

15 January 2020
EMA/HMPC/88010/2020
Inspections, Human Medicines Pharmacovigilance & Committees Division

HMPC work plan

2020 – adopted by the Committee on 15 January 2020¹

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¹

The activities outlined in the work plan for 2020 have been agreed taking into consideration that activities are gradually reinstated following a phase of business continuity.

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1. Evaluation activities for herbal medicinal products as defined in Reg. (EC) No 726/2004 and Dir. 2001/83/EC

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

Activity area

The HMPC provides scientific opinions on questions relating to herbal medicines. Its mandate 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 2020

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
	2020
Herbal monographs, new*	3
Herbal monographs, reviewed**	15
Herbal monographs, revised	8
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

Activity area

The Committee develops scientific and regulatory guidance to support 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 2020

Scientific guidelines: Key objectives and activities for the development of new guidance or revision of existing scientific guidance are outlined in **Annex 2** when related to the safety and efficacy evaluation of HMP. During BCP phase 3/4 guideline development is on hold (Oct 2018 – currently xxx 2020) unless of urgent public health need, necessary in the context of Brexit or for the implementation of revised legislation.

Procedural guidance: Key objectives and activities for the development of new guidance or revision of existing guidance are outlined in **Annex 2**. During BCP phase 3/4 guideline development is on hold (Oct 2018 – currently xxx 2020) unless of urgent public health need, necessary in the context of Brexit or for the implementation of revised legislation or relevant for committee's core operations.

1.3. Other specialised areas and activities

1.3.1. Activity area: Implementation of a modified procedure for EU herbal monograph establishment and maintenance

Key objectives

Prevent European Union herbal monographs from becoming outdated by periodically retrieving and evaluating new data to maintain monographs as workable standard for applicants and NCAs to facilitate national registration and authorisation procedures.

Activities in 2020

HMPC activities to achieve the objectives set for this area:

- Develop a strategy for use of available safety data from pharmacovigilance tools (signal detection, PSUR assessments, literature monitoring, Art. 57 database) to amend the procedure on systematic review/revisions as well as establishment of new monographs by updating data search and presentation
- Further adapt HMPC working methodology initiated during suspended working/drafting groups' activities following EMA BCP (streamlining of procedures and best use of resources to publish high quality documents) and develop a HMPC Plenary Best Practice Guide with a Reader's Guidance template annexed
- Update regularly new information on national experiences with HMPC monographs at NCAs and implement its use by Rapporteurs during systematic review and revisions

HMPC topic leader: HMPC Chair; Other Committee participants:

Member/alternate	Name	Member State
Member	E. Svedlund	SE
Member	C. Purdel	RO
Member	R. Laenger	AT
Member	A. Assisi	IT

1.3.2. Activity area: 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 2020

HMPC activities to achieve the objectives set for this area:

- Update HMPC Work programme (priority list) taking into account the resources for 2021/2022. After informed decision by HMPC, discuss a proposal for two years in preparation of the work plan 2021

HMPC topic leader: HMPC Vice Chair; Other Committee participants:

Member/alternate	Name	Member State
Member	E. van Galen	NL
Alternate	M. Soderberg	SE
Member	I. Chinou	EL
Co-opted member	G. Laekeman	Experimental/non-clinical pharmacology
Member	A. Le	FR

2. Horizontal activities and other areas

2.1. Cross-committee activities and coordination in the wider network

2.1.1. Activity area: Coordination on safety assessments of herbal constituents

Key objectives

Coordinate the safety assessment of herbal constituents in contaminants, active substances or excipients with impact on herbal and non-herbal medicinal products and the subsequent regulatory measures with other committees and working groups.

Activities in 2020

HMPC activities to achieve the objectives set for this area:

- Finalise the revised public statement on estragole in coordination with CHMP/SWP and CMDh and inform relevant EFSA panels
- Revise the Public statement on contamination of herbal medicinal products/traditional herbal medicinal products with pyrrolizidine alkaloids (PAs) (EMA/HMPC/328782/2016) and the Public statement on the use of herbal medicinal products containing toxic, unsaturated pyrrolizidine alkaloids (PAs) (EMA/HMPC/893108/2011) in order to provide direction for industry and NCAs (drafts for public consultation in 2020, finals latest by May 2021)
- Cooperate as appropriate with EDQM, EFSA and interested parties regarding data collection, method development and communication/publication of documents

HMPC topic leader: J. Wiesner (DE); Other Committee participants:

Member/alternate	Name	Member State
Co-opted member	H. Foth	Toxicology
Alternate	M. Brum	FR
Member	I. Chinou	EL
Member	E. Svedlund	SE

2.1.2. Activity area: Patients involvement in assessment work

Key objectives

Facilitate involvement of patients and consumers in benefit/risk evaluation and related activities, to capture patient's preferences and obtain information on the current use and understanding of medicines and their therapeutic environment (acknowledging the self-medication character of most herbal medicines).

Activities in 2020

HMPC activities to achieve the objectives set for this area:

- Continue with the regular practice to inform patient representatives on draft HMPC documents for the possibility for written comments (Herbal summaries for the public, draft monographs) and organise information session to raise understanding of different document functions (e.g. MO, AR, vs SmPC and labelling)
- Make use of the possibility to consult patient representatives for specific questions via established structure at PCWP/HCPWP (e.g. relevance and understanding of wording of indications or posology in the monographs vis-a-vis the current medicinal use)
- If useful invite patient representatives (TC in person at HMPC) for discussion of relevant key points on specific assessments

HMPC topic leader: S. Bager (DK); Other Committee participants:

Member/alternate	Name	Member State
Member	A. Le	FR
Co-opted Member	G. Laekeman	Experimental/non-clinical pharmacology

2.1.3. Activity area: Use of PhV, non-clinical and real-world data for HMPC relevant safety assessments

Key objectives

In absence of sufficient clinical study data develop a common understanding for the interpretation of toxicological, PhV and usage data from products on the market for safety assessments (in particular risks for children) in order to harmonise practice for HMPC monographs and streamline discussions.

Activities in 2020

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
- Coordinate with PRAC and PDCO (incl. use of specific examples e.g. Hedera contraindication as precautionary measure extrapolated from other cough products)
- Include agreed principles into the HMPC Best Practice Guide

HMPC topic leader: S. Giroto (Co-opt. Paediatrics); Other Committee participants:

Member/alternate	Name	Member State
Member	J. Wiesner	DE
Co-opted Member	H. Foth	Toxicology
Member	M. Petrikova/ P. Šišovský (PDCO member)	SK
Member	E. Svedlund	SE
Member	Zs. Birone-Sandor	HU

2.2. European collaboration

2.2.1. Activity area: Development of training on assessment of applications for herbal medicinal products

Key objectives

Develop a herbal product specific curriculum from and for herbal assessors at NCAs in the framework of the European network training centre activities.

Activities in 2020

HMPC activities to achieve the objectives set for this area:

- Develop and agree on documents for priorities, principles and curriculum as such
- Development training in the identified high priority areas, for first delivery during Q2 – Q4 2020

HMPC topic leader: E. Svedlund; Other Committee participants:

Member/alternate	Name	Member State
Member	J. Wiesner	DE
Member	R. Länger	AT
Member	C. Purdel	RO

Annex 1: EU herbal monographs/list entries

Planned new assessments, reviews and revisions in 2020

1. New EU herbal monographs and list entries

The following herbal substances and preparations thereof shall be assessed with a view to publishing¹ an EU herbal monograph or EU herbal monograph and list entry. When no monograph can be established, a public statement² will be published.

1.1. *For finalisation*

- Herniariae herba

1.2. *Draft to be released for public consultation*

- Cisti cretici folium
- Menyanthidis trifoliatae folium
- Saccharomyces cerevisiae CBS 5926
- Salvia miltiorrhizae radix et rhizoma
- Species amarae
- Species digestivae or species stomachicae
- Species sedativae
- Vaccinii macrocarpi fructus
- Verbenae citriodoraе folium

1.3. *Assessment to be started*

- Andrographidis paniculatae folium
- Centella asiatica herba
- Taraxaci radix

2. Review and revision of final EU herbal monographs and list entries³

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*

- Absinthi herba

¹ See 'Timelines for establishment of Community list entries and Community herbal monographs' (EMA/HMPC/126542/2005 Rev. 2)

² 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)

³ See Procedure for the review and revision of European Union herbal monographs and European Union list entries (EMA/HMPC/124695/2011 Rev.2)

- Pelargonii radix
- Sabalis serrulatae fructus
- Euphrasiae herba (public statement)
- Visci albi herba (public statement)

2.2. Periodic review

2.2.1. Periodic reviews to be finalised

- Arctii radix
- Filipendulae ulmariae flos
- Filipendulae ulmariae herba
- Juniperi aetheroleum
- Juniperi pseudo-fructus
- Rosmarini aetheroleum
- Rosmarini folium
- Solidaginis virgaureae herba

2.2.2. Periodic reviews to be started

- Agropyri repentis rhizoma
- Carvi aetheroleum
- Carvi fructus
- Caryophylli floris aetheroleum
- Chamomillae romanae flos
- Cinnamomi cortex
- Cinnamomi corticis aetheroleum
- Colae semen
- Fucus vesiculosus
- Fumariae herba
- Lavandulae aetheroleum
- Lavandulae flos
- Mate folium
- Plantaginis lanceolatae folium
- Solani dulcamarae stipites
- Urticae folium
- Urticae herba
- Viola tricoloris herba
- Zingiberis rhizoma

2.3. Revision

2.3.1. Revisions to be finalised

- Hippocastani semen
- Hyperici herba
- Menthae piperitae aetheroleum
- Menthae piperitae folium
- Millefolii herba
- Rhamni purshianae cortex
- Rhei radix
- Tanaceti parthenii herba
- Thymi aetheroleum

2.3.2. Draft revisions to be released for public consultation

- Foeniculi amari fructus
- Foeniculi amari fructus aetheroleum
- Foeniculi dulcis fructus
- Orthosiphonis folium
- Trigonellae foenugraeci semen

2.3.3. Revisions to be started

According to review outcome – see 2.2.

Annex 2: Guidance and procedural documents¹

Planned new or revised scientific, regulatory and procedural guidance documents in 2020

1. Scientific guidelines (new or update/revision)

1.1. For finalisation

- Public statement on the use of herbal medicinal products containing estragole (EMA/HMPC/137212/2005)

Action: Finalisation and publication of the revised PS and coordination with CHMP/SWP and CMDh on implementation

- Revision of the Guideline on quality of herbal medicinal products

Action: Finalisation of the revised guideline after public consultation ending Nov 2018.

- Revision of the Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and HMP/THMPs

Action: Finalisation of the revised guideline after public consultation ending Nov 2018.

1.2. Draft to be released for public consultation

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

Action: Continuation of the PS revision for public consultation of the draft

- Public statement on contamination of HMP/THMP with pyrrolizidine alkaloids (PAs) (EMA/HMPC/328782/2016)

Action: Continuation of the PS revision for public consultation of the draft

1.3. To be started in 2020

No new guidelines or guideline revisions are currently foreseen to be started in 2020.

¹ The activities outlined in the work plan for 2020 have been agreed taking into consideration that activities are gradually reinstated following a phase of business continuity.

2. Regulatory or procedural guidance²

2.1. *For finalisation*

- 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

- Update the HMPC Assessment Report template in order to ameliorate instructions for the Rapporteur for streamlining and improving the quality of the documents

Action: Modify AR template in accordance with the experience gained and the new strategy for use of available safety data for publication on the EMA website and use by HMPC Rapporteurs

2.2. *Draft to be released for public consultation*

No new or revised guidance documents, procedures or templates are currently foreseen to be released for public consultation in 2020.

2.3. *To be started in 2020*

No new guidance documents, procedures or templates are currently foreseen to be started in 2020.

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