08 March 2021
EMA/HMPC/146382/2021
Committee on Herbal Medicinal Products (HMPC)

Call for scientific data for the periodic review of the monograph on Urticae radix

Submission period: 01 April 2021 – 30 June 2021

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 periodic review of the monograph on *Urtica dioica* L.; *Urtica urens* L., radix 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

Domenico Scarlattilaan 6

1083 HS Amsterdam

The Netherlands

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.

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Unpublished proprietary data may be included.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.

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.

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.