



European Medicines Agency  
Evaluation of Medicines for Human Use

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**COMMITTEE ON HERBAL MEDICINAL PRODUCTS  
(HMPC)**

**FINAL**

**PUBLIC STATEMENT ON “CPMP LIST OF HERBAL DRUGS WITH SERIOUS RISKS,  
DATED 1992”**

<b>ADOPTION BY HMPC FOR RELEASE FOR CONSULTATION</b>	July 2005
<b>END OF CONSULTATION (DEADLINE FOR COMMENTS)</b>	September 2005
<b>REDISCUSSION IN HMPC</b>	November 2005
<b>ADOPTION BY HMPC</b>	November 2005

**PUBLIC STATEMENT ON “CPMP LIST OF HERBAL DRUGS WITH SERIOUS RISKS,  
DATED 1992”**

During its meetings in 2005, the Committee on Herbal Medicinal Products (HMPC) has reflected on the status of the following document: ‘CPMP List of herbal drugs<sup>1</sup> with serious risks’, dated 1992.

The document was considered by the previous Herbal Medicinal Products Working Party between 1997 and 2004 and a strategy for updating the document had been prepared.

The Committee during its discussions balanced the importance of the document from a public health point of view and the need for its update. In the context of its priority tasks, notably in the field of traditional herbal medicinal products, the Committee could not commit to carry out the update of the list in the months ahead. Nevertheless, the Committee considers important to clarify to parties concerned with the use of herbal medicinal products that:

- the list was prepared and adopted by the Committee for Proprietary Medicinal Products (CPMP) under a different regulatory framework than the current one;
- the list was published by the European Commission in October 1992;
- national actions resulted from this publication in a number of Member States.

Furthermore, reference is made to the new legislative framework<sup>2</sup> under which the safety of herbal preparations must be documented with an assessment on a case-by-case basis.

The Committee considers that this list is a useful source of information on plants with intrinsic safety risks and therefore decides to publish the list as it stands. New safety aspects concerning the plants on list may be identified during the establishment of Community herbal monographs or entries to the Community ‘List of herbal substances, preparations or combinations thereof for use in traditional herbal medicinal products’.

Parties concerned with the use of herbal medicinal products are advised to consult other guidance documents published by the Committee such as the Public statements on the use of medicinal products containing asarone, estragole and methyleugenol.

HMPC Public statement on the use of herbal medicinal products containing asarone  
<http://www.emea.eu.int/pdfs/human/hmpc/13921505en.pdf>

HMPC Public statement on the use of herbal medicinal products containing estragole  
<http://www.emea.eu.int/pdfs/human/hmpc/13721205en.pdf>

HMPC Public statement on the use of herbal medicinal products containing methyleugenol  
<http://www.emea.eu.int/pdfs/human/hmpc/13836305en.pdf>

Information on additional substances can be found at the following location:  
<http://www.emea.eu.int/htms/human/hmpc/hmpcguide.htm>

**The ‘CPMP List of herbal drugs with serious risks’, dated 1992 can be found [here](#).**

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<sup>1</sup> The term “herbal drug” as defined in the European Pharmacopoeia is considered as equivalent to the term “herbal substance” referred to in HMPC guidance documents, including guidelines on the quality of herbal medicinal products.

<sup>2</sup> Directive 2004/24/EC of 31 March 2004 amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use.