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Committee on Herbal Medicinal Products (HMPC)

Public statement on *Piper methysticum* G. Forst., rhizoma Draft

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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 March 2017

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Public statement on *Piper methysticum* G. Forst., rhizoma

PROBLEM STATEMENT

The HMPC/MLWP decided to prepare a European Union herbal monograph on *Piper methysticum* G. Forst., rhizoma as announced in the 2016 MLWP work programme and the May 2015 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/MLWP concluded that the following requirements for the establishment of a European Union herbal monograph on traditional or well-established herbal medicinal products containing *Piper methysticum* G. Forst., rhizoma are not fulfilled:

- 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 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 HMPC has found sufficient evidence of toxicological concerns (carcinogenic potential in animals) in relation to a herbal preparation.

The HMPC noticed the presence of spontaneously reported liver adverse drug reactions, including cases of liver failure resulting in liver transplants and deaths and the withdrawal of products in some Member States due to safety concerns related to liver toxicity. Therefore the benefit-risk assessment on *Piper methysticum* G. Forst., rhizoma is considered negative with respect to the establishment of a European Union herbal monograph.

CONCLUSIONS

Based on the above-mentioned concerns the HMPC is of the opinion that a European Union herbal monograph on *Piper methysticum* G. Forst., 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 *Piper methysticum* G. Forst., rhizoma and its list of references.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/herbal/medicines/herbal_med_000222.jsp&mid=WC0b01ac058001fa1d

The HMPC/MLWP will welcome the provision of the necessary data to allow continuation of the assessment work.