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Committee on Herbal Medicinal Products (HMPC)

## Addendum to Assessment report on *Hamamelis virginiana* L., folium

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HMPC decision on review of monograph <i>Hamamelis virginiana</i> L., folium 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 folium/leaf
- Pharmacovigilance databases
  - data from EudraVigilance
  - from other sources (VigiBase)
- Other

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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, 10 new references not yet available during the previous assessment were identified. Three references were related to the antimicrobial and/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* L., 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*.

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.

Wojcieak *et al.* (2025) analysed the qualitative and quantitative composition of phenolic compounds in the leaves and bark of *Hamamelis virginiana*, together with the antioxidant, anti-inflammatory and extracellular matrix protective activities of their extracts in skin cell models. Results showed that both part plants are rich in tannins with more complex forms in the leaves, together with flavonoids of quercetin and kaempferol classes. Also, the assayed extracts of both part plants showed antioxidant and anti-inflammatory properties.

*Assessor's comments: No new data regarding chemical composition or pharmacological properties of hamamelis leaf were included in this publication and thus, a revision of the monograph is not needed.*

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, or the intake of several concomitant treatments. Thus, this information does not trigger a revision of the monograph.

*Assessor's comments: The data received from Eudravigilance do 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.

The European Pharmacopoeia monograph for *Hamamelis leaf* remains unchanged (01/2011:0909).

#### 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**

Wójciak M, Pacuła W, Tyszczyk-Rotko K, Ziemińska A, Zagórska-Dziok M, Nizioł-Łukaszewska Z, et al. Comparative analysis of polyphenol-rich extracts from *Hamamelis virginiana* Leaves and Bark: ROS scavenging and anti-inflammatory effects on skin cells. *Molecules* 2025, 30 (17):3572. doi: 10.3390/molecules30173572.

**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