European Medicines Agency
Evaluation of Medicines for Human Use

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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

FINAL

GUIDELINE ON THE DOCUMENTATION TO BE SUBMITTED FOR INCLUSION INTO THE 'COMMUNITY LIST OF HERBAL SUBSTANCES[1], PREPARATIONS[2] AND COMBINATIONS THEREOF FOR USE IN TRADITIONAL HERBAL MEDICINAL PRODUCTS'

DISCUSSION IN HMPC	January 2005 March 2005
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[1] The term "herbal substance" should be considered equivalent to the term "herbal drug" as defined in the European Pharmacopoeia

[2] The term "herbal preparation" should be considered equivalent to the term "herbal drug preparation" as defined in the European Pharmacopoeia

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GUIDELINE ON THE DOCUMENTATION TO BE SUBMITTED FOR INCLUSION INTO THE 'COMMUNITY LIST OF HERBAL SUBSTANCES, PREPARATIONS AND COMBINATIONS THEREOF FOR USE IN TRADITIONAL HERBAL MEDICINAL PRODUCTS'

Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004[3], amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use

Article 16h indicates that:
"A Committee for Herbal Medicinal Products is hereby established. That Committee shall…have the following competence:

(a) as regards simplified registrations, to:

…

- prepare a draft list of herbal substances, preparations and combinations thereof as refered to in Article 16f (1);

…".

Article 16f (1) reads as follows:
1. A list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products shall be established in accordance with the procedure referred to in Article 121(2). The list shall contain, with regard to each herbal substance, the indication, the specified strength and the posology, the route of administration and any other information necessary for the safe use of the herbal substance as a traditional medicinal product.

[3] Published in the Official Journal of the EU on 30 April 2004

Documents to be submitted for inclusion in the 'Community list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products'

1. Scientific name of the plant

- Binomial scientific name of plant (genus, species, variety and author), and chemotype (where applicable)
- Reference to a Pharmacopoeia in the following order of priority: Official monograph European Pharmacopoeia, Official national Pharmacopoeia, Other Pharmacopoeia, Index Kewensis
- Botanical family
- Common name in all EU official languages if available

2. Herbal substance(s) or Herbal preparation(s) or Combination(s)

Description of formula

Description of fixed combination related to the indication (Article 16f(3))

Information on the **herbal substance** should be provided:
- Binomial scientific name of plant (genus, species, variety and author), and chemotype (where applicable)
- Parts of the plants
- Definition of the herbal substance
- Other names (synonyms mentioned in the European Pharmacopoeia and other Pharmacopoeias)
- Common name in all EU official languages

Information on the **herbal preparation** should be provided:
- Binomial scientific name of plant (genus, species, variety and author), and chemotype (where applicable)
- Parts of the plants
- Definition of the herbal preparation
- Genuine ratio of the herbal substance to the herbal preparation
- Extraction solvent(s)
- Other names (synonyms mentioned in the European Pharmacopoeia and other Pharmacopoeias)
- Excipients, where applicable

The following information for **herbal substance(s) and herbal preparation(s)** where applicable, should be provided:

- Physical form
- Description of the constituents with known therapeutic activity or markers (molecular formula, relative molecular mass, structural formula, including relative and absolute stereochemistry, the molecular formula, and the relative molecular mass).
- Other constituent(s)

Description of the structure

Information on the **herbal substance(s)** should be provided:

- Information on the botanical, macroscopical, microscopical, phytochemical characterisation, and biological activity if necessary, should be provided:

Information on the **herbal preparation(s)** should be provided:

- Information on the phyto- and physicochemical characterisation, and biological activity if necessary, should be provided:

3. Specified strength, posology, route of administration and duration of use

Information on the **specified strength** should be provided:

- The declaration of the strength should be in accordance with the 'Guideline on quality of herbal medicinal products/traditional herbal medicinal products' (CPMP/QWP/2819/00 Rev.1)
- Information on the dose range

Information on the **posology** should be provided:

- Information should be provided per population group

Information on the route of administration should be provided:

- The route of administration should be specified: oral, external or inhalation
- The route of administration should be expressed in accordance with the Standard Terms of the European Pharmacopoeia.

Information on the duration of use or any restrictions on the duration of use should be provided:

- Any specific data should be submitted when available

4. Traditional medicinal use

The documentation should demonstrate compliance with the requirements for traditional use laid down in Article 16.c.1.c. including:

- 30/15 years medicinal use within the Community
- Bibliographical or expert evidence of medicinal use in specified indication
- Bibliographical review of safety data

The type of tradition should be provided, where relevant.

5. Any other information necessary for the safe use

Information on any other information for the safe use should be provided:

- The SPC sections should be in line with the 'Guideline on the Summary of Product Characteristics' (Notice to Applicants, Volume 2C Regulatory guidelines).
- Documentation on undesirable effects should provide comprehensive information based on all adverse reactions (ADRs).

Pharmacological effects and efficacy plausible on the basis of long-standing use and experience

- Such information shall be included if necessary for the safe use of the product.