9 April 2014
EMA/HMPC/87618/2014 *Corr.*
Committee on Herbal Medicinal Products (HMPC)

Call for scientific data for use in HMPC assessment work on Glycine max and/or lecithin derived from Glycine max (soy bean lecithin)
Submission period: 15 February 2014 - 15 June 2014

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, which may be used in the assessment of Glycine max and/or lecithin derived from Glycine max (soy bean lecithin) as part of the establishment of Community herbal monographs and/or Community list entries.

Scientific contributions should be sent to:

By post	By email
European Medicines Agency 7 Westferry Circus Canary Wharf UK-London E14 4HB Att.: HMPC secretariat either one CD-rom or paper prints (2 copies)	hmpc.secretariat@ema.europa.eu

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.

Unpublished data may be included.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 Community list entries and Community herbal monographs. Such development is

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Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7051
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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

1. Scientific contributions should be classified by the interested party as (i) peer-reviewed data; or (ii) non peer-reviewed data. 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.
2. 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.