12 May 2023
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Committee on Herbal Medicinal Products (HMPC)

Addendum to assessment report on *Rubus idaeus* L., folium

Rapporteur(s)	G. Fossum
Peer-reviewer(s)	E. Svedlund

HMPC decision on review of monograph *Rubus idaeus* L., folium adopted on 28 January 2014	26 January 2022
Call for scientific data (start and end date)	From 15 April 2022 to 14 July 2022
Discussion in Committee on Herbal Medicinal Products (HMPC)	September 2022 March 2023 May 2023
Adoption by Committee on Herbal Medicinal Products (HMPC)	12 May 2023

Review of new data

Periodic review (from 2012 to 2022)

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 2022-08-01
- ☒ 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

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, 224 new references not yet available during the first/previous assessment were identified (time period from 2012-08-01 to 2022-08-01). A search was performed on PubMed with

the key words: "*Rubus idaeus* L.", "Rubi idaei foli" and "Raspberry leaf" (*Rubus ideaus* L.,: 303 references, Raspberry leaf: 224 references, Rubi idaei folium : no references). None of these results were found relevant for the monograph.

No references were provided by Interested Parties during the Call for data.

The Eudravigilance database was searched on 2022-08-16 for the search terms "*Rubus idaeus* L.", "Rubi idaei., folium" and "Raspberry leaf". There are no new safety issues detected from the EudraVigilance database.

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

No new products containing raspberry leaf as a single active substance have been reported from the Member States, but a raspberry leaf aqueous dry extract hard capsules has been registered according to Art.16a of Directive 2001/83/EC as amended relying on traditional medicinal use in a decentralised procedure including 12 member states. The approved product, the proposed indication, the claimed posology and the provided data are in line with the HMPC monograph.

Assessor's comment:

This product will be included in the market overview in the assessment report when there is a need to revise the monograph.

A monograph on Raspberry leaf (ref.:2950) was newly included in Ph.Eur. (European Pharmacopoeia, 2020). The content is expressed in tannins expressed as pyrogallol (minimum 3 %). In the French pharmacopoeia (the quality reference declared in the EU herbal monograph) the content was expressed only in tannins with another limit (minimum 5.0%).

Assessor's comment:

Reference to the new pharmacopoeia monograph should be adapted in the HMPC monograph and supporting documents when there is a need to revise the monograph. No new data/findings of relevance for the content of the monograph were found.

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

The Ph.Eur. monograph on Raspberry leaf (ref.:2950, European Pharmacopoeia, 2020).

References

Ph. Eur. monograph for Raspberry leaf

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