



4 March 2026
EMA/HMPC/8050/2026
Committee on Herbal Medicinal Products (HMPC)

Addendum to Assessment report on *Centaurium erythraea* Rafn. s.l., herba

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HMPC decision on review of monograph <i>Centaurium erythraea</i> Rafn. s.l., herba adopted on 24 November 2015	22 January 2025
Call for scientific data (start and end date)	From 15 February 2025 to 15 May 2025
Discussion in HMPC	January 2026 March 2026
Adoption by HMPC	4 March 2026

Review of new data

Periodic review (from 2015 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 9 January 2026 with the searchterms [*Centaurium erythraea* OR *Centaurium majus* OR *Centaurium suffruticosum* OR *Erythraea centaurium* OR *Centaurium umbellatum* OR *Centaurium minus* OR Centaury] for the period 2015-2025.

Pharmacovigilance databases

data from EudraVigilance

from other sources (VigiBase)

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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

	Yes	No
<i>Scientific data</i>		
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 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 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, 69 new references not yet available during the first assessment were identified. Out of these new references no other ones were considered to be relevant for 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

Eudravigilance was searched on 9th of January 2026 with the search term *Centaureum erythraea* and retrieved one case report, which was with co-medication and concomitantly used herbal. Therefore, this case was not relevant for the single component product. The term Centaury extract also retrieved one case report with co-medication and concomitantly used herbals has been found out.

Vigibase was searched on the 9th of January 2026 with the search term *Centaureum erythraea* (as active substance). 3 cases were retrieved of which none was without co-medication or concomitantly used herbals.

Assessor's comment:

The reported adverse events 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

Two registered mono-component products were reported. Moreover, 3 countries reported the marketing presence of a combination product containing Centaurii. Combination products do not trigger a revision of the EU herbal monograph.

Assessor's comment:

Two mono-component products have been reported so far but both of them are already covered by the TU monograph. Therefore, the products do not trigger a revision of the EU herbal monograph.

The Ph. Eur. monograph on Centaurii herba has been revised July 2024. The revision includes the deletion of the botanical species *Centaureum majus* and *C. suffruticosum* because the name of the herbal substance is covered by referencing sensu lato (*s.l.*); number of synonyms listed are reduced to two in order to keep the most commonly used.

The definition of the herbal material in Ph. Eur. monograph 1301 is: "Whole or fragmented dried flowering aerial parts of *Centaureum erythraea* Rafn s.l. (syn. *Centaureum umbellatum* Gilib.; *Erythraea centaureum* Pers.)."

The name of the HMPC monograph is *Centaurium erythraea* Rafn. s.l., herba; The definition of the herbal material in section 2. Qualitative and quantitative composition of the HMPC monograph is: “*Centaurium erythraea* Rafn. s.l. including *C. majus* (H. et L.) Zeltner and *C. suffruticosum* (Griseb.) Ronn. (syn.: *Erythraea centaurium* Persoon; *C. umbellatum* Gilibert; *C. minus* Gars.), herba (Centaury).”

Assessor’s comment:

The change of botanical definition of the herbal material according the Ph. Eur. monograph is not yet reflected in the existing EU herbal monograph. The description of the herbal material in section 2. of the monograph does mention the two species that are deleted from the Eur. Ph. monograph, namely C. majus (H. et L.) Zeltner and C. suffruticosum (Griseb.) Ronn. and also C. minus Gars. as a synonym. This, however, does not trigger a revision of the EU herbal monograph, because these are also covered by the existing Ph. Eur. 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