



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

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

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HMPC decision on review of monograph <i>Carum carvi</i> L., fructus 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 fruit".

☒ 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, 145 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 fruit" (32 references). Out of these new references, 105 were excluded because they were related to other species (such as *Carum copticum* or *Nigella sativa*), herbal combinations, addressed different herbal substances of *Carum carvi* (such as the essential oil, not the fruit covered by this monograph), addressed crop and harvest aspects, or were otherwise not relevant to the monograph. Among the references considered, most were related to the phytochemical composition, extraction methods, the development of nanoparticle-based dosage forms, and/or new analytical methods applied for the chemical characterization of *Carvi fructus*.

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

Forty references were provided by Interested Parties during the Call for data.

Assessment of new data

New scientific data that could trigger a revision of the monograph

Not applicable.

During the periodic review, three serious case reports were identified in EudraVigilance: one case in a neonate who had received *Carum carvi* suppositories with the reported adverse reaction of diarrhoea; one case in an adult who had taken *Carum carvi* in combination with *Mentha piperita* with reported adverse reactions of urticaria, angioedema and pruritus; and one case involving a multi-botanical medicinal product (including *Carum carvi*) with the reported adverse reaction of "stomach flu". The two cases involving combination products cannot be attributed to the intake of *Carum carvi* 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 fructus* 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