



30 January 2018  
EMA/HMPC/142826/2018  
Committee on Herbal Medicinal Products (HMPC)

## Work plan for the Working Party on European Union Monographs and List (MLWP) 2018<sup>1</sup>

Final

<b>Chair</b>	<b>Status</b>
I. Chinou	Final

### 1. Meetings scheduled for 2018

- 29 January – 1 February
- 27 - 28 March
- 4 - 7 June
- 23 – 26 July
- 24 – 27 September
- 19 - 22 November

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<sup>1</sup> '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.'

## 2. New EU herbal monographs and list entries

The following herbal substances and preparations thereof shall be assessed with a view to publishing<sup>2</sup> an EU herbal monograph or EU herbal monograph and list entry. When no monograph can be established, a public statement<sup>3</sup> will be published.

### 2.1. For finalisation

- Fragariae folium
- Glycini semen (PS)
- Malvae sylvestris flos
- Malvae folium
- Sennae folium
- Sennae fructus
- Silybi mariani fructus

### 2.2. Draft to be released for public consultation

- Calendulae herba
- Cisti cretici folium
- Vaccinii macrocarpi fructus
- Saccharomyces cerevisiae CBS 5926
- Species sedativae
- Species amarae
- Species digestivae or species stomachicae

### 2.3. To be started in 2018

- Herniariae herba
- Verbenae citriodorae folium
- Menyanthidis trifoliatae folium
- Salvia miltiorrhizae radix et rhizoma

## 3. Review and revision of final EU herbal monographs and list entries<sup>4</sup>

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).<sup>3</sup>

### 3.1. *Unscheduled review*<sup>3</sup>

- Pelargonium radix

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

<sup>3</sup> 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)

<sup>4</sup> See draft Procedure for the review and revision of European Union herbal monographs and European Union list entries (EMA/HMPC/124695/2011 Rev.2)

### **3.2. Periodic review<sup>3</sup>**

#### **3.2.1. Periodic reviews to be finalised in 2018**

- Avenae fructus
- Avenae herba
- Frangulae cortex
- Polypodii rhizoma
- Rhamni purshianae cortex
- Rhei radix

#### **3.2.2. Periodic reviews to be started in 2018**

##### **Herbal monographs**

- Bursae pastoris herba
- Echinaceae angustifoliae radix
- Filipendulae ulmariae flos
- Filipendulae ulmariae herba
- Hamamelidis cortex
- Hamamelidis folium
- Hamamelidis folium et cortex aut ramunculus destillatum
- Hippocastani semen
- Leonuri cardiaca herba
- Mate folium
- Myrrha (Commiphora molmol)
- Phaseoli fructus (sine semine)
- Quercus cortex
- Solidaginis virgaureae herba
- Tormentillae rhizoma
- Trigonellae foenugraeci semen

##### **Public Statements**

- Adhatoda vasica folium
- Andrographidis paniculatae folium
- Angelicae sinensis radix
- Centellae asiaticae herba
- Withaniae somniferae radix

### **3.3. Revision<sup>3</sup>**

#### **3.3.1. Revisions to be finalised in 2018**

- Agni casti fructus
- Calendulae flos
- Cimicifugae rhizoma
- Curcumae longae rhizoma
- Cynarae folium
- Menthae piperitae aetheroleum
- Menthae piperitae folium
- Rusci aculeati rhizoma
- Valerianae radix/Lupuli flos

### 3.3.2. Revisions to be published for public consultation 2018

- Echinaceae pallidae radix
- Foeniculi amari fructus
- Foeniculi amari fructus aetheroleum
- Foeniculi dulcis fructus
- Gentianae radix
- Hyperici herba (TU)
- Oenotherae biennis oleum
- Sambuci flos
- Tanacetii parthenii herba
- Thymi aetheroleum
- Verbasci flos

### 3.3.3. Revisions to be started in 2018

- Millefolii flos
- Millefolii herba

## 4. Guidelines and other guidance documents

### 4.1. Develop HMPC guidelines and guidance documents

Upon request from the HMPC, develop guidelines, public statements, reflection papers on (traditional) herbal medicinal products or other guidance documents, according the 'Procedure for European Union guidelines and related documents within the pharmaceutical legislative framework' (EMA/P/24143/2009 rev.).

### 4.2. Revise HMPC guidelines and guidance documents

Upon request from the HMPC, revise guidelines, public statements, reflection papers on (traditional) herbal medicinal products or other guidance documents, according the 'Procedure for European Union guidelines and related documents within the pharmaceutical legislative framework' (EMA/P/24143/2009 rev.).

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

*Action:* Finalisation of revision after public consultation

#### **'Guideline on non-clinical documentation for herbal medicinal products in applications for marketing authorisation (bibliographical and mixed applications) and in applications for simplified registration' (EMA/HMPC/32116/2005)**

*Action:* Finalisation of revision after public consultation

#### **'Reflection paper on markers used for quantitative and qualitative analysis of herbal medicinal products and traditional herbal medicinal products' (EMA/HMPC/253629/2007)**

*Action:* Comment on Q DG proposal of revised marker concept as necessary

### **4.3. 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).

## **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. In principle, procedural guidance is drafted by ORGAM DG, but when it refers to MLWP activities, MLWP should be always consulted before adoption.

### **'Best practice guide for revisions' (EMA/HMPC/433002/2017)**

Action: New guidance document for revision of monographs and list entries

## **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
- procedures for scientific advice and support by the HMPC.

## **7. Interactions with interested parties**

The following interactions are anticipated:

<b>Type</b>	<b>Interested party</b>	<b>Framework</b>	<b>Time</b>
Hearing	AESGP	Joint HMPC/MLWP hearing during MLWP meeting	25 September 2018