24 January 2019
EMA/HMPC/39600/2019
Committee on Herbal Medicinal Products (HMPC)

Call for scientific data for use in HMPC assessment work on 'Public statement on the use of herbal medicinal products containing toxic, unsaturated pyrrolizidine alkaloids (PAs) (EMA/HMPC/893108/2011)'

Submission period: 28 February 2019 – 31 August 2019

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 data, which may be used in the assessment of safety and risks related to the use of herbal medicinal products/traditional herbal medicinal products containing pyrrolizidine alkaloids.

As informed in the HMPC public meeting report of the January 2019 meeting (EMA/HMPC/26549/2019) and as part of the HMPC work plan, the '**Public statement on the use of herbal medicinal products containing toxic, unsaturated pyrrolizidine alkaloids (PAs)** (EMA/HMPC/893108/2011) will be revised to provide updated direction/guidance for industry and NCAs.

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

or by post Attention: HMPC secretariat. Please see EMA website for further details.

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.

To avoid submission of data which were already evaluated during the initial assessment's work, interested parties are invited to carefully check the listed references in the current public statement and corresponding overview of comments.

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 guidance documents which will be made public in accordance with measures taken by the Agency to ensure an appropriate level of transparency.

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Unpublished proprietary data may be included.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.

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 the scope of the current PS EMA/HMPC/893108/2011 as published on the EMA website.

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 - can be taken into consideration provided that they are of an adequate quality including sufficient background information on sampling and statistical analysis.