



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 November 2011
EMA/HMPC/509702/2011
Committee on Herbal Medicinal Products (HMPC)

Work programme for the Working Party on Community Monographs and Community List (MLWP)

Chair	Status
I. Chinou	22 November 2011

1. Meetings scheduled for 2012

- 24 - 26 January
- 27 - 29 March
- 22 - 24 May
- 25 - 27 September
- 20 - 22 November

2. Guidelines and other guidance documents

2.1. Develop HMPC guidelines and guidance documents

Upon request from the HMPC, develop guidelines, public statements, reflection paper on (traditional) herbal medicinal products or other guidance documents, according the 'Procedure for European Union guidelines and related documents within the pharmaceutical legislative framework' (EMEA/P/24143/2004 rev.).

Draft Public statement on herbal medicinal products containing polycyclic aromatic hydrocarbons (PAH)

Action: For release for public consultation



Draft Public statement on pyrrolizidine alkaloids (PA)

Action: For release for public consultation

Comments: In coordination with Q DG

2.2. Coordination on non-HMPC guidelines and other guidance documents

Prepare comments upon request on guidelines and guidance documents established by other EMA Scientific Committees/Working Parties, following the principles laid down in the 'EMA policy for the appropriate coordination between the scientific committees of the Agency' (Policy 0009 - EMA/124704/2005 Rev.1).

3. New Community herbal monographs, Community list entries and public statements

The following herbal substances and preparations thereof shall be assessed with a view to publishing¹ a Community herbal monograph, a Community list entry and/or a public statement² when no monograph can be established.

For finalisation

Allii cepae bulbus (PS)	Pelargonii radix
Citri bergami aetheroleum (PS)	Rhodiolae rosae rhizoma et radix
Cucurbitae semen	Symphyti radix
Echinaceae angustifoliae radix	Thymi herba/Primulae radix
Fraxini folium	Tiliae flos
Hippocastani cortex	Tiliae tomentosae flos (PS)
Lavandulae flos	Zingiberis rhizoma
Lavandulae aetheroleum	Visci albi herba (PS)
Liquiritiae radix	Urticae radix (M)

Draft to be released for public consultation (amongst the following)

Agrimoniae herba	Grindeliae herba
Allii sativi bulbus	Guaranae semen
Andrographidis paniculatae folium	Juglandis folium
Arnicae flos	Marrubii herba
Camelliae sinensis non fermentata folia	Matricariae aetheroleum

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)

Cichorii intybi folium	Matricariae flos
Cichorii intybi radix	Melaleucaae alternifoliae aetheroleum
Crataegi folium cum flore	Myrtilli folium
Crataegi fructus	Myrtilli fructus siccus
Erysimi officinalis flos	Pruni spinosae flos
Eucalypti aetheroleum	Pruni spinosae summitates
Eucalypti folium	Salbalis serrulatae fructus
Ginseng radix	Silybi mariani fructus
Ginkgo folium	Solani dulcamarae stipites
Levistici radix	Uncaria tomentosa cortex

4. Revision of final Community herbal monographs, Community list entries and public statements

The MLWP will implement the principles and steps for the systematic review of adopted monographs as laid down in the 'Procedure for the systematic review of adopted Community herbal monographs and supporting documents' (EMA/HMPC/124695/2011).

Experience will be gained in a pilot phase and reported to the HMPC for finetuning the long-term strategy for the systematic review and possible revision – as anticipated in the HMPC 2012-2015 work programme (EMA/HMPC/501139/2011).

The establishment of Key Performance Indicator(s) for this activity will be discussed in the second half of 2012 when the review/revision has become effective for a certain number of monographs, with a view to making recommendations to the HMPC.

5. Procedural and regulatory guidance

The MLWP will collaborate to the development by the HMPC Organisational Matters Drafting Group (ORGAM DG) of new or the revision of existing procedural and regulatory guidance.

6. Scientific recommendations to the HMPC

The MLWP will provide the HMPC with scientific recommendations on the safety and efficacy of (traditional) herbal medicinal products upon request, in the context of:

- referral procedures to the HMPC (see 'Guidance on documentation to be provided by Member States and applicants/MAHs in support of a simplified registration referral under Articles 16c(1)c and 16c(4)' EMEA/HMPC/431129/2005)
- procedures for scientific advice and support by the HMPC (see 'Guidance for companies seeking scientific support and advice on traditional herbal medicinal products' EMA/HMPC/127670/2011).

7. Interactions with interested parties

The following interactions are anticipated:

Type	Interest party	Framework	Timing
Hearing	AESGP	During MLWP	May 2012

8. Other

The MLWP will also assist the HMPC in the achievement of tasks and projects laid down in the HMPC 2012-2015 work programme (EMA/HMPC/501139/2011) as required by the Committee.