



23 September 2020
EMA/HMPC/616091/2019
Committee on Herbal Medicinal Products (HMPC)

Addendum to Assessment report on *Juniperus communis* L., aetheroleum

Rapporteur(s)	Gert Laekeman
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HMPC decision on review of monograph <i>Juniperus communis</i> L., aetheroleum adopted on November 2010	16 January 2019
Call for scientific data (start and end date)	From 15 February 2019 to 15 May 2019
Adoption by Committee on Herbal Medicinal Products (HMPC)	23 September 2020

Review of new data on *Juniperus communis* L., aetheroleum

Periodic review (from 2010 to 2019)

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

- Pharmacovigilance data (data from EudraVigilance database)
- Scientific/Medical/Toxicological databases: Embase, PubMed, reference lists of publications.
Search terms: *Juniperus, juniper, oil.*
- Other

Regulatory practice

- Old market overview in AR (i.e. products fulfilling 30/15 years on the market)
- New market overview (including pharmacovigilance actions taken in member states)
- Referral
- Ph.Eur. monograph
- Other

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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 (i.e. likely to lead to a relevant change of the monograph)

<i>Scientific data</i>	Yes	No
New non-clinical safety data likely to lead to a relevant change of the monograph	<input type="checkbox"/>	<input checked="" type="checkbox"/>
New clinical safety data likely to lead to a relevant change 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 likely to lead to a relevant change 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 likely to lead to a relevant change 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"/>
Other regulatory practices likely to lead to a relevant change of the monograph	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Referrals likely to lead to a relevant change of the monograph	<input type="checkbox"/>	<input checked="" type="checkbox"/>
New/Updated Ph. Eur. monograph likely to lead to a relevant change of the monograph	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<i>Consistency</i>	Yes	No
New or revised public statements or other HMPC decisions likely to lead to a relevant change of the monograph	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Relevant inconsistencies with other monographs within the therapeutic area that require a change of the monograph	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Other relevant inconsistencies that require a change of the monograph	<input type="checkbox"/>	<input checked="" type="checkbox"/>

MARKET OVERVIEW

There are no new preparations on the market.

EUDRAVIGILANCE DATABASE

A search in the EudraVigilance database was done for the period from 1996 until 2019. It resulted in 124 hits on 'juniper', most of them related to *Juniperus ashei*. *Juniperus* oil was solely mentioned in 5 cases and in 8 cases other agents were also involved. The cases were reported in European countries and Canada. The age of the patients varied from 35 to 90 years, without gender specification. The pharmacovigilance information obtained does not reveal any need to revise the monograph on *Juniperus aetheroleum* for safety reasons.

Summary and conclusions on the review

No references were provided by Interested Parties during the Call for data. References not yet available at the time of the first assessment (n=305) were evaluated on their relevance (title, abstract and content).

There are no new references related to human therapeutic use or human safety aspects. Most of the references are dealing with preclinical studies of *Juniperus communis aetheroleum* not relevant for one or more of the existing therapeutic indications in the monograph (2010).

No reference justify a revision of the monograph.

No revision is required because:

- There are no new preparations on the market, that fulfil the criteria for traditional or well-established use.
- There is no clinical information leading to new indications.
- There are no relevant pharmacovigilance data.
- There are no new safety or clinical data to be incorporated in the monograph.
- There are no new data that justify the consideration of a list entry.

References

a) References relevant for the assessment:

None

b) References that justify the need for the revision of the monograph:

None

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

The HMPC agreed not to revise the monograph, assessment report and list of references on ***Juniperus communis aetheroleum***, by consensus.