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

DRAFT

COMMUNITY HERBAL MONOGRAPH ON *CURCUMA LONGA* L., RHIZOMA

DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	September 2008 November 2008
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REDISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	
ADOPTION BY HMPC	

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KEYWORDS	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; <i>Curcuma longa</i> L.; Curcumae longae rhizoma; turmeric root.
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COMMUNITY HERBAL MONOGRAPH ON *CURCUMA LONGA* L., RHIZOMA

1. NAME OF THE MEDICINAL PRODUCT

To be specified for the individual finished product.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION^{1,2}

<u>Well-established use</u>	<u>Traditional use</u>
	<p>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended</p> <p><i>Curcuma longa</i> L., rhizoma (turmeric root)</p> <p>i) Herbal substance Not applicable</p> <p>ii) Herbal preparations A) Powdered herbal substance B) Comminuted herbal substance C) Tincture (1:10; ethanol 70% v/v)</p>

3. PHARMACEUTICAL FORM

<u>Well-established use</u>	<u>Traditional use</u>
	<p>Comminuted herbal substance, herbal tea or other herbal preparations in liquid or solid dosage forms for oral use.</p> <p>The pharmaceutical form should be described by the European Pharmacopoeia full standard term.</p>

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

<u>Well-established use</u>	<u>Traditional use</u>
	<p>Traditional herbal medicinal product used for the symptomatic relief of dyspepsia.</p> <p>The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon longstanding use and experience.</p>

¹ The material complies with the Ph. Eur. monograph (ref. 01/2005:0865).

² The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance

4.2 Posology and method of administration

<u>Well-established use</u>	<u>Traditional use</u> Posology <i>Adults and elderly</i> A) Powdered herbal substance: 1.5-3.0 g daily; B) Comminuted herbal substance for tea preparation: 0.5-1 g, up to 3 times daily; C) Tincture (1:10): daily dose: 0.5-1 ml 3 times daily The use in children and adolescents under 18 years of age is not recommended (see section 4.4 ‘Special warnings and precautions for use’). Duration of use If the symptoms persist longer than 2 weeks, a doctor or a qualified health care practitioner should be consulted. Method of administration Oral use
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4.3. Contraindications

<u>Well-established use</u>	<u>Traditional use</u> Hypersensitivity to the active substance(s). Obstruction of bile duct, cholangitis, liver disease, gallstones and any other biliary disorders that require medical supervision and advice.
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4.4. Special warnings and precautions for use

<u>Well-established use</u>	<u>Traditional use</u> The use in children and adolescents is not recommended because of lack of data. For tinctures 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.
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4.5. Interactions with other medicinal products and other forms of interaction

<u>Well-established use</u>	<u>Traditional use</u> Special care should be taken with warfarin because of the risk of bleeding.
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4.6. Pregnancy and lactation

<u>Well-established use</u>	<u>Traditional use</u> Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.
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4.7. Effects on ability to drive and use machines

<u>Well-established use</u>	<u>Traditional use</u> No studies on the effect on the ability to drive and use machines have been performed.
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4.8. Undesirable effects

<u>Well-established use</u>	<u>Traditional use</u> Mild symptoms of dry mouth, flatulence and gastric irritation 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.
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4.9. Overdose

<u>Well-established use</u>	<u>Traditional use</u> No case of overdose has been reported.
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5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

<u>Well-established use</u>	<u>Traditional use</u> Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.
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5.2 Pharmacokinetic properties

<u>Well-established use</u>	<u>Traditional use</u> Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.
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5.3 Preclinical safety data

<u>Well-established use</u>	<u>Traditional use</u> Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended, unless necessary for the safe use of the product. Available tests on genotoxicity (aqueous turmeric extract and curcumin) did not give any reason for concern. Tests on reproductive toxicity have not been performed.
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6. PHARMACEUTICAL PARTICULARS

<u>Well-established use</u>	<u>Traditional use</u> Not applicable.
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7. DATE OF COMPILATION/LAST REVISION

6 November 2008