prepare a second draft for discussion at the HMPC September meeting.

- (2.2.2) Training on assessment of applications for herbal medicinal products issues

Documents tabled: Herbal Curriculum Training Planning 2023-2026, email

**Action:** For information

**Outcome:**

HMPC endorsed the overview table with planned EU NTC herbal curriculum trainings following a new template including the next one planned for beginning Q1/2024 on contaminants, microbiological testing and impurities as agreed at the HMPC May meeting.

- (2.3.1) Implement new working methodology for HMPC – new main procedure and revised template documents

Document tabled: Draft revised AR template

**Action:** For discussion

**Outcome:**

HMPC discussed latest modifications to the AR template.

Members were invited to send further comments to the Rapporteur before a mature draft revised template is prepared for **discussion** or **possible adoption** for public consultation at the **HMPC September 2023** meeting.

## 5.8. Planning and reporting

### 5.8.1. HMPC meeting organisation 2024

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Report: HMPC Chair

**Action:** For information

Document tabled: Presentation

**Outcome:**

The HMPC noted the proposed arrangements for scientific committee meetings as regards number and distribution of face-to-face meetings following generally the 50% principle.

HMPC meetings in 2024: January, May and September to be held face-to-face; March, July

and November to be held as virtual.

HMPC Members to provide their views regarding HMPC meetings in 2024 (frequency and timing of face-to-face vs virtual meetings) to the Chair/secretariat for an overall HMPC view for feedback to EMA management.

## 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 *Foeniculi amari fructus* and supporting documents

---

**Action:** For 2<sup>nd</sup> discussion

Documents tabled: Draft MO, LE, AR, LoR, OoC, Reader's Guidance

**Outcome:**

Rapporteur to introduce changes in the draft revised EU herbal monograph and list entry and supporting documents according to the discussion and possible additional comments from peer-reviewer and HMPC members.

Peer-reviewer to double-check coherence of the content of revised MOs and draft revised LEs and substantiated justification in AR and OoC.

Next **discussion** scheduled at the **HMPC September 2023** meeting.

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

---

**Action:** For 2<sup>nd</sup> discussion

Documents tabled: Draft MO, LE, AR, LoR, OoC, Reader's Guidance

**Outcome:**

See topic 6.1.1.

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

---

**Action:** For 2<sup>nd</sup> discussion

Documents tabled: Draft PS, AR, LoR, OoC, Reader's Guidance

**Outcome:**

Rapporteur to introduce changes in the draft public statement and supporting documents according to the discussion and possible additional comments from peer-reviewer and HMPC members.

Next **discussion** scheduled at the **HMPC September 2023** meeting.



The Rapporteur summarised responses given in the OoC to comments from IPs on the draft PS taking into account the outcome of the discussion held at HMPC in May:

- rewording of conclusions on non-clinical data in the AR as clear evidence that the carcinogenic effect of estragole could be counterbalanced by other constituents of the essential oil in humans, is missing;
- the possible mitigating effect of herbal tea or aqueous extract preparation to reduce estragole intakes is not valid for the essential oils;
- the guidance value of 0.05 mg person/day should not be interpreted as a strict regulatory limit for use of fennel preparations;
- there is no further posology for bitter fennel oil in adults and adolescents supported by evidence of TU.

#### 6.1.4. Monograph on Hippocastani cortex and supporting documents

---

**Action:** For 1<sup>st</sup> discussion

Documents tabled: Draft MO, AR, LoR

**Outcome:**

Postponed.

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

---

**Action:** For 1<sup>st</sup> discussion

Documents tabled: Draft MO, AR, OoC

**Outcome:**

HMPC noted comments received during public consultation and discussed options to introduce a new cutaneous indication taking into account information from MSs and wordings of comparable uses in other monographs.

Rapporteur to introduce changes in the draft revised EU herbal monograph and supporting documents according to the discussion and possible additional comments from peer-reviewer and HMPC members.

Next **discussion** scheduled at the **HMPC September 2023** meeting.

After public consultation, the Rapporteur proposed changes to MO sections 3 (to add the liquid dosage form for cutaneous use) and 4.2 (to have a second indication for wound healing and as a mild antiseptic, and with the posology 2% V/V in ethanol).

The liquid dosage form based on Ph. Fr. in the first version of the monograph had been deleted 'as obsolete' during the revision as no products had been detected on the market. An IP had asked to keep it with reference to some products and long-standing tradition, which was acknowledged, although data are not entirely coherent regarding mono- vs combi-products, period of marketing and wording of indications reflecting broad traditional uses.

HMPC members emphasised that other MOs with a similar therapeutic indication for wound healing should be taken into account.

#### 6.1.6. Monograph on Rosmarini folium and supporting documents

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**Action:** For 1<sup>st</sup> discussion

Documents tabled: Draft MO, AR, LoR

**Outcome:**

No comments were received during public consultation.

Rapporteur to finalise the draft revised EU herbal monograph and supporting documents for peer review. (See also topic 6.1.5)

The Rapporteur informed that no comments were received during the public consultation and few comments have been made by the Peer-reviewer before regarding posology and MO section 4.2.. However, as the AR for Rosmarini folium is the same as the one for Rosmarini aetheroleum, both monographs should be finalised together having the same supporting documents in order to allow coherent publication of new and superseding of old documents on the web.

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

### 6.2.1. Monograph on Eucalypti aetheroleum and supporting documents

---

**Action:** For 1<sup>st</sup> discussion

Documents tabled: Draft MO, AR, LoR

**Outcome:**

Rapporteur to introduce changes in the draft revised EU herbal monograph and supporting documents according to the discussion and possible further comments from peer-reviewer and HMPC members.

Next **discussion** scheduled at the **HMPC September 2023** meeting.

The Rapporteur presented briefly changes introduced in MO sections 3, 4.2, 4.4, 4.8 and 4.9 and highlighted topics still for discussion, mainly relating to the duration of use in indication 2) (cutaneous use – 1 week vs use as bath additive – 2 weeks); and the age limit for the contraindication in children (24 months vs 30 months). It was recapitulated what led to the value that was based on a CHMP decision (EMA/CHMP/763180/2011) in 2012 from an Article 31 referral following assessment and PhV action in FR for suppositories containing terpenic derivatives. Members discussed comparability of 1.8 - cineole with other terpenes and risks from application of suppositories compared to other forms, such as solutions to be inhaled or rubbed into the skin, that may continue to be used as previously approved.

### 6.2.2. Monograph on Lavandulae aetheroleum and supporting documents

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**Action:** For 11<sup>th</sup> discussion

Documents tabled: Draft MO, AR, LoR, Reader's Guidance, List of PSUSA's, presentation

**Outcome:**

Rapporteur to introduce changes in the draft revised EU herbal monograph and supporting documents according to the discussion and possible further comments from Peer-reviewer and HMPC members.

Next **discussion** or **possible adoption** for public consultation scheduled at the **HMPC September 2023** meeting, taking into account the presence of the Rapporteur.

Timetable:

Documents to be sent to Peer-reviewer: **14 August 2023**

Peer-review documents to be sent to Rapporteur: **28 August 2023**

Final documents to be included latest in 2<sup>nd</sup> premail: **11 September 2023**

The Rapporteur summarised changes introduced since last meeting.

### 6.2.3. Monograph on *Pelargonii radix* and supporting documents

---

**Action:** For 8<sup>th</sup> discussion

Documents tabled: Draft MO, AR, LoR, Reader's Guidance, comparison table

**Outcome:**

Rapporteur to introduce changes in the draft revised EU herbal monograph and supporting documents according to the discussion and possible further comments from Peer-reviewer, for **possible adoption** for public consultation at the **HMPC September 2023** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **14 August 2023**

Peer-review documents to be sent to Rapporteur: **28 August 2023**

Final documents to be included latest in 2<sup>nd</sup> premail: **11 September 2023**

### 6.2.4. Monograph on *Urticae herba* and supporting documents

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**Action:** For 4<sup>th</sup> discussion

Documents tabled: Draft MO, AR, LoR

**Outcome:**

Postponed.

### 6.2.5. Monograph on *Urticae radix* and supporting documents

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**Action:** For 1<sup>st</sup> discussion

Documents tabled: Draft MO, AR, LoR, Reader's Guidance, clinical studies table

**Outcome:**

Rapporteur to introduce changes in the draft revised EU herbal monograph and supporting documents according to the discussion and possible further comments from peer-reviewer and HMPC members.

Next **discussion** scheduled at the **HMPC September 2023** meeting.

The Rapporteur proposed to include two new preparations (dry extracts) in the MO, i.e., f) dry extract (7-9:1), extraction solvent ethanol 60% (V/V); and g) dry extract (5.4-6.6:1), extraction solvent ethanol 20% (V/V). In the AR the market overview has been updated and new clinical data added.

### 6.2.6. Monograph on *Zingiberis rhizoma* and supporting documents

---

**Action:** For 7<sup>th</sup> discussion

**Outcome:**

Rapporteur to introduce changes in the draft revised EU herbal monograph and supporting documents according to the discussion and possible further comments from Peer-reviewer and HMPC members.

Next **discussion** scheduled at the **HMPC September 2023** meeting.

The Rapporteur informed that the package has been peer-reviewed already. A few issues remain to be solved between the Rapporteur and Peer-reviewer to improve the AR but will not change the overall assessment of the Rapporteur and the outcome in the monograph- (no changes since March 2023).

Adaptations had mainly been made in AR section 2.3 to explain the content of the monograph. The HMPC noted the Rapporteur's and Peer-reviewer's views relating to the quotation of references from WHO and ESCOP monographs but not as original references (suggestion to mention them as "as cited in WHO/ESCOP monograph"). Regarding the preparations and posologies included in the WEU *and* TU parts, additional explanations may be added (AR sections 2.3 and 4.4).

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

#### **6.3.1. Monographs with diuretic indications**

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**Action:** For discussion

Document tabled: Presentation

**Outcome:**

A majority endorsed the therapeutic indication "Traditional herbal medicinal product used for the relief of symptoms associated with minor urinary tract complaints in addition to the general recommendation of a sufficient fluid intake to increase the amount of urine" as primary option for the so-called EU "diuretic" monographs.

HMPC agreed also that there is no strict mandatory alignment. According to specific product use/characteristics and available data, other options are possible if duly justified.

New improved indications will be introduced gradually with periodic review procedures or upon specific request by an Interested Party (unscheduled review).

#### **6.3.2. Monograph on *Fragariae folium* and supporting documents**

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**Action:** For 1<sup>st</sup> discussion

Documents tabled: Review report, presentation

**Outcome:**

Postponed.

#### **6.3.3. Monograph on *Ononidis radix* and supporting documents**

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**Action:** For 4<sup>th</sup> discussion

Document tabled: Review report

**Outcome:**

HMPC endorsed the Rapporteur's position that the adopted harmonised therapeutic indication for the (traditional) use of the so-called EU "diuretic" monographs could change

the content of the EU herbal monograph and therefore a revision of the complete package is advocated.

Rapporteur to finalise the review report and send for peer review before **adoption** at the **HMPC September 2023** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **14 August 2023**

Peer-review documents to be sent to Rapporteur: **28 August 2023**

Final documents to be included latest in 2<sup>nd</sup> premail: **11 September 2023**

(See also topic 6.3.1)

#### 6.3.4. Monograph on *Pilosellae herba cum radice* and supporting documents

**Action:** For 3<sup>rd</sup> discussion

Document tabled: Review report

**Outcome:**

HMPC endorsed the Rapporteur's position that the adopted harmonised therapeutic indication for the (traditional) use of the so-called EU "diuretic" monographs could change the content of the EU herbal monograph and therefore a revision of the complete package is advocated.

Rapporteur to finalise the review report and send for peer review before **adoption** at the **HMPC September 2023** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **14 August 2023**

Peer-review documents to be sent to Rapporteur: **28 August 2023**

Final documents to be included latest in 2<sup>nd</sup> premail: **11 September 2023**

(See also topic 6.3.1)

#### 6.3.5. Monograph on *Polygoni avicularis herba* and supporting documents

**Action:** For 4<sup>th</sup> discussion

Document tabled: Review report

**Outcome:**

HMPC endorsed the Rapporteur's position that the adopted harmonised therapeutic indication for the (traditional) use of the so-called EU "diuretic" monographs could change the content of the EU herbal monograph and therefore a revision of the complete package is advocated.

Rapporteur to finalise the review report and send for peer review before **adoption** at the **HMPC September 2023** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **14 August 2023**

Peer-review documents to be sent to Rapporteur: **28 August 2023**

Final documents to be included latest in 2<sup>nd</sup> premail: **11 September 2023**

(See also topic 6.3.1)

### 6.3.6. Monograph on Pruni africanae cortex and supporting documents

---

**Action:** For 2<sup>nd</sup> discussion

Documents tabled: Review report, references

**Outcome:**

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

Next **discussion** or **possible adoption** scheduled at the **HMPC September 2023** meeting.

The Rapporteur summarised that there are no new herbal substances/preparations with 30/15 years of TU or 10 years of WEU. EudraVigilance outcome to be added.

### 6.3.7. Monograph on Rosae flos and supporting documents

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**Action:** For 2<sup>nd</sup> discussion

Documents tabled: Review report, references

**Outcome:**

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

Next **discussion** or **possible adoption** scheduled at the **HMPC September 2023** meeting.

The Rapporteur pointed out that there are no new products on the EU market and from the search of literature no relevant new information was found. EudraVigilance outcome to be added.

### 6.3.8. Monograph on Sideritis herba and supporting documents

---

**Action:** For 2<sup>nd</sup> discussion

Documents tabled: Review report, references

**Outcome:**

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

Next **discussion** or **possible adoption** scheduled at the **HMPC September 2023** meeting.

The Rapporteur emphasised that there are no new herbal substances/preparations with 30/15 years of TU or 10 years of WEU. EudraVigilance outcome to be added.

### 6.3.9. Monograph on Symphyti radix and supporting documents

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**Action:** For 1<sup>st</sup> discussion

Documents tabled: Review report, Reader's Guidance

**Outcome:**

Rapporteur to modify the review report according to the discussion and possible additional comments from Peer-reviewer and HMPC Members.

Next **discussion** scheduled at the **HMPC September 2023** meeting.

Two reasons had been identified by the Rapporteur that would justify the revision of the monograph: (A) The recommended limit for the PA content in line with the meanwhile revised HMPC PS changed from (0.35 µg/day) in 2014 to 1 µg/day in 2021. As MO sections 5.3 and 6 explicitly mention the old value, it should be updated since the PA content is a main safety aspect for this herbal substance. (B) Some PhV data have been found that should be added to the AR. A rewording of adverse reactions in the MO section 4.8. (currently 'none known') may also be indicated after a thorough assessment (taking into account exact product and its inclusion in the MO).

As apart from a few the safety-relevant data for addition to the AR no other changes to the MO are likely, the Rapporteur proposed a correction of the MO only, instead of a revision of the whole package. The review report should justify the correction proposed instead of a revision for re-discussion and agreement at the Committee.

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

### 6.4.1. Monograph on *Cnici benedicti herba* and supporting documents

---

**Action:** For 1<sup>st</sup> discussion

Documents tabled: Draft MO, AR, LoR

**Outcome:**

No comments received during public consultation.

Rapporteur to finalise the draft EU herbal monograph and supporting documents for peer review and **adoption** of the completed package including full text references at the **HMPC September 2023** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **14 August 2023**

Peer-review documents to be sent to Rapporteur: **28 August 2023**

Final documents to be included latest in 2<sup>nd</sup> premail: **11 September 2023**

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

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

---

**Action:** For 6<sup>th</sup> discussion

Documents tabled: Draft MO, AR, Reader's Guidance, LoR

**Outcome:**

Rapporteur to introduce changes in the draft EU herbal monograph and supporting documents according to the discussion and possible additional comments from Peer-reviewer and HMPC members.

AT member and other HMPC members were invited to support the Rapporteur with the scientific/regulatory expert reasoning for the re-confirmed inclusion of a second fixed

combination despite some data limitations.

Next **discussion** scheduled at the **HMPC September 2023** meeting.

The Rapporteur informed that a justification to include both preparations a) and b) under TU has been added in the AR chapter 2.3. according to majority decision at the HMPC May meeting.

## 6.5.2. Monograph on Tribuli terrestris herba and supporting documents

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**Action:** For 4<sup>th</sup> discussion

Documents tabled: Draft PS, AR, Reader's Guidance, LoR, references

**Outcome:**

Rapporteur to introduce changes in the draft public statement and supporting documents according to the discussion and possible additional comments from Peer-reviewer and HMPC members.

The reasons why a monograph cannot be established despite marketed products in the EU as presented in the comprehensive AR should briefly be explained to foster the understanding of Interested Parties which missing data may support a MO.

Next **discussion** scheduled at the **HMPC September 2023** meeting.

The reasons, why the Rapporteur considers a MO not possible, were explained highlighting the heterogenous data situation for 'herba' vs 'fructus', the regulatory status and period of use of marketed products in BG and CZ, the therapeutic indication, and the unusual highly purified special extract registered/ authorised in the EU.

As formally all prerequisites according to legislation could appear fulfilled, the Chair and secretariat gave initial suggestions to communicate also for non-European IPs the granularity of the HMPC assessment and offered their support to extent the wording in the PS to better summarise the complex reasons explained in Reader's guidance and AR.

## 7. Any other business

### 7.1. Topics for discussion

#### 7.1.1. Workshop on use of herbal medicinal products in Children, Bonn, 19 June 2023

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Report: HMPC Chair

**Action:** For discussion

Documents tabled: Short report Workshop for HMPC, Program, Presentations

**Outcome:**

The HMPC Chair reported briefly from the Workshop on use of herbal medicinal products in Children.

Under the topic 'Paediatric Phytotherapy: Rationalizing optimal Dosing for use in Children by Real World Data' both the Chair and the German member had also contribution on the regulators' view on a topic of high interest by patients, health care professionals and industry and some expectations regarding the respective HMPC work plan topic (see also 5.7.1).



### 7.1.2. Herbal Assessment Reports Summaries for the Public (ARSPs)

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**Action:** For discussion

Document tabled: Presentation

**Outcome:**

HMPC Members were informed on reasons why it had been decided that also after BCP the generation of herbal ARSPs is not taken up again by medical writers. It was proposed to wait for analysis of the survey from the ongoing HMPC work plan project before deciding on the appropriateness of activity/format for European patients and whether a lay language document is necessary on top of MOs and ARs.

The Chair and some members pointed to the importance of reliable EMA information for self-medicating patients as one of the few reliable sources for EU citizen to find understandable trustworthy assessments for herbal product uses among thousands of potentially confusing commercial and scientific online sources. He proposed simple steps to provide in established format herbal summaries. For the few new monographs IPs find only a sentence on the web that 'The EMA is currently developing this information', while for revisions MOs and ARs are updated but not the corresponding summaries.

It was proposed to form a small group between the HMPC project team and medical writers to inform each other and find solutions.

### 7.1.3. New voting system

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**Action:** For information

Document tabled: Email

**Outcome:**

HMPC members were informed that, at face-to-face meetings, all voting will be carried out using the internal meeting room system, which means that members must be present in the meeting room at the time of voting (proxy voting is still possible in exceptional circumstances).

### 7.1.4. ISO Identification of Medicinal Products (IDMP) – current status of development and implementation for herbal substances - postponed

### 7.1.5. EU survey opioids

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Action: For discussion

Document tabled: Questionnaire

**Outcome:**

The HMPC Members were informed that EMA is conducting a consultation to explore the interest of patients, healthcare professionals and other specialists on an outer packaging warning for opioid-containing medicines regarding their risk of opioid use disorder (OUD) (deadline: September 8<sup>th</sup>).

HMPC members discussed NCA views and whether a consolidated HMPC view on top is appropriate and possible given that most opioid containing products are outside the remit of HMPC. Members were invited to send their comments to the HMPC representative at the

HCPWP (Secretariat /Chair in copy) before taking the decision on such activity and its practical implementation.

## **7.2. Documents for information**

### **7.2.1. HMPC**

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Table of Decisions from HMPC meeting held on 10-12 May 2023

Overview of expertise of members HMPC and subgroups

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

[List of abbreviations used in EMA human medicines scientific committees & CMDh documents and in relation to EMA's regulatory activities](#)

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)**

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On hold

### **7.2.3. Other**

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- Agenda - HCPWP plenary meeting - 27 June 2023
- Agenda - PCWP and HCPWP joint meeting - 28 June 2023
- Agenda - PCWP plenary meeting - 27 June 2023
- Meeting Summary - PCWP HCPWP meeting - 3 March 2023
- [Real-world evidence framework to support EU regulatory decision-making - Report on the experience gained with regulator-led studies from September 2021 to February 2023](#)
- Eudralink is switching to multi-factor authentication (MFA) login

- **List of participants**

List of participants including any restrictions with respect to involvement of members/ alternates/experts following evaluation of declared interests for the 17-19 July 2023 meeting.

<b>Name</b>	<b>Role</b>	<b>Member state or affiliation</b>	<b>Outcome restriction following evaluation of e-DoI</b>	<b>Topics on agenda for which restrictions apply</b>
Reinhard Länger	Member	Austria	No interests declared	
Astrid Obmann	Alternate	Austria	No interests declared	
Patricia Bodart	Member	Belgium	No interests declared	
Gert Laekeman	Co-opted member	Belgium	No interests declared	
Radina Dimitrova	Alternate	Bulgaria	No interests declared	
Ivan Kosalec	Member	Croatia	No interests declared	
Darko Trumbetic	Alternate	Croatia	No interests declared	
Christina Sylvia Chrysostomou	Member	Cyprus	No interests declared	
Alexandra Demetriou	Alternate	Cyprus	No interests declared	
Markéta Příhodová	Member	Czechia	No restrictions applicable to this meeting	
Marie Heroutova	Alternate	Czechia	No interests declared	
Melanie Bald	Observer	EDQM	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	
Heidi Foth	Co-opted member	Germany	No interests declared	
Ioanna Chinou	Member	Greece	No interests declared	
Stavroula Mamoucha	Alternate	Greece	No interests declared	
Julia Pallos	Member	Hungary	No restrictions applicable to this meeting	
Rita Nemeth	Alternate	Hungary	No interests declared	
Sarah Kellaghan	Member	Ireland	No interests declared	
Jacqueline Masterson	Alternate	Ireland	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Alessandro Assisi	Member	Italy	No interests declared	
Anna Maria Serrilli	Alternate	Italy	No interests declared	
Inga Sile	Member	Latvia	No interests declared	
Gabriele Balciunaite Murziene	Member	Lithuania	No interests declared	
Everaldo Attard	Member	Malta	No interests declared	
Matthew Camilleri	Alternate	Malta	No interests declared	
Emiel Van Galen	Chair	Netherlands	No interests declared	
Burt H Kroes	Member	Netherlands	No interests declared	
Hilda Kuin	Alternate	Netherlands	No interests declared	
Gro Anita Fossum	Member	Norway	No interests declared	
Marianne Loiten Dalhus	Alternate	Norway	No interests declared	
Wojciech Dymowski	Member	Poland	No interests declared	
Ana Paula Martins	Member	Portugal	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	
Carmen Purdel	Member	Romania	No interests declared	
Ligia Elena Dutu	Alternate	Romania	No interests declared	
Miroslava Horváth Petriková	Member	Slovakia	No interests declared	
Jaroslav Tóth	Alternate	Slovakia	No interests declared	
Barbara Razinger	Member	Slovenia	No interests declared	
Olga Maria Palomino	Member	Spain	No interests declared	
Olga Teresa Esteban	Alternate	Spain	No interests declared	
Malin Kyllikki Hobro Soderberg	Alternate	Sweden	No interests declared	
Peter Sisovsky	Expert	Slovakia	No interests declared	
Meeting run with support from relevant EMA staff				