European Medicines Agency
Evaluation of Medicines for Human Use

London, 12 March 2009
Doc. Ref.: EMEA/HMPC/578324/2008

COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

DRAFT

COMMUNITY HERBAL MONOGRAPH ON *GENTIANA LUTEA* L., RADIX

DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	January 2009 March 2009
ADOPTION BY HMPC FOR RELEASE FOR CONSULTATION	12 March 2009
END OF CONSULTATION (DEADLINE FOR COMMENTS)	15 July 2009
REDISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	
ADOPTION BY HMPC	

Comments should be provided using this template to hmpc.secretariat@emea.europa.eu
Fax: +44 20 75 23 70 51

KEYWORDS	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; *Gentiana lutea* L.; Gentianae radix; gentian root

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 75 23 70 51
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

COMMUNITY HERBAL MONOGRAPH ON *GENTIANA LUTEA* L., RADIX

1. NAME OF THE MEDICINAL PRODUCT

To be specified for the individual finished product.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION[1,2]

	Traditional use With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended *Gentiana lutea* L., radix (gentian root) (dried, fragmented underground organs) i) Herbal substance Not applicable ii) Herbal preparations a) comminuted herbal substance b) dry extract (4.5-5.5:1) ethanol 53% v/v c) tincture (1:5) ethanol 70% v/v d) liquid extract (1:1) ethanol 45% v/v

3. PHARMACEUTICAL FORM

	Traditional use Comminuted herbal substance or herbal preparation in solid or liquid dosage forms or as herbal tea for oral use. The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

	Traditional use Traditional herbal medicinal product used in mild dyspeptic/gastrointestinal disorders, and/or in temporary loss of appetite.

[1] The material complies with the Eur. Ph. monograph (ref.: 01/2008:0392).
[2] The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

	The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.

4.2. Posology and method of administration

	Traditional use **Posology** *Adults, Elderly* Average daily dose a) comminuted herbal substance for tea preparation: 1-2 g, 3-4 times daily b) dry extract: 2-capsule a 120 mg dry extract, 2-3 times daily c) tincture: 1 ml, 1-3 times daily d) liquid extract: 1 g, 2-4 times daily For the indication “loss of appetite”, in the literature, it is described that the liquid preparations a), c) and d) are supposed to be taken ½ hour before meal. Correspondingly, the solid dosage form b) is supposed to be taken 1 hour before meal due to the additional mechanism of disintegration of the solid form. 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 during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. **Method of administration** Oral use.

4.3. Contraindications

	Traditional use Hypersensitivity to the active substance. Peptic ulcer.

4.4. Special warnings and precautions for use

	Traditional use The use in children and adolescents under 18 years of age is not recommended due to lack of adequate data. For tinctures and liquid 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.

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

	Traditional use None reported.

4.6. Pregnancy and lactation

	Traditional use 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 also section 5.3 'Preclinical safety data')

4.7. Effects on ability to drive and use machines

	Traditional use No studies on the effect on the ability to drive and use machines have been performed.

4.8. Undesirable effects

	Traditional use Uncommon undesirable effects are diarrhoea, spasmodic stomach ache and headache. In rare cases tachycardia and pruritus were observed. If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.

4.9. Overdose

	Traditional use No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

	Traditional use Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.2. Pharmacokinetic properties

	Traditional use Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.3. Preclinical safety data

	Traditional use 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. Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed. For xanthones that are constituents of *Gentiana lutea* positive results were found in the AMES test (preincubation method). Assessment of pre-clinical safety requires further studies in those effects.

6. PHARMACEUTICAL PARTICULARS

	Traditional use Not applicable.

7. DATE OF COMPILATION/LAST REVISION

12 March 2009