15 July 2016
EMA/HMPC/403792/2016
Committee on Herbal Medicinal Products (HMPC)

Call for scientific data for the systematic review of the monograph on *Trigonella foenum-graecum* L., semen

Submission period: 15 July 2016 - 15 October 2016

The HMPC invites all interested parties 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 to submit any scientific data that the HMPC should consider at the review of the monograph on *Trigonella foenum-graecum* L., semen towards a possible revision of the monograph and supporting documents. The publication of this call is the first step in the procedure established by the committee so that adopted monographs remain up-to-date (scientific state of the art).

To avoid submission of data which were already evaluated during the initial assessment work, interested parties are invited to carefully check the published 'List of references supporting the assessment' and 'Overview of comments received during the public consultation'.

The HMPC is looking to receive scientific literature published since the end date of the public consultation on the monograph and supporting documents.

Scientific contributions should be sent in electronic format by e-mail or Eudralink to hmpc.secretariat@ema.europa.eu

or by post to:

European Medicines Agency
30 Churchill Place
Canary Wharf
UK-London E14 5EU
Att.: HMPC secretariat

If an interested party intends to send scientific contributions in response to several calls for scientific data, response should be sent separately to each call.

A list of all scientific contributions and their references should be enclosed.

The name and contact details of the interested party providing the scientific contributions is required.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Unpublished data may be included. However, the consent of the data owner is a necessary requirement. The owner of the data will be given the opportunity to review the assessment report to remove any confidential data. The HMPC will consider such submissions on a case-by-case basis. Submitting parties are bound to obey existing copyrights. Contributors should also take duly into account the rights of interested parties, as the documentation provided will be used for the development of European Union list entries and European Union 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.

As regards **copyright**, it is important to clarify that the use by the HMPC of the bibliographic material is entirely for a non-commercial purpose. As its non-commercial use by the Committee is guaranteed, any interested party will not incur in any liability as to the use intended by the HMPC by forwarding the bibliographic literature to the Committee. The HMPC is in all cases willing to confirm in writing the non-commercial use of documents sent in by interested parties.

Documents should be submitted in **English** where possible since this is the working language of the HMPC, but documents in other official languages of the European Union 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.

Conditions for data submissions

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

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.

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 European Union.

Furthermore, the 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.