28 January 2019
EMA/HMPC/37920/2019
Committee on Herbal Medicinal Products (HMPC)

Call for scientific data for use in HMPC assessment work on 'Public statement on contamination of herbal medicinal products/traditional herbal medicinal products with pyrrolizidine alkaloids (EMA/HMPC/328782/2016)'

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 to be taken into consideration to update recommendations for risk management and quality control related to the **contamination** of herbal medicinal products/traditional herbal medicinal products with 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 contamination of herbal medicinal products/traditional herbal medicinal products with pyrrolizidine alkaloids**' (EMA/HMPC/328782/2016) will be revised to provide updated direction/guidance for industry and National Competent Authorities.

Since the HMPC Public Statement from May 2016, new information on the risks of pyrrolizidine alkaloids in honey, tea, herbal infusions (herbs) and food supplements was published by the European Food Safety Authority (EFSA). Furthermore, the European Directorate for Quality of Medicines (EDQM) has established a Working Party to develop a general Ph. Eur. method for testing pyrrolizidine alkaloids (PAs); this work is ongoing.

Due to ongoing European discussions and efforts for harmonization to characterise the risk of exposure of PAs to human health, the HMPC has agreed by consensus to extend the transitional period for products with levels up to 1.0 µg PAs/day for a further 2 years.

Whilst difficulties for manufacturers of herbal medicinal products to implement measures to reduce PA contamination are acknowledged, manufacturers should continue to take appropriate actions including implementation of enhanced GACP to ensure daily intake does not exceed 1.0 µg PAs/day.

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.

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Send a question via our website www.ema.europa.eu/contact

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.

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.

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/328782/2016 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.