EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 March 2012
EMA/HMPC/748220/2011
Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Grindelia robusta* Nutt., *Grindelia squarrosa* (Pursh) Dunal, *Grindelia humilis* Hook. et Arn., *Grindelia camporum* Greene, herba

Draft

Discussion in Working Party on Community monographs and Community list (MLWP)	September 2011 November 2011 January 2012
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	15 April 2012
End of consultation (deadline for comments). Comments should be provided using this template to hmpc.secretariat@ema.europa.eu	15 August 2012
Rediscussion in Working Party on Community monographs and Community list (MLWP)	
Adoption by Committee on Herbal Medicinal Products (HMPC)	

Keywords	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; *Grindelia robusta* Nutt., *Grindelia squarrosa* (Pursh) Dunal, *Grindelia humilis* Hook. et Arn., *Grindelia camporum* Greene, herba; Grindeliae herba; Gumweed herb

BG (bălgarski): Гринделия, стрък CS (čeština): Grindeliová nať DA (dansk): Grindeliaurt DE (Deutsch): Grindeliakraut EL (elliniká): Πόα γρινδελίας EN (English): Grindelia ES (espanol): Grindelia, sumidades floridas de ET (eesti keel): Vaiguvaagiürt FI (suomi): Rohtorilpiö FR (français): Grindélia (sommité fleurie de) HU (magyar): Grindélia virágos hajtás IT (italiano): Grindelia parti aeree	LT (lietuvių kalba): LV (latviešu valoda): Grindēliju laksti MT (malti): NL (nederlands): Gomplant PL (polski): Ziele doględy PT (português): Grindélia RO (română): Iarbă de grindelia SK (slovenčina): Vňať grindélie SL (slovenščina): Zel zdravilne grindelije SV (svenska): Klibbgrindelia *IS (íslenska)*: *NO (norsk)*: Grindelia

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Community herbal monograph on *Grindelia robusta* Nutt., *Grindelia squarrosa* (Pursh) Dunal, *Grindelia humilis* Hook. et Arn., *Grindelia camporum* Greene, herba

1. Name of the medicinal product

To be specified for the individual finished product.

2. Qualitative and quantitative composition[1, 2]

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended *Grindelia robusta* Nutt., *Grindelia squarrosa* (Pursh) Dunal, *Grindelia humilis* Hook. et Arn., *Grindelia camporum* Greene, herba or a mixture of them (Gumweed herb) i) Herbal substance Not applicable. ii) Herbal preparations a) Comminuted herbal substance b) Liquid extract (DER 1:1), extraction solvent ethanol 22.5% V/V c) Tincture (ratio of herbal substance to extraction solvent 1:10), extraction solvent ethanol 60% V/V

[1] The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.
[2] The material complies with the French pharmacopoeia monograph (January 1998).

3. Pharmaceutical form

Well-established use	Traditional use
	Herbal preparations in liquid dosage forms for oral use. Comminuted herbal substance 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

Well-established use	Traditional use
	Traditional herbal medicinal product for relief of cough associated with cold. The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.

4.2. Posology and method of administration[3]

Well-established use	Traditional use
	Posology *Adults and Elderly* a) Herbal tea: 2 - 3 g of the comminuted herbal substance in 150 ml of boiling water as a herbal infusion up to 3 times daily b) Liquid extract: 0.6 - 1.2 ml 3 times daily Daily dose: 1.8 - 3.6 ml c) Tincture: 0.5 – 1 ml 3 times daily Daily dose: 1.5 - 3 ml 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 1 week during the use of the medicinal product, a doctor

[3] For guidance on herbal substance/herbal preparation administered as herbal tea or as infusion/decoction/macerate preparation, please refer to the HMPC 'Glossary on herbal teas' (EMA/HMPC/5829/2010 Rev.1).

	or a qualified health care practitioner should be consulted. **Method of administration** Oral use.

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance and to other plants of the Asteraceae (Compositae) family.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	The use in children and adolescents under 18 years of age has not been established due to lack of adequate data. If the symptoms worsen during the use of the medicinal product or if dyspnoea, high fever or purulent sputum occurs, a doctor or a qualified health care practitioner should be consulted immediately. For tinctures and 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

Well-established use	Traditional use
	None reported.

4.6. Fertility, pregnancy and lactation

Well-established use	Traditional use
	No fertility data available. 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

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

4.8. Undesirable effects

Well-established use	Traditional use
	None known. If adverse reactions occur, a doctor or a qualified health care practitioner should be consulted.

4.9. Overdose

Well-established use	Traditional use
	No case of overdose has been reported.

5. Pharmacological properties

5.1. Pharmacodynamic properties

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

5.2. Pharmacokinetic properties

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

5.3. Preclinical safety data

Well-established use	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.

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

7. Date of compilation / last revision

27 March 2012