EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Addendum to Assessment report on *Glycine max* (L.) Merr., oleum raffinatum

Rapporteur(s)	E. Svedlund
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HMPC decision on review of monograph *Glycine max* (L.) Merr., oleum raffinatum adopted on 31 January 2017	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)	November 2023 March 2024 July 2024
Adoption by Committee on Herbal Medicinal Products (HMPC)	24 July 2024

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 search 29 April 2024 using the following search terms: soybean or "soy food" or ("glycine max" or soybean* or soya* or soy). The following filters were applied: Case Reports, Clinical Study, Clinical Trial, Clinical Trial, Phase III, Clinical Trial, Phase IV, Comparative Study, Controlled Clinical Trial, Letter, Meta-Analysis, Observational Study, Practice Guideline, Pragmatic Clinical Trial, Review, Systematic Review, Humans, Danish, English, French, German, Norwegian, Swedish, 2015-2024. 2039 results.

☒ Pharmacovigilance databases

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☒ 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: Annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use'

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 non-clinical 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 2039 new references not yet available during the first/previous assessment were identified. Applying further search terms, i.e., "bath additive" and ("dry skin condition" or eczema) there were no results. Applying the search terms ("dry skin condition" or eczema) there were four results. Out of these new references no reference was considered to be relevant for the monograph and no reference that 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

EudraVigilance data

The EudraVigilance was search on 7 February 2024 with the active substance (high level) contains: soya-bean, soybean, lecithinum, lecithin, soiae oleum, soya-bean oil, soiae, soybean phospholipids.

Assessor's comment: No new safety issues detected that will 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

Active substance	**Indication**	**Pharmaceutical form** **Strength (where relevant)** **Posology** **Duration of use**	**Regulatory Status (date, Member State)**
Refined soy oil	Symptomatic treatment of dermatoses with dry and slightly itching skin	Bath additive 100 g contain 84.75 g refined soy oil. Adults, adolescents: full bath 30 ml; partial bath 1 ml per 5 l bath Children 1-11 years: 5 ml per 25 l bath Children below 1 year: only on recommendation by a doctor	Authorisation acc. to 8(3) Date of authorisation 16.11.1967 in AT

This overview is not exhaustive. It is provided for information only and reflects the situation at the time when it was established.

Assessor's comment: The product is considered to correspond to products included in market overview in the first version of the assessment report. Hence, there are no new information that will trigger a revision of the monograph.

Updated Ph. Eur. monograph

The Ph. Eur. monograph on soya-bean oil, refined, was updated January 2024 (ref.:1473). The maximum limit of stearic acid has been changed from 2.5% to 2.0% and the maximum limit of linolenic acid has been changed from 5.0% to 4.5%.

Assessor's comment: The updated Ph. Eur. monograph does not trigger a revision of 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

Not applicable.

References

Not applicable.

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