22 March 2010
EMA/HMPC/160866/2010
Committee on Herbal Medicinal Products (HMPC)

# Grindelia robusta Nutt., G. squarrosa Dunal, G. humilis Hook. et Arn., G. camporum Greene, herba

Grindeliae herba (grindelia)

**Requested date for submissions: 22 May 2010**

## Background

The Committee on Herbal Medicinal Products (HMPC) was established in September 2004, in accordance with Regulation (EC) No 726/2004. The duties of HMPC are laid down in Directive 2004/24/EC amending, as regards traditional herbal medicinal products, Directive 2001/83/EC. They aim at enhancing the harmonisation of procedures and provisions concerning herbal medicinal products laid down in EU Member States, and further integrating herbal medicinal products in the European regulatory framework.

The establishment of Community herbal monographs as well as a draft Community 'list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products' are among the core duties of the HMPC. Public calls for submission of relevant scientific data represent an important part of the HMPC's efforts to obtain the best possible basis for the related assessment work.

## Call for scientific data

The HMPC invites all interested parties[1] to submit any scientific data, which may be used in the assessment of **Grindeliae herba** as part of the establishment of Community herbal monographs, and/or entries to the Community 'list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products'.

## Conditions for data submissions

Scientific contributions should be relevant to the purpose of the assessment, and their scope should address either:

[1] Such as pharmaceutical industry associations, health care professional groups, learned societies, consumers and patients' associations, governmental institutions as well as EU and EEA-EFTA Member States.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
**Telephone** +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8668
**E-mail** info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

1. Well-established medicinal use: Submitted data should provide evidence that the constituent or the constituents of the medicinal product has or have a well-established medicinal use with recognised efficacy and an acceptable level of safety within the meaning of Directive 2001/83/EC as amended.
2. Traditional use: Submitted data should provide evidence that the medicinal product in question, or a corresponding product, has been in medicinal use throughout a period of at least 30 years preceding the date of the application, including at least 15 years within the Community.

Furthermore, the acceptance of scientific contributions will be based on compliance with the following general criteria:

1. The name and contact details of the party providing the scientific contribution is required.
2. Scientific contributions should be classified by the interested party as (i) peer-reviewed data; or (ii) non peer-reviewed data. The European Medicines Agency encourages submission of peer-reviewed data/publications (not just the reference) as the most relevant and reliable documents. Non peer-reviewed data such as references from older standard books of phytotherapy or comparable scientific sources can be taken into consideration provided that they are of an adequate quality.
3. A document providing a specification of the literature search strategy, the date of the search, search terms (inclusion/exclusion terms) as well as a listing of databases used for the search should be enclosed.
4. All contributions should be provided in either electronic format (e.g. via e-mail or a CD-ROM) or paper format (2 copies) and a list of attached documents and their references should be enclosed.

Non-compliance with any of these requirements for data submission may result in the rejection of the contribution provided.

To facilitate an effective handling of incoming documents and/or CD-ROMs etc., interested parties are requested to submit documents:

either to the following email address: hmpc.secretariat@ema.europa.eu

or by post:

European Medicines Agency (EMA)
7 Westferry Circus
Canary Wharf
London E14 4HB
United Kingdom
Att.: HMPC secretariat

or by fax: (44-20) 75 23 70 51, Att.: HMPC secretariat.

Any submissions are kindly requested by 22 May 2010 at the latest.

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in all cases willing to confirm in writing the non-commercial use of documents sent in by interested parties.

**Confidentiality**

Unpublished data may be included. Confidentiality will be lifted in cases where the contributor has given its consent. In other cases where confidential data are presented, it should be duly justified why these data are protected and how transparency in the procedure of assessment can be assured. The HMPC will consider such submissions on a case-by-case basis. The contributor should also take duly into account the rights of interested parties, as the documentation provided will be used for the development of Community list entries and Community herbal monographs. Such development is underpinned by assessment reports, which will be made public in accordance with measures taken by the Agency to ensure an appropriate level of transparency.

**Language requirements**

Documents should be submitted in English where possible since this is the working language of the HMPC, but documents in other official Community languages will be accepted. In order to facilitate the assessment, the HMPC strongly recommends the submission of an abstract in English when original references are provided.