EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Human Medicines Division

HMPC work plan

2023- adopted by the Committee on 25 January 2023

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The activities outlined in the HMPC work plan for 2023 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 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 2023

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*	2
Herbal monographs, reviewed**	20
Herbal monographs, revised	6
List entries	1 (2 revised LEs)

* 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 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 2023

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 medicinal products on the market on acceptable indications for children in order to harmonise practice for HMPC monographs and streamline discussions on specific cases. After HMPC agreement, cooperation with PDCO is planned on criteria and possible extrapolations according to therapeutic indication and available well-established (WEU) or traditional use (TU) evidence. In a second project phase (2024), the dialogue with external stakeholders will be sought, and opportunities for improved access to data for herbal products used in children in analogy to RWD/RWE elements will be explored.

Key objectives

- Improve the HMPC's WEU and TU assessments for children in order to harmonise practice for HMPC monographs;
- After in depth analysis of previous practice agree at HMPC on future principles to be applied (2023);
- Establish expert exchange including *ad hoc* joined expert group with PDCO on specific questions (2023) and experts of Academia and Scientific societies (2024); check opportunities of modified applicability of RWD/RWE elements to improve access to usage data (2024).

Activities in 2023

HMPC activities to achieve the objectives set for this area:

- Establish experts exchange on **HMPC discussion 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.
- Improve **cooperation with the Paediatric Committee (PDCO)** for specific questions on paediatric use of marketed herbal substances, and explore input of PDCO in *ad hoc* joined expert group

HMPC topic leader: M. Horvath-Petrikova.

Other Committee participants:

Member / Alternate	Name	Member State
Co-opted	P Voitl	Paediatrics
PDCO member	P. Šišovský	SK
Co-opted	M. H. Pinto Ferreira	General / Family medicine
Member	J. Wiesner	DE

1.3.2. Harmonise the approach for the use of EU herbal monographs in the assessment of combination products

About a third of all herbal authorisations / registrations are on combination products and EU herbal monographs with one herbal active substance are widely used for the assessment of combinations. Beside an old Guideline on the clinical assessment of fixed herbal combinations (EMEA/HMPC/166326/2005) HMPC has, as guidance published so far, 2 fixed combination monographs and 4 herbal tea combination monographs. For the latter some flexibility is applied via ranges of traditionally used tea mixtures and the applied principles for monograph establishment are published in a Q&A only (R9 in EMA/HMPC/345132/2010 - Rev.5).

Key objectives

- Develop a harmonised view on how to use EU (mono and combi) herbal monographs in the assessment of herbal combination products, in order to facilitate the EU procedures for (T)HMP combination products (2024);
- Select relevant EU monographs related to fixed combination products with wide use on the market;
- Develop a harmonised view on the revision of the Guideline on the clinical assessment of fixed herbal combinations or incorporation of combination aspects into other existing guidance documents (2023)

Activities in 2023

HMPC activities to achieve the objectives set for this area:

- Establish a shortlist of fixed combination products with a long market presence in MSs suitable for MO establishment, for prioritisation (to be added to WP 2024-2025);
- Identify the need for additional procedural guidance for monograph establishment / principles in analogy to recently established Q&A on herbal tea combinations;
- Decide on the Revision of the guideline on the clinical assessment of fixed combinations of herbal substances / herbal preparations (EMEA/HMPC/166326/2005) or plan alternative.

HMPC topic leader: O. M. Palomino (ES)

Other Committee participants:

Member / Alternate	Name	Member State
Member	R. Länger	AT
Member	W. Dymowski	PL
Member	S. Kellaghan	IE
Member	J. Wiesner	DE

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 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 could serve as guidance for the demarcation between medical devices, food supplements, cosmetics and HMPs (including traditional HMPs). In fact, the EU herbal monographs are already discussed in the MDCG 2022 – 5 'Guidance on borderline between medical devices and medicinal products under Regulation (EU) 2017/745 on medical devices' (April 2022).

Although a product containing a herbal substance/preparation included in a EU herbal monograph is not automatically a medicinal product or a traditional HMP and EU herbal monographs carry legal value in the marketing authorisation/registration process only, compliance with the EU herbal monograph regarding product composition/preparation, dosage and therapeutic indication is a good indicator that a product may fall into the HMP definition.

Key objectives

- To elaborate on the possibility to establish and communicate a HMPC position on how EU herbal monographs and assessment reports could serve as guidance in borderline issues
- Increased harmonisation in the EU on product classification in the herbal area

Activities in 2023

HMPC activities to achieve the objectives set for this area:

- Organise a workshop during the Strategic Review and Learning Meeting
- Explore the possibility for collaboration with the EU-IN HMA Borderline Classification Group (BLCG) and EDQM Network of Experts of Borderline Products
- Explore the possibility to find a HMPC position on the usefulness of the information in EU herbal monographs and assessment report in borderline issues

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

2.2. Partners and stakeholders

2.2.1. Prepare a new Communication Initiative for HMPC stakeholders on herbal products

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 for what the patients/consumers and healthcare professionals want to know on herbal products. Sharing the knowledge on herbal medicinal products with HMPC stakeholders in an informative and well-balanced manner can contribute to safer use of herbal products, 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 Member States.
- Propose after survey and analysis key elements for a communication initiative focused on patient's needs; what to communicate, in which form, to whom and identify the opportunities/ limits for NCAs on one side and HMPC/EMA on the other for a possible start in 2024

Activities in 2023

HMPC activities to achieve the objectives set for this area:

- Compare existing national initiatives via a survey performed by project participants in selected MSs, in order to identify needs and experiences other than covered by previous HMPC initiatives for patient involvement;
- 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);
- Explore achievable opportunities (nationally and on the EMA website) to publish information on the differences between THMP, food supplements, medical devices and cosmetics to patients and other stakeholders in cooperation with relevant groups/bodies within and outside EMA;
- Summarise the information gathered into selected practical proposals for a patient-focused communication initiative to enhance public health and better medical practice and present to PCWP/ HCPWP before agreement on specific activities in 2024

HMPC topic leader: A. Lê

Other Committee participants:

Member / Alternate	Name	Member State
Member	O. Palomino	ES
Member	M. Da Graça Campos	Co-opted member
Member	E. Svedlund	SE
Member	B. Razinger	SI

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 2022 four courses have been established and successfully held. Based on interest, participation and positive feedback, the extension of the curriculum is requested and planned, including also now EDQM for quality-related topics.

Key objectives

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

Activities in 2023

HMPC activities to achieve the objectives set for this area:

- Collaboration with EDQM for specific quality key topics of importance for assessors (cross reference to work plan topic 2.3.1)
- Development and delivery of training(s) in the areas of the herbal curriculum

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 Laenger	AT
Member	B Kroes	NL

2.3. Process improvement

2.3.1. Implement new working methodology for HMPC following the reorganisation of EMA WPs/DGs

Adapt current working methodology for drafting EU herbal monographs and herbal guidance documents for HMPC assessment in the new architecture for WPs and DGs within the European medicines regulatory network and implement virtual meetings into working procedures.

Adapt consequently current processes and templates for drafting EU herbal monographs.

Key objectives

- To adapt the HMPC working methodology for drafting EU herbal monographs in the new architecture for WPs and DGs and reflect accordingly in procedural guidance
- To enhance a regular communication and cooperation with other EMA committees within the new architecture where required
- Strengthen the collaboration with EDQM for specific quality key topics

- Foster HMPC cooperation with regulatory experts / assessors from the specialised herbal expert community to actively participate in drafting of guidelines, EU herbal monographs and specific items (e.g. from academia)

Activities in 2023

HMPC activities to achieve the objectives set for this area:

- Implement new DG entities as part of new working methodology in drafting of EU herbal monographs / list entries / revisions without the input of the Monograph and List WP
- Re-establish a herbal Quality DG within the new architecture (quality domain) and communicate key topics with EDQM (cross reference to work plan topic 2.2.2.)
- Update and implement affected process documents summarising 6 old procedural documents into one main procedure for monograph establishment reflecting new practice (for details see Annex 2)
- Update and implement affected template documents: Template for assessment report for the development of EU herbal monographs and list entries (EMEA/HMPC/418902/2005 Rev. 5) and Template for a EU herbal monograph (EMEA/HMPC/107436/2005 Rev. 7) (see Annex 2)

HMPC topic leader: E van Galen (Chair) /E. Svedlund (Vice chair)

Other Committee participants:

Member/alternate	Name	MS
Chair	E van Galen (architecture DGs)	NL
Member	C. Purdel (all activities)	RO
Member	M. Paile Hyvarinen (templates)	FI
Member	R. Laenger (process)	AT
Member	A. Assisi (process)	IT
Member	A. Lê (process)	FR

Annex 1: EU herbal monographs/list entries

Planned new assessments, reviews and revisions in 2023[1]

1. New EU herbal monographs and list entries

The following herbal substances and preparations 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
- Cnici benedicti herba

1.2. Draft to be released for public consultation

- Combination: Cimicifugae rhizoma/ Hyperici herba
- Tribuli herba

1.3. Assessment to be started

- Cannabis flos
- Pruni cerasi stipites
- Species pectoralis (incl. Species antitussivae, Species expectorantes)

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

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).

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

- Capsici fructus

[1] The activities outlined in the HMPC work plan for 2023 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)

[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)

- Crataegi folium cum flore
- Ginkgo folium
- Helichrysi flos
- Matricariae flos
- Melaleucae aetheroleum

- Myrtilli fructus siccus
- Myrtilli fructus recens
- Ononidis radix
- Origani majoranae herba
- Pilosellae herba cum radice
- Polygoni avicularis herba

- Pruni africanae cortex
- Ricini oleum
- Rosae flos
- Rubi idaei folium
- Sideritis herba
- Sisymbrii officinalis herba
- Symphyti radix

2.2.2. Periodic reviews to be started

- Allii sativi bulbus
- Fragariae folium
- Lecithinum ex soya
- Malvae folium
- Malvae sylvestris flos
- Mastic (Mastix, Pistaciae lentisci resina)

- Silybi mariani fructus
- Soiae oleum raffinatum
- Species diureticae
- Thymi herba

2.3. Revision

2.3.1. Revisions to be finalised

- Juniperi pseudo-fructus
- Foeniculi amari fructus
- Foeniculi amari fructus aetheroleum
- Foeniculi dulcis fructus
- Fumariae herba
- Rosmarini aetheroleum
- Rosmarini folium

2.3.2. Draft revisions to be released for public consultation

- Arnicae flos
- Eucalypti aetheroleum
- Ginseng radix
- Hippocastani cortex
- Lavandulae aetheroleum
- Liquiritiae radix

- Pelargonii radix
- Plantaginis lanceolatae folium
- Rhodiolae roseae rhizoma et radix
- 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 2023[5]

1. Scientific guidelines (new or update/revision)

1.1. For finalisation in 2023

QUALITY

• **Questions & answers on quality** of herbal medicinal products / traditional herbal products (EMA/HMPC/41500/2010 Rev.6)

Rapporteurs:[6] ***B Kroes****, R Länger*

Actions: Remove Q&A now addressed in revised guidelines and add new ones collected/answered during past HMPC assessors' trainings and meetings (including on elemental impurities, skip testing, stability, GACP/GMP, assay and microbiological issues), publish Rev. 7

1.2. Draft to be released for public consultation in 2023

QUALITY

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

Rapporteurs: ***A.P. Martins****, H. Kuin, E. Attard*

Actions: Draft the revised guideline taking into account responses received on the concept paper; coordinate with Inspectors WG before publication; publish draft revised GL for consultation

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

1.3. To be started in 2023

QUALITY

• Guidance on **newly used manufacturing techniques** regarding herbal preparations

Rapporteur: ***O Palomino****, C Purdel*

[5] The activities outlined in the HMPC work plan for 2023 have been agreed taking into consideration the Agency's prioritisation set forth in the EMA multi-annual work programme 2023-2025.
[6] All Quality guidance documents will be supported by the Herbal Quality Drafting Group

Action: Draft a reflection paper for interaction with stakeholders addressing the absence of guidance on issues causing difficulties at national level and for EU herbal monograph assessments (e.g. inclusion of supercritical CO_2-extracts); initiate first steps to identify appropriate experts

• Guideline on **declaration** of herbal substances and herbal preparations in herbal medicinal products / traditional herbal medicinal products (EMA/HMPC/CHMP/CVMP/287539/2005 Rev.1)

Rapporteur: K. Hvolby, F. Stolte, ***S. Koski***

Action: Publish a concept paper, start guideline revision considering the responses received on the concept paper

• **Reflection paper on markers** used for quantitative and qualitative analysis of herbal medicinal products and traditional herbal medicinal products (EMEA/HMPC/253629/2007)

*Rapporteurs****: R Länger****, B Kroes*

Actions: Review for suitability vis-a-vis Ph. Eur. definitions and HMPC monographs/assessment reports taking into account regulatory practice and different views on the role of active and analytical markers; draft a discussion paper with proposals for better definitions vis-à-vis existing Ph. Eur. defined extract types (particularly quantified extracts); specify potentially affected EMA and Ph. Eur. guidance documents and prepare necessary coordination with EDQM (e.g. joint working group)

SAFETY/EFFICACY

• Guideline on the **clinical assessment of fixed combinations** of herbal substances / herbal preparations (EMEA/HMPC/166326/2005)

Rapporteur: ***O Palomino****, J Wiesner*

Actions: Re-evaluate need of revision, publish a concept paper;

2. Regulatory or procedural guidance

2.1. For finalisation in 2023

No new or revised guidance documents, procedures or templates are currently foreseen to be finalised in 2023.

2.2. Draft to be released for public consultation in 2023

• 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. Laenger, A. Le, A. Assisi*

Action: Draft new procedure summarising and replacing 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)

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

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

Action: Draft and publish revised template

2.3. To be started in 2023

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

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

Action: Start drafting revised template