



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Addendum to Assessment report on *Carum carvi* L., aetheroleum

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HMPC decision on review of monograph <i>Carum carvi</i> L., aetheroleum adopted on 07 July 2015	19 March 2025
Call for scientific data (start and end date)	01 April 2025 to 30 June 2025
Discussion in HMPC	September 2025 November 2025
Adoption by HMPC	19 November 2025

Review of new data

Periodic review (from 2020 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 was searched on 13 August 2025 using the key words "carum carvi" and "caraway essential oil".

☒ Pharmacovigilance databases

☒ data from EudraVigilance

☒ from other sources (e.g. data from VigiBase, national databases)

☐ 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	☐	☒
New clinical safety data that could trigger a revision of the monograph	☐	☒
New data introducing a possibility of a new list entry	☐	☒
New clinical data regarding the paediatric population or the use during pregnancy and lactation that could trigger a revision of the monograph	☐	☒
New clinical studies introducing a possibility for new WEU indication/preparation	☐	☒
Other scientific data that could trigger a revision of the monograph	☐	☒
<i>Regulatory practice</i>	Yes	No
New herbal substances/preparations with 30/15 years of TU	☐	☒
New herbal substances/preparations with 10 years of WEU	☐	☒
New recommendations from a finalised PSUSA	☐	☒
Feedback from experiences with the monograph during MRP/DCP procedures that could trigger a revision of the monograph	☐	☒
New/Updated Ph. Eur. monograph that could trigger a revision of the monograph	☐	☒
Other regulatory practices that could trigger a revision of the monograph	☐	☒
<i>Consistency</i>	Yes	No
New or revised public statements or other HMPC decisions that could trigger a revision of the monograph	☐	☒

Relevant inconsistencies with other monographs within the therapeutic area that could trigger a revision of the monograph	☐	☒
Other relevant inconsistencies that could trigger a revision of the monograph	☐	☒

Summary of new references

During the review, 153 new references not yet available during the first/previous assessment were identified (period from 13 June 2020 to 13 August 2025). The PubMed search was performed using the key words "Carum carvi" (134 references) and "caraway essential oil" (72 references). Out of these new references, 139 were excluded as they did not meet the scope of the assessment. Specifically, these included publications on plant species other than *Carum carvi*, studies on combinations of plants containing *Carvi aetheroleum*, reports addressing agricultural or harvest aspects (e.g. herbicides, repellents, insecticides) or use in food preservation, as well as publications that do not provide evidence clarifying the mechanism of action or supporting the safety and efficacy of *Carvi aetheroleum* for the indications as established in the monograph on *Carum carvi* L., *aetheroleum*. Relevant publications on *Carvi aetheroleum* mainly addressed its phytochemical composition, innovative extraction methods, and diverse biological activities, including antimicrobial, antioxidant, anti-inflammatory, and antidiabetic properties, as well as novel pharmaceutical formulations.

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

During the Call for data, for caraway essential oil a total of 24 references were submitted by Interested Parties, including 12 scientific publications from one source and 12 traditional bibliographic references (aromatherapy books) from another.

Assessment of new data

New scientific data that could trigger a revision of the monograph

Not applicable.

During the periodic review, three non-serious case reports were identified in EudraVigilance describing the use of a combination product containing *Mentha piperita* essential oil and *Carum carvi* essential oil. As these reports refer to a combination product, they cannot be attributed to *Carum carvi aetheroleum* as a single herbal substance and therefore do not trigger a revision of the monograph.

New regulatory practice that could trigger a revision of the monograph

New herbal substances/preparations with 30/15 years of TU or 10 years of WEU.

Not applicable.

No recent updates to the Ph. Eur. have been identified that would justify an amendment to the *Carvi aetheroleum* monograph.

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