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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

PUBLIC STATEMENT ON THE INTERPRETATION OF THE TERM 'EXTERNAL USE' FOR USE IN THE FIELD OF TRADITIONAL HERBAL MEDICINAL PRODUCTS

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BACKGROUND

As part of Directive 2004/24/EC, amending Directive 2001/83/EC, as regards traditional herbal medicinal products, a simplified registration procedure has been established for herbal medicinal products, which fulfil certain criteria as laid down in Article 16a of the Directive. One of these criteria states that the herbal medicinal product should be "*…an oral, external and/or inhalation preparation"*. However, the legislation remains silent on the interpretation for the term "external".

The necessity of having a harmonised interpretation of this term at European level has arisen in light of the various approaches applied in the Member States that may lead to disagreement and misinterpretation of the scope of the simplified registration of traditional herbal medicinal products. In addition, the lack of a harmonised interpretation and application of this term among the EU Member States may cause problems in relation to drafting of EU herbal monographs and the EU list of traditional herbal substances.

To allow the HMPC to carry out its tasks relevant to its mandate as established by the EU legislation, the Committee has taken action to reach agreement on a harmonised interpretation for use in the framework of the traditional use registration only. It should be noted that the safe use of the product must be guaranteed, even if it is used without any medical advice.

CONCLUSION AND RECOMMENDATION

The HMPC agreed at the 11-12 January 2006 meeting on the following wording for a harmonised interpretation of the term 'external use', for use in the framework of the traditional use registration:

"For the purpose of traditional use registration, the term 'external use' shall be interpreted as 'application to the skin'; however if the traditional use of a herbal substance, preparation or medicinal product refers to the delivery to the oral, nasal, rectal, vaginal mucosae or to ocular or auricular use, such use may be acceptable if no safety concerns exist and if local action is intended."