



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

21 January 2026  
EMA/HMPC/359574/2025  
Committee on Herbal Medicinal Products (HMPC)

## Addendum to Assessment report on *Hamamelis virginiana* L., folium et cortex aut ramunculus destillatum

Rapporteur(s)	O. Palomino
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HMPC decision on review of monograph <i>Hamamelis virginiana</i> L., folium et cortex aut ramunculus destillatum adopted on 12 November 2009	19 March 2025
Call for scientific data (start and end date)	From 01 April 2025 to 30 June 2025
Discussion in HMPC	November 2025 January 2026
Adoption by HMPC	21 January 2026

### Review of new data

#### Periodic review (from 2019 to 2025)

#### Sources checked for new information:

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

Scientific/Medical/Toxicological databases

PubMed/ Search period was set from September 2019 until October 2025. Search terms: *Hamamelis virginiana* leaf, cortex/bark

Pharmacovigilance databases

data from EudraVigilance

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from other sources (VigiBase)

Other

#### Regulatory practice

Old market overview in AR (i.e. check products fulfilling 30/15 years of TU or 10 years of WEU on the market)

New market overview (including pharmacovigilance actions taken in member states)

PSUSA

Feedback from experiences with the monograph during MRP/DCP procedures

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 that could trigger a revision of the monograph

<i>Scientific data</i>	Yes	No
New non-clinical safety data that could trigger a revision of the monograph	<input type="checkbox"/>	<input checked="" type="checkbox"/>
New clinical safety data that could trigger a revision 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 that could trigger a revision 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 that could trigger a revision 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"/>
New recommendations from a finalised PSUSA	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Feedback from experiences with the monograph during MRP/DCP procedures that could trigger a revision of the monograph	<input type="checkbox"/>	<input checked="" type="checkbox"/>
New/Updated Ph. Eur. monograph that could trigger a revision of the monograph	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Other regulatory practices that could trigger a revision of the monograph	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<i>Consistency</i>	Yes	No

New or revised public statements or other HMPC decisions that could trigger a revision of the monograph	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Relevant inconsistencies with other monographs within the therapeutic area that could trigger a revision of the monograph	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Other relevant inconsistencies that could trigger a revision of the monograph	<input type="checkbox"/>	<input checked="" type="checkbox"/>

### Summary of new references

During the review since 2019, no new references regarding *Hamamelis virginiana* L., folium et cortex aut ramunculus destillatum were identified. Seven new references not yet available during the previous assessment were identified for Hamamelis folium. Three references were related to the antimicrobial or antibacterial properties of different plant extracts. Two articles referred to the treatment of haemorrhoids in combination products or with purified fractions from the plant. One article was related to the chemical composition and antioxidant activity of both leaves and bark from *Hamamelis virginiana* and another one was a review of the pharmacological profile of the species.

No references were provided by Interested Parties during the Call for data for *Hamamelis virginiana* L., folium et cortex aut ranunculus destillatum.

No references that could trigger a revision of the monograph were identified.

### Assessment of new data

#### New scientific data that could trigger a revision of the monograph

Not applicable.

During the periodic review, 72 case reports were recorded in Eudravigilance including hypersensitivity reactions. In no case the relationship between the use of witch hazel leaf and the observed adverse reactions was established; they could have been related to the symptom to be treated itself (*i.e.* blepharitis or conjunctivitis), the intake of several concomitant treatments or randomly appeared during the period of treatment.

**Assessor's comment:** *The case reports in Eudravigilance did not differentiate between "folium" and "folium et cortex aut ranunculus destillatum". In no case, the relationship between the use of witch hazel and the observed adverse reactions was established and thus, this information does not trigger a revision of the monograph.*

#### New regulatory practice that could trigger a revision of the monograph

There are no new herbal substances/preparations with 30/15 years of TU or 10 years of WEU.

#### Inconsistency that could trigger a revision of the monograph

Not applicable.

#### Other issues that could trigger a revision of the monograph

Not applicable.

#### New information not considered to trigger a revision at present but that could be relevant for the next review

Not applicable.

**References**

Not applicable.

**Rapporteur's proposal on revision**

- Revision needed, i.e. new data/findings of relevance for the content of the monograph
- Revision likely to have an impact on the corresponding list entry (if applicable)
- 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