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FINAL

**COMMUNITY HERBAL MONOGRAPH ON *ECHINACEA PALLIDA* (NUTT.) NUTT.,  
RADIX**

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| <b>DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)</b>   | July 2008<br>September 2008 |
| <b>ADOPTION BY HMPC FOR RELEASE FOR CONSULTATION</b>                                   | 4 September 2008            |
| <b>END OF CONSULTATION (DEADLINE FOR COMMENTS)</b>                                     | 15 January 2009             |
| <b>REDISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)</b> | May 2009<br>July 2009       |
| <b>ADOPTION BY HMPC</b>  | 16 July 2009                |

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| <b>KEYWORDS</b> | Herbal medicinal products; HMPC; Community herbal monographs; Traditional use; <i>Echinacea pallida</i> (Nutt.) Nutt.; Echinaceae pallidae radix; pale coneflower root |
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**COMMUNITY HERBAL MONOGRAPH ON *ECHINACEA PALLIDA* (NUTT.) NUTT.,  
RADIX**

**1. NAME OF THE MEDICINAL PRODUCT**

To be specified for the individual finished product.

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION<sup>1,2</sup>**

| <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>Echinacea pallida</i> (Nutt.) Nutt., radix, (pale coneflower root)</p> <p>i) Herbal substance<br/>Not applicable.</p> <p>ii) Herbal preparations</p> <ul style="list-style-type: none"> <li>- dry extract (4-8:1), extraction solvent: ethanol 50% (v/v)</li> <li>- tincture (1:5), extraction solvent: ethanol 50% (v/v)</li> </ul> |

**3. PHARMACEUTICAL FORM**

| <u>Well-established use</u> | <u>Traditional use</u>  |
|-----------------------------|---|
|                             | <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> |

<sup>1</sup> The material complies with the European Pharmacopoeia monograph (ref.: 01/2008:1822)

<sup>2</sup> 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><br><br>Traditional herbal medicinal product for supportive treatment of common cold.<br><br>The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use. |
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### 4.2. Posology and method of administration

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|-----------------------------|--|
| <u>Well-established use</u> | <u>Traditional use</u><br><br><b>Posology</b><br><i>Adolescents, adults, elderly</i><br><br>1) 3 times daily 1 tablet containing 30 mg dry extract (4-8:1)<br>2) 4 times daily 2 tablets containing 12 mg dry extract (4-8:1)<br>3) 5 times daily 25 drops containing 100% tincture (1:5)<br><br>The use in children under 12 years of age is contraindicated (see section 4.3. 'Contraindications').<br><br><b>Duration of use</b><br><br>The therapy should start at first signs of common cold.<br><br>If the symptoms persist longer than 10 days during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.<br><br><b>Method of administration</b><br><br>Oral use. |
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### 4.3. Contraindications

| <u>Well-established use</u> | <u>Traditional use</u>  |
|-----------------------------|---|
|                             | <p>Hypersensitivity to the active substance or to plants of the Asteraceae (Compositae) family.</p> <p><i>Echinacea</i> must not be used in cases of progressive systemic diseases such as: tuberculosis, diseases of the white blood cells system, collagenoses, multiple sclerosis, AIDS, HIV infections, and other immune diseases.</p> <p>Children under 12 years of age.</p> |

### 4.4. Special warnings and precautions for use

| <u>Well-established use</u> | <u>Traditional use</u>  |
|-----------------------------|---|
|                             | <p>If the symptoms worsen or high fever occurs during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>There is a possible risk of allergic reactions in sensitive individuals. Those patients should consult their doctor before using <i>Echinacea</i>.</p> <p>There is a possible risk of anaphylactic reactions in atopic patients. Atopic patients should consult their doctor before using <i>Echinacea</i>.</p> <p>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.</p> |

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

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

### 4.6. Pregnancy and lactation

| <u>Well-established use</u> | <u>Traditional use</u>  |
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|                             | <p>Safety during pregnancy and lactation has not been established.</p> <p>In the absence of sufficient data, the use during pregnancy and lactation is not recommended.</p> |

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

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

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| <u>Well-established use</u> | <u>Traditional use</u><br>Hypersensitive reactions (skin reactions). The frequency is not known.<br>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

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

#### 5.1. Pharmacodynamic properties

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|-----------------------------|--|
| <u>Well-established use</u> | <u>Traditional use</u><br>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><br>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><br>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.<br>Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed. |
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**6. PHARMACEUTICAL PARTICULARS**

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

16 July 2009

Superseded