



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 July 2011
EMA/HMPC/347189/2011
Committee on Herbal Medicinal Products (HMPC)

Public statement on *Allium cepa* L., bulbus

Draft

Discussion in Working Party on Community Monographs and Community List (MLWP)	May 2011
Adoption by HMPC for release for consultation	12 July 2011
End of consultation (deadline for comments). Comments should be provided using this template . The completed comments form should be sent to hmpc.secretariat@ema.europa.eu	15 November 2011
Rediscussion in MLWP	
Adoption by HMPC	

Keywords	Herbal medicinal products; HMPC; Community herbal monographs; Community list entries; Public statements; <i>Allium cepa</i> L., bulbus; <i>Allii cepae</i> bulbus; Onion
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Public statement on *Allium cepa* L., bulbus

PROBLEM STATEMENT

The HMPC/MLWP decided to prepare a Community herbal monograph on *Allium cepa* L., bulbus as announced in the meeting report from the January 2010 HMPC meeting.

After reviewing information on the products containing *Allium cepa* L., bulbus and preparations thereof marketed in the Community, it appears that very few products (single-ingredient and combination) are available.

A comprehensive literature search was conducted and available data, including information on products on the market in the Community, are assessed vis-à-vis 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 requirements for the establishment of a Community herbal monograph on traditional and well-established herbal medicinal products containing *Allium cepa* L., bulbus are not fulfilled:

- 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)(d) of Directive 2001/83/EC that “the period of traditional use as laid down on Article 16c(1)(c) has elapsed”

CONCLUSIONS

Based on the above-mentioned information, the HMPC is of the opinion that a Community herbal monograph on *Allium cepa* L., bulbus cannot be established.

To read more about the assessment carried out, a link is provided to the page where to access the draft assessment report on *Allium cepa* L., bulbus and its list of references.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/herbal/medicines/herbal_med_000156.jsp&murl=menus/medicines/medicines.jsp&mid=WC0b01ac058001fa1d