3 December 2015
EMA/HMPC/816399/2015
Committee on Herbal Medicinal Products (HMPC)

Call for scientific data for use in HMPC assessment work on herbal tea combinations traditionally used in the therapeutic area 'urinary tract disorders'

Submission period: 15 December 2015 - 15 March 2016

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 herbal tea combinations traditionally used in the therapeutic area 'urinary tract disorders' (so called historically '*Species diureticae')* as part of the establishment of European Union herbal monographs and European Union list entries.

The planned assessment is a pilot project to generate harmonized European standards for traditional herbal tea combinations. The HMPC welcomes all relevant information on combinations of herbal substances used as herbal tea to increase the amount of urine, to achieve flushing of the urinary tract and/or as an adjuvant in minor urinary complaints. Particularly formulas of herbal tea combinations with a documented medicinal use in the mentioned indication for more than 30 years are of interest. The submissions should be supported by data regarding the reference (dating at least 30 years back), posology, instructions for the preparation etc.

The aim is to establish EU herbal monographs covering a range of herbal substances used in similar indications but with some variation of combinations, strength and posology.

Scientific contributions should be sent to:

By post	By email
European Medicines Agency 30 Churchill Place Canary Wharf UK-London E14 4EU Att.: HMPC secretariat either one CD-rom or paper prints (2 copies)	hmpc.secretariat@ema.europa.eu

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

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Unpublished data may be included.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 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.

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

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.