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

DRAFT

**COMMUNITY HERBAL MONOGRAPH ON *ELEUTHEROCOCCUS SENTICOSUS* (RUPR.
ET MAXIM.) MAXIM., RADIX**

DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	October 2006 March 2007 May 2007 July 2007
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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 monograph; traditional use; <i>Eleutherococcus senticosus</i> (Rupr. Et Maxim.) Maxim; Eleutherococci radix; eleutherococcus root; adaptogenic properties; adaptogens
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**COMMUNITY HERBAL MONOGRAPH ON
ELEUTHEROCOCCUS SENTICOSUS (RUPR. ET MAXIM.) MAXIM., RADIX**

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>Eleutherococcus senticosus</i> (Rupr. et Maxim.) Maxim., radix (eleutherococcus root)</p> <p>i) Herbal substance Not applicable</p> <p>ii) Herbal preparations</p> <ul style="list-style-type: none"> - Comminuted herbal substance for tea preparation - Liquid extract (1:1, ethanol 30-40 % v/v) - Dry extract (14-25 : 1, ethanol 40 % v/v) - Dry extract (17-30 : 1, ethanol 70 % v/v) - Tincture (1:5, ethanol 40 % v/v)

3. PHARMACEUTICAL FORM

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

¹ The material complies with the Ph. Eur. monograph (ref. 01/2005:1419)

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

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

<u>Well-established use</u>	<u>Traditional use</u> Herbal medicinal product traditionally used for symptoms of asthenia such as fatigue and weakness. The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.
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4.2 Posology and method of administration

<u>Well-established use</u>	<u>Traditional use</u> Posology <i>Adolescents over 12 years of age, adults, elderly</i> Herbal preparations Daily dose 2-3 g per day as comminuted herbal substance as herbal tea or similar preparation. Liquid extract: 2-3 ml Dry extract (14-25 : 1, ethanol 40% v/v) Dry extract (17-30 : 1, ethanol 70% v/v) 65-195 mg correspond to 2-3 g dried root Tincture: 10-15 ml The daily dose can be taken in one to three doses. The use is not recommended in children under 12 years of age (see also section 4.4 Special warnings and precautions for use). Duration of use Not to be taken for more than 2 months. If the symptoms persist for more 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. Tea preparation: 2 to 3 g of comminuted herbal substance for decoction in 150 ml of water. Dosage frequency: 150 ml should be divided in one to three doses taken during the day; the last dose should be taken before 3 p.m. to avoid insomnia.
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4.3. Contraindications

<u>Well-established use</u>	<u>Traditional use</u>
	Hypersensitivity to the active substance. Arterial hypertension.

4.4. Special warnings and precautions for use.

<u>Well-established use</u>	<u>Traditional use</u>
	The use in children under 12 years of age is not recommended because there is insufficient experience available. If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.

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

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

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.

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.

4.8. Undesirable effects

<u>Well-established use</u>	<u>Traditional use</u>
	Insomnia, irritability, tachycardia and headaches may occur. The frequency is not known.

4.9. Overdose

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

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. The use of Eleutherococcus preparations relates to their adaptogenic ³ properties.
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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. Tests on reproductive toxicity and carcinogenicity have not been performed. <i>In vitro</i> experiments, using the <i>Salmonella typhimurium</i> strains TA 100 and TA 98 assay and the micronucleus test in mice, and <i>in vivo</i> experiments on rats did not reveal any mutagenic potential of aqueous and ethanolic extracts.
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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

5 July 2007

³ Please see the draft HMPC 'Reflection paper on the adaptogenic concept' (EMEA/HMPC/102655/2007)