



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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EMA/HMPC/75972/2010 Rev. 1 *Corr.*<sup>1</sup>  
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

<b>Keywords</b>	Herbal medicinal products; HMPC; European Union herbal monographs; European Union list entries; Public statements
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<sup>1</sup> Changed 'Community' to '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)	
Adoption by HMPC for release for consultation	
End of consultation (deadline for comments) <sup>2</sup> . <i>This foot note only to appear in the final doc</i> Comments should be provided using this <a href="#">template</a> . The completed comments form should be sent to <a href="mailto:hmpc.secretariat@ema.europa.eu">hmpc.secretariat@ema.europa.eu</a>	
Rediscussion in MLWP	
Adoption by HMPC	

<b>Keywords</b>	Herbal medicinal products; HMPC; European Union herbal monographs; European Union list entries; Public statements; <plant, plant part> <i>Insert botanical name of the plant according to the binomial system (genus, species, variety and author), [comma] the plant part in Latin</i> ; <Latin term for herbal substance>; <English common name of herbal substance>
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<sup>2</sup> 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](http://www.ema.europa.eu/ema/index.jsp?curl=/pages/medicines/landing/herbal_search.jsp&murl=menus/medicines/medicines.jsp&mid=WC0b01ac058001fa1d)