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Committee on Herbal Medicinal Products (HMPC)

Glossary on herbal teas

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Comments received on the 'Concept paper on the development of a guideline on preparation on herbal teas' released for consultation on 15 October 2008 have been taken into account in the preparation of this Glossary.

Revision 1 consists of the integration of the new annex.

Keywords	Herbal medicinal products; traditional herbal medicinal products; HMPC; herbal substances; herbal preparations; herbal tea; infusion; decoction; maceration; digestion; quality
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Executive summary

The purpose of this paper is to define the terms applied to the preparation of herbal teas by patients. The definitions will help to clarify the terms used to describe the preparation of herbal teas in documents related to the Community monographs for herbal medicinal products (HMPs)/traditional herbal medicinal products (THMPs) and in the entries to the Community list of herbal substances, preparations and combinations thereof for use in THMPs.

In annex, this paper includes guidance on how to describe, in section 4.2 of a Community herbal monograph or in the section 'Specified posology' of a Community list entry, the single dose or the average daily dose

- for herbal substance or comminuted herbal substance for herbal tea for oral use
- for herbal substance or comminuted herbal substance for infusion/decoction/macerate preparation for oromucosal use, cutaneous use or other relevant route of administration.

1. Introduction

For herbal substances/preparations that are administered as herbal tea, instructions on the method of preparation 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 need to be applied. A harmonised approach at European level on the terms used for the preparation of herbal teas in Community herbal monographs and related documents is considered necessary as no current guidelines exist.

2. Scope

This paper applies to HMPs /THMPs intended to be administered in the form of herbal teas.

Instant herbal teas as defined by the European Pharmacopoeia monograph are not covered by this paper, because the preparation of the instant herbal tea in this case consists solely of reconstitution with water.

The paper describes and defines the terms used to describe the preparation of herbal teas for use as HMPs/THMPs for which the HMPC establishes Community herbal monographs or which are proposed for inclusion in the Community list.

Applicants should consider this paper in conjunction with the relevant legislation on Community herbal monographs and Community list and the HMPC 'Guideline on declaration of herbal substances and herbal preparations in herbal medicinal products/traditional herbal medicinal products in the SPC'.

3. Legal basis and considerations

One of the main tasks given to HMPC by Directive 2001/83/EC, as amended, is to prepare a draft list of herbal substances, preparations and combinations thereof for use in THMPs and to establish Community herbal monographs for HMPs having well-established use as well as traditional use.

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 HMPs/THMPs and to the efficacy of HMPs having well-established use. The HMPC assesses mostly bibliographic safety and efficacy data, which are usually combined, for well-established use products, with product specific

data. For traditional herbal medicinal products, the HMPC assesses specifically historical data on the medicinal uses as well as the plausibility of such uses and the conditions for a safe use.

Many HMPs, and in particular THMPs, are administered in the form of herbal teas. The definition of herbal teas is given in the European Pharmacopoeia with reference to the intended purpose, preparing aqueous preparations for oral use, by means of decoction, infusion or maceration. However, the European Pharmacopoeia does not include details on how to prepare these preparations.

Therefore this paper provides an explanation of the terms used.

4. Definitions

Herbal teas (plantae ad ptisanam) consist of one or more herbal substances intended for oral aqueous preparations prepared by means of decoction, infusion or maceration¹. The preparation is prepared immediately before use. Herbal teas are usually supplied in bulk form or in sachets (Ph. Eur.). The herbal substance(s) used for the herbal teas may be processed in advance (e.g. comminuted, crushed, etc.).

The term 'herbal teas' is also used to designate the oral aqueous preparations (tisanes or ptisanae) obtained by means of decoction, infusion or maceration.

Usually, infusion is appropriate for leaves, flowers and delicate parts whereas decoction or maceration are appropriate for roots, rhizomes and barks.

Infusions² (infusa) are liquid preparations extemporaneously prepared by pouring boiling water on the herbal substance(s), whole or reduced to a suitable size and allowing to steep for a defined period of time, usually 5 to 15 minutes, when not otherwise specified. The corresponding operation is referred to as 'infusion'.

The use of boiling water is important for lowering the microbial bioburden of the herbal substances. This is recognised by the European Pharmacopoeia in determining the different recommendations on microbiological quality for medicinal products containing herbal substances and/or herbal preparations.

Decoctions² (decocta) are liquid preparations extemporaneously prepared by pouring cold water on the herbal substance(s), reduced to a suitable size, heating to the boil and allowing to simmer for a defined period of time depending upon the type and size of the plant material, usually for 15 to 30 minutes when not otherwise specified. The corresponding operation is referred to as 'decoction'. Decoction is generally not applicable to herbal substances containing volatile active constituents.

Macerates² (macerata) are liquid preparations extemporaneously prepared by soaking the herbal substance(s), reduced to a suitable size, in water at room temperature for a defined period of time, usually for 30 minutes, when not otherwise specified. The corresponding operation is referred to as 'maceration'. When the maceration is performed with gentle heating at a temperature higher than room temperature, but not to boiling, the process is termed 'digestion'.

Herbal tea mixtures (species ad ptisanam) are mixtures of herbal substances prepared in appropriate dimensions to facilitate mixing and to reduce the potential separation and settling of the different ingredients.

¹ Infusion, decoction and maceration are procedures that can also be used for extemporaneous herbal preparations for other routes of administration such as cutaneous or oromucosal use.

² This kind of extemporaneous preparation can also be used for other routes of administration such as cutaneous or oromucosal use.

References

1. European Pharmacopoeia General Monograph "Herbal Teas" 01/2008:1435
2. European Pharmacopoeia General Chapter "Microbiological quality of medicinal products containing herbal drugs and/or herbal drug preparations" 04/2010:50108
3. Farmacopea Ufficiale Italiana XII ed. Istituto Poligrafico e Zecca dello Stato
4. Pharmacopée française Xème éd. Monographie "Tisanes" (2007)
5. Formulario Nazionale della Farmacopea Ufficiale Italiana IX ed. Istituto Poligrafico e Zecca dello Stato.
6. Procedure for the preparation of Community monograph for traditional herbal medicinal products (EMA/HMPC/182320/2005) Current Rev.
7. Procedure for the preparation of Community monograph for herbal medicinal products with well-established medicinal use (EMA/HMPC/182352/2005) Current Rev.
8. Concept paper on the development of a guideline on preparation of herbal teas (EMA/HMPC/451978/2008)
9. Guideline on declaration of herbal substances and herbal preparations in herbal medicinal products/traditional herbal medicinal products in the SPC (EMA/HMPC/CHMP/CVMP/287539/05 Rev. 1)

Guidelines are available on the Agency website (www.ema.europa.eu).

The pharmaceutical legislation (Eudralex) is available on the European Commission website (http://ec.europa.eu/enterprise/sectors/pharmaceuticals/documents/eudralex/index_en.htm)

Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, as amended.

Annex

Guidance on how to describe, in section 4.2 of a Community herbal monograph or in the section 'Specified posology' of a Community list entry, the single dose or the average daily dose

- for herbal substance or comminuted herbal substance for herbal tea for oral use
- for herbal substance or comminuted herbal substance for infusion/decoction/macerate preparation for oromucosal use, cutaneous use or other relevant route of administration

	Herbal substance	Herbal preparations
Single dose	Herbal tea: ... g of the <freshly> fragmented ³ herbal substance in ... ml of boiling water as a herbal infusion ... times daily	Herbal tea: ... g of the comminuted herbal substance in ... ml of boiling water as a herbal infusion ... times daily
	Herbal tea: ... g of the herbal substance in ... ml of water as a decoction ... times daily	Herbal tea: ... g of the comminuted herbal substance in ... ml of water as a decoction ... times daily
	Herbal tea: ... g of the <freshly> fragmented herbal substance in ... ml of water as a macerate ... times daily	Herbal tea: ... g of the comminuted herbal substance in ... ml of water as a macerate ... times daily
	Herbal substance for <infusion> <or> <decoction> <or> <macerate> preparation for <oromucosal> <or> <cutaneous use> <or> <bath preparation> <or> <other relevant route of administration>: ... g of the <freshly> fragmented herbal substance in ... ml of water ... times daily	Comminuted herbal substance for <infusion> <or> <decoction> <or> <macerate> preparation for <oromucosal> <or> <cutaneous use> <or> <bath preparation> <or> <other relevant route of administration>: ... g of the comminuted herbal substance in ... ml of water ... times daily
Average daily dose	Herbal tea: ... g of the <freshly> fragmented herbal substance in ... ml of boiling water as a herbal infusion, divided in ... single doses	Herbal tea: ... g of comminuted herbal substance in ... ml of boiling water as a herbal infusion, divided in ... single doses
	Herbal tea: ... g of the herbal substance in ... ml of water as a decoction, divided in ... single doses	Herbal tea: ... g of comminuted herbal substance in ... ml of water as a decoction, divided in ... single doses
	Herbal tea: ... g of the <freshly> fragmented herbal substance in ... ml of water as a macerate, divided in ... single doses	Herbal tea: ... g of the comminuted herbal substance in ... ml of water as a macerate, divided in ... single doses
	Herbal substance for <infusion> <or> <decoction> <or> <macerate> preparation for <oromucosal use> <or> <cutaneous use> <or> <bath preparation> <or> <other relevant route of administration>: ... g of the <freshly> fragmented herbal substance in ... ml of water, divided in ... single doses	Comminuted herbal substance for <infusion> <or> <decoction> <or> <macerate> preparation for <oromucosal use> <or> <cutaneous use> <or> <bath preparation> <or> <other relevant route of administration>: ... g of the comminuted herbal substance in ... ml of water, divided in ... single doses

The DER, the indication of contact time and indication of the therapeutic dose should be taken into consideration by the Rapporteur. The standard wording shall be complemented by additional specific instructions to explain any deviation from the usual procedure or in particular circumstances, that shall be specified case by case: for instance qualitative and quantitative composition of solvents when different from potable water, any substances to be added to improve the dissolution of particular herbal constituents, precaution in the administration and the preservation conditions.

³ The term 'fragmented' encompasses the terms 'broken' and 'crushed'.