



21 September 2022
EMA/HMPC/648153/2022
Committee on Herbal Medicinal Products (HMPC)

Addendum to Assessment report on *Eschscholzia californica* Cham., herba

Rapporteur(s)	O. Palomino
Peer-reviewer(s)	G. Laekeman

HMPC decision on review of monograph <i>Eschscholzia californica</i> Cham., herba adopted on 21 September 2022	26 January 2022
Call for scientific data (start and end date)	15 February 2022 to 14 May 2022
Discussion in Committee on Herbal Medicinal Products (HMPC)	July 2022 September 2022
Adoption by Committee on Herbal Medicinal Products (HMPC)	21 September 2022

Review of new data

Periodic review (from 2015 to 2022)

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

Scientific/Medical/Toxicological databases

PubMed/ Search period was set from 2015 until June 2022. Search terms: *Eschscholzia californica*, California poppy (39 and 52 references were found, respectively).

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 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"/>

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

Not applicable.

There are no new products in the EU market containing *Eschscholzia californica* Cham., herba, as the single active substance different from those included in the current EU MO and no references justify a revision of the monograph.

No clinical studies or new safety concerns related to the use of *Eschscholzia californica* Cham., herba were found. Thus, no new relevant data have been found which could affect the existing monograph, and no changes in the regulatory practice have been introduced. As a result of this review, no revision is considered required.

References

Not applicable.

Rapporteur's proposal 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

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