



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Addendum to Assessment report on *Primula veris* L. *Primula elatior* (L.) Hill, *flos*

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HMPC decision on review of monograph <i>Primula veris</i> L.; <i>Primula elatior</i> (L.) Hill, <i>flos</i> adopted on 19 September 2012	22 January 2025
Call for scientific data (start and end date)	From 01 March to 31 May 2025
Discussion in Committee on Herbal Medicinal Products (HMPC)	July 2025 September 2025
Adoption by HMPC	24 September 2025

Review of new data

Periodic review (from 2012 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/ Search period was set from September 2012 until May 2025. Search terms: *Primula* and (*veris* or *elatior*)

☒ Pharmacovigilance databases

☒ data from EudraVigilance

☒ from other sources (VigiBase)

☐ 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 83 new references not available during the first/previous assessment were identified. Out of these new references, 71 were excluded as were related to other *Primula* species, combinations or not relevant to the existing monograph. Among the evaluated references, most of them were related to phytochemical composition, extraction methods and/or new analytical methods applied for the chemical characterization of *Primula flos*. Some *in vitro* studies were performed with specific extracts, not fully elucidated or different from the preparations included in the current monograph.

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

Twelve references were provided by Interested Parties during the Call for data for both *Primula* ssp. *herba* and *radix*. Most of them coincided with the ones found in the review; others didn't differentiate the plant part used or referred to phytochemical or *in vitro* studies not relevant for this review.

Assessment of new data

New scientific data that could trigger a revision of the monograph

Not applicable.

During the periodic review, 2 case reports were recorded in Eudravigilance: 1 case of insomnia and 1 case of angioedema. None of them could be related to the intake of *Primula* flower and thus, this information does 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.

Up to date, there is no European Pharmacopoeia's monograph on *Primula flos*.

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