EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 March 2024
EMA/HMPC/107436/2005 Rev. 8
Committee on Herbal Medicinal Products (HMPC)

Template for a European Union herbal monograph

Draft – Revision 8

Adoption by Committee on Herbal Medicinal Products (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 HMPC Organisational Matters Drafting Group (ORGAM DG)	January 2014 May 2014 February 2014 September 2014
Revision 7 agreed by HMPC Working Party on European Union Monographs and European Union List (MLWP)	July 2014
Revision 7 adopted by HMPC[1]	September 2014
Draft Revision 8 adopted by HMPC for release for consultation	20 March 2024
Start of public consultation	15 April 2024
End of consultation (deadline for comments)	15 July 2024

Comments should be provided using this template. The completed comments form should be sent to hmpc.secretariat@ema.europa.eu

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

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Note:

- *All instruction notes (in green) must be deleted before finalising the AR.*
- *None of the headings should be deleted.*
- *There are several examples of standard sentence to be used, if appropriate.*
- *All sections of the monograph should have a justification in the AR.*

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

'Procedure for the preparation of European Union herbal monographs and European Union list entries and appointment of HMPC rapporteurs and peer-reviewers' (EMA/HMPC/887331/2022)

'Procedure for the review and revision of European Union herbal monographs and European Union list entries' (EMA/HMPC/124695/2011)

'Template for assessment report for the development of European Union herbal monographs and European Union list entries' (EMA/HMPC/418902/2005 Rev.6)

'Guideline on declaration of herbal substances and herbal preparations1 in herbal medicinal products2 /traditional herbal medicinal products' (EMA/HMPC/CHMP/CVMP/287539/2005 Rev. 1)

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

'Public statement on the interpretation of therapeutic indications appropriate to traditional herbal medicinal products in Community herbal monographs' (EMA/HMPC/473587/2011)

'Public statement on the interpretation of the term 'external use' for use in the field of traditional herbal medicinal products (EMEA/HMPC/31897/2006)

'A guideline on summary of product characteristics (SmPC)' September 2009 Revision 2

'Addendum to the Quality Review of Documents templates for SmPC, Labelling and Package Leaflet on Mutual recognition and Decentralised procedures specific for (Traditional) Herbal Medicinal Products ((T)HMPs)' (CMDh/349/2016)

<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) Assessment Report (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><insert number as appropriate> systematic review	
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>.	
Rediscussion in MLWP	
Adoption by HMPC	

Keywords	Committee on Herbal Medicinal Products; HMPC; European Union herbal monographs; herbal medicinal products; traditional herbal medicinal products; <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): CS (čeština): DA (dansk): DE (Deutsch): EL (elliniká): EN (English): ES (español): ET (eesti keel): FI (suomi): FR (français): HR (hrvatski): HU (magyar): IT (italiano):	LT (lietuvių kalba): LV (latviešu valoda): MT (Malti): NL (Nederlands): PL (polski): PT (português): RO (română): SK (slovenčina): SL (slovenščina): SV (svenska): IS (íslenska): NO (norsk):

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 (whether dried or fresh, whether whole or fragmented[3]) when there*	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])*

[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
is no European or national pharmacopoeia monograph. ii) Herbal preparations *Examples are given below. The list is not exhaustive.* 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*>> *Native DER should be given.* 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)*	*when there is no European or national pharmacopoeia monograph.* ii) Herbal preparations *Examples are given below. The list is not exhaustive.* 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*>> *Native DER should be given.* 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

To be specified for the individual finished product.

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)

Well-established use	Traditional use
	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.

68 ## *4.2. Posology and method of administration*[7]

Well-established use	Traditional use
Posology *If necessary, it should be distinguished between different indications.* *<Adults,><and><Elderly>* <Single dose> <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, but the letter of the preparations in section 2 should be used.* *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 stated.* *Additional sub-headings such as "Elderly" or "Renal impairment" can be stated if necessary.*	**Posology** *If necessary, it should be distinguished between different indications.* *<Adults><and><Elderly>* <Single dose> <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, but the letter of the preparations in section 2 should be used.* *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 stated.* *Additional sub-headings such as "Elderly" or "Renal impairment" can be stated if necessary.*

[7] *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
Paediatric population *<Children><and><Adolescents>* <Single dose> <Average daily dose><Daily dose> *See QRD templates for appropriate wording for the paediatric population. Cross reference to other sections only needed in case of safety concerns.* **Duration of use** <If the symptoms persist during the use of the medicinal product, a doctor or a qualified health care practitioner 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* *For macerates include the following standard sentence:* <The macerate should be used immediately after preparation.>	Paediatric population *<Children><and><Adolescents>* <Single dose> <Average daily dose><Daily dose> *See QRD templates for appropriate wording for the paediatric population. Cross reference to other sections only needed in case of safety concerns.* **Duration of use** *As per Article 16g(2)(b) of Directive 2001/83/EC, labelling and user package leaflet of THMPs shall contain a statement that the user should consult a doctor or a qualified health care practitioner if the symptoms persist during the use of the medicinal product. Therefore, one of the following options should be included:* *EITHER* *When there is no cause for concerns but related to the medical condition.* <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.> *OR* *When there is a cause for concerns e.g. presence of certain constituents.* <Not to be used for more than *xxx*. If the symptoms persist during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.> **Method of administration** <Oral use.><Cutaneous use.><Cutaneous <and><or> transdermal use.><Oromucosal

Well-established use	Traditional use
	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.>

69 *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>.>

70 *4.4. Special warnings and precautions for use*

Well-established use	Traditional use
<u><Paediatric population></u>	<u><Paediatric population></u> <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 because of concerns <requiring medical advice><*insert reason*>.>

71 *4.5. Interactions with other medicinal products and other forms of*
72 *interaction*

Well-established use	Traditional use
<No <adequate> interaction studies have been performed.> <u><Paediatric population></u>	<No <adequate> interaction studies have been performed.> <u><Paediatric population></u>

73 ## *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.> <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 *[insert 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.>	*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.> <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 *[insert 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.>

74 ## *4.7. Effects on ability to drive and use machines*

Well-established use	**Traditional use**
<Not relevant.> <*[insert herbal substance/preparation]* has <no or negligible> <minor or moderate> <major>	<Not relevant.> <*[insert herbal substance/preparation]* has <no or negligible> <minor or moderate> <major>

Well-established use	Traditional use
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.>	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.>

75 ## *4.8. Undesirable effects*

Well-established use	Traditional use
Should be based on the most suitable representation within the MedDRA terminology. The SOC should be followed by the relevant PT in accordance with MedDRA terminology. When available, frequencies of cited adverse reactions should be stated according to the convention laid down in the SmPC guideline. For example, Gastrointestinal disorders: Diarrhoea. Frequency: common (≥1/100 to <1/10). <None known.> <u><Paediatric population></u>	*Should be based on the most suitable representation within the MedDRA terminology. The SOC should be followed by the relevant PT in accordance with MedDRA terminology. When available, frequencies of cited adverse reactions should be stated according to the convention laid down in the SmPC guideline. For example, Gastrointestinal disorders: Diarrhoea. Frequency: common (≥ 1/100 to <1/10).* <None known.> *As per Article 16g(2)(b) of Directive 2001/83/EC, labelling and user package leaflet of THMPs shall contain a statement that the user should consult a doctor or a qualified health care practitioner if adverse effects not mentioned in the package leaflet occur. Therefore, one of the following options should be included:* *EITHER When there is none known:* <If adverse reactions occur, a doctor or a qualified health care practitioner should be consulted.> *OR When adverse reactions are listed:*

Well-established use	Traditional use
	<If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.> <Paediatric population>

76 ### *4.9. Overdose*

Well-established use	Traditional use
<No information available.> <Paediatric population>	<No information available.> <Paediatric population>

77 # 5. Pharmacological properties

78 ### *5.1. Pharmacodynamic properties*

Well-established use	Traditional use
Pharmacotherapeutic group: {*group*} Proposed ATC code: {*code*} <Paediatric population>	*Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC.* <No information required.>

79 ### *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.* <No information required.>

80 ### *5.3. Preclinical safety data*[8]

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.>	*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>

[8] *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.>

Well-established use	Traditional use
<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.> <Tests><Adequate tests> on <reproductive toxicity><,> <genotoxicity> <and> <carcinogenicity> <have not been performed>.> *The wording 'Adequate tests' should be used when tests are available but not in accordance with the requirements.*	<carcinogenicity> <have not been performed>.> *The wording 'Adequate tests' should be used when tests are available but not in accordance with the requirements.*

81 # Additional information

Well-established use	Traditional use
<Not applicable.> *Additional information e.g. limits of constituents with safety concerns could be added, if appropriate.* *Dosage forms for efficacy or safety reasons.*	<Not applicable.> *Additional information e.g. limits of constituents with safety concerns could be added, if appropriate.* *Dosage forms for efficacy or safety reasons.*

82

83 **Annex**

	Herbal substance	Herbal preparations
Single dose	Herbal tea: … g of the <freshly> fragmented[9] 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

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

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