29 September 2014
EMA/HMPC/107436/2005 Rev. 7, *Corr. 1*[1]
Committee on Herbal Medicinal Products (HMPC)

Template for a European Union herbal monograph

Final

Adoption by HMPC	20 September 2005
Revision 2 adopted by HMPC	11 January 2007
Revision 3 adopted by HMPC	6 March 2008
Revision 4 adopted by HMPC	16 July 2009
Revision 5 adopted by HMPC	15 July 2010
Revision 6 adopted by HMPC	12 July 2011
Revision 7 agreed by ORGAM DG	January 2014 May 2014 February 2014 September 2014
Revision 7 agreed by MLWP	July 2014
Revision 7 adopted by HMPC	September 2014

[1] Corrected reference to legislation: e.g. 'Directive 2001/83/EC as amended' replaced with 'Directive 2001/83/EC'.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

This template is to be read in conjunction with the following documents:

'Procedure for the preparation of European Union monographs for herbal medicinal products with well-established medicinal use' (EMA/HMPC/182352/2005 Rev.2)

'Procedure for the preparation of European Union monographs for traditional herbal medicinal products' (EMA/HMPC/182320/2005 Rev.2)

'Template for assessment report for the development of European Union herbal monographs and European Union list entries' (EMA/HMPC/418902/2005 Rev.3)

'Glossary on herbal teas' (EMA/HMPC/5829/2010 Rev.1)

'Principles for declaration of herbal preparations in HMPC monographs' (EMA/HMPC/641515/2010) - internal document

'Regulatory Q&A on herbal medicinal products' (EMA/HMPC/345132/2010)

- *All instruction notes (in green) must be deleted before finalising the monograph.*

<date>
<doc ref>
Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on <plant>, <plant part>, <aetheroleum>

Insert botanical name of the plant according to the binomial system (genus, species, variety and author), [comma] the plant part in Latin.

<Draft><Final>

Initial assessment	
Discussion in Working Party on European Union monographs and European Union list (MLWP)	
Adopted by Committee on Herbal Medicinal Products (HMPC) for release for consultation	
Start of public consultation	
End of consultation (deadline for comments[2]). <Comments should be provided using this template to hmpc.secretariat@ema.europa.eu>	
Rediscussion in MLWP	
Adoption by HMPC Monograph (EMEA/HMPC/XXX/20XX) AR (EMEA/HMPC/ XXX/20XX) List of references (EMEA/HMPC/ XXX/20XX) <Overview of comments received during the public consultation (EMEA/HMPC/ XXX/20XX)> HMPC Opinion (EMEA/HMPC/ XXX/20XX)	
First systematic review	
Discussion in MLWP	
Adopted by HMPC for release for consultation	
Start of public consultation	
End of consultation (deadline for comments[3]). <Comments should be provided using this template to hmpc.secretariat@ema.europa.eu>.	
Re-discussion in MLWP	
Adoption by HMPC	

Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; <well-established medicinal use>; <traditional use>; <plant, plant part> *Insert botanical name of the plant according to the binomial system (genus, species, variety and author), [comma] the plant part in Latin.*; <Latin term for herbal substance>; <English common name of herbal substance>

[2] No comments were received during the period of public consultation. Therefore the final monograph is published together with the final assessment report and list of references, without an 'Overview of comments received during the public consultation'.

[3] No comments were received during the period of public consultation. Therefore the final monograph is published together with the final assessment report and list of references, without an 'Overview of comments received during the public consultation'.

The footnote 1 should only appear in the final monograph and when relevant.

BG (bulgarski):	LT (lietuvių kalba):
CS (čeština):	LV (latviešu valoda):
DA (dansk):	MT (Malti):
DE (Deutsch):	NL (Nederlands):
EL (elliniká):	PL (polski):
EN (English):	PT (português):
ES (español):	RO (română):
ET (eesti keel):	SK (slovenčina):
FI (suomi):	SL (slovenščina):
FR (français):	SV (svenska):
HR (hrvatski):	IS (íslenska):
HU (magyar):	NO (norsk):
IT (italiano):	

European Union herbal monograph on <plant>, <plant part>, <aetheroleum>

Insert botanical name of the plant according to the binomial system (genus, species, variety and author), [comma] the plant part in Latin.

1. Name of the medicinal product

To be specified for the individual finished product.

2. Qualitative and quantitative composition[4, 5]

Well-established use	**Traditional use**
With regard to the marketing authorisation application of Article 10(a) of Directive 2001/83/EC <Latin binomial name of plant>, <plant part used in Latin> (<herbal substance name in English>) *In case of essential oil* <Latin binomial name of plant>, <aetheroleum> (<essential oil name in English>) i) Herbal substance <Not applicable. > *OR* <As defined in the Ph. Eur. monograph.>*OR* <*xxx*> *Insert description of the HS*	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC <Latin binomial name of plant>, <plant part used in Latin> (<herbal substance name in English>) *In case of essential oil* <Latin binomial name of plant>, <aetheroleum> (<essential oil name in English>) i) Herbal substance <Not applicable. > *OR* <As defined in the Ph. Eur. monograph.> *OR* <*xxx*> *Insert description of the HS (whether dried or fresh, whether whole or fragmented[6]) when there*

[4] *Always insert standard footnote:* The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

[5] *Insert footnote on material compliance to European Pharmacopoeia* <The material complies with the Ph. Eur. monograph (ref.: <*insert number*>, *or in absence thereof, a national pharmacopoeia currently used officially in a Member State. Otherwise, include the following statement:* <Detailed specifications for the herbal substance shall be given by references to bibliographic sources in absence of a monograph in the European Pharmacopoeia, a national pharmacopoeia or national codex currently used officially in a Member State>.

[6] *The term 'fragmented' encompasses the terms 'broken' and 'crushed'.*

Well-established use	Traditional use
(whether dried or fresh, whether whole or fragmented[3]) when there is no European or national pharmacopoeia monograph. ii) Herbal preparations a) <Comminuted herbal substance> b) <Powdered herbal substance> c) <Dry extract (DER *x*-*y*:1), extraction solvent <*solvent*>> d) <Liquid extract (DER 1: *x*-*y*), extraction solvent <*solvent*>> e) <Tincture (ratio of herbal substance to extraction solvent <1:5><1:10>), extraction solvent <*solvent*>> *Examples of extraction solvents:* <water><ethanol *xx*% V/V> <methanol *xx*% V/V><ethanol *yy*% m/m><ethanol *xx*-*yy*% V/V> *In case of essential oil* Essential oil *(description to be given only in the absence of the Ph. Eur. Monograph)*	*is no European or national pharmacopoeia monograph* ii) Herbal preparations[7] a) <Comminuted herbal substance> b) <Powdered herbal substance> c) <Dry extract (DER *x*-*y*:1), extraction solvent <*solvent*>> d) <Liquid extract (DER 1: *x*-*y*), extraction solvent <*solvent*>> e) <Tincture (ratio of herbal substance to extraction solvent <1:5><1:10>), extraction solvent <*solvent*>> *Examples of extraction solvents:* <water><ethanol *xx*% V/V> <methanol *xx*% V/V><ethanol *yy*% m/m><ethanol *xx*-*yy*% V/V> *In case of essential oil* Essential oil *(description to be given only in the absence of the Ph. Eur. Monograph)*

3. Pharmaceutical form

Well-established use	Traditional use
<<Herbal substance> <or><comminuted herbal substance> as herbal tea for oral use.> <Herbal preparations in <liquid> <or> <solid> dosage forms for oral use.> <<Herbal substance> <or> <comminuted herbal substance> for <infusion> <or> <decoction> <or> <macerate> preparation for <oromucosal use> <or> <cutaneous use> <or>	<<Herbal substance> <or><comminuted herbal substance> as herbal tea for oral use.> <Herbal preparations in <liquid> <or> <solid> dosage forms for oral use.> <<Herbal substance> <or> <comminuted herbal substance> for <infusion> <or> <decoction> <or> <macerate> preparation for <oromucosal use> <or> <cutaneous use> <or> <*insert*

[7] *As appropriate, reference to a national compendium or the characteristics of a given preparation should be given in a separate footnote for this preparation*

Well-established use	Traditional use
<*insert other relevant route of administration*>.> <Herbal preparations in <liquid> <or> <semi-solid> <or> <solid> dosage forms for <*insert relevant route of administration other than oral use*.> The pharmaceutical form should be described by the European Pharmacopoeia full standard term.	*other relevant route of administration*>.> <Herbal preparations in <liquid> <or> <semi-solid> <or> <solid> dosage forms for <*insert relevant route of administration, other than oral use*.> The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
<Indication 1) Herbal medicinal product *XXX* .> <Indication 2) Herbal medicinal product *XXX* .	<Indication 1) Traditional herbal medicinal product <used> for *XXX* <after serious conditions have been excluded by a medical doctor>.> <Indication 2) Traditional herbal medicinal product <used> for *XXX* <after serious conditions have been excluded by a medical doctor>.> The product is a traditional herbal medicinal product for use in <the specified indication> <specified indications> exclusively based upon long-standing use.

4.2. Posology and method of administration[8]

Well-established use	Traditional use
Posology *If necessary, it should be distinguished between different indications.* *<Children,> <Adolescents,> <Adults,><and> <Elderly>* <Single dose>	**Posology** *If necessary, it should be distinguished between different indications.* *<Children,> <Adolescents,> <Adults><and> <Elderly>* <Single dose>

[8] *If section 4.2 contains a posology for herbal tea or for (comminuted) herbal substance for decoction/infusion/macerate preparation, include the standard footnote* <For guidance on herbal substance/herbal preparation administered as herbal tea or as infusion/decoction/macerate preparation, please refer to the HMPC 'Glossary on herbal teas' (EMA/HMPC/5829/2010 Rev.1).>

Well-established use	Traditional use
<Average daily dose><Daily dose> *If there is no risk of confusion between the different preparations (dry extract, liquid extract, etc), the DER and extraction solvent do not need to be repeated in the posology section.* *For guidance on how to present available data on the single dose or the average daily dose for herbal tea and for (comminuted) herbal substance for decoction/infusion/macerate preparation, please refer to the annex. If no data are available, this should be discussed.* <The use in <children and adolescents under 18 years of age><children under 12 years of age><children between *A* and *B* years of age> is not recommended (see section 4.4 'Special warnings and precautions for use').> <The use in <children and adolescents under 18 years of age><children under 12 years of age><children between *A* and *B* years of age> is contraindicated (see section 4.3 'Contraindications').> <There is no relevant indication in <the paediatric population><children and adolescents under 18 years of age>< children under 12 years of age><children between *A* and *B* years of age>. **Duration of use** <If the symptoms persist during the use of the medicinal product, a doctor or a pharmacist should be consulted.> *As required, insert information about restriction to the duration of use.* **Method of administration** *Insert route of administration* *Add instructions as relevant*	<Average daily dose><Daily dose> *If there is no risk of confusion between the different preparations (dry extract, liquid extract, etc), the DER and extraction solvent do not need to be repeated in the posology section.* *For guidance on how to present available data on the single dose or the average daily dose for herbal tea and/or for (comminuted) herbal substance for decoction/infusion/macerate preparation, please refer to the annex. If no data are available, this should be discussed.* <The use in <children and adolescents under 18 years of age><children under 12 years of age><children between *A* and *B* years of age> is not recommended (see section 4.4 'Special warnings and precautions for use').> <The use in <children and adolescents under 18 years of age><children under 12 years of age><children between *A* and *B* years of age> is contraindicated (see section 4.3 'Contraindications').> <There is no relevant use in <the paediatric population><children and adolescents under 18 years of age>< children under 12 years of age><children between *A* and *B* years of age>. **Duration of use** *EITHER* <If the symptoms persist longer than *XXX* during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.> *When there is no cause for concern.* *OR* <Not to be used for more than *XXX*. If the symptoms persist during the use of the

Well-established use	Traditional use
For macerates include the following standard sentence: <The macerate should be used immediately after preparation.>	medicinal product, a doctor or a qualified health care practitioner should be consulted.> *When there is a cause for concerns e.g. presence of certain constituents.* **Method of administration** <Oral use.> <Cutaneous use.> <Cutaneous <and><or> transdermal use.> <Oromucosal use.> <Inhalation.> <Rectal use.> <Anorectal use.> <Auricular use.> <Dental use.> <Gingival use.> <Nasal use.> <Ocular use.> <Use as bath additive.> *Add instructions as relevant* *For macerates include the following standard sentence:* <The macerate should be used immediately after preparation.>

4.3. Contraindications

Well-established use	Traditional use
<Hypersensitivity <to the active substance(s)> <and> <to other *[insert species name]* species><and><to other plants of the *[insert botanical family name]* family>.>	<Hypersensitivity <to the active substance(s)> <and><to other *[insert species name]* species><and><to other plants of the *[insert botanical family name]* family>.> <Children and adolescents under 18 years of age><children under 12 years of age> <children between *A* and *B* years of age> <because of the presence of *xxx*><because of *[insert*

Well-established use	Traditional use
	reason]>

4.4. Special warnings and precautions for use

Well-established use	Traditional use
<The use is not recommended in children <above> <below> {age *Y*} due to <a lack of> <insufficient> data on <safety> <and> <or> <efficacy>. <If the symptoms worsen during the use of the medicinal product, a doctor or a pharmacist should be consulted.> <For <tinctures><extracts> containing ethanol the appropriate labelling for ethanol, taken from the 'Guideline on excipients in the label and package leaflet of medicinal products for human use', must be included.> *This standard statement is relevant in case of liquid preparations for oral use.*	<The use in <children and adolescents under 18 years of age><children under 12 years of age><children between *A* and *B* years of age> <has not been established due to lack of adequate data.><is not recommended because of concerns requiring medical advice.> <If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.> <For <tinctures><extracts> containing ethanol, the appropriate labelling for ethanol, taken from the 'Guideline on excipients in the label and package leaflet of medicinal products for human use', must be included.> *This standard statement is relevant in case of liquid preparations for oral use.*

4.5. Interactions with other medicinal products and other forms of interaction

Well-established use	Traditional use
<None reported.>	<None reported.>

4.6. Fertility, pregnancy and lactation

Well-established use	Traditional use
See examples of statements in the appendix 3 of the 'Guideline on risk assessment of medicinal products on human reproduction and lactation: from data to labelling' (EMA/CHMP/203927/2005). <Not relevant.> <Safety during pregnancy and lactation has not been established.><In the absence of sufficient data, the use during pregnancy and lactation is not recommended.>	*See examples of statements in the appendix 3 of the 'Guideline on risk assessment of medicinal products on human reproduction and lactation: from data to labelling' (EMA/CHMP/203927/2005).* <Not relevant.> <Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.>

Well-established use	Traditional use
<There are no or limited data from use during pregnancy and lactation.> <Studies in animals have shown reproductive toxicity (see section 5.3 'Preclinical safety data').> <The use is not recommended <during pregnancy and lactation><during *{trimester}* of pregnancy><during lactation>.> <There are no data from use during pregnancy or lactation.> <No concern has arisen about any malformation in humans.> <No fertility data available.>	<The use should be avoided during pregnancy and lactation <(see section 5.3 'Preclinical safety data')>.> <There are no or limited data from use during pregnancy and lactation.> <Studies in animals have shown reproductive toxicity (see section 5.3 'Preclinical safety data').> <The use is not recommended <during pregnancy and lactation><during *{trimester}* of pregnancy><during lactation>.> <There are no data from use during pregnancy or lactation.> <No concern has arisen about any malformation in humans.> <No effects during pregnancy are anticipated, since systemic exposure is negligible.> <No fertility data available.>

4.7. Effects on ability to drive and use machines

Well-established use	Traditional use
<Not relevant.> <No studies on the effect on the ability to drive and use machines have been performed.> <*{Herbal substance/preparation}* has <no or negligible> <minor or moderate> <major> influence on the ability to drive and use machines.> <May impair ability to drive and use machines. Affected patients should not drive or operate machinery.>	<Not relevant.> <No studies on the effect on the ability to drive and use machines have been performed.> <*{Herbal substance/preparation}* has <no or negligible> <minor or moderate> <major> influence on the ability to drive and use machines.> <May impair ability to drive and use machines. Affected patients should not drive or operate machinery.>

4.8. Undesirable effects

Well-established use	Traditional use
<None known. If adverse reactions occur, a doctor or a pharmacist should be consulted.>	<None known. If adverse reactions occur, a doctor or a qualified health care practitioner should be consulted.>

Well-established use	Traditional use
OR <*XXX* <has> <have> been reported. The frequency is not known. If other adverse reactions not mentioned above occur, a doctor or a pharmacist should be consulted.> **OR** <*XXX* may occur. The frequency is not known. If other adverse reactions not mentioned above occur, a doctor or a pharmacist should be consulted.> **OR** *When available, frequencies of cited adverse reactions should be stated according to the convention laid down in the SmPC guideline.*	**OR** <*XXX* <has> <have> been reported. The frequency is not known. If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.> **OR** <*XXX* may occur. The frequency is not known. If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.> **OR** *When available, frequencies of cited adverse reactions should be stated according to the convention laid down in the SmPC guideline.*

4.9. Overdose

Well-established use	Traditional use
<No case of overdose has been reported.>	<No case of overdose has been reported.>

5. Pharmacological properties

5.1. Pharmacodynamic properties

Well-established use	Traditional use
Pharmacotherapeutic group: {*group*} Proposed ATC code: {*code*}	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC.

5.2. Pharmacokinetic properties

Well-established use	Traditional use
<No data available.>	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC.

5.3. Preclinical safety data[9]

Well-established use	Traditional use
<Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction.> <Effects in non-clinical studies were observed only at exposures considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use.> <Adverse reactions not observed in clinical studies, but seen in animals at exposure levels similar to clinical exposure levels and with possible relevance to clinical use were as follows.>	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC, unless necessary for the safe use of the product. <Tests><Adequate tests> on <reproductive toxicity><,> <genotoxicity> <and> <carcinogenicity> have not been performed.>

6. Pharmaceutical particulars

Well-established use	Traditional use
<Not applicable.>	<Not applicable.>

7. Date of compilation / last revision

<*insert date*>

This date should always be identical to the date on the first page. For publication on the Agency website, the date shall be the date of adoption by the HMPC.

[9] *When necessary, insert the following footnote:* <Where herbal preparations from <*insert Latin HS name*> are used, the total exposure to <*insert name of constituent*> should be considered from a safety standpoint.>

	Herbal substance	Herbal preparations
Single dose	Herbal tea: … g of the <freshly> fragmented[10] 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.

[10] The term 'fragmented' encompasses the terms 'broken' and 'crushed'.