EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Addendum to Assessment report on *Oenothera biennis* L.; *Oenothera lamarckiana* L., oleum

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HMPC decision on review of monograph *Oenothera biennis* L.; *Oenothera lamarckiana* L., oleum adopted on 05 June 2018	31 January 2024
Call for scientific data (start and end date)	From 01 April 2024 to 30 June 2024
Discussion in Committee on Herbal Medicinal Products (HMPC)	May 2025 September 2025 November 2025
Adoption by HMPC	19 November 2025

Review of new data

Periodic review (from 2017 to 2024)

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 2024-11-16; period covered: September 2017 - November 2024; keywords: "evening primrose oil" or "oenotherae oil": 104 hits (22 reviews; 17 clinical studies/trials)
- ☒ Pharmacovigilance databases
  - ☒ data from EudraVigilance
  - ☐ from other sources (e.g. data from VigiBase, national databases)
- ☐ 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

Scientific data	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	☐	☒
Regulatory practice	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	☐	☒
Consistency	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, 104 new references not yet available during the first/previous assessment were identified. When the new reference was a systematic review (22 reviews were identified), the original studies included in the review were investigated, and only the clinical studies/trial conducted in the selected period (Sept 2017 - Nov 2024) were further considered (17 clinical trials were identified). A further selection was performed in order to identify the studies conducted only on evening primrose oil, not in association with other drugs. None of these new references was considered to be relevant for the monograph or could trigger a revision of the EU herbal monograph.

No 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

Clinical safety data

EudraVigilance was searched by the Pharmacovigilance Department of NAMDMR for adverse reactions on 4-07-2024, using the keywords "evening primrose oil" and "oenotherae oil"; 11 cases were identified, but 9 cases thereof related with concomitant administration with other drugs were excluded.

Two ICSR reports were found for the reference period, with non-serios adverse events: nausea and vomiting, blister and erythema. The causality between exposure to evening primrose oil and vomiting and nausea is assessed as "possible" in the descriptive part of ICSR.

Assessor's comments:
These adverse reactions are already covered in the EU monograph, section 4.8 Undesirable effects. The frequency is unknown. Therefore, these data do not trigger a revision of the EU herbal 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.

Updated Ph. Eur. Monograph.

The monograph (Oenotherae oleum raffinatum 01/2020:2104) was updated in Ph.Eur edition 10. The content in brassicasterol (max. 0.3 per cent) moved to the "production" section and the section "labelling" was updated.

Assessor's comments:
No revision is considered required. Reference to the updated pharmacopoeia monograph should be adapted in the HMPC monograph and supporting documents when there is a need to revise the EU herbal 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

Several trials investigated the clinical efficacy of evening primrose oil, but only a few used only Oenotherae oleum, and not in association with other drugs. Oral use of 1000 mg evening primrose oil, for 8 weeks showed some potential benefits for the psychological symptoms (e.g. anxiety, depressive mood, irritability) of postmenopausal women, assessed using the menopause rating scale (MRS) quality of life questionnaire, but more data are necessary to confirm the observed effect (Sharif *et al*., 2020).

References

European Pharmacopoeia 10th ed. Oenotherae oleum raffinatum. Council of Europe. 01/2020:2104

Sharif SN, Darsareh F. Impact of evening primrose oil consumption on psychological symptoms of postmenopausal women: a randomized double-blinded placebo-controlled clinical trial. Menopause. 2020 Feb;27(2):194-198.

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