



20 March 2024  
EMA/HMPC/408283/2023  
Committee on Herbal Medicinal Products (HMPC)

## Addendum to Assessment report on *Malva sylvestris* L.; *Malva neglecta* Wallr., folium

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HMPC decision on review of monograph <i>Malva sylvestris</i> L.; <i>Malva neglecta</i> Wallr., folium 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



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 nonclinical 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 checked="" type="checkbox"/>	<input 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 checked="" 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 checked="" 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, 25 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 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 folium"; cases related to concomitant administration with other drugs were excluded.

One ICSR report was found for the reference period, related to the use of herbal tea prepared from malvae leaves; a non-serious reaction was reported: throat irritation. The causality between exposure to mallow tea and reported adverse reaction is considered "possible" in the descriptive part of ICSR. The ICSR mentioned that the problem was solved after the drug was withdrawn.

*Assessor's comment: This limited data does 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

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) or the beneficial effects of the use of methanolic extracts from mallow leaves (both species) on cutaneous wounds in rats (Alsarayeh et al., 2022; Saleem, 2020).

## 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 Nov 15, 27(22):7869

Alsarayeh AZ, Oran SA, Shakhanbeh JM, Khleifat KM, Al Qaisi YT, *et al.* Efficacy of methanolic extracts of some medicinal plants on wound healing in diabetic rats. *Heliyon* 2022 Aug 2, 8(8):e10071

Saleem U, Khalid S, Zaib S, Anwar F, Ahmad B, Ullah I, *et al.* Phytochemical analysis and wound healing studies on ethnomedicinally important plant *Malva neglecta* Wallr. *J Ethnopharmacol* 2020 Mar 1, 249:112401

**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