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EMA/HMPC/359539/2025
Committee on Herbal Medicinal Products (HMPC)

Addendum to Assessment report on *Hamamelis virginiana* L., cortex

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HMPC decision on review of monograph <i>Hamamelis virginiana</i> L., cortex 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 cortex/bark
- 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 20219, 8 new references not yet available during the previous assessment were identified. Two references were related to the antimicrobial and/or antibacterial properties of different plant extracts. One article was related to the chemical composition and antioxidant activity of both leaves and bark from *Hamamelis virginiana* L., and four articles reviewed or assayed the pharmacological properties and therapeutic uses of the species. Another article referred to herbal mixtures.

No references were provided by Interested Parties during the Call for data for *Hamamelis virginiana* L., cortex.

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 witch-hazel bark were included in this publication and thus, a revision of the monograph is not needed.

During the periodic review, no case reports were recorded in Eudravigilance.

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 bark* remains unchanged (01/2016:2532).

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