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Committee on Herbal Medicinal Products (HMPC)

Committee on Herbal Medicinal Products (HMPC): work plan 2022

Adopted by the Committee on 26 January 2022

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The activities outlined in the HMPC work plan for 2022 have been agreed taking into consideration the Agency's prioritisation set forth in the EMA multi-annual work programme 2022-2024.

1. Evaluation activities for human medicines

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

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

Key objectives and activities in 2022

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

For finalisation	Forecast
Herbal monographs, new*	4
Herbal monographs, reviewed**	22
Herbal monographs, revised	3
List entries	0

* 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 HMPC develops scientific and regulatory guidance to support 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 herbal monographs and list entries.

Key objectives and activities in 2022

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 use of data sources for HMPC relevant safety assessments

To implement a structured approach for the use of data from existing databases, including Eudravigilance, concerning herbal substances in the context of monograph establishment to support the safe use of (T)HMPs on the EU market.

Key objectives

To improve the use of relevant safety data in the establishment and review / revision of monographs, to strengthen the safe use of (T)HMPs in the EU

Activities in 2022

HMPC activities to achieve the objectives set for this area:

- Adapt templates (Review report, Assessment report) to improve harmonisation via specified instructions on data sources including Eudravigilance database and presentation of relevant data
- Adapt affected process documents:
  - 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)
- Organise a training session for HMPC Rapporteurs

HMPC topic leader: E. Svedlund (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

1.3.2. 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 pharmacovigilance and clinical practice data from medicinal products on the market for safety assessments for children in order to harmonise practice for HMPC monographs and streamline discussions on specific cases.

Key objectives

- To improve the HMPC safety assessments for children in order to harmonise practice for HMPC monographs

Activities in 2022

HMPC activities to achieve the objectives set for this area:

- 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 following a questionnaire

- 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 the Paediatric Committee (PDCO) to coordinate specific questions on paediatric use of marketed herbal substances (e.g. joint expert group for consultation)

HMPC topic leader: P. Voitl (Co-opted Paediatric medicine)

Other Committee participants:

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

1.3.3. Evaluation of a harmonised approach for the use of monographs in procedures for combination products

About a third of all herbal authorisations / registrations are combination products. The current guideline on the clinical assessment of fixed herbal combinations is 17 years old and requires updates taking into account new non-herbal guidance and advanced experiences in the Member States. Interested parties and NCAs experience the need for extended combination monographs to facilitate and harmonise the EU procedures for (T)HMP combination products.

Key objectives

- Develop a harmonised view on how to use EU herbal monographs in the assessment of combination products, in order to facilitate the EU procedures for (T)HMP combination products

Activities in 2022

HMPC activities to achieve the objectives set for this area:

- Start revision of the guideline on the clinical assessment of fixed combinations of herbal substances / herbal preparations (EMEA/HMPC/166326/2005)
- Based on feedback from NCAs decide on the need for new combination monographs (to be added to WP 2023-2025) and/or harmonised principles in use of mono monographs in the evaluation of combination products
- Identify the need for additional procedural guidance for monograph establishment / principles in analogy to recently established Q&A on use / principles in herbal tea combinations
- Communicate the outcome of the evaluation to interested parties

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
Co-opted member	H. Foth	Toxicology
Co-opted member	M. da Graça Ribeiro Campos	Clinical pharmacology
Co-opted member	G. Laekeman	Experimental / non-clinical pharmacology

2. Horizontal activities and other areas

2.1. Partners and stakeholders

2.1.1. Collaboration with EC on the feasibility to establish a EU herbal monograph for Cannabis flos

Due to political and market developments in relation to the therapeutic use of cannabis-derived substances and products, European Medicines Agency (EMA) and specifically HMPC are often approached by European Parliament (EP), European Commission (EC), industry and the public on regulatory questions with regard to the market access and regulatory requirements / standards for herbal medicinal products and their applicability for cannabis-derived products for medicinal use. The EC requested a compilation of terms and definitions (finalised in 2021) but also suggested to check the possibility for a EU herbal monograph.

Key objectives

- Explore the feasibility to establish a EU herbal monograph for Cannabis flos and initiate first steps to clarify to the EC and the public the opportunities and limitations of the pharmaceutical legislative framework and the HMPC mandate

Activities in 2022

HMPC activities to achieve the objectives set for this area:

- Establish specific short Q&A for some basic information regarding existing standard requirements for (herbal) medicinal products regulation and authorisation and the remit of HMPC to avoid wrong expectations to EMA as regards extras in 'medicinal cannabis' regulation
- Publish a call for data tailored to the specific complexity of cannabis derived substances and for Cannabis flos medicinal products on the EU market
- Establish a drafting multidisciplinary group for the assessment
- Coordinate with the European Directorate for the Quality of Medicines (EDQM) to clarify scope of specific Ph. Eur. in relation to possible EU herbal monographs as well as other EU institutions as appropriate

- Coordinate with the Committee for Medicinal Products for Human Use (CHMP) and the Co-ordination group for Mutual recognition and Decentralised procedures – human (CMDh), when appropriate for any issues related to cannabis-derived medicinal products

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

Other Committee participants:

Member / Alternate	Name	Member State
Member	B. Razinger	SL
Member	E. Attard	MT
Member	B. Kroes	NL
Member	I. Chinou	EL
Expert	P. Duez	BE

2.1.2. 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 first 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 2022

HMPC activities to achieve the objectives set for this area:

- Development and delivery of trainings in the identified high priority areas of the herbal curriculum
- Collaboration with EDQM for specific quality key topics of importance for assessors

HMPC topic leader: E. Svedlund (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

2.2. Process improvement

2.2.1. Implementation of new architecture for WP/DG

To 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 implementing virtual meeting facilities into working procedures.

Key objectives

- To adapt the HMPC working methodology in the new architecture for WPs and DGs (mainly on quality guidance for herbals, and for drafting new monographs / revision)
- To introduce a regular and structural communication and cooperation with other EMA committees within the new architecture

Activities in 2022

HMPC activities to achieve the objectives set for this area:

- Implement new WP/DG entities as part of new working methodology in drafting of EU herbal monographs / list entries / revisions
- Re-establish a herbal QDG within the new architecture (quality domain)
- Find and bind not only HMPC members but also 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)

HMPC topic leader: E. van Galen (Chair)

Other Committee participants:

Member / Alternate	Name	Member State
Member (HMPC, QWP)	C. Purdel	RO
Member	I. Chinou	EL
Member	J. Wiesner	DE
Member	O. M. Palomino	ES
Alternate	S. Flemisch	DE
Expert	S. Bodemann	DE
Expert	K. Almgren	SE

Annex 1: EU herbal monographs / list entries

Planned new assessments, reviews and revisions in 2022[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

- Centellae asiaticae herba
- Cisti cretici folium
- Species digestivae / stomachicae
- Vaccinii macrocarpi fructus

1.2. Draft to be released for public consultation

- Cnici benedicti herba
- Combination: Cimicifugae rhizoma/ Hyperici herba
- Tribuli herba

1.3. Assessment to be started

- Cannabis flos (specifically modified call for data)
- 1-3 other proposed substances according to validation and agreement on proposals

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

[1] The activities outlined in the HMPC work plan for 2022 have been agreed taking into consideration the Agency's prioritisation set forth in the EMA multi-annual work programme 2022-2024
[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.2)

2.2. Periodic review

2.2.1. Periodic reviews to be finalised

- 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
- Hippocastani cortex
- Juglandis folium
- Liquiritiae radix
- Marrubii herba
- Origani dictamni herba
- Paulliniae semen
- Plantaginis lanceolatae folium
- Rhodiolae roseae rhizoma et radix
- Thymi herba
- Tiliae flos
- Urticae folium
- Urticae radix

2.2.2. Periodic reviews to be started

- Agrimoniae herba
- Capsici fructus
- Crataegi folium cum flore
- Epilobii herba
- Eschscholziae herba
- 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

2.3. Revision

2.3.1. Revisions to be finalised

- Agropyri repentis rhizoma
- Hyperici herba
- Juniperi pseudo-fructus

2.3.2. Draft revisions to be released for public consultation

- Arnicae flos
- Foeniculi amari fructus
- Foeniculi amari fructus aetheroleum
- Foeniculi dulcis fructus
- Fumariae herba
- Lavandulae aetheroleum
- Pelargonii radix
- Plantaginis lanceolatae folium
- Rosmarini aetheroleum
- Rosmarini folium
- Urticae herba
- 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 2022[5]

1. Scientific guidelines (new or update / revision)

1.1. For finalisation in 2022

No new or revised guidance documents are currently foreseen to be finalised in 2022.

1.2. Draft to be released for public consultation in 2022

QUALITY

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

Actions: publish a concept paper; start drafting the revised guideline taking into account responses received on the concept paper; coordinate with Inspectors WG before publication; publish for consultation

NON-CLINICAL

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

Actions: publish a concept paper; start drafting 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

SAFETY/EFFICACY

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

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

1.3. To be started in 2022

QUALITY

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

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)

[5] The activities outlined in the HMPC work plan for 2022 have been agreed taking into consideration the Agency's prioritisation set forth in the EMA multi-annual work programme 2022-2024

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

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)

Action: draft a concept paper for the revision of the guideline in response to new practices and experiences identified as well as new Ph. Eur. and EMA quality standards/guidelines in order to update for a more harmonised view

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

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).

2. Regulatory or procedural guidance

2.1. For finalisation in 2022

• **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 (CMDh/349/2016, Rev.0 - EMA/HMPC/770889/2014)

Action: update addendum to QRD template specific for traditional herbal medicinal products in an appropriate user- and update-friendly format for use in MRP/DCP procedures and coordinate with QRD and CMDh

• 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 Rev. 1)

Action: finalise the revision of the guidance document according to present practice and new proposals in order to even out workload and make best use of limited resources and multinational teams according to expertise available and required

2.2. Draft to be released for public consultation in 2022

No new or revised guidance documents, procedures or templates are currently foreseen to be released for public consultation in 2022.

2.3. To be started in 2022

None