30 January 2018
EMA/HMPC/150152/2018
Inspections, Human Medicines Pharmacovigilance & Committees Division

HMPC work plan

2018 – adopted by the Committee on 30 January 2018[1]

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[1] 'The activities outlined in the work plan for 2018 have been agreed considering the respective business priorities, as well as the Agency's relocation as a result of the UK's exit from the EU and its impact on the Agency's business continuity, and may be subject to further review and reprioritisation in accordance with the business continuity plan of the Agency.'

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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, establishes European Union herbal monographs for traditional and well established use herbal medicines, and 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 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 2018

Detailed objectives as regards new draft and final monographs and list entries as well as monograph and list entry reviews/revisions are outlined in the annual work plan of the Monograph and List Working Party (MLWP) (**Annex 1**).

Workload indicators

	Forecast
	2018
Herbal monographs, new*	5
Herbal monographs, reviewed**	15
Herbal monographs, revised	7
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/list entry is required, an addendum to the previous assessment is prepared

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 2018

Scientific guidelines: Key objectives and activities for the development of new guidance or revision of existing scientific guidance are outlined in the annual work plan of the Monograph and List Working Party (MLWP) (**Annex 1**) when related to the safety and efficacy evaluation of HMP and in the annual work plan of the Quality Drafting Group (QDG) when related to the quality of HMP (**Annex 2**).

Procedural guidance: Key objectives and activities for the development of new guidance or revision of existing guidance are outlined in the annual work plan of the Organisational Matters Drafting Group (ORGAM) (**Annex 3**) and the Monograph and List Working Party (MLWP) (**Annex 1**).

1.3. Other specialised areas and activities

1.3.1. Activity area: Implementation of a modified review / revision procedure for EU herbal monographs

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 2018

HMPC activities to achieve the objectives set for this area:

- Fine-tune and finalise the new 'Procedure for the review and revision of European Union herbal monographs and European Union list entries' in line with comments received during public consultation and experiences from pilot reviews/revisions (publish final procedure and OoC on EMA website)
- Implement the new 'Procedure for the review and revision of European Union herbal monographs and European Union list entries' as standard practice of Rapporteurs, MLWP and HMPC (use of new templates, adapt agendas of HMPC/MLWP, change of publication practice)

HMPC topic leader: HMPC Chair; Other Committee participants:

Member / alternate	Name	Member State
Co-opted member; ORGAM Chair	G. Laekeman	Experimental/Non-clinical pharmacology
Member, MLWP Chair	I. Chinou	EL
Alternate; MLWP Vice-Chair	B. Kroes	NL

1.3.2. Activity area: Forward planning and prioritisation

Key objectives

Identify 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 2018

HMPC activities to achieve the objectives set for this area:

- Perform validation step on proposals before start assessment work for new herbal substances/preparations used by European citizens and market relevance but without harmonised EU standards (pre-evaluation of available data), considering options to involve, if applicable interested parties at an earlier stage to provide data
- Update priority list only after informed decision by HMPC following validation of available information by MLWP based on a new proposal template

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

Member/alternate	Name	Member State
Member; MLWP Chair	I. Chinou	EL
Alternate	M. Soderberg	SE
Alternate; MLWP Vice-Chair	B. Kroes	NL

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

Key objectives

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

Activities in 2018

HMPC activities to achieve the objectives set for this area:

- Finalise the revised public statement on estragole in coordination with CHMP/SWP and CMDh
- Determine next steps on the reflection paper on Polycylic Aromatic Hydrocarbons
- Draft a project plan on the development of suitable toxicological models for the safe use of herbal substances/preparations in medicinal products in view of background exposure via food
- Cooperation with EFSA and EDQM as necessary regarding safety and quality evaluation/standards for contaminants in herbal products
- Follow up activities further to the Public statement on Contamination of herbal medicinal products/traditional herbal medicinal products with pyrrolizidine alkaloids (PAs) (EMA/HMPC/328782/2016) (Devise a plan/recommendation for harmonisation and guidance documents as necessary)

HMPC topic leader: J. Wiesner; Other Committee participants:

Member / alternate	Name	Member State
HMPC Chair	M. Delbò	IT
Member; Quality DG Chair	L. Anderson	UK
Member	M. Heroutova	CZ
Member	E. Svedlund	SE
Member	Zs. Birone-Sandor	HU
Co-opted member	H. Foth	Toxicology
Member	A. Martins	PT
Member, MLWP Chair	I. Chinou	EL

1.3.4. Activity area: European collaboration

Key objectives

Develop feedback mechanisms from National Agencies on European and national procedures as well as pharmacovigilance to support HMPC tasks keeping EU herbal monographs up to date

Activities in 2018

HMPC activities to achieve the objectives set for this area:

- Inform regularly on national experiences at NCAs with HMPC monographs to be considered for systematic review and revisions (regular information point at HMPC agendas)
- Develop a strategy for other new data -in particular safety related- such as from pharmacovigilance signal detection, PSUR assessments and literature monitoring potentially useful to be included in the procedure on systematic review and revisions

HMPC topic leader: Reinhard Laenger; Other Committee participants:

Member / alternate	Name	Member State
Member	Zs. Biro-Sandor	HU
Member	A. Assisi	IT
Member	E. Svedlund	SE

2. Horizontal activities and other areas

2.1. Participation in cross-committee activities

2.1.1. Activity area: Patients involvement in assessment work

Key objectives

Facilitate participation of patients and consumers in benefit/risk evaluation and related activities, to capture patient's values and preferences and obtain information on the current use of medicines and their therapeutic environment

Activities in 2018

HMPC activities to achieve the objectives set for this area:

- Establish a regular practice to inform patient representatives on draft HMPC documents for comments
- For specific issues raised invite patient representatives (via teleconference or face to face meeting participation) for discussion of relevant key points

HMPC topic leader: S. Bager; Other Committee participants:

Member/alternate	Name	Member State
Member	Una Mockler	IR
Alternate	Baiba Jansone	LV
Co-opted Member	G. Laekeman	Experimental/non-clinical pharmacology

3. Annex

1) MLWP work plan 2018

2) Quality DG work plan 2018

3) ORGAM DG work plan 2018