



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

09 July 2025  
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Committee on Herbal Medicinal Products (HMPC)

## Addendum to Assessment report on *Calendula officinalis* L., flos

Rapporteur(s)	C. Purdel
Peer-reviewer(s)	I. Chinou

HMPC decision on review of monograph <i>Calendula officinalis</i> L., flos adopted on 27 March 2018	31 January 2024
Call for scientific data (start and end date)	From 01 March 2024 to 31 May 2024
Discussion in Committee on Herbal Medicinal Products (HMPC)	January 2025 May 2025 July 2025
Adoption by HMPC	09 July 2025

### 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 2024-06-16; period covered: July 2017 - May 2024
- ☒ 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

<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 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 checked="" type="checkbox"/>	<input 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 67 new references not yet available during the first/previous assessment were identified. When the new reference was a systematic review, the original studies included in the review were investigated, and only the studies conducted in the selected period (July 2017 - May 2024) were further considered. None of these new references was considered to be relevant for the monograph or 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 15 June 2022, using the keywords "calendula flos" and "calendula"; cases related with concomitant administration with other drugs were excluded.

Fifteen ICSR reports were found for the reference period, one related with accidental oral exposure (ingestion of ointment); reaction list: erythema, pruritus, papule, burning sensation. The causality between exposure to calendula ointment and adverse reactions reported is assessed as "possible" in the descriptive part of ICSRs, due to the known allergic potential.

#### **Assessor's comment:**

*The reported adverse reactions are covered by the skin sensitization already listed in EU monograph, in section 4.8 Undesirable effects EMA/HMPC/437450/2017. The frequency is unknown. Therefore, these data do 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.

#### *Updated Ph. Eur. monograph*

The monograph (Calendula flower 04/2020:1297) were updated in Ph.Eur edition 10. For the Identification C, TLC was replaced by HPTLC.

#### **Assessor's comment:**

*No revision is considered required. Reference to the updated pharmacopoeia monograph should be adapted in the EU herbal monograph and supporting documents when there is a need to revise the monograph.*

### 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

Two references focused on quality/chemistry referred to two new sesquiterpenes glycosides isolated from calendula flower (Zaki *et al.*, 2021, Samra *et al.*, 2022).

#### **Assessor's comment:**

*The recent literature on chemical composition offer further scientific data not previously reported.*

Some systematic reviews collected the current evidence for the use of *Calendula officinalis* extract in management of wound care (Givol *et al.*, 2019) or mucositis induced by oncotherapy (Eubank *et al.*, 2021).

### References

Eubank PLC, Abreu LG, IP Violante & LER Volpato Medicinal plants used for the treatment of mucositis induced by oncotherapy: a systematic review *Supportive Care in Cancer* 2021, 29(11): 6981–6993

European Pharmacopoeia 10<sup>th</sup> ed. *Calendula Flower*. Council of Europe. 04/2020:1297

Givol O, Kornhaber R, Visentin D, Cleary M, PhD, Haik J, MPH, Harats MD. A systematic review of *Calendula officinalis* extract for wound healing, *Wound Repair and Regeneration* 2019, 27(5):548–561

Samra RM, Maatooq GT, Zaki AA. A new antiprotozoal compound from *Calendula officinalis*. *Nat Prod Res.* 2022 Nov;36(22):5747-5752

Zaki AA, Ashour AA, Qiu L. New sesquiterpene glycoside ester with antiprotozoal activity from the flowers of *Calendula officinalis* L. *Nat Prod Res.* 2021 Dec;35(23):5250-5254

### 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