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**COMMITTEE ON HERBAL MEDICINAL PRODUCTS  
(HMPC)**

**DRAFT**

**PUBLIC STATEMENT ON *EUPHRASIA OFFICINALIS* L. AND *EUPHRASIA ROSTKOVIANA* HAYNE, HERBA**

<b>DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)</b>	May 2009 September 2009 November 2009
<b>ADOPTION BY HMPC FOR RELEASE FOR CONSULTATION</b>	12 November 2009
<b>END OF CONSULTATION (DEADLINE FOR COMMENTS)</b>	15 May 2010
<b>REDISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)</b>	
<b>ADOPTION BY HMPC</b>	

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<b>KEYWORDS</b>	Herbal medicinal products; HMPC; Community herbal monographs; Public statement; traditional use; <i>Euphrasia officinalis</i> L.; <i>Euphrasia rostkoviana</i> Hayne; Euphrasiae herba; eyebright herb
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**PUBLIC STATEMENT ON *EUPHRASIA OFFICINALIS* L. AND *EUPHRASIA ROSTKOVIANA* HAYNE, HERBA**

## **PROBLEM STATEMENT**

The HMPC/MLWP decided to prepare a Community herbal monograph on *Euphrasia officinalis* L. and *Euphrasia rostkoviana* Hayne, herba, as announced in the May 2009 HMPC meeting report. A comprehensive literature search was conducted and available data, including information on products on the market in the Community, were assessed vis-à-vis the requirements laid down in Chapter 2a of Directive 2001/83/EC as amended. The HMPC/MLWP concluded that the requirements for the establishment of a Community herbal monograph on traditional herbal medicinal products containing *Euphrasia officinalis* L. and *Euphrasia rostkoviana* Hayne, herba are fulfilled except the requirement laid down in Article 16a(1)(e) “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”.

Traditional herbal preparations from *Euphrasiae herba* are mainly liquid water extracts which are *ex tempore* made as infusions for application as an ocular impregnated dressing, in the following indication “Traditional herbal medicinal product for symptomatic treatment of minor irritation of the eye”.

The use of a nasal ointment containing an *Euphrasia* tincture<sup>1</sup> 20% as a traditional herbal medicinal product for the relief of local nasal irritation in common cold has also been documented.

No adequate data are however available for these preparations concerning:

- their safe use
- the plausibility of their pharmacological effects.

## **CONCLUSIONS**

Based on the above-mentioned concerns, the HMPC is of the opinion that no Community herbal monograph on *Euphrasia officinalis* L. and *Euphrasia rostkoviana* Hayne, herba can 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 *Euphrasiae herba* and its list of references.

<http://www.emea.europa.eu/htms/human/hmpc/hmpcmonographs.htm>

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<sup>1</sup> Specifications of the tincture not available.