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Committee on Herbal Medicinal Products (HMPC)

Public statement on the interpretation of therapeutic indications appropriate to traditional herbal medicinal products in Community herbal monographs

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Background

In May 2010, the HMPC sought a legal interpretation from the European Commission of the provisions regarding indications appropriate to traditional herbal medicinal products laid down in Article 16a(1)(a) of Directive 2001/83/EC.

“...they have indications 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 HMPC enquired about the possibility for the indications of traditional herbal medicinal products to refer to a prior medical diagnosis with a view to excluding serious conditions, thus ensuring that patients safely use traditional herbal medicines for self-medication. The preceding medical diagnosis can be remote in time from the decision to take a traditional herbal medicine.

The HMPC welcomed in July 2010¹ the legal interpretation received from the European Commission that Community herbal monographs with indications relating to traditional use may refer to a prior medical diagnosis intended to prevent treatment of more serious pathologies with traditional herbal medicinal products. In any case, the traditional herbal medicinal product still needs to be “intended and designed for use without the supervision of a medical practitioner”. The traditional herbal medicinal product has to be a non-prescription medicine.

Conclusion and recommendation

In Community herbal monographs, it is possible for the indications of traditional herbal medicinal products to refer to the use ‘after exclusion of serious conditions by a medical doctor’, to prevent treatment of more serious pathologies with traditional herbal medicinal products. Each indication needs a careful medical evaluation and decisions will be taken on a case-by-case basis.

Examples from published Community herbal monographs:

- *Tanacetum parthenium* (L.) Schulz Bip., herba (feverfew) - *final*

Traditional herbal medicinal product for the prophylaxis of migraine headaches, after serious conditions have been excluded by a medical doctor.

- *Leonurus cardiaca* L., herba (motherwort) - *final*

Traditional herbal medicinal product used to relieve symptoms of nervous cardiac complaints such as palpitations, after serious conditions have been excluded by a medical doctor.

- *Capsella bursa-pastoris* (L.) Medikus, herba (shepherd's purse) - *final*

Traditional herbal medicinal product for the reduction of heavy menstrual bleeding in women with regular menstrual cycles, after serious conditions have been excluded by a medical doctor.

¹ See HMPC meeting report 14-15 July 2010 (EMA/HMPC/468796/2010)
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/document_listing/document_listing_000193.jsp&murI=menus/about_us/about_us.jsp&mid=WCOb01ac0580028e96

- *Quercus robur L., Q. petraea (Matt.) Liebl. and Q. pubescens Willd., cortex (oak bark) - final*

Traditional herbal medicinal product for symptomatic relief of itching and burning associated with haemorrhoids, after serious conditions have been excluded by a medical doctor.

- *Cucurbita pepo L., semen (pumpkin seed) - draft*

Traditional herbal medicinal product for the relief of lower urinary tract symptoms related to benign prostatic hyperplasia and/or related to an overactive bladder, after serious conditions have been excluded by a medical doctor.

- *Urtica dioica L., Urtica urens L., their hybrids or mixtures, radix (nettle root) - draft*

Traditional herbal medicinal product for the relief of lower urinary tract symptoms related to benign prostatic hyperplasia, after serious conditions have been excluded by a medical doctor.

Please refer to the corresponding monograph for all information on safety and efficacy of the herbal substance and/or herbal preparation(s).