EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Addendum to Assessment report on *Malva sylvestris* L., flos

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HMPC decision on review of monograph *Malva sylvestris* L., flos adopted on 20 November 2018	25 January 2023
Call for scientific data (start and end date)	From 31 March 2023 to 30 June 2023
Discussion in Committee on Herbal Medicinal Products (HMPC)	January 2024 March 2024
Adoption by Committee on Herbal Medicinal Products (HMPC)	20 March 2024

Review of new data

Periodic review (from 2015 to 2022)

Sources checked for new information:

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

- ☒ Scientific/Medical/Toxicological databases: PubMed was searched on 2023-06-16; period covered: March 2018 - June 2023
- ☒ Pharmacovigilance databases
  - ☒ data from EudraVigilance
  - ☐ from other sources (e.g. data from VigiBase, national databases)
- ☐ 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

Scientific data	Yes	No
New nonclinical 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, 14 new references not yet available during the first/previous assessment were identified. Out of these new references, none was considered to be relevant to the monograph, and none could trigger the revision of the 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 07-08-2023, using the keywords "*Malvae flos*"; cases related to concomitant administration with other drugs were excluded.

One ICSR report was found for the reference period, related to the use of a combination containing Malvae sylvestris flos aqueous extract (DER 1:5), Plantago lanceolata herba extract, ascorbic acid; serious reported reactions: laryngeal oedema, angioneurotic oedema. The causality between exposure the combination and the adverse reaction reported is considered "possible" in the descriptive part of ICSR.

Assessor's comment: Both ADRs could be a hypersensitivity reaction to any component from the combination. As a general precaution, in the published EU herbal monograph, in section 4.3, the contraindication 'Hypersensitivity to active substance' is already mentioned. This data 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.

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

There are some in vivo nonclinical studies conducted on different mallow extracts obtained from leaves and aerial parts of *Malva neglecta* that investigated in rats a possible beneficial effect on endometriosis (Akkol *et al*., 2022).

References

Akkol EK, Karpuz B, Türkcanoğlu G, Coşgunçelebi FG, Taştan H et al. The Phytochemical Profile and Biological Activity of *Malva neglecta* Wallr. in Surgically Induced Endometriosis Model in Rats. *Molecules* 2022, 15;27(22):7869

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