



6 May 2020
EMA/HMPC/232764/2020
Committee on Herbal Medicinal Products (HMPC)

Addendum to Assessment report on *Filipendula ulmaria* (L.) Maxim. (= *Spiraea ulmaria* L.), flos

Rapporteur(s)	B Kroes
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HMPC decision on review of monograph <i>Filipendula ulmaria</i> (L.) Maxim. (= <i>Spiraea ulmaria</i> L.), flos adopted on July 2011	30 January 2018
Call for scientific data (start and end date)	From 30 April 2018 to 31 July 2018
Adoption by Committee on Herbal Medicinal Products (HMPC)	6 May 2020

Review of new data on *Filipendula ulmaria* (L.) Maxim., flos

Periodic review (from 2011 to 2018)

Scientific data (e.g. non-clinical and clinical safety data, clinical efficacy data)

- Pharmacovigilance data (e.g. data from EudraVigilance, VigiBase, national databases)
- Scientific/Medical/Toxicological databases: Scopus, PubMed, Embase, ToxNet
- Other

Regulatory practice

- Old market overview in AR (i.e. products fulfilling 30/15 years on the market)
- New market overview (including pharmacovigilance actions taken in member states)
 - information from member state (reporting between November 2018 and January 2019)
- Referral
- Ph.Eur. monograph
- Other

Consistency (e.g. scientific decisions taken by HMPC)

- Public statements or other decisions taken by HMPC



- Consistency with other monographs within the therapeutic area
 Other

Availability of new information (i.e. likely to lead to a relevant change of the monograph)

<i>Scientific data</i>	Yes	No
New non-clinical safety data likely to lead to a relevant change of the monograph	<input type="checkbox"/>	<input checked="" type="checkbox"/>
New clinical safety data likely to lead to a relevant change of the monograph	<input type="checkbox"/>	<input checked="" type="checkbox"/>
New data introducing a possibility of a new list entry	<input type="checkbox"/>	<input checked="" type="checkbox"/>
New clinical data regarding the paediatric population or the use during pregnancy and lactation likely to lead to a relevant change of the monograph	<input type="checkbox"/>	<input checked="" type="checkbox"/>
New clinical studies introducing a possibility for new WEU indication/preparation	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Other scientific data likely to lead to a relevant change of the monograph	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<i>Regulatory practice</i>	Yes	No
New herbal substances/preparations with 30/15 years of TU	<input type="checkbox"/>	<input checked="" type="checkbox"/>
New herbal substances/preparations with 10 years of WEU	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Other regulatory practices likely to lead to a relevant change of the monograph	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Referrals likely to lead to a relevant change of the monograph	<input type="checkbox"/>	<input checked="" type="checkbox"/>
New / Updated Ph. Eur. monograph likely to lead to a relevant change of the monograph	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<i>Consistency</i>	Yes	No
New or revised public statements or other HMPC decisions likely to lead to a relevant change of the monograph	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Relevant inconsistencies with other monographs within the therapeutic area that require a change of the monograph	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Other relevant inconsistencies that require a change of the monograph	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Summary and conclusions on the review

During the review 60 new references on *Filipendula ulmaria* (L.) Maxim not yet available during the first/previous assessment were identified.

No references were provided by Interested Parties during the Call for data.

The EudraVigilance database contains no cases of *Filipendula* flos.

3 new references related to the flowers were considered to be relevant for the assessment.

No references justify a revision of the monograph.

No revision is considered required because there are no new data of relevance for the content of the monograph, see below.

Scientific data

Barros *et al.*, (2018) reports on the phytochemical composition and *in vitro* antioxidant activity of a methanol extract of *F. ulmaria* flowers. Samardžić *et al.*, (2016) studied the antihyperalgesic and antiedematous activities of orally administered lyophilized flower infusions (LFIs) of *F. ulmaria* and *F. vulgaris* in rats and toxicity in mice. Fasted mice (3 groups with 2 mice) received a single oral dose (2000 mg/kg) of the *F. vulgaris* or *F. ulmaria* LFI, or an equivalent amount of vehicle. No lethality was observed with the dose of 2000 mg/kg (p.o.) during the 14 days observation period. Samardžić *et al.*, (2018) reported on *in vitro* antioxidant and anti-inflammatory activity and gastroprotective effects in rats of *F. ulmaria* and *F. vulgaris* lyophilized flower infusions (LFIs) as well as the *F. vulgaris* isolated compounds.

Assessor's comment:

There are no new safety concerns from the non-clinical studies above.

References

a) References relevant for the assessment:

Barros L., Cabrita L., Boas M.V., Carvalho A.M., Ferreira I.C.F.R. Chemical, biochemical and electrochemical assays to evaluate phytochemicals and antioxidant activity of wild plants Food Chemistry 2011, 127(4):1600-1608

Samardžić S, Arsenijević J, Božić D, Milenković M, Tešević V, Maksimović Z. Antioxidant, anti-inflammatory and gastroprotective activity of *Filipendula ulmaria* (L.) Maxim. and *Filipendula vulgaris* Moench. *J Ethnopharmacol* 2018, 213:132-137

Samardžić S, Tomić M, Pecikoza U, Stepanović-Petrović R, Maksimović Z. Antihyperalgesic activity of *Filipendula ulmaria* (L.) Maxim. and *Filipendula vulgaris* Moench in a rat model of inflammation. *J Ethnopharmacol* 2016, 193:652-656

b) References that justify the need for the revision of the monograph:

None.

Rapporteur's proposal on revision

- Revision needed, i.e. new data/findings of relevance for the content of the monograph
- No revision needed, i.e. no new data/findings of relevance for the content of the monograph

HMPC decision on revision

- Revision needed, i.e. new data/findings of relevance for the content of the monograph
- No revision needed, i.e. no new data/findings of relevance for the content of the monograph

The HMPC agreed not to revise the monograph, assessment report and list of references on *Filipendula ulmaria* (L.) Maxim. (= *Spiraea ulmaria* L.), flos by consensus.