29 September 2014
EMA/HMPC/75972/2010 Rev. 1 *Corr*. [1]
Committee on Herbal Medicinal Products (HMPC)

# Template for a public statement when no European Union herbal monograph is established

Final

| | |
|---|---|
| Adoption by HMPC for release for consultation | 15 July 2010 |
| Publication | 15 February 2011 |
| Adoption by HMPC | 12 July 2011 |
| Revision 1 adopted by HMPC | 24 January 2012 |



| | |
|---|---|
| **Keywords** | Herbal medicinal products; HMPC; European Union herbal monographs; European Union list entries; Public statements |



[1] Changed 'Community' to 'European Union'


**Official address** Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
**Address for visits and deliveries** Refer to www.ema.europa.eu/how-to-find-us
**Send us a question** Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000
An agency of the European Union

<*date*>
<*doc ref*>
Committee on Herbal Medicinal Products (HMPC)

# Public statement on <plant, plant part>

*Insert botanical name of the plant according to the binomial system (genus, species, variety and author), [comma] the plant part in Latin.*

<Draft><Final>

| | |
|---|---|
| Discussion in Working Party on European Union Monographs and European Union List (MLWP) | |
| Adopted by Committee on Herbal Medicinal Products (HMPC) for release for consultation | |
| Start of public consultation | |
| End of consultation (deadline for comments)[2]. *This foot note only to appear in the final doc* Comments should be provided using this template. The completed comments form should be sent to hmpc.secretariat@ema.europa.eu | |
| Re-discussion in MLWP | |
| Adoption by HMPC | |

| | |
|---|---|
| **Keywords** | Herbal medicinal products; HMPC; European Union herbal monographs; European Union list entries; Public statements; <plant, plant part> *Insert botanical name of the plant according to the binomial system (genus, species, variety and author), [comma] the plant part in Latin*; <Latin term for herbal substance>; <English common name of herbal substance> |

[2] No comments were received during the period of public consultation. Therefore the final public statement is published together with the final assessment report and list of references, without an 'Overview of comments received during the public consultation'.

# Public statement on <plant, plant part>

*Insert botanical name of the plant according to the binomial system (genus, species, variety and author), [comma] the plant part in Latin.*

**PROBLEM STATEMENT**

The HMPC/MLWP decided to prepare a European Union herbal monograph on <*plant, plant part*> as announced in the <*year* MLWP work programme><*month year* HMPC meeting report>.

A comprehensive literature search was conducted and available data, including information on products on the market in the European Union, were assessed in relation to the requirements laid down in Directive 2001/83/EC and its Annex I, in particular Article 1, Article 10a and Chapter 2a.

The HMPC/MLWP concluded that the following <requirement><requirements> for the establishment of a European Union herbal monograph on <traditional><well-established> herbal medicinal products containing <*plant, plant part*> <is><are> not fulfilled:

<- the requirement laid down in Article 1 of Directive 2001/83/EC on the definition of the <'herbal substance'><'herbal preparation'> (despite the existence of data on the safety, efficacy and historical data on the medicinal uses within the European Union of products containing <substance(s)><preparation(s)> allegedly presented as <'herbal substance'><'herbal preparation'>)>

<- the requirement laid down in Article 10a of Directive 2001/83/EC that the active substance has a recognised efficacy and an acceptable level of safety and that the period of well-established medicinal use has elapsed>

<- the requirement laid down in Article 16a(1)(a) of Directive 2001/83/EC that the indications are "exclusively appropriate to traditional herbal medicinal products which, by virtue of their composition and purpose, are intended and designed for use without the supervision of a medical practitioner for diagnostic purposes or for prescription or monitoring of treatment">

<- the requirement laid down in Article 16a(1)(b) of Directive 2001/83/EC that the herbal substance or herbal preparation is "exclusively for administration in accordance with a specified strength and posology">

<- the requirement laid down in Article 16a(1)(c) of Directive 2001/83/EC that the herbal <substance><preparation> is an "oral, external and/or inhalation" <substance><preparation>>

<- the requirement laid down in Article 16a(1)(d) of Directive 2001/83/EC that "the period of traditional use as laid down on Article 16c(1)(c) has elapsed">

<- the requirement laid down in Article 16a(1)(e) of Directive 2001/83/EC that "the data on the traditional use of the medicinal product are sufficient; in particular the product proves not to be harmful in the specified conditions of use and the pharmacological effects or efficacy of the medicinal product are plausible on the basis of long-standing use and experience" >

<*Insert other justification or additional text as required*>

**CONCLUSIONS**

Based on the above-mentioned <concerns><information>,
<the HMPC is of the opinion that a European Union herbal monograph on <*plant, plant part*> cannot be established.>
<the HMPC decided that a European Union herbal monograph on <*plant, plant part*> is not established.>

<To read more about the assessment carried out, a link is provided to the page where to access the <draft> assessment report on <*plant, plant part*> and its list of references. >

http://www.ema.europa.eu/ema/index.jsp?curl=/pages/medicines/landing/herbal_search.jsp&murl=menus/medicines/medicines.jsp&mid=WC0b01ac058001fa1d