EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

31 January 2024
EMA/HMPC/512506/2023
Human Medicines Division

Committee on Herbal Medicinal Products (HMPC): Work Plan 2024

Adopted by the Committee on 31 January 2024

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The activities outlined in the HMPC work plan for 2024 have been agreed taking into consideration the Agency's prioritisation set forth in the EMA multi-annual work programme 2023-2025.

1. Evaluation activities for human medicines

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

The HMPC provides scientific opinions on questions relating to herbal medicinal products. Its mandate as defined in Regulation (EC) No 726/2004 and Directive 2001/83/EC, as amended by Directive 2004/24/EC, is to establish EU herbal monographs for traditional and well-established use of herbal substances/preparations, and to draft entries to the EU list of herbal substances/preparations and combinations thereof for use in traditional herbal medicinal products. Monographs and list entries as prepared by the Committee facilitate granting nationally traditional use registrations and well-established use marketing authorisations for herbal medicinal products, allowing them to be placed onto the EU market.

Key objectives and activities in 2024

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 2024
Herbal monographs, new*	3
Herbal monographs, reviewed**	24
Herbal monographs, revised	5
List entries, revised	2

* 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/list entry is required, an addendum to the existing assessment report is published

1.2. Establishment of guidance documents

The Committee develops scientific and regulatory guidance to support pharmaceutical industry and national competent authorities (NCAs) in the national evaluation of herbal medicinal products according to harmonised European standards as well as procedural guidance to support establishment of EU herbal monographs and list entries.

Key objectives and activities in 2024

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. Improved evaluation of data from paediatric clinical practice for the safe use of herbal substances in children

In absence of sufficient clinical study data, develop a common understanding for the interpretation of clinical practice from herbal medicinal products on the market for conclusions of the HMPC on acceptable indications for children in order to harmonise practice for EU herbal monographs and streamline discussions on specific cases. In 2024, cooperation with the Paediatric Committee (PDCO) will be initiated on criteria and the use of available data for most likely therapeutic areas herbal medicinal products which are used in different children age groups. Available scientific data will be evaluated both according to requirements for well-established use (WEU) and for traditional use (TU). In collaboration with PDCO the dialogue with external stakeholders will be started in 2024 to look for perspectives of new data resources for the use in children, including RWD/RWE.

Key objectives

- Improve the HMPC's WEU and TU assessments for children in order to harmonise practice for EU herbal monographs.
- Strengthen **cooperation with PDCO** for specific questions on paediatric use of marketed herbal medicinal products.

Activities in 2024

HMPC activities to achieve the objectives set for this area:

- Establish experts exchange on **HMPC reflection paper** for principles to be applied for data requirements and possible extrapolations to evaluate the use in children for TU versus WEU in different therapeutic areas.
- Initiate expert exchange considering an *ad hoc* joined expert group with PDCO on specific questions as well as including experts of academia and scientific societies at a next stage.
- Start a pilot within the EMA's RWD/RWE project, to explore available data resources for the use in children's age groups of (traditional) herbal substances/preparations, if feasible.

HMPC topic leader: M. H. Pinto Ferreira (Co-opted member)

Other Committee participants:

Member/Alternate	Name	Member State
Member	I. Chinou	EL
PDCO member	P. Šišovský	SK
Member	J. Wiesner	DE

1.3.2. Development of further guidance on particulars for signal detection for (traditional) herbal medicinal products

Signal detection is the process of looking for and/or identifying signals using data from any source. This potentially includes all scientific information concerning the use of medicinal products and the outcome of the use, i.e., quality, non-clinical and clinical data. Common sources for signals include spontaneous reporting systems, active surveillance systems, studies and the scientific literature. Signal detection should follow a methodology which takes into account the nature of data and the characteristics (e.g., time on market, patient exposure, target population) as well as the type of medicinal product concerned. The 'Guideline on good pharmacovigilance practices (GVP) Module IX – Signal management' (EMA/827661/2011) provides general guidance and requirements on scientific and quality aspects of signal management. The addendum to this Module, the GVP Module IX Addendum I (EMA/209012/2015), describes methodological aspects of signal detection from spontaneous reports of suspected adverse reactions. In addition, the EMA scientific guidance on 'Screening for adverse reactions in EudraVigilance' (EMA/849944/2016) serve as a basis for EMA, NCAs and pharmaceutical industry for the guidance on methods of routine signal detection as used on EudraVigilance database together with the elements for their interpretation and their potential advantages and limitations in the frame of pharmacovigilance. For the moment, there are no particular considerations mentioned regarding (traditional) herbal medicinal products ((T)HMPs) in current guidelines.

Key objectives

- Develop further guidance on particulars for signal detection for (T)HMPs.

Activities in 2024

HMPC activities to achieve the objectives set for this area:

- Establish a draft document regarding particulars for signal detection for (T)HMPs.
- Start exchanging views with the Pharmacovigilance Risk Assessment Committee (PRAC).

HMPC topic leader: E. Svedlund (Vice-chair)

Other Committee participants:

Member/Alternate	Name	Member State
Member	J. Pallos	HU
Member	H. Kuin	NL

2. Horizontal activities and other areas

2.1. Committees and working parties

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

HMPC is responsible for compiling and assessing scientific data on herbal substances/preparations and combinations, to support the harmonisation of the European market for herbal medicinal products (HMPs). In order to support member states (MSs) in borderline issues, for products to be marketed under harmonised conditions in the EU and to ensure the protection of public health, EU herbal monographs and supporting assessment reports (ARs) could serve as guidance for MSs for the demarcation between medical devices, food supplements, cosmetics and HMPs (including traditional HMPs). In this aspect EU herbal monographs are already discussed in the Medical Device Coordination Group (MDCG) 2022 – 5 'Guidance on borderline between medical devices and medicinal products under Regulation (EU) 2017/745 on medical devices' (April 2022).

Key objectives

- Establish an HMPC position on EU herbal monographs and ARs in relation to borderline issues.

Activities in 2024

HMPC activities to achieve the objectives set for this area:

- Develop an HMPC position and start exchanging views with relevant EU bodies, where appropriate.
- Extend the exchange of views with the Heads of Medicines Agencies (HMA) EU-Innovation Network (EU-IN) - Borderline Classification Group (BLCG) and the European Directorate for the Quality of Medicines & HealthCare (EDQM) - Network of Experts on Borderline Products.

HMPC topic leader: E. Svedlund (Vice-chair)

Other Committee participants:

Member/alternate	Name	MS
Member	B. Razinger	SI
Member	A. P. Martins	PT
Member	A. Assisi	IT
Member	I. Chinou	EL

2.2. Partners and stakeholders

2.2.1. HMPC communication of information on herbal medicinal products to the public and stakeholders

The HMPC has an immense knowledge on the assessment of over 200 herbal substances/preparations mostly used in self-medication. Beyond the HMPC core task of monograph and guideline development, it is proposed to expand communication targeted to what the patients/consumers and healthcare professionals want to know on (T)HMPs. Sharing the knowledge on (T)HMPs with the Committee stakeholders in an informative and well-balanced manner can contribute to safer use of (T)HMPs, and an increased public health.

Key objectives

- Identify topics on which the external communication will focus and bring together similar initiatives already set up by regulatory agencies of MSs.
- Based on the outcome of the survey in 2023, establish elements for a communication initiative focused on patient's and healthcare professionals needs; what to communicate, in which form, to whom and identify the opportunities/limits for NCAs on one side and HMPC/EMA.
- Resume publication of Assessment Report Summary for the Public (ARSP) for new Herbal Monographs, and for revisions.

Activities in 2024

HMPC activities to achieve the objectives set for this area:

- Collect existing national initiatives in providing information on the safe use of (T)HMPs, especially information on interactions between (T)HMPs and regular medicinal products.
- Analyse the information collected towards a common feasible proposal for opportunities for improved presentation of HMPC assessments (monographs/guidance) to health practitioners and patients/consumers (communication formats, emphasis on safety and interactions of recently assessed substances).
- Revise the HMPC template for establishment of ARSP for EU herbal monographs.
- Explore opportunities (nationally and on the EMA website) to publish information on the differences between the different herbal products categories on the EU market to patients and other stakeholders in cooperation with relevant groups/bodies within and outside EMA.
- Develop selected practical proposals for a patient-focused communication regarding the safe use of herbal substances-preparations to present to the Patients and Consumers Working Party (PCWP) and Healthcare Professionals Working Party (HCPWP) in 2025.

HMPC topic leader: A. Lê

Member / Alternate	Name	Member State
Member	O. Palomino	ES
Co-opted member	M. Da Graça Campos	PT
Member	B. Razinger	SI
Chair	E. van Galen	NL

2.2.2. Training on assessment of applications for herbal medicinal products

Since 2019 the herbal curriculum within the EU Network Training Centre (EU-NTC) framework has started to be developed and end of 2023 five courses have been established and successfully held. Based on interest, participation and positive feedback, the extension of the curriculum is requested and planned, where possible in collaboration with EDQM on specific quality-topics.

Key objectives

- Extend the herbal product specific curriculum for assessors at NCAs in the framework of the EU-NTC activities.

Activities in 2024

HMPC activities to achieve the objectives set for this area:

- Continue the collaboration with EDQM for specific quality key topics of importance for assessors.
- Development and delivery of training(s) in the areas of the herbal curriculum, in particular, a training on the procedure for the preparation of EU herbal monographs and EU list entries and the AR template.

HMPC topic leader: E. Svedlund (Vice-chair)

Other Committee participants:

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

2.3. Process improvement

2.3.1. Enable better worksharing and facilitate broader participation of members in assessment tasks

For the core activities of HMPC, i.e., the assessment of data for the establishment (or review/revision) of EU herbal monographs/list entries, the majority of the work is carried out by a small active group of rapporteurs, supplemented by peer-reviewers. In this group, a high level of experience is centralised. This topic is aiming to come to a better system of worksharing in 2024, to ensure a better distribution of assessment tasks and to enhance the sharing and transfer of regulatory and scientific experience to the next generation of HMPC members.

Key objectives

- Implement a system of worksharing which is both feasible and practical and leads to more involvement of members in the assessment of data and/or peer-review.
- Develop a practice where members can apply to get involved in assessments on different levels, depending on their experience and available resources.
- Raise awareness at the HMA that an active participation in HMPC on behalf of NCAs is beneficial to maintain regulatory and scientific experience for the evaluation of (T)HMPs at national level.

Activities in 2024

HMPC activities to achieve the objectives set for this area:

- Establish common principles to extend worksharing and develop different levels of participation in the regular procedure of establishing EU herbal monographs/list entries, and the review/revisions thereof.
- Include not-yet-active members in new rapporteurships from Q2 on and implement this shared assessment responsibilities in Q3.
- Take initiatives to maximize resources for HMPC members to actively participate in herbal core tasks, at level of national agencies.
- Development and delivery of training on the procedure for the preparation of EU herbal monographs and EU list entries and the AR template, to facilitate for new rapporteurs and peer-reviewers.

HMPC topic leader: E. van Galen (Chair)

Other Committee participants:

Member/Alternate	Name	Member State
Vice-Chair	E. Svedlund	SE
Member	J. Wiesner	DE

Member	I. Chinou	EL
Member	C. Purdel	RO

Annex 1: EU herbal monographs/list entries

Planned new assessments, reviews and revisions in 2024[1]

1. New EU herbal monographs and list entries

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

1.1 For finalisation

- Cisti cretici folium
- Hyperici herba/Cimicifugae rhizoma
- Tribuli terrestris herba

1.2 Draft to be released for public consultation

- Cannabis flos
- Maydis stigma
- Pruni avium peduncle
- Species pectoralis

1.3. Assessment to be started

No new EU herbal monographs and list entries are currently foreseen to be started.

2. Review and revision of final EU herbal monographs and list entries[4]

The review of the following herbal substances/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).

2.1. Unscheduled review

According to request by Interested Parties or NCAs and data submitted.

[1] The activities outlined in the HMPC work plan for 2024 have been agreed taking into consideration the Agency's prioritisation set forth in the EMA multi-annual work programme 2023-2025.
[2] See 'Timelines for the establishment of a European Union herbal monograph and/or a European Union list entry' (EMA/HMPC/126542/2005 Rev.2 Corr.)
[3] 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 Rev.2)
[4] See 'Procedure for the review and revision of European Union herbal monographs and European Union list entries' (EMA/HMPC/124695/2011 Rev.3)

2.2. Periodic review

2.2.1. Periodic reviews to be finalised

- Allii sativi bulbus
- Lecithinum ex soya
- Malvae folium
- Malvae sylvestris flos
- Mastic (Mastix, Pistaciae lentisci resina)
- Matricariae aetheroleum
- Silybi mariani fructus
- Soiae oleum raffinatum
- Species diureticae
- Symphyti radix
- Thymi herba

2.2.2. Periodic reviews to be started

- Agni casti fructus
- Avenae fructus
- Avenae herba
- Boldi folium
- Calendulae flos
- Cimicifugae rhizoma
- Curcumae longae rhizoma
- Cynarae folium
- Echinaceae angustifoliae radix
- Echinaceae pallidae radix
- Echinaceae purpureae herba
- Echinaceae purpureae radix
- Gentianae radix
- Lini semen
- Lupuli flos
- Meliloti herba
- Melissae folium
- Myrrha
- Oenotherae oleum
- Oleae folium
- Plantaginis ovatae semen
- Plantaginis ovatae seminis tegumentum
- Polypodii rhizoma
- Ribis nigri folium
- Rusci rhizoma
- Sambuci flos
- Thymi herba/Primulae radix
- Uvae ursi folium
- Verbasci flos
- Vitis viniferae folium

2.3. Revision

2.3.1. Revisions to be finalised

- Foeniculi amari fructus
- Foeniculi amari fructus aetheroleum
- Foeniculi dulcis fructus
- Ginseng radix
- Pelargonii radix
- Rhodiolae roseae rhizoma et radix
- Rosmarini aetheroleum
- Rosmarini folium

2.3.2. Draft revisions to be released for public consultation

- Arnicae flos
- Crataegi folium cum flore
- Eucalypti aetheroleum
- Fragariae folium
- Ginkgo folium
- Lavandulae aetheroleum
- Liquiritiae radix
- Matricariae flos
- Ononidis radix
- Pilosellae herba cum radice
- Plantaginis lanceolatae folium
- Polygoni avicularis herba
- Urticae herba
- Urticae radix
- Zingiberis rhizoma

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 2024[5]

1. Scientific guidelines (new or update/revision)

1.1. For finalisation in 2024

QUALITY[6]:

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

Rapporteurs: ***QDG***

Actions: Draft the revised guideline taking into account the responses received on the concept paper; coordinate with Quality WP and domain/expert community before publication; publish for consultation.

• Guideline on the **declaration of herbal substances and herbal preparations** in herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/CHMP/CVMP/287539/2005)

Rapporteurs: ***QDG***

Actions: Draft the revised guideline taking into account the responses received on the concept paper; coordinate with Quality WP and domain/expert community before publication; publish for consultation.

1.2. Draft to be released for public consultation in 2024

NON-CLINICAL

• Guideline on the **assessment of genotoxicity** of herbal substances/preparations (EMEA/HMPC/107079/2007)

Rapporteurs: ***H Foth****, J Wiesner*

Actions: Draft the revised guideline taking into account the responses received on the concept paper; coordinate with non-clinical WP and domain/expert community before publication; publish for consultation.

[5] The activities outlined in the HMPC work plan for 2024 have been agreed taking into consideration the Agency's prioritisation set forth in the EMA multi-annual work programme 2023-2025.
[6] As foreseen in the three-year work plan 2024-2026 of the herbal Quality Drafting Group (QDG).

1.3. To be started in 2024

QUALITY[7]:

• Guidance on the **classification and the role of markers of medicinal products qualitative analysis** of herbal medicinal products and traditional herbal medicinal products

Rapporteurs: ***QDG***

Actions: Review the role of active and analytical markers taking into account regulatory practice; draft a discussion paper with proposals for better definitions vis-à-vis existing Ph. Eur. defined extract types (particularly quantified extracts).

• Guidance on **comparability** between herbal preparations

Rapporteurs: ***QDG***

Actions: Investigate the possibility to identify appropriate criteria; draft a concept paper.

2. Regulatory or procedural guidance

2.1. For finalisation in 2024

• Procedure for the **preparation of European Union herbal monographs and European Union list entries** and appointment of HMPC rapporteurs and peer-reviewers

Rapporteur: ***E. Svedlund,*** *C. Purdel, R. Länger, A. Lê, A. Assisi*

Action: Draft and publish new procedure summarising and replacing the following old procedures:

Procedure for the preparation of Community monographs for traditional herbal medicinal products (EMEA/HMPC/182320/2005 Rev. 2)

Procedure for the preparation of Community monographs for herbal medicinal products with well-established medicinal use (EMA/HMPC/182352/2005 Rev. 2)

Standard operating procedure on the establishment of European Union herbal monographs and European Union list entries and related documents (SOP/H/3163, first published 2009, last updated 2016)

Procedure for the preparation of an entry to the Community list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products' (EMA/HMPC/57137/2007)

Procedure for the Appointment by the HMPC of a rapporteur responsible for a scientific evaluation or the establishment of a Community herbal monograph and/or Community list entry (EMEA/HMPC/108877/2005)

Timelines for the establishment of a European Union herbal monograph and/or a European Union list entry (EMA/HMPC/126542/2005)

[7] As foreseen in the three-year work plan 2024-2026 of the herbal Quality Drafting Group (QDG).

• Template for **assessment report for the development of European Union herbal monographs and EU list entries** (EMEA/HMPC/418902/2005 Rev. 5)

*Rapporteur: **E Svedlund,** C. Purdel, M. Paile Hyvarinen*

Action: Draft and publish revised template

• Template for a **European Union herbal monograph** (EMEA/HMPC/107436/2005 Rev. 7)

*Rapporteur: **E Svedlund,** C. Purdel, M. Paile Hyvarinen*

Action: Draft and publish revised template.

2.2. Draft to be released for public consultation in 2024

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

2.3. To be started in 2024

No new or revised guidance documents, procedures or templates are currently foreseen to be started.