



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29 September 2015
EMA/HMPC/682247/2013 Rev. 1
Committee on Herbal Medicinal Products (HMPC)

Public statement on prioritisation for assessment of herbal substances associated with safety concerns

Final

Discussion in Working Party on European Union Monographs and List (MLWP)	November 2013 January 2014 March 2014
Adoption by Committee on Herbal Medicinal Products (HMPC)	6 May 2014
Discussion Revision 1 in MLWP	July 2015
Adoption Revision 1 by HMPC	29 September 2015

Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; European Union list entries; Public statements; herbal substances containing constituents associated with safety concerns, prioritisation
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PROBLEM STATEMENT

The HMPC/MLWP previously reviewed all the proposals for herbal substances in medicinal use in Europe included in the inventory list ([EMA/HMPC/494079/2007](#)) for preparation of European Union herbal monographs and Entries to the European Union list. The review was carried out to address the need to assign the Rapporteur and to start with a comprehensive literature search on the available data, including information on products on the market in the European Union, thus facilitating the assessment in relation to the requirements laid down in Directive 2001/83/EC, in particular Article 1, Article 10a and Chapter 2a, and its Annex I.

During the prioritisation it was recognised that some herbal substances included in the inventory list are known to be toxic, to contain constituents known to be toxic or to pose serious safety concerns.

A positive benefit-risk assessment outcome was considered unlikely for these herbal substances as the following requirements for the establishment of a European Union herbal monograph on traditional or well-established herbal medicinal products would not be 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
- 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 to prove that the product is not harmful in the specified conditions of use

It was recognised that some of these herbal substances, used for medicinal purposes, are widely traded via the internet or sold as different categories of products despite the fact that concerns had been raised about their safety in medicinal products resulting in restrictive actions in some Member States. (See HMPC Public Statement on CPMP list of herbal drugs with serious risks dated 1992, [EMA/HMPC/246736/2005](#)).

Having concluded that updating the CPMP list dated 1992 would require a considerable amount of resources with no guarantee of a positive conclusion, the HMPC decided to restrict the evaluation to only those herbal substances that were proposed for the preparation of European monographs.

Since the HMPC primary task is to establish monographs and list entries to facilitate the marketing authorisation/registration of herbal medicinal products in the Member States, it is considered important to focus the limited existing resources on preparing monographs on herbal substances with a likely positive outcome, rather than to perform a detailed assessment of herbal substances with recognised safety concerns.

However, the use of these herbal substances outside of the medicinal legislative framework is not recommended and should be evaluated critically.

Moreover, it is possible that these herbal substances and preparations thereof can be the active substance(s) in registered or authorised medicinal products, provided that an adequate dossier meeting all the requirements and providing sufficient information to result in a positive benefit-risk assessment is presented by the applicant.

CONCLUSIONS

Based on the concerns outlined above, the HMPC is of the opinion that priority should not be given to assessment of the list of herbal substances in the Annex below because it is likely that an EU herbal monograph would not be established due to the probability of an unfavourable benefit-risk assessment.

The list is not exhaustive and will be updated should further proposals be made for the development of monographs where the herbal substances have safety concerns likely to lead to a negative benefit-risk assessment.

Any herbal substance included in the list could be reconsidered for prioritisation depending on new information or need for assessment arising from specific circumstances.

ANNEX

List of herbal substances

Acorus calamus, rhizoma

Angelica archangelica, radix

Chelidonium majus, rhizoma

Convallaria majalis, herba

Ephedra spp., herba

Piper methysticum, rhizoma

Rauwolfia spp., radix