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Committee on Herbal Medicinal Products (HMPC)

Public statement on *Citrus bergamia* Risso et Poiteau, aetheroleum

Draft

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Public statement on *Citrus bergamia* Risso et Poiteau, aetheroleum

PROBLEM STATEMENT

The HMPC/MLWP decided to prepare a Community herbal monograph on *Citrus bergamia* Risso et Poiteau, aetheroleum, as announced in the 2011 MLWP work programme.

The HMPC concluded that the following requirement for the establishment of a Community herbal monograph on traditional herbal medicinal products containing *Citrus bergamia* Risso et Poiteau, aetheroleum, is not fulfilled: 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”, because adequate information on posology on monotherapy for traditional use as an antiseptic and as an aid in healing of minor wounds is not available in the literature.

The HMPC/MLWP also concluded that the following requirement for the establishment of a Community herbal monograph on well-established herbal medicinal products containing *Citrus bergamia* Risso et Poiteau, aetheroleum, is 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. Non-clinical and clinical studies are not sufficient to support any well-established use indication and no single preparation medicinal product is authorised in the European Community.

CONCLUSIONS

Based on the above-mentioned information, the HMPC is of the opinion that a Community herbal monograph on *Citrus bergamia* Risso et Poiteau, aetheroleum, cannot be established unless new data are provided.

To read more about the assessment carried out, a link is provided to the page where to access the draft assessment report on *Citrus bergamia* Risso et Poiteau, aetheroleum, and its list of references.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/herbal/medicines/herbal_med_000059.jsp&mid=WC0b01ac058001fa1d