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Committee on Herbal Medicinal Products (HMPC)

Public statement on *Salvia miltiorrhiza* Bunge, radix et rhizoma

Final

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[1] 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'.

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PROBLEM STATEMENT

The HMPC decided to prepare a European Union herbal monograph on *Salvia miltiorrhiza* Bunge, radix et rhizoma as announced in the January 2018 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 concluded that the following requirements for the establishment of a European Union herbal monograph on traditional or well-established herbal medicinal products containing *Salvia miltiorrhiza* Bunge, radix et rhizoma 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)(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)(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".

The HMPC acknowledges the existence of numerous publications on the use in the European Union of *Salvia miltiorrhiza* Bunge, radix et rhizoma or constituents thereof. However, often an appropriate description of herbal substance or herbal preparations used are missing. Available data are not sufficient to establish a European Union herbal monograph at present.

CONCLUSIONS

Based on the above-mentioned concerns, the HMPC is of the opinion that an European Union herbal monograph on *Salvia miltiorrhiza* Bunge, radix et rhizoma cannot be established.
To read more about the assessment carried out, a link is provided to the page where to access the assessment report on *Salvia miltiorrhiza* Bunge, radix et rhizoma and its list of references.

https://www.ema.europa.eu/en/medicines/herbal/salviae-miltiorrhizae-rhizoma