



London, 4 September 2008  
Doc. Ref. EMEA/HMPC/451978/2008

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

**DRAFT**

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

<b>AGREED BY HMPC WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)</b>	September 2008
<b>ADOPTION BY HMPC FOR RELEASE FOR CONSULTATION</b>	4 September 2008
<b>END OF CONSULTATION (DEADLINE FOR COMMENTS)</b>	15 January 2009
<b>AGREED BY HMPC WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)</b>	
<b>ADOPTION BY HMPC</b>	

Comments should be provided to [hmpc.secretariat@emea.europa.eu](mailto:hmpc.secretariat@emea.europa.eu)  
Fax: +44 20 75 23 70 51

**KEYWORDS**

herbal medicinal products; traditional herbal medicinal products; herbal substances; herbal preparations; herbal tea; herbal infusion; decoction; maceration; HMPC; quality

16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60  
61  
62  
63  
64  
65  
66  
67  
68  
69  
70  
71

## 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.

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

#### 81 **4. RECOMMENDATION**

83 The HMPC recommends the development of a guideline on the instructions for the preparation of  
84 herbal teas and the standardisation of terminology used in Community herbal monographs/Community  
85 list entries and related documents.

86 The guideline shall provide, for each standard tea preparation method, the definition, the instructions  
87 for the preparation of the starting plant material and the herbal tea, including tools, qualitative and  
88 quantitative composition of solvents, DER, time, temperature of various preparation steps, the  
89 precaution in the administration and the preservation conditions. Criteria for the choice of the tea  
90 preparation method shall also be provided referring to its suitability.

91 It is expected to have general standard processing methods that shall be complemented by additional  
92 specifications applicable in particular circumstances and that shall be specified case by case.

93 The guideline shall address herbal teas prepared from one or more herbal substances and shall provide  
94 directions for appropriate combination and processing of mixtures.

95 Combined methods shall also be described.

96 The evaluation of the above mentioned issues will result in standardised wording to be used within the  
97 relevant sections of Community herbal monographs/Community list entries (pharmaceutical form,  
98 posology and method of administration) and related documents.

99 An outline of different traditional preparations (e.g. Traditional Chinese Medicine) will be useful to  
100 identify the need for further instructions.

101 The guideline shall apply to HMPs for human use and THMPs.

#### 104 **5. PROPOSED TIMETABLE**

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

#### 111 **6. RESOURCE REQUIREMENTS FOR PREPARATION**

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

#### 118 **7. IMPACT ASSESSMENT (ANTICIPATED)**

120 Industry attributes great importance to the development of the Community List and Community herbal  
121 monographs which offer significant advantages to applicants.

122 Consistency in terminology and instructions used in monographs and related documents together with  
123 definition of each standard method will help to clarify the preparation, avoiding misunderstanding  
124 among different parties, and will give to the Rapporteur a guidance for providing specification on  
125 posology and/or special instructions, particularly where deviations from the standard preparation  
126 procedure is required.

127 Health care professionals, patients and consumers will also have an useful reference paper.

128  
129  
130  
131  
132  
133  
134  
135  
136  
137  
138  
139  
140  
141  
142  
143  
144  
145  
146  
147  
148

## 8. INTERESTED PARTIES

Comments from Interested Parties<sup>1</sup> 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.

---

<sup>1</sup> Pharmaceutical industry associations, learned societies, academic groups, health care professional groups, consumers and patients' associations, etc.