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Committee on Herbal Medicinal Products (HMPC)

Public statement on *Euphrasia officinalis* L. and *Euphrasia rostkoviana* Hayne), herba

Final

Discussion in Working Party on Community monographs and Community list (MLWP)	September 2009 November 2009
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	November 2009
End of consultation (deadline for comments). Comments should be provided using this template to hmpc.secretariat@ema.europa.eu	15 May 2010
Rediscussion in Working Party on Community monographs and Community list (MLWP)	July 2010
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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* tincture¹ 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. Since the efficacy of the claimed uses is undocumented, and external eye application of *ex tempore* preparations is not hygienic and not safe, therapeutic use cannot be recommended.

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.ema.europa.eu/ema/index.jsp?curl=pages/medicines/herbal/medicines/herbal_med_000088.jsp&murl=menus/medicines/medicines.jsp&mid=WC0b01ac058001fa1d

¹ Specifications of the tincture not available.