EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Inspections, Human Medicines Pharmacovigilance & Committees Division

HMPC work plan

2017 – adopted by the Committee on 31 January 2017

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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 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 2017

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

Workload indicators

	Forecast
	2017
Herbal monographs, new*	5
Herbal monographs, revised	15
List entries	1

* when the assessment does not lead to the establishment of a monograph, a public statement is prepared

1.2. Establishment 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 2017

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: Forward planning and prioritisation

Key objectives

- Identify herbal substances, preparations and combinations in medicinal use by European citizen for which monographs are useful as basis for national assessments of medicinal products

Activities in 2017

HMPC activities to achieve the objectives set for this area:

- Establish a pragmatic approach setting European standards for herbal combination products (monographs) including solutions for tea combinations
- Consult interested parties on justified proposals for assessment and monograph establishment
- Review data from NCAs on substances registered/ authorised in several member states without European standards and decide on additions to HMPC priority list
- Identify herbal substances, preparation and combinations from non-European traditions, qualifying for establishing a EU herbal monographs as basis for regulation of herbal medicinal products from non-European traditions (see also 1.3.3) and conclude on a shortlist for HMPC priority list and work plan 2018

HMPC topic leader: M. Delbò; Other Committee participants:

Member/alternate	Name	Member State
Member; HMPC Vice-Chair	E. v. Galen	NL
Member; MLWP Chair	I. Chinou	GR
Member	R. Laenger	AT

1.3.2. Activity area: Coordination related to quality issues in herbal medicinal products

Key objectives

- Coordinate and harmonise activities following the Public statement on Contamination of herbal medicinal products/traditional herbal medicinal products with pyrrolizidine alkaloids (PAs) (EMA/HMPC/328782/2016)

Activities in 2017

HMPC activities to achieve the objectives set for this area:

- Collect relevant data from all NCAs and stakeholders such as industry associations to compile a knowledge database on PAs findings for identifying most affected substances and extent of contaminations (e.g. substances of high, medium, low, no risk)
- Start integrating measures and testing requirements in relevant HMPC quality guidance
- Coordinate with EDQM the establishment of a Ph. Eur. assay method for quantification of relevant PAs

- Discuss at HMPC and outline testing requirements, timelines and transitional measures according to risk considerations and testing capacities; coordinate with CMDh and GMP/GDP Inspectors Working Group as necessary
- Communicate risk assessment and risk management measures with EFSA according to MoU between both agencies

HMPC topic leader: P. Claeson; 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	J. Wiesner	DE
Member	Zs. Birone-Sandor	HU
Alternate; MLWP Vice-Chair	B. Kroes	NL

1.3.3. Activity area: Regulatory guidance for non-European interested parties and harmonisation of assessment practice for herbal substances of non-European origin

Key objectives

- Identify and collect proposals to overcome obstacles for using the framework of Dir. 2004/24/EC for non-European traditional substances/uses

Activities in 2017

HMPC activities to achieve the objectives set for this area:

- Establish a closer communication with relevant scientific and/or regulatory institutions / organisations, e.g. in China, India and Europe in order to (1) improve an appropriate input in possible work on draft EU herbal monographs via consultation on specific substances and invitation to HMPC/MLWP meetings and (2) select efficiently non-European herbal substance/preparations according to specified criteria for HMPC assessment work
- Prepare a consultation model for use in 2018 with interested parties representing non-European traditions, for information on the procedure on submitting proposals for HMPC assessment work, and how to contribute to the work on monographs within established standard procedures
- Clarify specific questions in relation to legal interpretations on the requirements in Article 16c (1)c (30/15 years of use) in cooperation with EMA Legal services and the European Commission and update relevant Questions & Answer documents as appropriate

HMPC topic leader: E. van Galen; Other Committee participants:

Member/alternate	Name	Member State
HMPC Chair	M. Delbò	IT
Alternate	M. Příhodová	CZ

1.3.4. Activity area: International collaboration

Key objectives

- Strengthen the scientific evaluation of traditional herbal medicines from a public health perspective at a global level in line with the EU network strategy until 2020 (theme 4)

Activities in 2017

HMPC activities to achieve the objectives set for this area:

- Develop a practice that EMA/HMPC experts participating in global discussions on herbal medicines in international regulatory organisations and conferences express a harmonized European view and regularly report to the HMPC.
- Report at HMPC meetings, record and plan in liaison with EMA International Affairs the international representation of HMPC members at IRCH, ICDRA and other meetings

HMPC topic leader: M. Delbò; Other Committee participants:

Member/alternate	Name	Member State
Member; MLWP Chair	I. Chinou	GR
Member; HMPC Vice-Chair	E. v. Galen	NL

1.3.5. 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 2017

HMPC activities to achieve the objectives set for this area:

- Develop a strategy on a structured feedback from NCAs to HMPC on marketing authorisation and registration procedures to be included in the procedure on systematic review and revisions
- Develop a strategy for other new data -in particular safety related- such as from pharmacovigilance signal detection and literature monitoring to be included in the procedure on systematic review and revisions

HMPC topic leader: R. Laenger; Other Committee participants:

Member/alternate	Name	Member State
Member	A. Le	FR
Member	J. Wiesner	DE
Member	Zs. Biro-Sandor	HU
Co-opted member	G. Laekeman	Experimental/Non-clinical pharmacology

2. Horizontal activities and other areas

2.1. Participation in cross-committee projects

2.1.1. Activity area: Patients involvement in assessment work

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

Key objectives

- Test the patients and consumers' organisations involvement as regards scope and timing of involvement according to HMPC and MLWP procedures and documents

Activities in 2017

HMPC activities to achieve the objectives set for this area:

- Train patient representatives via exposure to discussions at HMPC meetings during the first half of 2017
- Summarise in discussion with patient representatives the best possible future structure for involvement in HMPC activities

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

Member/alternate	Name	Member State
Co-opted member	M. H. Pinto Ferreira	General and family medicine
Co-opted member	G. Laekeman	Experimental/Non-clinical pharmacology

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

Key objectives

- Coordinate the safety assessment of herbal constituents in 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 2017

HMPC activities to achieve the objectives set for this area:

- Finalise the revised public statement on estragole in coordination with CHMP/SWP and CMDh
- Follow-up on the reflection paper on Polycylic Aromatic Hydrocarbons and decide on appropriate guidance for coordination with CHMP/SWP and cooperation EDQM and EFSA
- Draft a project 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 for start in 2018

HMPC topic leader: H. Foth (Co-opted member toxicology); Other Committee participants:

Member/alternate	Name	Member State
Member	J. Wiesner	DE
Member	A. P. Martins	PT

2.1.3. Activity area: Cooperation with Academia

Key objectives

- Develop a strategy for cooperation with Academia to include HMPC monographs, guidelines and documentation in the usual teaching activities and to stimulate research in specific neglected areas of herbal medicinal products

Activities in 2017

HMPC activities to achieve the objectives set for this area:

- Identify possible tools to raise awareness of Academia for the HMPC work and methodology to stimulate their integration in the academic programs and teaching activities
- Discuss at HMPC the opportunity to issue general recommendation to support any project, study or scientific work leading to further data assisting the risk assessment of selected herbal products/constituents/contaminants (e.g. pyrrolizidine alkaloids)

HMPC topic leader: I. Chinou; Other Committee participants:

Member/alternate	Name	Member State
Member	E. Attard	MT
Co-opted member	G. Calapai	Clinical Pharmacology
Co-opted member	G. Laekeman	Experimental/Non-clinical Pharmacology
Alternate	C. Purdel	RO
Member	S. Kreft	SL
Co-opted member	H. Foth	Toxicology

2.2. Partners and stakeholders

2.2.1. Activity area: Training of Assessors

Key objectives

- Train assessors from National Competent Authorities on relevant ongoing issues to foster European harmonisation

Activities in 2017

HMPC activities to achieve the objectives set for this area:

- Organisation of an Assessors training on quality of herbal medicinal products

HMPC topic leader: B. Kroes; Other Committee participants:

Member/alternate	Name	Member State
Member; QDG Chair	L. Anderson	UK
Member	H. Neef	BE

2.2.2. Activity area: Dialogue with users of European Union herbal monographs

Key objectives

Exchange of information and discussion of current issues and future developments with stakeholders in the field of herbal medicinal products

Activities in 2017

HMPC activities to achieve the objectives set for this area:

- Prepare the organisation of a hearing with Interested parties to exchange information on the utility of HMPC monographs and on how to foster dialogue, improve transparency and meet patients' and consumers' needs.
- Upon request by interested parties organise hearings on issues related to monograph/list entry establishment as appropriate

HMPC topic leader: I. Chinou; Other Committee participants:

Member/alternate	Name	Member State
Member	J. Wiesner	DE
Member	S. Bager	DK

3. Annex

1) MLWP work plan 2017

2) Quality DG work plan 2017

3) ORGAM DG work plan 2017