EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

31 March 2018
EMA/HMPC/188875/2018
Committee on Herbal Medicinal Products (HMPC)

Call for scientific data for use in HMPC assessment work on *Aloysia citriodora* Paláu *(syn. Aloysia triphylla* (L'Hér.) Kuntze; *Verbena triphylla* L'Hér.; *Lippia citriodora* Kunth.), folium

Submission period: 31 March 2018 – 30 June 2018

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 *Aloysia citriodora* Paláu *(syn. Aloysia triphylla* (L'Hér.) Kuntze; *Verbena triphylla* L'Hér.; *Lippia citriodora* Kunth.) folium as part of the establishment of European Union herbal monographs and/or European Union list entries.

Please note that the Rapporteur is seeking to receive copies of scientific contributions other than those referred to in the annex to this call for submission of scientific data.

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

Submitting parties are bound to obey existing **copyrights**. Contributors should also take duly into account the rights of third 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.

Unpublished proprietary data may be included. However, in this case the consent of the data owner is a necessary requirement and therefore it must be provided simultaneously with the contributions. If the party submitting the data is not the data owner, the consent of the latter is needed. If the data owner is the interested party itself, the voluntary submission of the data as a contribution to the HMPC assessment constitutes consent that the HMPC may evaluate and use the submitted data in the course of the procedure announced in the call for scientific data.

Before its publication, the owner of the data will be given the opportunity to review the assessment report to request the removal of any confidential data. Such request must be duly justified by evidencing the confidential nature of the data (e.g. that it includes confidential intellectual property). The HMPC will consider such requests on a case-by-case basis.

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

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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.

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. (Details of herbal substance / herbal preparation, pharmaceutical form and posology in medicinal use should be given.)

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.