EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Addendum to Assessment report on *Epilobium angustifolium* L. and/or *Epilobium parviflorum* Schreb., herba

Rapporteur	R Länger
Peer-reviewer(s)	M Příhodová / M Heroutová

HMPC decision on review of monograph *Epilobium angustifolium* L. and/or *Epilobium parviflorum* Schreb., herba adopted on 24 November 2015	26 January 2022
Call for scientific data (start and end date)	From 15 February 2022 to 14 May 2022
Discussion in Committee on Herbal Medicinal Products (HMPC)	July 2022 September 2022
Adoption by Committee on Herbal Medicinal Products (HMPC)	21 September 2022

Review of new data on *Epilobium angustifolium* L. and/or *Epilobium parviflorum* Schreb., herba

Periodic review (from 2014 to 2022)

Scientific data (e.g. non-clinical and clinical safety data, clinical efficacy data)

☒ Scientific/Medical/Toxicological databases

Scopus, period 2014 – 2022, search date 15 June 2022, keyword 'Epilobium': in total 257 documents could be retrieved

☒ Pharmacovigilance databases

☒ data from EudraVigilance

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

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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

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	☐	☒
Other	Yes	No
	☐	☒

Summary of new references:

During the review 257 new references, not yet available during the first/previous assessment, were identified. Out of these new references 16 of them were considered to be relevant for the monograph. One reference (clinical trial related to the indication) was identified that could potentially trigger a revision of the monograph:

Reviews, conference papers: 5

Constituents and *in vitro* activities: 3

In vivo (related to indication): 4

In vivo (not related to indication): 2

Clinical trial (related to indication): 1 (see discussion below)

Clinical trial (not related to indication): 1

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

Esposito, C. *et al.* (2021):

A standardised extract of *E. angustifolium* (standardised to >= 15% oenothein B, no further details on extraction solvent and drug-extract ratio) was tested in a monocentric, randomised, double-blind, placebo-controlled clinical trial in order to evaluate if a daily intake of 500 mg extract for 6 months may allow a significant improvement in symptoms in subjects with BPH. 128 adult men were randomly assigned to verum (n=70) or placebo (n=58). Evaluated criteria: Post-void Residual (PVR) and Prostate Volume (PV) by means of prostate ultrasound, Prostate-specific Antigen (PSA) and Neutrophile /Lymphocyte ratio (N/L), nycturia before the clinical visits and International Prostate Specific Score (IPSS) registered by the physicians. The authors report a decrease in PVR and nycturia, which led also to a decrease of the IPSS. No adverse events are reported. Moreover, no signs of hepatic or renal toxicity were observed.

Assessor's comment:

No details on the herbal preparation (except standardisation) are published. The evaluation of the observed criteria was done by descriptive statistics. The clinical trial was performed with a non-medicinal product. As the herbal preparation is not adequately described and no extract of E. angustifolium is in medicinal use in the EU for more than 10 years, this study does not trigger a revision of the EU herbal monograph in order to include well-established use. However, the absence of adverse events is well noted.

The reported safety of the herbal preparation is in line with the reports contained in the Eudravigilance database. Only one report related to *Epilobium* is contained (vertigo after intake of a homoeopathic medicine containing *Epilobium*; the patient took a lot of unspecified concomitant

medication). These data support the wording in the monograph, that undesirable effects are not known.

New regulatory practice that could trigger a revision of the monograph

Not applicable.

Inconsistency that could trigger a revision of the monograph

Not applicable.

Other

Not applicable.

References

Esposito, C. *et al. Epilobium angustifolium* L. extract with high content in oenothein B on benign prostatic hyperplasia: A monocentric, randomized, double-blind, placebo-controlled clinical trial. *Biomedicine and Pharmacotherapy* 2021, 138, art. no. 111414

Rapporteur's proposal 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

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