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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

DRAFT

CONCEPT PAPER ON THE DEVELOPMENT OF A GUIDELINE ON PREPARATION OF HERBAL TEAS

AGREED BY HMPC WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	September 2008
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1. INTRODUCTION

One of the main tasks given to the Committee on Herbal Medicinal Products (HMPC) by Directive 2001/83/EC, as amended by Directive 2004/24/EC, is to prepare a draft list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products (THMPs) and to establish Community herbal monographs for herbal medicinal products (HMPs) having well established use as well as traditional use.

The Community list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products (Community list), prepared by HMPC and issued by the European Commission, in accordance with the procedure referred to in Article 121(2) of Directive 2001/83/EC as amended, 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 THMP. If an application for traditional-use registration relates to a herbal substance, preparation or a combination thereof contained in the Community list, the applicant is not required to provide evidence of the safe and long standing use of the THMP in question if he demonstrates that the proposed products and the related claims in the application comply with the information contained in the Community list.

The Community herbal monographs established by the HMPC have relevance for the authorisation or registration of HMPs/THMPs; they shall be taken into account by the Member States when examining an application and the application/registration holder shall consider whether it is necessary to modify the registration dossier accordingly.

2. PROBLEM STATEMENT

In Community herbal monographs and Community list entries primary importance is given to the strength and posology and to the method of administration of the herbal substance/preparation for each specified indication, because they are related to the safe use of the THMPs/HMPs and to the efficacy of HMPs having well established use, as assessed by HMPC on the basis of the historic use of that product in the European Community (traditional use) and the available scientific data (well-established use).

For herbal substances/preparations that require to be administered as herbal tea, instructions on the method of preparation and the concentration of the herbal tea may be crucial, because different preparations may exert different actions and in some circumstances may have a different safety profile. Moreover, in particular traditions or for specified herbal substances/preparations, specific methods of preparation of the herbal tea shall be applied.

A harmonised approach at EU level for providing the above-mentioned information on preparation of herbal teas according to standard terminology in herbal monographs and related documents is therefore considered necessary, provided that no specific guidelines exist on the matter.

3. DISCUSSION (ON THE PROBLEM STATEMENT)

Herbal teas are oral aqueous preparations, usually prepared immediately before use, obtained exclusively from one or more herbal substance(s) by means of decoction, infusion or maceration. The herbal substance(s) may be processed in advance (e.g. comminuted, crushed, etc.), resulting in herbal preparation(s), supplied in bulk or in sachets.

Herbal teas can show wide fluctuation in concentration of their constituents, due to the intrinsic characteristics of the plant material or as a consequence of a wrong tea preparation procedure, that is influenced by the type (tissue) of plant material and by the characteristics of the constituents to be extracted into the tea (heat resistance, solubility, toxicity, organoleptic properties). As far as concern the microbiological aspects, the European Pharmacopoeia gives different recommendation on microbiological quality of the herbal substance(s) taking into account the prescribed method of preparation of the herbal tea, i.e. the use of boiling or non-boiling water.

Like for the preparations obtained by means of other extraction methods, the composition of a herbal tea is affected not only by the quality and the intrinsic characteristic of the herbal substance/preparation, but also by the drug extract ratio (DER), time and temperature of the tea preparation operations and the possible addition of other substances used to facilitate the extraction of specific constituents (e.g. organic acids to improve the extraction of alkaloids). Instructions for preparation of a herbal tea should therefore specify these parameters together with the method used (infusion, decoction or maceration).

4. RECOMMENDATION

The HMPC recommends the development of a guideline on the instructions for the preparation of herbal teas and the standardisation of terminology used in Community herbal monographs/Community list entries and related documents.
The guideline shall provide, for each standard tea preparation method, the definition, the instructions for the preparation of the starting plant material and the herbal tea, including tools, qualitative and quantitative composition of solvents, DER, time, temperature of various preparation steps, the precaution in the administration and the preservation conditions. Criteria for the choice of the tea preparation method shall also be provided referring to its suitability.
It is expected to have general standard processing methods that shall be complemented by additional specifications applicable in particular circumstances and that shall be specified case by case.
The guideline shall address herbal teas prepared from one or more herbal substances and shall provide directions for appropriate combination and processing of mixtures.
Combined methods shall also be described.
The evaluation of the above mentioned issues will result in standardised wording to be used within the relevant sections of Community herbal monographs/Community list entries (pharmaceutical form, posology and method of administration) and related documents.
An outline of different traditional preparations (e.g. Traditional Chinese Medicine) will be useful to identify the need for further instructions.
The guideline shall apply to HMPs for human use and THMPs.

5. PROPOSED TIMETABLE

It is anticipated that a draft guideline could be available 6 months after the adoption of the concept paper. The draft will then be released for external consultation for three months. The guideline could be finalised within 6 months after external consultation.

6. RESOURCE REQUIREMENTS FOR PREPARATION

The Rapporteur will prepare a draft guideline. The preparation of this guideline will involve coordination with CHMP Quality Working Party (QWP). Member States are invited to provide comments via their Committee and/or working party members.

7. IMPACT ASSESSMENT (ANTICIPATED)

Industry attributes great importance to the development of the Community List and Community herbal monographs which offer significant advantages to applicants.
Consistency in terminology and instructions used in monographs and related documents together with definition of each standard method will help to clarify the preparation, avoiding misunderstanding among different parties, and will give to the Rapporteur a guidance for providing specification on posology and/or special instructions, particularly where deviations from the standard preparation procedure is required.
Health care professionals, patients and consumers will also have an useful reference paper.

8. INTERESTED PARTIES

Comments from Interested Parties[1] could be integrated during the development of the guideline, should they wish to submit comments at this stage.

9. REFERENCES TO LITERATURE, GUIDELINES ETC

1. European Pharmacopoeia General Monograph "Herbal Teas" 01/2008:1435
2. European Pharmacopoeia General Chapter "Microbiological quality of pharmaceutical preparations" 01/2008:50104.
3. Farmacopea Ufficiale Italiana XI ed. Istituto Poligrafico e Zecca dello Stato.
4. Formulario nazionale della Farmacopea Ufficiale Italiana IX ed. Istituto Poligrafico e Zecca dello Stato.
5. Farmacopea Ufficiale Italiana VII ed. Istituto Poligrafico e Zecca dello Stato.
6. Procedure for the Preparation of Community monograph for traditional herbal medicinal products (EMEA/HMPC/182320/2005) Current Rev.
7. Procedure for the Preparation of Community monograph for herbal medicinal products with well established medicinal use (EMEA/HMPC/182352/2005) Current Rev.

[1] Pharmaceutical industry associations, learned societies, academic groups, health care professional groups, consumers and patients' associations, etc.