



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

20 September 2023  
EMA/HMPC/321020/2023  
Committee on Herbal Medicinal Products (HMPC)

## Addendum to Assessment report on *Prunus africana* (Hook f.) Kalkm., cortex

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

|                                                                                                              |                                         |
|--------------------------------------------------------------------------------------------------------------|-----------------------------------------|
| HMPC decision on review of monograph <i>Prunus africana</i> (Hook f.) Kalkm., cortex adopted on 12 July 2016 | 26 January 2022                         |
| Call for scientific data (start and end date)                                                                | From 15 March 2022 to 14 June 2022      |
| Discussion in Committee on Herbal Medicinal Products (HMPC)                                                  | May 2023<br>July 2023<br>September 2023 |
| Adoption by Committee on Herbal Medicinal Products (HMPC)                                                    | 20 September 2023                       |

### Review of new data

#### Periodic review (from 2016 to 2023)

#### Sources checked for new information:

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

☒ Scientific/Medical/Toxicological databases

Scientific data of the period 2016 -2023 was reviewed using Google Scholar browsing machine and sources available in library of Medline, PubMed, Reaxys, SciFinder, Scopus, The Cochrane Library, ScienceDirect. Search terms "Prunus + cortex", "Prunus + africana"

☒ Pharmacovigilance databases

☒ data from EudraVigilance

☒ from other sources (e.g. data from VigiBase; National sources)

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☐ 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"/> |

## Summary of new references

During the review 31 references have been collected among which there were several ethnopharmacological studies, chemical analyses and LC-TOF-MS profiles, *in vitro* cytotoxicity and chemo-preventive studies, *in vitro* antibacterial activities, anti-osteoporosis effects, action against obesity, together with two recent reviews (Namboozee *et al.*, 2022; Rubegeta *et al.*, 2023).

None of the references 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

Not applicable.

### 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.

### Inconsistency that could trigger a revision of the monograph

Not applicable.

### Other issues that could trigger a revision of the monograph

Nor applicable.

### New information not considered to trigger a revision at present but that could be relevant for the next review

EudraVigilance was searched for adverse reactions on March 2023, using the keywords "Prunus africana bark, cortex". Only three ICSRs were identified in EudraVigilance.

#### Assessor's comment:

*None of the new references are considered to be relevant for the monograph on Prunus africana (Hook f.) Kalkm., cortex. Moreover, no safety issues signals appeared during the search on Eudravigilance and Vigilyze as all cases involved concomitant administration with other medicinal products. The causality between adverse reactions and exposure to Pruni africanae cortex is not considered plausible, so such data do not trigger a revision of the EU herbal monograph.*

## References

References that could be relevant for the next review:

Namboozee J, Erukainure OL, Chukwuma CI. Phytochemistry of *Prunus africana* and its therapeutic effect against prostate cancer. *Comparative Clinical Pathology* 31, 2022, 875–893

Rubegeta E, Makolo F, Kamatou G, Enslin G, Chaudhary S, Sandasi M, et al. The African cherry: A review of the botany, traditional uses, phytochemistry, and biological activities of *Prunus africana* (Hook. f.) Kalkman. *Journal of Ethnopharmacology* 305, 2023, 116004

## 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