



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

19 November 2025  
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Committee on Herbal Medicinal Products (HMPC)

## Addendum to Assessment report on *Althaea officinalis* L., radix

|                  |             |
|------------------|-------------|
| Rapporteur(s)    | O. Palomino |
| Peer-reviewer(s) | J. Wiesner  |

|   |                                    |
|---|------------------------------------|
| HMPC decision on review of monograph <i>Althaea officinalis</i> L., radix adopted on 12 July 2016 | 22 January 2025                    |
| Call for scientific data (start and end date)   | From 01 April 2025 to 30 June 2025 |
| Discussion in HMPC  | September 2025<br>November 2025    |
| Adoption by HMPC  | 19 November 2025                   |

### Review of new data

#### Periodic review (from 2016 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 2016 until June 2025. Search terms:  
*Althaea officinalis* radix

☒ Pharmacovigilance databases

☒ data from EudraVigilance

☒ from other sources (VigiBase)

☐ Other

Regulatory practice

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- ☒ 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  | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| New clinical safety data that could trigger a revision of the monograph  | <input type="checkbox"/> | <input checked="" 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 covering the last 10 years, 19 new references not yet available during the first/previous assessment were identified. Three references referred to different species, *Althaea rosea* Cavan., while several references were related to the isolation, structural properties, and bioactivities of polysaccharides from *Althaea officinalis* Linn. Two references were related to the content and exposure of heavy metals (Pb and/or Cd) in marshmallow root preparations.

Thirty-nine references were provided by Interested Parties during the Call for data for *Althaea officinalis* radix.

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

## Assessment of new data

### New scientific data that could trigger a revision of the monograph

Not applicable.

During the call for data, 39 references were provided by Interested Parties: 11 of them referred to the antioxidant ability or to *in vitro* studies; 6 references were related to the topical use of different extracts or isolated compounds from marshmallow and several studies included other plant parts different from the radix; 11 articles related to the chemical composition of the radix; two studies investigated the accumulation of heavy metals; one article referred to uses different from medicinal use while 3 studies included medicinal uses different from the ones included in the monograph.

According to the Drug and Lactation Database report (LactMed, 2024), marshmallow is generally recognized as safe (GRAS) in amounts found in foods by the US Food and Drug Administration.

Three articles were related to the use of *Althaea* radix for the relief or treatment of respiratory symptoms:

Silveira *et al.* (2020) provided a benefit/risk assessment of selected herbal medicines traditionally used for respiratory diseases as an adjuvant treatment for COVID-19. Preclinical and clinical data on efficacy and safety were collected from authoritative sources and were evaluated according to a modified ProACT-URL method with paracetamol, ibuprofen and codeine as reference drugs. The authors concluded that the use of *Althaea officinalis* root in the context of upper respiratory conditions was not backed up by robust clinical data, but the evidence allowed to infer a potential use in the relief of early symptoms of COVID-19. While it will not cure or prevent the flu, it may both improve general patient well-being and offer them an opportunity to personalize the therapeutic approaches.

#### Assessor's comments:

No new preclinical data were included in this publication different from those discussed and assessed during the first Assessment Report on *Althaea officinalis* root. The revision of clinical data by Silveira *et al.* (2020) stated that "clinical evidence may be considered as high"; this conclusion is supported by 2 studies (Rouhi and Ganji, 2007 and Fink *et al.* 2018); the former study was already discussed in the existing AR where the clinical relevance was not considered clear and furthermore the placebo preparation was not known; the latter is a 2-prospective, non-interventional survey about effectiveness and tolerability among users of an aqueous extract of marshmallow root. This conclusion is based only on subjective perception of the users and so, it cannot be taken in account as a proof of effectiveness. Thus, a revision of the monograph is not needed.

The article by Mahboubi (2020) reviewed the efficacy of marshmallow for the treatment of cough. This review included publications with preparations from *Althaea officinalis* leaves, flowers and roots, together with the isolated compound rhamnogalacturonan, as one of the principal constituents of the root.

**Assessor's comments:**

*Most of the cited studies were included and evaluated during the first Assessment Report on Althaea officinalis root. This review also included the study by Fink et al, 2018 (see above). In summary, no new preclinical or clinical data that could trigger a revision of the monograph were included in the publication.*

Fink *et al.* (2018) published the results of a 2 prospective non-interventional surveys for the treatment of irritative cough. The aim of these surveys was to record the users' impression of the effectiveness and tolerability of a marshmallow root extract (as lozenges or syrup), for the treatment of dry cough. This consumer-reported outcome showed a good effect for both preparations with respect to the symptomatic treatment of oral or pharyngeal irritation and associated dry cough with a very rapid onset of effects. Tolerability was rated as good or very good by more than 96% of the participants. No adverse events were reported with the lozenges; with the syrup, 1 case of bloating, 1 case of abdominal discomfort and 1 more case of poor tolerability (no further details) were reported.

**Assessor's comments:**

*These studies were performed with an extract from Althaea officinalis root commercially available as medicinal products in the form of syrup or lozenges. The surveys were uncontrolled, and the results could not be compared with the usual course of episodes of irritative cough; also, the effect of co-medication used by the participants was not assessed. For all the above-mentioned reasons, this study cannot be taken in account and does not trigger a revision of the monograph.*

During the periodic review, three case reports were recorded in Eudravigilance: one case of palpitations, one case of pharyngeal swelling and one case of throat irritation. They were considered as non-serious adverse events. There exists no certainty of the relationship between the intake of *Althaea radix* and the observed adverse reactions; they could have been related to the symptom to be treated, the intake of several concomitant treatments or randomly appeared during the period of marshmallow root intake. Thus, this information does not trigger a revision of the monograph.

**New regulatory practice that could trigger a revision of the monograph**

There are no new herbal substances/preparations with 30/15 years of TU or 10 years of WEU.

The European Pharmacopoeia monograph for *Althaea radix* remains unchanged (01/2012:1126).

**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

LactMed, 2024. Drugs and Lactation Database (LactMed). National Institute of Child Health and Human Development; 2006. Marshmallow. [Updated 2024 May 15]. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK501839/>

Fink C, Schmidt M, Kraft K. Marshmallow Root Extract for the Treatment of Irritative Cough: Two Surveys on Users' View on Effectiveness and Tolerability. *Complement Med Res* 2018, 25(5):299-305. doi:10.1159/000489560

Mahboubi M. Marsh Mallow (*Althaea officinalis* L.) and Its Potency in the Treatment of Cough. *Complement Med Res* 2020, 27(3):174-183. doi:10.1159/000503747

Silveira D, Prieto-Garcia JM, Boylan F, Estrada O, Fonseca-Bazzo YM, Jamal CM et al. COVID-19: Is There Evidence for the Use of Herbal Medicines as Adjuvant Symptomatic Therapy? *Front Pharmacol* 2020, 11:581840. doi:10.3389/fphar.2020.581840

## 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