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Committee on Herbal Medicinal Products (HMPC)

Patient Leaflet template concerning advice on the preparation of herbal teas as (traditional) herbal medicinal products by end-users

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1. Executive summary

This document is prepared for consideration by National Competent Authorities and Applicants with the purpose of proposing a template providing instructions to the user on the best practice for preparing a herbal tea (by infusion, decoction, maceration), using standard terminology.

This template describes the preparation of herbal teas depending on the prescribed method.

2. 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.

Since the wide variability in the concentration of the constituents of a herbal tea can be due to intrinsic characteristics (i.e. growing, harvesting, drying and preservation conditions of the plant material) and to the tea preparation procedure, in order to limit fluctuation from the extraction procedures, detailed instructions to users should be provided (e.g. solvent when different from drinking water, temperature and time of the operations).

Combination methods are necessary if a tea mixture includes ingredients that need different methods of preparation. For example, in a tea mixture some ingredients might need to undergo maceration and others need to be infused or decocted. Aromatic herbs like mint may be infused at the end of a decoction.

Moreover, for 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 European Union herbal monographs and related documents is given in the Glossary of herbal teas (EMA/HMPC/5829/2010 Rev.1).

3. Scope

This paper applies to herbal medicinal products (HMPs)/traditional herbal medicinal products (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.

This template should be considered in conjunction with the relevant legislation on European Union herbal monographs and European Union list, the 'Guideline on declaration of herbal substances and herbal preparations in herbal medicinal products/traditional herbal medicinal products', the 'Glossary on herbal teas', the 'Concept paper on the development of a guideline on preparation on herbal teas', the 'Addendum to the Quality Review of Documents templates for SmPC, Labelling and Patient Leaflet on Mutual-recognition and Decentralised procedures specific for (Traditional) Herbal Medicinal Products ((T)HMPs)', and the 'Guideline on Summary of Product Characteristics' as published on the Website of the European Commission in the Notice to Applicants, Volume 2C.

4. Definitions

Decoctions¹ (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.

Drug extract ratio (DER) means the ratio between the quantity of herbal substance used in the manufacture of a herbal preparation and the quantity of the herbal preparation obtained. The number (given as the actual range) written before the colon is the relative quantity of the herbal substance; the number written after the colon is the relative quantity of the herbal preparation obtained.

Herbal medicinal products are any medicinal product, exclusively containing as active substances one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations.

Herbal preparations are obtained by subjecting herbal substances to treatments such as extraction, distillation, expression, fractionation, purification, concentration or fermentation. These include comminuted or powdered herbal substances, tinctures, extracts, essential oils, expressed juices and processed exudates.

Herbal substances all, mainly whole, fragmented or cut plants, plant parts, algae, fungi, lichen in an unprocessed, usually dried form but sometimes fresh. Certain exudates that have not been subjected to a specific treatment are also considered to be herbal substances. Herbal substances are precisely defined by the plant part used and the botanical name according to the binomial system (genus, species, variety and author).

Herbal teas (plantae ad ptisanam) consist of one or more herbal substances intended for oral aqueous preparations prepared by means of decoction, infusion or maceration². 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 is appropriate for roots, rhizomes and barks.

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.

Infusions (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.

¹ This kind of extemporaneous preparation can also be used for other routes of administration such as cutaneous or oromucosal use.

² 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.

Macerates¹ (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'.

Traditional herbal medicinal products: Herbal Medicinal Products for human use that fulfil the conditions laid down in Article 16a (1) of Directive 2001/83/EC.

5. Legal basis and considerations

Directive 2001/83/EC introduces the legal framework for the provision of European Union herbal monographs covering the therapeutic uses and safe conditions of well-established and/or traditional use for herbal substances and preparations.

This document aims to provide guidance on how to provide further explanation on the preparations of herbal teas according to the prescribed method in the patient leaflet.

The same approach is also recommended to be considered for HMPs/THMPs authorised or registered according to a national procedure.

It is suggested that the patient leaflet of HMPs/THMPs for human use intended to be administered in form of herbal tea or for infusion/decoction/macerate preparation includes under the section 3. 'How to take use X' a subsection 'Instructions for preparation'. This subsection is also recommended to be described in the SmPC under section 6.6. Special precautions for disposal and other handling or under section 4.2 Posology and method of administration.

6. Template

The 'Instructions for preparation' subsection is recommended to be structured as follows.

Standard statements are given in the template, which is recommended to be used whenever they are applicable.

If the applicant needs to deviate from these statements to accommodate medicinal product-specific requirements, alternative or additional statements will be considered on a case-by-case basis by the National Competent Authority.

Bracketing convention:

{text}: Information to be filled in

<text>: Text to be selected or deleted as appropriate

[text]: instructions

[The standard wording is recommended to be complemented by additional specific instructions to explain any deviation from the usual procedure or in particular circumstances, that should be specified case by case: e.g. qualitative and quantitative composition of solvents when different from drinking water, any substances (e.g. small amount of acid or alkaline substances) to be added to improve the dissolution of selected herbal constituents, the need to previously moisten with cold water tough plant material (e.g. barks, woods, seeds, dry fruits, roots, and rhizomes), preservation conditions, precaution in the administration. It is up to the applicant to convert the grams in other suitable measure more friendly for the patients (e.g. measuring spoon)].

Infusion

The herbal tea is supplied <loose> <in sachets>.

To make an infusion, pour {...} ml of boiling drinking water over {...} g ({...} <sachet(s)> <measuring spoon(s)>) of <name of the herbal medicinal product>. Let steep for {...} minutes keeping covered with a lid, stirring at regular intervals.

[If loose] Gently stir before filtering through a tea strainer. <Press the herbal residue in the tea strainer <with a spoon> to obtain more liquid filtered and to enrich the final solution.>

[If in sachets] <Gently squeeze the sachet(s) <with a spoon> in order to obtain more liquid filtered and to enrich the final solution.>

<In order to obtain the recommended final volume of herbal infusion, you may have to rinse the <herbal residue in the tea strainer><sachet(s)> with boiling water.>

[Where recommended] <Add {...} to <sweeten> <flavour>. <Do not <sweeten>.>

[Where relevant] <Add <tincture to be defined><extract to be defined> to the hot herbal infusion.>

Let the herbal infusion cool down to an appropriate temperature [to be specified where relevant] before drinking³. Always stir <with a spoon> before taking the recommended dosage.

Drink³ the herbal infusion shortly after preparation; if not, the herbal infusion should be stored covered with a lid in the fridge maximum for 24 hours.

Decoction

To make a decoction, submerge {...} g ({...} <sachet(s)> <measuring spoon(s)>) of <name of the herbal medicinal product> with {...} ml of cold drinking water, heating to the boil and allowing to simmer (maintaining a gentle boil) for {...} minutes keeping covered with a lid, stirring at regular intervals.

<Use with the herbal residue.>

[When only the liquid is used] Gently stir before filtering through a tea strainer. <Press the herbal residue in the tea strainer <with a spoon> to obtain more liquid filtered and to enrich the final solution.> <Rinse the herbal residue in the tea strainer with boiling water> <Repeat decoction on the herbal residue a second time> to obtain the recommended final volume of herbal decoction.>

[When second decoction is necessary] <<Discard> <Set aside> the liquid of the first decoction and repeat decoction on the herbal residue a second time. <In order to obtain the recommended final volume of herbal decoction, you may have to rinse the herbal residue in the tea strainer with boiling water>>. <Mix the liquids obtained from the two decoctions>. <Use with the herbal residue.>

[Where recommended] <Add {...} to <sweeten> <flavour>. <Do not sweeten>

[Where relevant] <Add <tincture to be defined><extract to be defined> to the hot herbal decoction.>

Let the herbal decoction cool down to an appropriate temperature [to be specified where relevant] before drinking³. Always stir <with a spoon> before taking the recommended dosage.

³ Infusions 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. In this case "drinking" should be substituted by "using" and "drink" by "use".

Drink³ the herbal decoction shortly after preparation; if not, the herbal decoction should be stored covered with a lid in the fridge maximum for 24 hours.

Maceration

To make a macerate, soak with {...} ml of <cold> <lukewarm <(maximum temperature of {...} °C)>> drinking water g ({...} <sachet(s)> <measuring spoon(s)>) of <name of the herbal medicinal product>.

[When digestion is required] <Heat gently and keep at lukewarm water <(30-50°C)>.>

Let steep for {...} <minutes> <hours> <overnight> keeping covered with a lid, <stirring <frequently> <at regular intervals>>.

<Use with the herbal residue.>

[When only the liquid is used] <Gently stir before filtering through a tea strainer. Press the residue in the tea strainer <with a spoon> to obtain more liquid filtered and to enrich the final solution.>

<Repeat maceration on the herbal residue a second time to obtain the recommended final volume of herbal macerate.>

<Add {...} to <sweeten> <flavour>.

<Add <tincture to be defined><extract to be defined> to the herbal macerate.>

Always stir <with a spoon> before taking the recommended dosage.

Drink³ the macerate immediately after preparation; if not, the herbal macerate should be discarded.

³ Infusions 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. In this case "drinking" should be substituted by "using" and "drink" by "use".

7. References

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)

Addendum to the Quality Review of Documents templates for SmPC, Labelling and Patient Leaflet on Mutual-recognition and Decentralised procedures specific for (Traditional) Herbal Medicinal Products ((T)HMPs) (CMDh/349/2016; EMA/HMPC/770889/2014)

Concept paper on the development of a guideline on preparation of herbal teas (EMA/HMPC/451978/08)

Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the European Union code relating to medicinal products for human use

European Pharmacopoeia General Monograph 'Herbal Teas' (Ref.: 1435)

European Pharmacopoeia General Chapter 5.1.8 'Microbiological quality of herbal medicinal products for oral use and extract used in their preparation' (Ref.: 50108)

Farmacopea Ufficiale Italiana XII ed. Istituto Poligrafico e Zecca dello Stato (2008)

Formulario Nazionale della Farmacopea Ufficiale Italiana IX ed. Istituto Poligrafico e Zecca dello Stato

Glossary of herbal teas (EMA/HMPC/5829/2010 Current Rev)

Guideline on declaration of herbal substances and herbal preparations in herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/CHMP/CVMP/287539/05 Current Rev)

Guideline on Summary of Product Characteristics (http://ec.europa.eu/health/files/eudralex/vol-2/c/smpc_guideline_rev2_en.pdf)

Pharmacopée française Xème éd. Monographie 'Tisanes' (2007)

Procedure for the preparation of European Union monographs for traditional herbal medicinal products (EMA/HMPC/182320/2005 Current Rev).

Procedure for the preparation of European Union monographs for herbal medicinal products with well-established medicinal use (EMA/HMPC/182352/2005 Current Rev.)

Template for a European Union herbal monograph (EMA/HMPC/30603/2005 Current Rev.)