



26 January 2022
EMA/HMPC/690227/2021
Committee on Herbal Medicinal Products (HMPC)

Addendum to Assessment report on *Fraxinus excelsior* L. or *Fraxinus angustifolia* Vahl, folium

Rapporteur(s)	Z. Biró-Sándor
Peer-reviewer	W. Dymowski

HMPC decision on review of monograph <i>Fraxinus excelsior</i> L. or <i>Fraxinus angustifolia</i> Vahl, folium adopted on 27 March 2012	13 January 2021
Call for scientific data (start and end date)	From 01 March 2021 to 31 May 2021
Adoption by Committee on Herbal Medicinal Products (HMPC)	26 January 2022

Review of new data on *Fraxinus excelsior* L. or *Fraxinus angustifolia* Vahl, folium

Periodic review (from 2010 to 2021)

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

- Pharmacovigilance data (e.g. data from EudraVigilance, VigiBase, national databases)

Eudravigilance database was searched on 15 November 2021 using the key words: "Ash", "Ash leaf", "Ash fresh bark leaf", and "Fraxini cortex extractum". No report can be found.

- Scientific/Medical/Toxicological databases (Web of Knowledge, PubMed, SciFinder)
 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)
 Referral
 Ph.Eur. monograph
 Other

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

An agency of the European Union



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

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

During the review 1,455 new references not yet available during the previous assessment were identified as a result of the literature search.

None of these references were considered to be relevant for the assessment and to justify a revision of the monograph.

No revision is considered required because neither the references published since the previous assessment nor other data (eg. pharmacovigilance data, data from the market overview) nor the result of the market overview justify the revision of the monograph.

Market overview

No herbal medicinal products were identified for which the period of traditional use as laid down in Article 16c(1)(c) of Directive 2001/83/EC has elapsed.

Scientific data

The literature search in 4 major scientific databases resulted in 1,455 references (Embase: 261; PubMed: 188; Cochrane Central: 4; and Web of Knowledge: 1,002) in the period 2010-2021 for the search terms "*Fraxinus excelsior*" or "*Fraxinus angustifolia*". During literature search, no filter was used for the language of publication. These articles were then analysed for papers containing data that may justify the revision of the assessment report or the monograph. The majority of the papers deal with issues that are out of the scope of the HMPC assessment (mainly ecological studies).

In the pharmacovigilance databases, there was no report on adverse effects of any *Fraxinus excelsior* L. or *Fraxinus angustifolia* Vahl, folium containing products.

Overall, the new data do not require changes in the monograph.

References

a) References relevant for the assessment:

None.

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 *Fraxinus excelsior* L. or *Fraxinus angustifolia* Vahl, folium, by consensus.