



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products

## HMPC work plan

2021 – adopted by the Committee on 13 January 2021

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***The activities outlined in the HMPC work plan for 2021 have been agreed taking into consideration the Agency's prioritisation set forth in the EMA multi-annual work programme 2021-2023.***

# 1. Evaluation activities for herbal medicines for human use

## 1.1. Establishment and update of EU herbal monographs and list entries

The HMPC provides scientific opinions on questions relating to herbal medicines. Its mandate as defined in Reg. (EC) No 726/2004 and Dir. 2001/83/EC is to establish European Union herbal monographs for traditional and well-established use herbal medicines, and to draft entries to the European Union list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products. Monographs and list entries as prepared by the Agency facilitate granting nationally traditional use registrations and well established use marketing authorisations for herbal medicines, allowing them to be placed onto the EU market.

### Key objectives and activities in 2021

Detailed objectives as regards new draft and final monographs and list entries as well as monograph and list entry reviews and revisions are outlined in **Annex 1**.

### Workload indicators

|                               | Forecast |
|-------------------------------|----------|
| Herbal monographs, new*       | 5        |
| Herbal monographs, reviewed** | 22       |
| Herbal monographs, revised    | 3        |
| List entries                  | 1        |

\* when the assessment does not lead to the establishment of a monograph, a public statement is prepared

\*\* when after review of new data no change in monograph/LE is required, an addendum to the existing assessment report is published

## 1.2. Establishment and update of guidance documents

The Committee develops scientific and regulatory guidance to support industry and National Competent Authorities in the national evaluation of herbal medicinal products according to harmonised European standards as well as procedural guidance to support establishment of herbal monographs and list entries.

### Key objectives and activities in 2021

Key objectives and activities for the development of new scientific, regulatory and procedural guidance or revision of existing guidance documents are outlined in **Annex 2**.

## 1.3. Other specialised areas and activities

### 1.3.1. Working methodology adaptations for herbal monograph and guideline establishment and maintenance

#### Key objectives

Implement an improved working methodology for drafting EU herbal monographs and herbal guidance documents for HMPC assessment

#### Activities in 2021

- Implementation of a HMPC Plenary Best Practice Guide for effective preparation and discussion
- Adapting working methodology for standard processes at the committee and for solution of specific questions using the support of smaller expert groups in line with a modified subgroup architecture strengthening the link to relevant expert communities and other working groups
- Use the SRLM under Portuguese EU Presidency (March 2021) to discuss implementation and best practices in line with modified architecture

HMPC topic leader: HMPC Chair

Other Committee participants:

| Member/alternate | Name         | Member State |
|------------------|--------------|--------------|
| HMPC Vice Chair  | E. Svedlund  | SE           |
| Member           | A.P. Martins | PT           |
| Member           | B. Razinger  | SI           |
| Member           | I. Chinou    | EL           |

### **1.3.2. Improved use of data sources for HMPC relevant safety assessments: PhV data and experiences in national assessments**

#### **Key objectives**

To implement a modernised approach for data collection and analysis for the safety assessment of herbal substances in the context of monograph establishment to support the safe use of (T)HMPs on the EU market.

#### **Activities in 2021**

- Implement the outcome of the pilot phase on how to use available safety data from pharmacovigilance tools (e.g. signal detection, PSUR assessments) to amend the procedure on systematic review/revisions and establishment of new monographs by updating data search and presentation with support of PhV experts at NCA level and explore future coordination with PRAC where appropriate
- Update regularly new information on national experiences with HMPC monographs at NCAs and during MRP/DCP procedures and implement its use by Rapporteurs during systematic review and revisions
- Adapt respective templates (assessment report, review reports) and introduce brief training sessions for HMPC Rapporteurs

HMPC topic leader: Vice Chair

Other Committee participants:

| Member/alternate | Name           | Member State |
|------------------|----------------|--------------|
| Member           | Z. Biró-Sandor | HU           |
| Member           | C. Purdel      | RO           |
| Member           | R. Laenger     | AT           |
| Member           | A. Assisi      | IT           |

### **1.3.3. Improved use of data sources for HMPC relevant safety assessments: Use of real-world data and requirements for the safe use of herbal substances in children**

#### **Key objectives**

In absence of sufficient clinical study data develop a common understanding for the interpretation of PhV and usage data from products on the market for safety assessments for children in order to harmonise practice for HMPC monographs and streamline discussions on specific cases

#### **Activities in 2021**

- Develop a discussion paper for principles to be applied for data requirements and possible extrapolations to accept the use in children for TU versus WEU in different therapeutic areas
- Update the pediatric use overview of HMPC conclusions on paediatric use within EU herbal monographs for practical use by medical doctors and patients and check possibility for a modernised use-friendly format for stakeholders
- Explore the possibility for improved interaction with PDCO to coordinate specific questions on paediatric use of marketed herbal substances (e.g. joint expert group for consultation)

HMPC topic leader: M. H. Pinto Ferreira (Co-opted General / Family medicine)

Other Committee participants:

| Member/alternate | Name           | Member State    |
|------------------|----------------|-----------------|
| Member           | M. Petrikova   | SK              |
| PDCO member      | P. Šišovský    | SK              |
| Member           | J. Wiesner     | DE              |
| Co-opted Member  | H. Foth        | Toxicology (DE) |
| Member           | Z. Biró-Sandor | HU              |

### 1.3.4. Forward planning and prioritisation

#### Key objectives

Identify and prioritise herbal substances, preparations and combinations in medicinal use by European citizens for which monographs are useful as basis for national assessments of medicinal products.

#### Activities in 2021

- Establish essential information and acceptance criteria for validation before adding new substances to the HMPC work programme and adapt templates and procedural guidance accordingly
- Update HMPC Work programme (priority list). After informed decision by HMPC, add 3-5 new substances in 2021 taking into account resources and BCP. Propose important substances for the next 3 years in preparation of work plans 2022 and 2023.
- Review the concept of combination monographs, clarify their use for stakeholders in specific Q&As and identify most used candidates to facilitate national assessments

HMPC topic leader: HMPC Vice Chair

Other Committee participants:

| Member/alternate | Name             | Member State                              |
|------------------|------------------|---|
| Co-opted Member  | G. Laekeman      | Experimental / Clinical pharmacology (BE) |
| Alternate        | H. Kuin          | NL  |
| Member           | Z. Biro - Sandor | HU  |
| Expert           | O.M. Palomino    | ES  |

## 2. Horizontal activities and other areas

### 2.1. Partners and stakeholders

#### 2.1.1. Support EC regarding terms, definitions and standards related to regulation of Cannabis-derived products for medicinal use

#### Key objectives

Establish a list of definitions with expert comments to comply with the request of the European Commission and explore the feasibility for a EU Herbal monograph for Cannabis flos

#### Activities in 2021

HMPC activities to achieve the objectives set for this area:

- Finalise an Inventory List of Terms and Definitions for Cannabis related products for the EC
- Coordinate with EDQM to clarify scope of Ph. Eur. monographs in relation to possible EU herbal monographs and publish a Call for data tailored to the complexity of cannabis derived substances
- Prepare specific Q&A as required for some basic information regarding so called 'medicinal cannabis' regulation

HMPC topic leader: A. P. Martins (PT)

Other Committee participants:

| Member/alternate | Name        | Member State |
|------------------|-------------|--------------|
| Member           | B. Razinger | SI           |
| Member           | B. Kroes    | NL           |
| Member           | J. Wiesner  | DE           |
| Member           | I. Chinou   | EL           |

### ***2.1.2. Training on assessment of applications for herbal medicinal products***

#### **Key objectives**

Update the herbal product specific curriculum for herbal assessors at NCAs in the framework of the European network training centre activities

#### **Activities in 2021**

- Development and delivery of trainings in the identified high priority areas of the herbal curriculum
- Include additional trainings in the herbal product specific curriculum already available in the EU NTC LMS and of relevance for herbal assessors

HMPC topic leader: Vice Chair

Other Committee participants:

| Member/alternate | Name       | Member State |
|------------------|------------|--------------|
| Member           | J. Wiesner | DE           |
| Member           | R. Länger  | AT           |
| Member           | C. Purdel  | RO           |
| Member           | B. Kroes   | NL           |

# Annex 1: EU herbal monographs/list entries

Planned new assessments, reviews and revisions in 2021<sup>1</sup>

## 1. New EU herbal monographs and list entries

The following herbal substances and preparations thereof shall be assessed with a view to publishing<sup>2</sup> an EU herbal monograph or EU herbal monograph and list entry. When no monograph can be established, a public statement<sup>3</sup> will be published.

### 1.1. For finalisation

- Aloysiae citriodoraefolium
- Menyanthidis trifoliataefolium

### 1.2. Draft to be released for public consultation

- Andrographidis paniculataefolium
- Centellae asiaticae herba
- Cisti cretici folium
- Saccharomyces cerevisiae CBS 5926
- Salviae miltiorrhizae radix et rhizoma
- Species digestivae / stomachicae
- Taraxaci radix
- Vaccinii macrocarpi fructus

### 1.3. Assessment to be started

- Cnici benedicti herba
- Combination: Cimicifugae rhizoma/ Hyperici herba
- (1-3 other proposed substances according to validation and agreement of proposals)

## 2. Review and revision of final EU herbal monographs and list entries<sup>4</sup>

The review of the following herbal substances and preparations thereof is to be initiated and/or finalised due to time elapsed since the previous published version (Periodic review) or due data submitted to HMPC at any time (Unscheduled review).

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<sup>1</sup> Disclaimer: The activities outlined in the HMPC work plan for 2021 have been agreed taking into consideration the Agency's prioritisation set forth in the EMA multi-annual work programme 2021-2023

<sup>2</sup> See 'Timelines for establishment of Community list entries and Community herbal monographs' (EMA/HMPC/126542/2005 Rev. 2)

<sup>3</sup> See 'Procedure on the publication of HMPC public statements when Community herbal monographs on herbal substances, preparations and/or combinations thereof are not established' (EMA/HMPC/84530/2010)

<sup>4</sup> See Procedure for the review and revision of European Union herbal monographs and European Union list entries (EMA/HMPC/124695/2011 Rev.2)



## **2.1. *Unscheduled review***

- According to request by IPs or NCAs and data submitted

## **2.2. *Periodic review***

### **2.2.1. Periodic reviews to be finalised**

- Cinnamomi cortex
- Cinnamomi corticis aetheroleum
- Colae semen
- Fumariae herba
- Mate folium
- Rosmarini aetheroleum
  
- Rosmarini folium
- Sabalis serrulatae fructus
- Solidaginis virgaureae herba
- Urticae folium
- Urticae herba
- Viola tricoloris herba
- Zingiberis rhizoma

### **2.2.2. Periodic reviews to be started**

- Arnicae flos
- Camelliae sinensis non fermentatum folium
- Cichorii intybi radix
- Cucurbitae semen
- Curcumae xanthorrhizae rhizoma
- Eucalypti aetheroleum
  
- Eucalypti folium
- Fraxini folium
- Fucus vesiculosus
- Ginseng radix
- Grindeliae herba
- Hippocastani cortex
  
- Juglandis folium
- Levistici radix
- Lichen islandicus
- Liquiritiae radix
- Marrubii herba

- Origani dictamni herba
- Paullinae semen
- Plantaginis lanceolatae folium
- Rhodiolae roseae rhizoma et radix
- Thymi herba
- Tiliae flos
- Urticae radix

## **2.3. Revision**

### **2.3.1. Revisions to be finalised**

- Hyperici herba
- Orthosiphonis folium

### **2.3.2. Draft revisions to be released for public consultation**

- Agropyri repentis rhizoma
- Foeniculi amari fructus
- Foeniculi amari fructus aetheroleum
- Foeniculi dulcis fructus
- Juniperi pseudo-fructus
- Lavandulae aetheroleum
- Pelargonii radix
- Trigonellae foenugraeci semen

### **2.3.3. Revisions to be started**

According to review outcome – see 2.2.

## Annex 2: Guidance and procedural documents

Planned new or revised scientific, regulatory and procedural guidance documents in 2021<sup>5</sup>

### 1. Scientific guidelines (new or update/revision)

#### 1.1. For finalisation in 2021

- Public statement on the **use of herbal medicinal products containing toxic, unsaturated pyrrolizidine alkaloids (PAs)** including recommendations regarding contamination with PAs (EMA/HMPC/893108/2011)

*Action: Consider comments from public consultation, coordinate with SWP/CHMP and EDQM, finalise combined and updated PS for direction for industry and NCAs (May 2021 = end of transition period)*

- Revision of the Guideline on **quality of herbal medicinal products** (EMA/HMPC/201116/2005)

*Action: Finalise the revised guideline after public consultation ended Nov 2018*

- Revision of the Guideline on **specifications: test procedures and acceptance criteria for herbal substances**, herbal preparations and HMP/THMPs – (EMA/HMPC/162241/2005)

*Action: Finalise the revised guideline after public consultation ended Nov 2018*

#### 1.2. Draft to be released for public consultation in 2021

No new or revised guidance documents are currently foreseen to be released for public consultation in 2021.

#### 1.3. To be started in 2021 (for 2022-2023)

- Guideline on Good Agricultural and Collection Practice (**GACP**) of starting materials of herbal origin (EMA/HMPC/246816/2005)

*Action: Draft a Concept paper for revision to address stakeholder requests on required update/clarifications (demarcation/overlap GMP vs. GACP, diverse practice in MSs, uncertainty about requirements, certification and dossier, comparison to other GACP standards such as WHO)*

- Update/revision of **Questions & answers on quality of herbal medicinal products** (EMA/HMPC/41500/2010)

*Action: Remove Q&A now addressed in revised guidelines and add new ones collected/answered during past HMPC assessors' trainings and meetings (incl. on skip testing, stability, GACP/GMP, assay and microbiological issues)*

- Guideline on **Assessment of genotoxicity of herbal substances/preparations** (EMA/HMPC/107079/2007)

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<sup>5</sup> Disclaimer: The activities outlined in the HMPC work plan for 2021 have been agreed taking into consideration the Agency's prioritisation set forth in the EMA multi-annual work programme 2021-2023

*Action: Draft a Concept paper for revision of the outdated guideline for adaptation to other HMPC, EMA and ICH guidance (coordination within non-clinical domain) and recent developments in assessment models and data analysis*

## **2. Regulatory or procedural guidance**

### **2.1. For finalisation in 2021**

- **Addendum to the Quality Review of Documents templates** for SmPC, Labelling and Patient Leaflet on Mutual-recognition and Decentralised procedures specific for (Traditional) Herbal Medicinal Products ((T)HMPs) (CMDh/349/2016, Rev.0 - EMA/HMPC/770889/2014)

*Action: Update Addendum to QRD template specific for traditional herbal medicinal products for use in MRP/DCP procedures and coordinate with QRD and CMDh*

### **2.2. Draft to be released for public consultation in 2021**

No new or revised guidance documents, procedures or templates are currently foreseen to be released for public consultation in 2021.

### **2.3. To be started in 2021**

- Update the **HMPC Review and Revision Best Practice Guides**, HMPC Assessment Report and Review Report templates

*Action: Modify relevant documents (EMA/HMPC/433002/2017 and EMA/HMPC/287394/2009 Rev.4). in accordance with experience gained and new assessment practice in order to ameliorate instructions for HMPC Rapporteurs, streamline procedures and improve the quality of the documents*