



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 November 2024
EMA/HMPC/438161/2024
Committee on Herbal Medicinal Products (HMPC)

Addendum to Assessment report on *Verbascum thapsus* L.; *V. densiflorum* Bertol. (*V. thapsiforme* Schrad); *V. phlomoides* L., flos

Rapporteur(s)	G. Fossum
Peer-reviewer(s)	E. Svedlund

HMPC decision on review of monograph <i>Verbascum thapsus</i> L.; <i>V. densiflorum</i> Bertol. (<i>V. thapsiforme</i> Schrad); <i>V. phlomoides</i> L., flos adopted on 27 March 2018	31 January 2024
Call for scientific data (start and end date)	From 1 April 2024 to 30 June 2024
Discussion in Committee on Herbal Medicinal Products (HMPC)	September 2024 November 2024
Adoption by HMPC	20 November 2024

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 2024-08-29

☒ Pharmacovigilance databases

☒ data from EudraVigilance

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

☐ Other

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

An agency of the European Union



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 20 new references not yet available during the first/previous assessment were identified (time period from 01-01-2017 -04-09-2024). A search was performed on Pubmed with the key words Verbascum thapsus: 122 articles, Verbascum thapsus L.: 44 articles, Verbascum densiflorum Bertol: 0 articles, Verbascum thapsiforme Schrad: 0 articles, Verbasci flos: 0 articles, Mullein flower: 20 articles. None of these references were found relevant for the monograph.

No references were provided by Interested Parties during the Call for data.

The Eudravigilance database was searched on 29-08-2024 for the search terms Verbascum thapsus, Verbascum thapsus L., Verbascum densiflorum Bertol, Verbasci flos, Mullein flower. The Vigibase was searched on 28-08-2024 with the same search terms. There are no new safety issues detected from the EudraVigilance or Vigibase database.

Assessment of new data

New scientific data that could trigger a revision of the monograph

Not applicable

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 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