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SCIENCE MEDICINES HEALTH

20 March 2024  
EMA/HMPC/85397/2024  
Human Medicines Division

## Committee on Herbal Medicinal Products (HMPC)

Minutes for the meeting on 29-31 January 2024

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

### Health and safety information

In accordance with the Agency's health and safety policy, delegates were briefed on health, safety and emergency information and procedures prior to the start of the 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 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 in person.

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 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 members who were leaving the Committee for all their valuable work and contributions to the HMPC for the last years.

### 1.2. Adoption of agenda

HMPC agenda for 29-31 January 2024.

**Action:** For adoption

**Outcome:**

Agenda and time schedule adopted.

### 1.3. Adoption of the minutes

HMPC minutes for 20-22 November 2023.

**Action:** For adoption

**Outcome:**

Minutes adopted including the changes proposed by HMPC members 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 January 2024

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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 March 2024 meeting according to the overview, Rapporteurs were asked to inform secretariat and Chair before the first pre-mail (by 5 March 2024) to allow best adaptation of agenda and time schedule.

### 2.1.2. Appointment of Rapporteurs and Peer-reviewers

Periodic reviews to start in 2024-2025 – Proposal to Sign-up

Report: HMPC Chair

**Action:** For discussion

Document tabled: Overview document to Sign-up as Rapporteur/Peer reviewer

**Outcome:**

Rapporteurs and Peer-reviewers were appointed for the planned periodic reviews to be started in 2024. Respective calls for data to be prepared and launched in the first half of 2024 (3 waves).

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

### 2.2.1. Monograph and List Entry on *Foeniculi amari fructus* and supporting documents

**Action:** For adoption

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

**Outcome:**

Final revised EU herbal monograph and list entry and supporting documents adopted by majority. Divergent opinions: Ireland and Poland.

The Rapporteur highlighted that in the MO section 4.4 "Special warnings and precautions for use" the sentence about the not recommended use in young children was rephrased to "The use is not recommended in children under 4 years of age due to the lack of adequate data". Moreover, the wording in the MO section 6 "Pharmaceutical particulars" was amended with the sentence "In the general population exposure to estragole should be kept as low as practically achievable".

Some HMPC members emphasised that, although more studies may be needed, there is general evidence supporting that the intake of HMPs containing estragole should be reduced to the lowest possible level, and therefore their use should not be recommended, especially for young children (under 4 years of age), as there are other "estragole-free" products available on the market that can be used as an alternative.

### 2.2.2. Monograph and List Entry on *Foeniculi dulcis fructus* and supporting documents

**Action:** For adoption

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

**Outcome:**

Final revised EU herbal monograph and list entry and supporting documents adopted by majority. Divergent opinions: Ireland and Poland.

See also topic 2.2.1..

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

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**Action:** For adoption

Documents tabled: MO, AR, LoR, OoC

**Outcome:**

Adoption postponed.

Rapporteur to modify the revised EU herbal monograph and assessment report according to the discussion and possible comments from peer-reviewer.

HMPC members were invited to send to the Rapporteur any information in relation to issues discussed.

Next **discussion** scheduled at the **HMPC March 2024** meeting.

The Rapporteur emphasised the remaining point whether to keep or not the liquid dosage form in the MO, for external use, related to the second indication (i.e., as an aid in healing of minor wounds).

Some HMPC members emphasised that, in the absence of products fulfilling the 30/15 years criteria, other sources of evidence (e.g., bibliographic references) may be available to support TU.

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

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**Action:** For adoption

Documents tabled: MO, AR, LoR

**Outcome:**

Adoption postponed.

Rapporteur to modify the revised EU herbal monograph and assessment report according to the discussion and possible comments from peer-reviewer.

HMPC members were invited to send to the Rapporteur any information in relation to issues discussed.

Next **discussion** scheduled at the **HMPC March 2024** meeting.

See also topic 2.2.3..

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

### 2.3.1. Monograph on Urticae herba and supporting documents

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**Action:** For adoption

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

**Outcome:**

Adoption postponed.

Rapporteur to introduce changes in the draft revised EU herbal monograph and assessment report according to the discussion and to send the package to the peer-reviewer. HMPC members were invited to send to the Rapporteur any information in relation to issues discussed.

Next **discussion** scheduled at the **HMPC March 2024** meeting.

The Rapporteur emphasised that this MO revision was initiated to include new herbal products on the market fulfilling the 30/15 years criteria (TU). Moreover, it was pointed out that for the diuretic indication, medical supervision is needed for children under 12 years of age; and for the articular pain indication, medical supervision in adolescents may be needed as it can be related to different problems (e.g., postural trauma). Finally, and for all three indications, the lack of sufficient data on use during pregnancy/lactation precludes recommending use in this population.

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

**Action:** For adoption

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

**Outcome:**

Adoption postponed.

Rapporteur to introduce changes in the draft revised EU herbal monograph and assessment report according to the discussion and to send the package to the peer-reviewer. HMPC members were invited to send to the Rapporteur any information in relation to issues discussed.

Next **discussion** scheduled at the **HMPC March 2024** meeting.

The Rapporteur emphasised that this review was initiated to include two new herbal products on the market fulfilling the 30/15 years criteria (TU), and that no new clinical or safety data was found. Moreover, it was pointed out that herbal preparations c) and g) can be merged as both have the same indication and posology, and DERs for these two preparations are within a similar range.

Some HMPC members highlighted that the general statement that a doctor should be consulted if the symptoms persist or worsen, should be considered in the MO section 4.2.

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

### 2.4.1. Monograph on *Allii sativi bulbus* and supporting documents

**Action:** For adoption

Document tabled: Review report; References 00/00

**Outcome:**

HMPC agreed with Rapporteur's position to revise the EU herbal 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 *Allii sativi bulbus*.

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



The Rapporteur emphasised that two new herbal products fulfilling the 30/15 years criteria (TU) were reported to be included in the MO/AR. Moreover, new scientific data related to non-clinical, clinical safety and clinical efficacy, together with the analysis of the retrieved data from pharmacovigilance systems, are justifying a more in-depth evaluation.

#### 2.4.2. [Monograph on \*Matricariae aetheroleum\* and supporting documents](#)

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**Action:** For adoption

Document tabled: Review report; References 00/03

**Outcome:**

HMPC agreed with Rapporteur's position to revise the EU herbal 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 *Matricariae aetheroleum*. The review report was adopted and HMPC tracking documents will be updated.

The Rapporteur emphasised that the MO revision is recommended in order to adapt the indication to the TU of marketed herbal preparations and to correct the posology.

#### 2.4.3. [Monograph on \*Silybi mariani fructus\* and supporting documents](#)

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**Action:** For adoption

Document tabled: Review report; References 00/05

**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 *Silybi mariani 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 highlighted that although new products on the EU market were reported they are equivalent to the already existing ones in the MO. Moreover, no new scientific data relating to non-clinical and clinical safety or clinical efficacy was identified.

#### 2.4.4. [Monograph on \*Species diureticae\* and supporting documents](#)

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**Action:** For adoption

Document tabled: Review report; References 0/0

**Outcome:**

HMPC agreed with Rapporteur's position to revise the EU herbal 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 *Species diureticae*.

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

The Rapporteur pointed out that the MO needs to be revised to take account of combinations with *Herniariae herba* and the recently adopted cross-monographs harmonisation for the so-called "diuretic herbal monographs".  
A new Rapporteur to be appointed for the next phase (MO revision).

#### 2.4.5. Monograph on *Symphyti radix* and supporting documents

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**Action:** For adoption

Document tabled: Review report; References 00/04

**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 *Symphyti radix*.

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 emphasised that although no additional risks resulted from the final HMPC's revised "Public statement on the use of herbal medicinal products containing toxic, unsaturated pyrrolizidine alkaloids (PAs) including recommendations regarding contamination of herbal medicinal products with PAs" (EMA/HMPC/893108/2011 Rev. 1), the MO sections 5.3 "Preclinical safety data" and 6 "Pharmaceutical particulars" should be adapted (corrected) to include the revised recommended PA limit.

#### 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 *Prunus avium peduncle* and supporting documents

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**Action:** For adoption

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

**Outcome:**

Adoption postponed.

Rapporteur to modify the draft monograph and assessment report according to the discussion and possible comments from peer-reviewer for **possible adoption** for public consultation at the **HMPC March 2024** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **21 February 2024**

Peer-review documents to be sent to Rapporteur: **01 March 2024**

Final documents to be included latest in 2<sup>nd</sup> premail: **11 March 2024**

The Rapporteur emphasised that the MO's name should comprise both *Prunus avium* L., peduncle and *Prunus cerasus* L., peduncle. To this end, and although at the moment only one product is fulfilling the 30/15 years criteria (TU), which contains *Prunus avium* L., peduncles to be used as a tea, the peduncles of both species are described in the French Pharmacopoeia, as well as in the traditional herbal literature. Moreover, and for the recommended posology (i.e., 2-6 g in 200 mL), reference is made to the traditional herbal literature (which mostly advises 30 g/L, or 6 g/200 mL) and the monograph on tisanes in the French Pharmacopoeia (which advises 5-10 g/L). Finally, the draft MO was updated in accordance with the recently adopted cross-monographs harmonisation for the so-called "diuretic herbal monographs".

The HMPC members agreed on the combined name (*Prunus avium* L., peduncle and *Prunus cerasus* L., peduncle) and some of them emphasised that the proposed posology should be clearly justified (including cross-references to different data sources).

## 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)

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**Action:** For discussion

Document tabled: Draft revised guideline

**Outcome:**

The Rapporteur highlighted that changes have been introduced in all sections of the draft revised guideline, in order to update it after more than 10 years, taking into account experiences gained during the use of this guideline in national and EU procedures and also during establishment of EU herbal monographs. Other related guidelines not yet available at time of the first version have been taken into consideration as well.

Next **discussion** scheduled at the **HMPC March 2024** meeting.

### 4.2. Quality

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

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**Action:** For discussion

Document tabled: Draft revised guideline

**Outcome:**

Draft revised "Guideline on good agricultural and collection practice (GACP) of starting materials of herbal origin" (EMA/HMPC/246816/2005) endorsed by HMPC for further coordination with QWP and GMDP IWG before release for public consultation.

The Rapporteur emphasised the main changes introduced in the draft revised guideline, also the format was updated to the latest guidelines layout, and information relating to the indoor cultivation is now clearly identified. In addition, the sections on quality management, personnel and training were extensively structured and the information compiled.

#### 4.2.2. [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 discussion

Document tabled: OoC received during public consultation

**Outcome:**

The Rapporteur summarised the OoC received during the public consultation. As a general comment, IPs emphasised that the so-called "modern techniques" are currently hardly used in the field of manufacturing of HMPs.

Some HMPC members highlighted that the QDG should reconsider the priority of this particular topic and in this regard members were invited to send comments or examples based on their national experience.

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

#### 4.3.1. [Procedure for the preparation of Monographs/List Entries \(EMA/HMPC/887331/2022\)](#)

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**Action:** For adoption

Documents tabled: Draft Procedure for the preparation of MO and LE, Reader's Guidance

**Outcome:**

Draft procedure "Procedure for the preparation of Monographs" (EMA/HMPC/887331/2022) adopted by consensus for release for public consultation.

The Rapporteur pointed out that unpublished references (i.e., those not in the public domain) had been removed from the draft procedure.

#### 4.3.2. [Template for Assessment report for the development of EU herbal monographs and EU list entries \(EMA/HMPC/418902/2005\)](#)

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**Action:** For discussion

Document tabled: Draft revised AR template

**Outcome:**

Draft revised MO template to be modified according to the discussion for **possible adoption** for public consultation at the **HMPC March 2024** meeting.

The Rapporteur pointed out that the revised AR template should make the assessment work easier as it works as a checklist for what needs to be done (step-by-step). To this end, unpublished references (i.e., those not in the public domain) were removed; chapter 1.1.

'Description of the herbal substance(s), herbal preparation(s) or combinations thereof' was updated regarding the content (reference to all monographs available in the pharmacopoeias but not to the list of preparations in the EU herbal monographs); subheading relating to compounds was complemented (i.e., "relevant main compounds to the assessment report"); heading "experimental model" in the table 'Overview of the main non-clinical data' in chapter 3.1 was changed to include animal species (i.e., "animal species/experimental model").

#### 4.3.3. Template for a European Union herbal monograph (EMA/HMPC/107436/2005)

**Action:** For discussion

Documents tabled: Draft revised MO template, Addendum to QRD templates

**Outcome:**

Draft revised MO template to be modified according to the discussion for **possible adoption** for public consultation at the **HMPC March 2024** meeting.

The Rapporteur summarised the main changes introduced in the draft revised MO template: regarding the "duration of use", the legal requirement that any labelling and package leaflet shall contain a statement that the user should consult a doctor or a qualified health care practitioner if the symptoms persist during the use of the medicinal product is now included in the TU MO section 4.2 only (i.e., deleted from section 4.4), and this to be in line with the addendum to QRD for (T)HMPs (for WEU MO this is optional text, i.e., not a legal requirement); standard texts for the use in children in the section 4.2 have been replaced with reference to the current QRD template, to avoid text in MO template to be outdated; if use in children is not recommended due to lack of data, no cross reference to section 4.4 is needed (according to the annotated QRD template, a lack of data does not justify a warning).

#### 4.3.4. Reflection paper on data recommendations for (T)HMPs used in children and adolescents

**Action:** For adoption

Document tabled: Draft reflection paper

**Outcome:**

Adoption postponed.

Draft reflection paper to be modified according to the discussion and additional comments from HMPC members for **possible adoption** for coordination with the PDCO at the **HMPC March 2024** meeting.

The Rapporteur summarised comments received from HMPC members, and with particular detail comments that were not implemented.

HMPC members to confirm through written procedure and within two weeks, their final comments.

### **4.4. Report on HMPC Drafting Groups activities**

#### 4.4.1. ORGAM DG

None

#### 4.4.2. Quality DG - report

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Report: Nicoleta Carmen Purdel

**Action:** For information

Document tabled: Minutes

**Outcome:**

The QDG activities were reported, with emphasis on the ongoing revision of the pharmaceutical legislation, including the [Commission Regulation \(EC\) No 1234/2008](#) ('the Variations\_Regulation'), the 'Variations guidelines' ([Guidelines on the details of the various categories of variations, on the operation of the procedures laid down in Chapters II, IIa, III and IV of Commission Regulation \(EC\) No 1234/2008](#)), and also the new EU-NTC training on contaminants and residues (Q1/2024).

## 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 January 2024

Report: HMPC Vice-Chair

**Action:** For information

Document tabled: Follow-up plan

**Outcome:**

Postponed.

- Belgian Presidency meeting – 24-25 April 2024

Report: Patricia Bodart

**Action:** For discussion

Document tabled: Draft Agenda

**Outcome:**

The next SRLM organised by the Belgian Presidency of the Council of the European Union will be held in person on 24-25 April 2024 in Louvain la Neuve and a first draft agenda was presented.

HMPC members were invited to propose topics that they would like to have for discussion during the next SRLM in Belgium.

#### 5.1.2. HMPC membership

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Report: HMPC Chair

**Action:** For information

New membership:

- Austria, Astrid Obmann, (Member) as of 01 January 2024
- Austria, Brigitte Hauser, (Alternate) as of 01 January 2024

- Denmark, Nanna Lundgaard Rasmussen, (Member) as of 01 January 2024
- Ireland, Jacqueline Masterson, (Member) as of 10 January 2024
- Slovakia, Dorota Distlerova, (Member) as of 03 January 2024

Re-nominated members:

- Portugal, Maria Helena Pinto Ferreira, (Co-opted member) as of 24 November 2023
- Sweden, Karin Erika Svedlund, (Member), as of 20 January 2024

End of membership:

- Austria, Reinhard Länger, (Member) as of 31 December 2023
- Austria, Peter Voitl, (Co-opted member) as of 03 November 2023
- Ireland, Sarah Kellaghan, (Member) as of 30 November 2023
- Slovakia, Miroslava Horvath Petrikova, (Member) as of 02 January 2024

### 5.1.3. HMPC Co-opted members

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- Appointment of expert: Clinical – Clinical trials methodology and statistics

Report: HMPC Chair

**Action:** For discussion

Documents tabled: Call for nominations dated 06 October 2023, [Procedure for the nomination and appointment of co-opted members of the CHMP, CVMP and HMPC](#), Candidatures, Expertise of HMPC members

**Outcome:**

Pierre Duez (Belgium) was appointed as co-opted member in the area of expertise “Clinical trials methodology and statistics” for a 3-year mandate starting on 01 February 2024.

Pierre Duez highlighted his extensive regulatory experience, as a member of various commissions in Belgium (pharmacopoeia, veterinary medicines, herbal medicines) and at European/International level (EDQM, TCM working group), as well as a member of the HMPC's MLWP (2017-2020).

- Appointment of expert: Paediatrics - Paediatric medicine

Report: HMPC Chair

**Action:** For discussion

Documents tabled: Call for nominations dated 11 December 2023, [Procedure for the nomination and appointment of co-opted members of the CHMP, CVMP and HMPC](#), Candidatures, Expertise of HMPC members

**Outcome:**

Appointment postponed.

## 5.2. EMA Scientific Committees or CMDh-v

None

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

#### 5.3.1. RWD/RWE pilot project for HMPC

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Report: HMPC Chair

**Action:** For information

Documents tabled: Feasibility assessment requests

**Outcome:**

HMPC noted the feasibility assessment outcome for the two pilot RWD/RWE research projects with specific emphasis on herbal medicinal products.

Both research projects to be developed in collaboration with the EMA's Data Analytics and Methods Taskforce - Real World Evidence workstream (TDA-RWE).

### 5.4. Cooperation within the EU regulatory network

#### 5.4.1. Coordination with European Pharmacopoeia

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None

#### 5.4.2. Coordination with European Commission

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None

#### 5.4.3. Coordination with European Food Safety Authority (EFSA)

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- HMPC observer to EFSA

Report: HMPC Vice Chair

**Action:** For discussion

Documents tabled: 6<sup>th</sup> WG Draft Agenda 2024-01-26, Invitation letter

**Outcome:**

HMPC welcomed the recent joint initiatives with EFSA (HMPC was invited as an observer to a EFSA working group), and advantages of re-establishing HMPC-EFSA coordination with regard to common interests were emphasised.

### 5.5. Cooperation with International Regulators

#### 5.5.1. Coordination with Swiss Agency for Therapeutic Products (Swissmedic)

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- Swissmedic observer to HMPC

Report: HMPC Chair

**Action:** For information

Documents tabled: [Confidentiality arrangement with Swissmedic](#); [HMPC Roles of Procedure](#)

**Outcome:**



HMPC welcome the Swissmedic's representative as an observer to the Committee, and advantages of re-establishing HMPC-Swissmedic coordination with regard to common interests were emphasised.

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

### 5.6.1. **Update on Pyrrolizidine alkaloid (PA) – review of data**

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**Action:** For information

Document tabled: PA data report

**Outcome:**

The Rapporteur summarised the updated data on PAs reported by the German Phytopharmaceutical Industry (BAH/BPI).

[Association of the European Self-Medication Industry \(AESGP\) – hearing on November 2023](#)

- AESGP hearing

Report: HMPC Chair

**Action:** For adoption

Document tabled: Draft hearing report

**Outcome:**

HMPC endorsed the draft hearing report to be released for the AESGP comments.

## 5.7. **Work plan and related activities**

### 5.7.1. **HMPC work plan 2024**

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Report: HMPC Chair

**Action:** For adoption

Documents tabled: Work plan 2024, Annex 1, Annex 2

**Outcome:**

HMPC work plan 2024, annex 1 and annex 2 adopted by consensus.

### 5.7.2. **Follow up on HMPC work plan 2023**

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

**Action:** For discussion

Documents tabled: Report of ad hoc meeting

**Outcome:**

The Rapporteur pointed out that criteria, scope, general considerations, definitions and information included in the existing guideline on the clinical assessment of fixed

combinations of herbal substances/herbal preparations are still considered valid and need no update. Moreover, it was decided that no update of procedural guidance documents is needed (no specific AR/MO templates for combinations) and that a revised list of fixed combinations on the EU market will be presented at the HMPC March 2024 meeting.

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

**Action:** For discussion

Document tabled: Draft-“The role of MO and AR in relationship to borderline issue”

**Outcome:**

The Rapporteur summarised the written comments received from HMPC members on this document intended to provide guidance on the usefulness of the information available in EU herbal MOs and ARs. Moreover, it was emphasised that the target (scope) of this document should be clearly identified.

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

**Action:** For discussion

Documents tabled: Draft presentation on contaminants training (EU-NTC), Herbal curriculum – contaminants and residues, Herbal curriculum priorities

**Outcome:**

The Rapporteur emphasised that the upcoming EU NTC training on contaminants and residues included in the Herbal Curriculum has been discussed with QDG and the Herbal Curriculum Steering group. Microbiological testing was taken out from the scope of this training and has been added to the HMPC Herbal Curriculum training plan 2024-2026 as a separate training. As next steps, HMPC members were invited to send comments within two weeks, i.e., no later than Wednesday 14 February; all outstanding issues and comments from HMPC to be discussed and solved during the QDG February meeting on 20 February, including QDG endorsement of the presentation; during the HMPC March meeting, present solutions to outstanding issues and changes in the presentation introduced after the January meeting, for endorsement by HMPC; training (webinar) delivered in the end of April/May (the training will be pre-recorded, i.e., no live session).

Moreover, the HMPC members noted the Herbal Curriculum priorities.

## **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 Foeniculi amari fructus aetheroleum and supporting documents - postponed

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

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

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

**Outcome:**

Comments were received during public consultation.

Rapporteur to finalise the draft revised EU herbal monograph and supporting documents for peer review and **adoption** at the **HMPC March 2024** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **21 February 2024**

Peer-review documents to be sent to Rapporteur: **01 March 2024**

Final documents to be included latest in 2<sup>nd</sup> premail: **11 March 2024**

The Rapporteur summarised the amendment of section 5.3. Adverse events, serious adverse events and deaths, and the adaption of conclusions in section 5.5.4 Drug interactions and other forms of interaction in the AR. Regarding MO, sections 4.5. Interactions with other medicinal products and other forms of interaction and 4.8. Undesirable effects were updated.

Some HMPC members pointed out that in the MO section 5.3, the template standard sentences should be followed.

### 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

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**Action:** For 2<sup>nd</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, for **possible adoption** for public consultation at the **HMPC March 2024** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **21 February 2024**

Peer-review documents to be sent to Rapporteur: **01 March 2024**

Final documents to be included latest in 2<sup>nd</sup> premail: **11 March 2024**

The Rapporteur summarised the changes introduced in the AR (table 3 in section 2.3, posology for inhalation (drops in hot water) by children 3-12 years of age; sections 5.5.1 and 5.5.2, children age limit for using essential oils containing menthol and camphor – 24 months vs 30 months, and children age limit for cutaneous use and use as bath additive – 3 years vs 4 years). Draft MO to be updated accordingly.

Some HMPC members pointed out that children age limit adopted for other essential oils MOs should be followed and that for cutaneous use and use as bath additive the lowest children age limit is acceptable.

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

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

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

**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 March 2024** meeting.

The Rapporteur emphasised that changes in the MO sections 4.1. Therapeutic indications, 4.2. Posology and method of administration, 4.3. Contraindications, and 4.4 Special warnings and precautions for use, are the result of the recently adopted cross-monographs harmonisation for the so-called "diuretic herbal monographs"; however, a slightly different wording is proposed.

Some HMPC members emphasised that more evidence is needed to support the deviation from the previously agreed wording.

### 6.2.3. Monograph on *Lavandulae aetheroleum* and supporting documents

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**Action:** For 14<sup>th</sup> discussion

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

**Outcome:**

Postponed.

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

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

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

**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 March 2024** meeting.

The Rapporteur emphasised that changes in the MO sections 4.1. Therapeutic indications, 4.2. Posology and method of administration, 4.3. Contraindications, and 4.4 Special warnings and precautions for use, are the result of the recently adopted cross-monographs

harmonisation for the so-called "diuretic herbal monographs"; however, a slightly different wording is proposed.

Some HMPC members emphasised that more evidence is needed to support the deviation from the previously agreed wording.

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

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

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

**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, for **possible adoption** for public consultation at the **HMPC March 2024** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **21 February 2024**

Peer-review documents to be sent to Rapporteur: **01 March 2024**

Final documents to be included latest in 2<sup>nd</sup> premail: **11 March 2024**

The Rapporteur summarised that the posologies' inconsistency between table 1 and table 2.3 in the AR was amended. Moreover, and taking into account products on the EU market, three posology options were proposed for the powdered herbal substance, and it was also proposed not to include a recommendation to ensure adequate fluid intake in the MO section 4.2. and amend the related warning in the MO section 4.4.

HMPC members endorsed the option for combining the posologies of all products (200-520 mg, 2-4 times daily. Daily dose: 560 mg up to 1300 mg) and also to update the botanical name of the herbal substance in the MO.

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

**Action:** For 9<sup>th</sup> discussion

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

**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 March 2024** meeting.

The Rapporteur highlighted that changes in the MO section 5.3 and in the corresponding AR sections are still under discussion, as an appropriate text is needed to explain information in the MO section 4.6 and should reflect the available studies. Moreover, it was proposed to have exactly the same information in the section 5.3 for both monographs (WEU and TU). Some HMPC members pointed out that the current wording used in the MO section 5.3 may be confusing, since the general statement 'adequate tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed' is included as well. Moreover, it was emphasised that relating to the indication 5 (i.e., relief of symptoms of common cold) bronchitis (cough and cold) is still mentioned in some bibliographic references.

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

### 6.3.1. Monograph on *Malvae sylvestris* flos and supporting documents

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

Document tabled: Review report

**Outcome:**

HMPC endorsed the Rapporteur's position that there is no new information available that could change the content of the EU herbal monograph.

Rapporteur to finalise the review report and send for peer review before **adoption** at the **HMPC March 2024** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **21 February 2024**

Peer-review documents to be sent to Rapporteur: **01 March 2024**

Final documents to be included latest in 2<sup>nd</sup> premail: **11 March 2024**

The Rapporteur emphasised that, although some clinical safety data is available from the EudraVigilance database, the current MO section 4.3 Contraindications is already including "hypersensitivity to active substance".

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

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

Document tabled: Review report

**Outcome:**

HMPC endorsed the Rapporteur's position that there is no new information available that could change the content of the EU herbal monograph.

Rapporteur to finalise the review report and send for peer review before **adoption** at the **HMPC March 2024** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **21 February 2024**

Peer-review documents to be sent to Rapporteur: **01 March 2024**

Final documents to be included latest in 2<sup>nd</sup> premail: **11 March 2024**

The Rapporteur emphasised that, although some clinical safety data is available from the EudraVigilance database, this data is considered to be limited.

### 6.3.3. Monograph on Mastic (*Mastix, Pistaciae lentisci resina*) and supporting documents

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

Document 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** scheduled at the **HMPC March 2024** meeting.

The Rapporteur highlighted that no data or comments were provided by IPs during the call for data; no new products in the market overview were reported from the MSs; only one clinical study was identified but out of scope of the MO and review procedure (essential oil of mastic gum); no safety data (EudraVigilance) has been found.

It was pointed out a footnote included in the first AR mentioning some bibliographic references to be reconsidered with the next systematic revision of the MO.

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

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**Action:** For 17<sup>th</sup> discussion

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

**Outcome:**

The Rapporteur presented an update on the perspective for the draft MO and highlighted the main points that are still under discussion.

Next **discussion** scheduled at the **HMPC March 2024** meeting.

##### **6.5.2. Monograph on *Maydis stigma* and supporting documents**

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

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

**Outcome:**

Postponed.

## **7. Any other business**

### **7.1. Topics for discussion**

#### **7.1.1. EU NTC Engagement Event, 5 December 2023**

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**Action:** For discussion

Documents tabled: Agenda, Presentations

**Outcome:**

A detailed report will be provided at the HMPC March 2024 meeting.

## 7.2. Documents for information

### 7.2.1. HMPC

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Table of Decisions from HMPC meeting held on 20-22 November 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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- HMA/EMA Big Data Stakeholder Forum 04 December 2023, program
- The new Ph. Eur. Cannabis flower monograph (3028) - presentation
- Report on the implementation of Regulation on nutrition and health claims made on foods [TA \(europa.eu\)](#)
- Society of Medicinal Plant and Natural Product Research GA – European Herbal Health Products Summit, 20 February 2024, Brussels – draft program, invitation



## List of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 29-31 January 2024 meeting, which was held in-person.

An asterisk (\*) after the role, in the second column, signals that the member/alternate attended remotely. Additional experts participated in (part of) the meeting, either in-person or remotely.

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Emiel Van Galen	Chair	Netherlands	No interests declared	
Astrid Obmann	Member	Austria	No interests declared	
Patricia Bodart	Member	Belgium	No interests declared	
Iliana Ionkova	Member	Bulgaria	No interests declared	
Ivan Kosalec	Member	Croatia	No interests declared	
Darko Trumbetic	Alternate*	Croatia	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	
Nanna Lundgaard Rasmussen	Member	Denmark	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	
Helene Ly	Alternate*	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	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Julia Pallos	Member	Hungary	No restrictions applicable to this meeting	
Rita Nemeth	Alternate*	Hungary	No interests declared	
Jacqueline Masterson	Member	Ireland	No interests declared	
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	
Sven Back	Member*	Luxembourg	No interests declared	
Everaldo Attard	Member*	Malta	No interests declared	
Burt H Kroes	Member	Netherlands	No interests declared	
Hilda Kuin	Alternate	Netherlands	No interests declared	
Wojciech Dymowski	Member	Poland	No interests declared	
Ana Paula Martins	Member	Portugal	No interests declared	
Carmen Purdel	Member	Romania	No interests declared	
Dorota Distlerova	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	
Karin Erika Svedlund	Member (Vice-Chair)	Sweden	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	Co-opted member	Portugal	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Ribeiro Campos				
Melanie Bald	Observer*	EDQM	No interests declared	
Reinhard Länger	Expert*	Austria	No interests declared	
Kristine Hvolby	Expert*	Denmark	No interests declared	
Pierre Duez	Expert*	Belgium	No interests declared	
Knut Almgren	Expert*	Sweden	No interests declared	
Charlotta Löfberg	Expert*	Sweden	No interests declared	
Peter Sisovsky	Expert*	Slovakia	No interests declared	
A representative from the European Commission attended the meeting.				
An observer from SwissMedic (Switzerland) attended the meeting.				
Meeting run with support from relevant EMA staff				

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