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

DRAFT

**COMMUNITY HERBAL MONOGRAPH ON
HAMAMELIS VIRGINIANA L., FOLIUM ET CORTEX DESTILLATUM AND
HAMAMELIS VIRGINIANA L., RAMUNCULUS DESTILLATIUM**

DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	March 2008 July 2008 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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Fax: +44 20 75 23 70 51

KEYWORDS	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; <i>Hamamelis virginiana</i> L.; Hamamelidis folium et cortex destillatum; hamamelis leaf and bark distillate; Hamamelidis ramunculus destillatum; hamamelis twigs distillate
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HAMAMELIS VIRGINIANA L., RAMUNCULUS DESTILLATUM**

1. NAME OF THE MEDICINAL PRODUCT

To be specified for the individual finished product.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION¹

<u>Well-established use</u>	<u>Traditional use</u>
With regard to the marketing authorisation application of Article 10(a) of Directive 2001/83/EC as amended	<p>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended</p> <p><i>Hamamelis virginiana</i> L., folium et cortex aut ramunculus destillatum (hamamelis leaf and bark or twigs distillate)</p> <p>i) Herbal substance Not applicable</p> <p>ii) Herbal preparations</p> <p>1. Distillate prepared from fresh leaves and bark (1:1.12 – 2.08; ethanol 6% m/m)</p> <p>2. Distillate prepared from dried twigs (1:2; ethanol 14-15%)²</p>

3. PHARMACEUTICAL FORM

<u>Well-established use</u>	<u>Traditional use</u>
	<p>Herbal preparations in semisolid dosage forms for cutaneous use and liquid dosage forms for ocular use.</p> <p>The pharmaceutical form should be described by the European Pharmacopoeia full standard term.</p>

¹ The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance

² According to USP (USP-31- NF 26, 2008 Vol 3:3526) Distillate prepared from dried twigs (1:2; ethanol 14-15%).

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

<u>Well-established use</u>	<u>Traditional use</u> <i>Children over 6 years of age, adolescents, adults and elderly</i> a) Traditional herbal medicinal product for relief of minor skin inflammation and dryness of the skin. <i>Adolescents, adults and elderly,</i> b) Traditional herbal medicinal product to be used for the temporary relief of eye discomfort due to dryness of the eye or to exposure to wind or sun. 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 Indication a) <i>Children over 6 years of age, adolescents, adults and elderly</i> Hamamelis water in a strength corresponding to 5-30% in semi-solid preparations, several times a day. The use is not recommended in children under 6 years of age (see section 4.4 Special warnings and precautions for use). Indication b) <i>Adolescents, adults and elderly</i> - Eye drops ³ : Hamamelis distillate (2) diluted (1:10), 2 drops/each eye, 3-6 times a day The use is not recommended in children under 12 years of age (see section 4.4 Special warnings and precautions for use).
	Duration of use

³ The medicinal product complies with the Ph. Eur. monograph on eye preparations (01/2008:1163)

	<p>Indication a) The average duration of use is 2 weeks.</p> <p>Indication b) The recommended duration of use as eye drops is 4 days.</p> <p>If the symptoms persist during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>Method of administration</p> <p>Cutaneous or ocular use</p>
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4.3. Contraindications

<u>Well-established use</u>	<u>Traditional use</u> Hypersensitivity to the active substance.
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4.4. Special warnings and precautions for use

<u>Well-established use</u>	<p><u>Traditional use</u></p> <p>If symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>Indication a) Due to the lack of adequate data the use is not recommended for children under 6 years of age.</p> <p>Indication b) Stop use and ask a doctor if you experience eye pain, changes in vision, continued redness, or irritation of the eye, or if the condition worsens or persists for more than 48 hours.</p> <p>Due to the lack of adequate data the use is not recommended for children under 12 years of age.</p>
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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> None reported.
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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. No concern has arisen about any malformation in humans.
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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> Allergic contact dermatitis may occur in sensitive patients. The frequency is very rare. Conjunctivitis has been reported with the eye drops. 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

Well-established use	<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. Reliable data from test on genotoxicity are available for hamamelis aqua preparations. The external application of preparations of <i>Hamamelis virginiana</i> can be regarded as safe. Tests on carcinogenicity have been performed.
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6. PHARMACEUTICAL PARTICULARS

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

6 November 2008