Committee on Herbal Medicinal Products (HMPC)
Draft Agenda for the meeting on 18-20 September 2023

Chair: Emiel Van Galen – Vice-Chair: Karin Erika Svedlund
18 September 2023, 13:00 – 18:00, room 2C
19 September 2023, 09:00 – 18:00, room 2C
20 September 2023, 09:00 – 16:00, room 2C

Health and safety information
In accordance with the Agency's health and safety policy, delegates are to be briefed on health, safety and emergency information and procedures prior to the start of the meeting.

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

Of note, this agenda 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 agenda 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 ongoing 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).
Table of contents

1. Introduction ................................................................. 5
   1.1. Welcome and declarations of interest of members, alternates and experts .......... 5
   1.2. Adoption of agenda................................................................................................. 5
   1.3. Adoption of the minutes ......................................................................................... 5

2. EU herbal monographs and list entries for adoption .................................................... 5
   2.1. Status of HMPC activities....................................................................................... 5
       2.1.1. Overview of HMPC assessment work including the Rapporteurship distribution – Status in September 2023....................................................................................................................... 5
       2.1.2. Appointment of Rapporteurs and Peer-reviewers ........................................................... 5
       2.1.3. Request for unscheduled review on Sennae folium and Sennae fructus............. 5
   2.2. Revised EU herbal monographs and list entries for final adoption ..................... 5
   2.3. Revised EU herbal monographs and list entries for public consultation .............. 6
       2.3.1. Monograph on Plantaginis lanceolatae folium and supporting documents - postponed........ 6
       2.3.2. Monograph on Pelargonii radix and supporting documents ................................. 6
   2.4. Reviewed EU herbal monographs and list entries for decision on revision .......... 6
       2.4.1. Monograph on Ononidis radix and supporting documents................................. 6
       2.4.2. Monograph on Pilosellae herba cum radice and supporting documents........... 6
       2.4.3. Monograph on Polygoni avicularis herba and supporting documents .............. 6
       2.4.4. Monograph on Polygoni avicularis herba and supporting documents .............. 6
       2.4.5. Monograph on Rosae flos and supporting documents......................................... 6
       2.4.6. Monograph on Sideritis herba and supporting documents.................................... 6
   2.5. EU herbal monographs, list entries and public statements for final adoption ....... 7
       2.5.1. Monograph on Cnici benedicti herba and supporting documents....................... 7
   2.6. EU herbal monographs, list entries and public statements for adoption for release for public consultation ................................................................. 7
       2.6.1. Monograph on Cisti cretici herba and supporting documents - postponed............... 7
   2.7. EU herbal monographs, list entries and public statements - post finalisation ....... 7

3. Referral procedures ........................................................................................................... 7

4. Guidelines and guidance documents ............................................................................... 7
   4.1. Non-clinical/clinical safety and efficacy and multidisciplinary......................... 7
   4.2. Quality....................................................................................................................... 7
       4.2.2. Q&A on quality of herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/41500/2010) ........................................................................................................ 7
   4.3. Regulatory / Procedural ............................................................................................. 8
4.3.1. Procedure for the preparation of Monographs/List Entries (EMA/HMPC/887331/2022) ........ 8
4.3.2. Reflection paper on data recommendations for (T)HMPs used in children and adolescents... 8
4.3.3. Template for Assessment report for the development of EU herbal monographs and EU list entries (EMA/HMPC/418902/2005) .............................................................................. 8
4.3.4. Questions & Answers on the EU framework for (traditional) herbal medicinal products, including those from a 'non-European' tradition (EMA/HMPC/402684/2013) ...................... 8
4.4. Report on HMPC Drafting Groups activities .............................................................................. 8
  4.4.1. ORGAM DG ................................................................. 8
  4.4.2. Quality DG - report ........................................................................................................ 8
  4.4.3. Quality DG – 3-year work plan .................................................................................... 8
5. Organisational, regulatory and methodological matters 9
  5.1. Mandate and organisation of the HMPC ................................................................. 9
    5.1.1. Strategic Review and Learning Meetings (SRLM) ....................................................... 9
    5.1.2. HMPC membership ............................................................................................... 9
    5.1.3. Preparation of nomination and appointment of Co-opted members ....................... 9
    5.1.4. General update on RWD/RWE projects at EMA ..................................................... 9
  5.2. EMA Scientific Committees or CMDh-v .............................................................................. 9
    5.2.1. Scientific Coordination Board Meeting................................................................... 9
  5.3. Coordination with EMA Working Parties/Working Groups/Drafting Groups .......... 9
  5.4. Cooperation within the EU regulatory network ..................................................... 10
    5.4.1. Coordination with European Pharmacopoeia ......................................................... 10
  5.5. Cooperation with International Regulators ........................................................................ 10
  5.6. Contacts of the HMPC with external parties and interaction with the Interested Parties to the Committee ................................................................. 10
    5.6.1. Association of the European Self-Medication Industry (AESGP) – request for a hearing in November 2023 ........................................................... 10
  5.7. Work plan and related activities .................................................................................. 10
    5.7.1. HMPC work plan 2023 .......................................................................................... 10
  5.8. Planning and reporting ............................................................................................. 10
    5.8.1. HMPC meeting organisation 2024 ........................................................................ 10
  5.9. Legislation and regulatory affairs .............................................................................. 10
  5.10. Questions from members .......................................................................................... 11
    5.10.1. Query from Slovenia NCA - THMP with vitamins/minerals .................................. 11
6. EU herbal monographs and list entries in preparation 11
  6.1. Revision of EU herbal monographs and list entries in preparation for adoption after public consultation ......................................................................................................................... 11
    6.1.1. Monograph and List Entry on Foeniculi amari fructus and supporting documents .... 11
    6.1.2. Monograph and List Entry on Foeniculi dulcis fructus and supporting documents .... 11
    6.1.3. Public Statement on Foeniculi amari fructus aetheroleum and supporting documents .... 11
    6.1.4. Monograph on Hippocastani cortex and supporting documents .......................... 11
<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.1.5.</td>
<td>Monograph on Rosmarini aetheroleum and supporting documents</td>
<td>11</td>
</tr>
<tr>
<td>6.1.6.</td>
<td>Monograph on Rosmarini folium and supporting documents</td>
<td>11</td>
</tr>
<tr>
<td>6.2.</td>
<td>Revision of EU herbal monographs and list entries in preparation for public consultation</td>
<td>12</td>
</tr>
<tr>
<td>6.2.1.</td>
<td>Monograph on Eucalypti aetheroleum and supporting documents - postponed</td>
<td>12</td>
</tr>
<tr>
<td>6.2.2.</td>
<td>Monograph on Lavandulae aetheroleum and supporting documents</td>
<td>12</td>
</tr>
<tr>
<td>6.2.3.</td>
<td>Monograph on Urticae herba and supporting documents</td>
<td>12</td>
</tr>
<tr>
<td>6.2.4.</td>
<td>Monograph on Urticae radix and supporting documents</td>
<td>12</td>
</tr>
<tr>
<td>6.3.</td>
<td>Review of EU herbal monographs and list entries in preparation for decision on revision</td>
<td>12</td>
</tr>
<tr>
<td>6.3.1.</td>
<td>Monograph on Fragariae folium and supporting documents</td>
<td>12</td>
</tr>
<tr>
<td>6.3.2.</td>
<td>Monograph on Malvae sylvestris flos and supporting documents</td>
<td>12</td>
</tr>
<tr>
<td>6.3.3.</td>
<td>Monograph on Malvae folium and supporting documents</td>
<td>12</td>
</tr>
<tr>
<td>6.3.4.</td>
<td>Monograph on Matricariae aetheroleum and supporting documents</td>
<td>12</td>
</tr>
<tr>
<td>6.3.5.</td>
<td>Monograph on Symphyti radix and supporting documents</td>
<td>12</td>
</tr>
<tr>
<td>6.4.</td>
<td>EU herbal monographs and list entries in preparation for adoption after public consultation</td>
<td>13</td>
</tr>
<tr>
<td>6.5.</td>
<td>EU herbal monographs and list entries in preparation for adoption for release for public consultation</td>
<td>13</td>
</tr>
<tr>
<td>6.5.1.</td>
<td>Monograph on Cannabis flos and supporting documents</td>
<td>13</td>
</tr>
<tr>
<td>6.5.2.</td>
<td>Monograph on Hyperici herba/Cimicifugae rhizoma and supporting documents</td>
<td>13</td>
</tr>
<tr>
<td>6.5.3.</td>
<td>Monograph on Pruni cerasi stipites and supporting documents</td>
<td>13</td>
</tr>
<tr>
<td>6.5.4.</td>
<td>Monograph on Species pectoralis and supporting documents</td>
<td>13</td>
</tr>
<tr>
<td>6.5.5.</td>
<td>Public Statement on Tribuli terrestris herba and supporting documents</td>
<td>13</td>
</tr>
<tr>
<td>7.</td>
<td>Any other business</td>
<td>13</td>
</tr>
<tr>
<td>7.1.</td>
<td>Topics for discussion</td>
<td>13</td>
</tr>
<tr>
<td>7.1.1.</td>
<td>Workshop on RWD/RWE for HMPs in children, Bonn, 19 June 2023</td>
<td>13</td>
</tr>
<tr>
<td>7.1.2.</td>
<td>Society for Medicinal Plant Research (GA) conference Dublin, 03-05 July 2023</td>
<td>13</td>
</tr>
<tr>
<td>7.1.3.</td>
<td>Update common names list</td>
<td>14</td>
</tr>
<tr>
<td>7.2.</td>
<td>Documents for information</td>
<td>14</td>
</tr>
<tr>
<td>7.2.1.</td>
<td>HMPC</td>
<td>14</td>
</tr>
<tr>
<td>7.2.2.</td>
<td>Assessment Report Summary for the Public (ARSP)</td>
<td>14</td>
</tr>
<tr>
<td>7.2.3.</td>
<td>Other</td>
<td>14</td>
</tr>
</tbody>
</table>
1. **Introduction**

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

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the HMPC plenary session to be held on 18-20 September 2023. See September 2023 HMPC minutes (to be published post November 2023 HMPC meeting).

1.2. **Adoption of agenda**

HMPC agenda for 18-20 September 2023.

**Action:** For adoption

1.3. **Adoption of the minutes**

HMPC minutes for 17-19 July 2023.

**Action:** For adoption

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 September 2023**

Report: HMPC Chair

**Action:** For discussion

Document tabled: Overview

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

None

2.1.3. **Request for unscheduled review on Sennae folium and Sennae fructus**

Rapporteur: HMPC Chair

**Action:** For discussion

Documents tabled: Email; Request for revision

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 - postponed

2.3.2. Monograph on Pelargonii radix and supporting documents

**Action:** For adoption
Documents tabled: MO, AR, LoR, Reader’s Guidance

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

2.4.1. Monograph on Ononis radix and supporting documents

**Action:** For adoption
Documents tabled: Review report; References 42/12

2.4.2. Monograph on Pilosellae herba cum radice and supporting documents

**Action:** For adoption
Documents tabled: Review report; References 0/0

2.4.3. Monograph on Polygoni avicularis herba and supporting documents

**Action:** For adoption
Documents tabled: Review report; References 05/05

2.4.4. Monograph on Pruni africanae cortex and supporting documents

**Action:** For adoption
Documents tabled: Review report, Reader’s Guidance, References 02/02

2.4.5. Monograph on Rosae flos and supporting documents

**Action:** For adoption
Document tabled: Review report, Reader’s Guidance, References 04/03

2.4.6. Monograph on Sideritis herba and supporting documents

**Action:** For adoption
Documents tabled: Review report, Reader’s Guidance, References 03/03
2.5. **EU herbal monographs, list entries and public statements for final adoption**

2.5.1. **Monograph on Cnici benedicti herba and supporting documents**

**Action:** For adoption

Documents tabled: Draft MO, AR, LoR

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**

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 (EMEA/HMPC/107079/2007)**

**Action:** For discussion

Document tabled: Concept paper, Oral report

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

Documents tabled: Draft revised guideline, OoC

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

**Action:** For adoption

Document tabled: Draft revised Q&A (Rev.7)
4.3. **Regulatory / Procedural**

4.3.1. **Procedure for the preparation of Monographs/List Entries**
(EMA/HMPC/887331/2022)

**Action:** For discussion
Document tabled: Draft Procedure for the preparation of MO and LE

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

**Action:** For discussion
Documents tabled: Draft reflection paper; Draft Annex: ‘Therapeutic areas for adolescents and children for traditional use (TU)’

4.3.3. **Template for Assessment report for the development of EU herbal monographs and EU list entries**
(EMA/HMPC/418902/2005)

**Action:** For discussion
Document tabled: Draft revised AR template

4.3.4. **Questions & Answers on the EU framework for (traditional) herbal medicinal products, including those from a ‘non-European’ tradition**
(EMA/HMPC/402684/2013)

Report: HMPC Chair

**Action:** For adoption
Document tabled: Draft revised Q&A (Rev.1)

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

4.4.1. **ORGAM DG**

None

4.4.2. **Quality DG - report**

Report: Nicoleta Carmen Purdel

**Action:** For information
Document tabled: Minutes

4.4.3. **Quality DG – 3-year work plan**

**Action:** For adoption
Document tabled: Draft work plan
5. **Organisational, regulatory and methodological matters**

5.1. **Mandate and organisation of the HMPC**

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

- HMPC SRLM Follow up plan - status September 2023
  
  Report: HMPC Chair

  **Action:** For information

  Document tabled: Follow-up plan

- Spanish Presidency meeting – 09-10 October 2023
  
  Report: Olga Palomino

  **Action:** For discussion

  Document tabled: Draft agenda

5.1.2. **HMPC membership**

  Report: HMPC Chair

  **Action:** For information

5.1.3. **Preparation of nomination and appointment of Co-opted members**

  Report: HMPC Chair

  **Action:** For discussion

  Document tabled: Procedure for the nomination and appointment of co-opted members of the CHMP, CVMP and HMPC, presentation

5.1.4. **General update on RWD/RWE projects at EMA**

  **Action:** For discussion

  Document tabled: Presentation

5.2. **EMA Scientific Committees or CMDh-v**

5.2.1. **Scientific Coordination Board Meeting**

  Report: HMPC Chair

  **Action:** For information

  Documents tabled: Agenda 15 September 2023, Minutes 26 June 2023

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**

None

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**

Report: HMPC Chair

**Action:** For discussion

Document tabled: Email

5.7. **Work plan and related activities**

5.7.1. **HMPC work plan 2023**

Report: HMPC Chair

**Action:** For discussion

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

- (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

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

  Document tabled: Draft-The role of MO and AR in relationship to borderline issues

  **Action:** For discussion

5.8. **Planning and reporting**

5.8.1. **HMPC meeting organisation 2024**

Report: HMPC Chair

**Action:** For information

Document tabled: Email

5.9. **Legislation and regulatory affairs**

None
5.10. **Questions from members**

5.10.1. **Query from Slovenia NCA - THMP with vitamins/minerals**

**Action:** For discussion  
Documents tabled: Email, presentation

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 and List Entry on Foeniculi amari fructus and supporting documents**

**Action:** For 3rd discussion  
Documents tabled: Draft MO, LE, AR, LoR, OoC, Reader’s Guidance

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

**Action:** For 3rd discussion  
Documents tabled: Draft MO, LE, AR, LoR, OoC, Reader’s Guidance

6.1.3. **Public Statement on Foeniculi amari fructus aetheroleum and supporting documents**

**Action:** For 3rd discussion  
Documents tabled: Draft PS, AR, LoR, OoC, Reader’s Guidance

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

**Action:** For 1st discussion  
Documents tabled: Draft MO, AR, LoR, Reference

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

**Action:** For 2nd discussion  
Documents tabled: Draft MO, AR, OoC

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

**Action:** For 2nd discussion  
Documents tabled: Draft MO, AR
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 - postponed

6.2.2. Monograph on Lavandulae aetheroleum and supporting documents

**Action:** For 12th discussion  
Documents tabled: Draft MO, AR, LoR, Reader’s Guidance, General comments, References

6.2.3. Monograph on Urticae herba and supporting documents

**Action:** For 4th discussion  
Documents tabled: Draft MO, AR, LoR

6.2.4. Monograph on Urticae radix and supporting documents

**Action:** For 2nd discussion  
Documents tabled: Draft MO, AR, LoR, Reader’s Guidance

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

6.3.1. Monograph on Fragariae folium and supporting documents

**Action:** For 1st discussion  
Document tabled: Review report

6.3.2. Monograph on Malvae sylvestris flos and supporting documents

**Action:** For 1st discussion  
Document tabled: Review report

6.3.3. Monograph on Malvae folium and supporting documents

**Action:** For 1st discussion  
Document tabled: Review report

6.3.4. Monograph on Matricariae aetheroleum and supporting documents

**Action:** For 1st discussion  
Document tabled: Review report

6.3.5. Monograph on Symphyti radix and supporting documents

**Action:** For 2nd discussion  
Document tabled: Review report
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 Cannabis flos and supporting documents

**Action:** For 1st discussion

Document tabled: Presentation

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

**Action:** For 7th discussion

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

6.5.3. Monograph on Pruni cerasi stipites and supporting documents

**Action:** For 1st discussion

Documents tabled: Draft MO, AR, LoR

6.5.4. Monograph on Species pectoralis and supporting documents

**Action:** For 1st discussion

Document tabled: Presentation

6.5.5. Public Statement on Tribuli terrestris herba and supporting documents

**Action:** For 5th discussion

Documents tabled: Draft PS, AR, LoR, Reader’s Guidance

7. **Any other business**

7.1. **Topics for discussion**

7.1.1. Workshop on RWD/RWE for HMPs in children, Bonn, 19 June 2023

Report: HMPC Chair

**Action:** For discussion

Document tabled: Oral report

7.1.2. Society for Medicinal Plant Research (GA) conference Dublin, 03-05 July 2023

Report: HMPC Vice-Chair

**Action:** For discussion
7.1.3. **Update common names list**

**Action:** For discussion

Document tabled: Oral presentation

7.2. **Documents for information**

7.2.1. **HMPC**

- Table of Decisions from HMPC meeting held on 17-19 July 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)**

On hold

7.2.3. **Other**

- Meeting Summary – PCWP and HCPWP - 27 and 28 June 2023
- Draft Agenda – PCWP and HCPWP Joint meeting - 19 and 20 September 2023
- New process to submit requests for MWP input
- New voting system – Test voting