



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

4 March 2020  
EMA/HMPC/13144/2020  
Committee on Herbal Medicinal Products (HMPC)

## Addendum to Assessment report on *Artemisia absinthium* L., herba

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HMPC decision on review of monograph <i>Artemisia absinthium</i> L., herba adopted on May 2017	15 January 2020
Adoption by Committee on Herbal Medicinal Products (HMPC)	4 March 2020

### Review of new data on *Artemisia absinthium* L., herba

#### Unscheduled review

Data submitted by AESGP to HMPC on October 2019

- ☐ Safety data
- ☐ Other scientific data
- ☐ Regulatory practice
- ☐ Referral
- ☒ Other: Consistency with other monographs within the therapeutic area

#### Availability of new information (i.e. likely to lead to a relevant change of the monograph)

Scientific data	Yes	No
New non-clinical safety data likely to lead to a relevant change of the monograph	<input type="checkbox"/>	<input type="checkbox"/>
New clinical safety data likely to lead to a relevant change of the monograph	<input type="checkbox"/>	<input type="checkbox"/>
New data introducing a possibility of a new list entry	<input type="checkbox"/>	<input type="checkbox"/>
New clinical data regarding the paediatric population or the use during pregnancy	<input type="checkbox"/>	<input type="checkbox"/>

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and lactation likely to lead to a relevant change of the monograph		
New clinical studies introducing a possibility for new WEU indication/preparation	<input type="checkbox"/>	<input type="checkbox"/>
Other scientific data likely to lead to a relevant change of the monograph	<input type="checkbox"/>	<input type="checkbox"/>
<i>Regulatory practice</i>	Yes	No
New herbal substances/preparations with 30/15 years of TU	<input type="checkbox"/>	<input type="checkbox"/>
New herbal substances/preparations with 10 years of WEU	<input type="checkbox"/>	<input type="checkbox"/>
Other regulatory practices likely to lead to a relevant change of the monograph	<input type="checkbox"/>	<input type="checkbox"/>
Referrals likely to lead to a relevant change of the monograph	<input type="checkbox"/>	<input type="checkbox"/>
New / Updated Ph. Eur. monograph likely to lead to a relevant change of the monograph	<input type="checkbox"/>	<input 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"/>

### Summary and conclusions on the review

In the first version of the European Union herbal monograph on *Artemisia absinthium* L., (adopted in July 2009) in section 4.7 "Effects on ability to drive and use machines", it was included a recommendation that preparations made from wormwood "May impair ability to drive and use machines. Affected patients should not drive or operate machinery". This precaution was based on the study by Dettling *et al.* (2004) on the effects of an alcoholic beverage containing thujone, but exclusively based on the substance thujone and not on other constituents of wormwood.

The first monograph on *Salvia officinalis* L., folium (EMA/HMPC/331653/2008) included restrictions on driving and operating machinery due to the presence of thujone as a single constituent of sage and were also based on the investigation by Dettling *et al.* (2004). Nevertheless, the revised version of *Salvia officinalis* L., folium (EMA/HMPC/277152/2015) took in account several studies which proved that thujone does not invoke cannabimimetic responses and consequently does not cause hallucinogenic effects this way (Meschler and Howlett, 1999). Moreover, the studies by Lachenmeier and Uebelacker (2010), Lachenmeier *et al.* (2008) and Lachenmeier (2008) were also considered relevant to prove that the phenomenon of "Absinthism" was caused by ethanol abuse and was not related to thujone. As a consequence of the above cited studies, the updated version of *Salvia officinalis* L. folium, does not include the original recommendation related to driving and using machinery, and references to the study of Dettling *et al.* (2004) have been removed from the assessment report.

The first revision of the European Union herbal monograph on *Artemisia absinthium* L., herba was adopted in May 2017. However, the need to updated section 4.7 in harmonisation with *Salvia officinalis* L., folium was overlooked and a corrected version of the monograph will be published (EMA/HMPC/751490/2016 Corr.).

Section 5.5.7 in the assessment on *Artemisia absinthium* L., herba, should be revised during the next revision of the monograph on *Artemisia absinthium* L., herba.

5 references were considered to be relevant for the assessment.

0 references justify a revision of the monograph.

## References

### a) References relevant for the assessment:

Dettling A, Grass H, Schuff A, Skopp G, Strohbeck-Kuehner P, Haffner HT. Absinthe: attention performance and mood under the influence of thujone. *J Stud Alcohol*, 2004. 65(5):573-81.

Lachenmeier DW, Uebelacker M. Risk assessment of thujone in foods and medicines containing sage and wormwood - evidence for a need of regulatory changes? *Regul Toxicol Pharmacol*, 2010. 58(3):437-43.

Lachenmeier DW, Nathan-Maister D, Breaux TA, Sohnius EM, Schoeberl K, Kuballa T. Chemical composition of vintage preban absinthe with special reference to thujone, fenchone, pinocamphone, methanol, copper, and antimony concentrations. *J Agric Food Chem*, 2008. 56(9):3073-81.

Lachenmeier DW. Thujon-Wirkungen von Absinth sind nur eine Legende - Toxikologie entlarvt Alkohol als eigentliche Absinthismus Ursache. *Medizinische Monatsschrift für Pharmazeuten*, 2008. 31(3):101-106.

Meschler JP, Howlett AC. Thujone exhibits low affinity for cannabinoid receptors but fails to evoke cannabimimetic responses. *Pharmacol Biochem Behav*, 1999. 62(3):473-80.

### 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 *Artemisia absinthium* L., herba, by consensus. HMPC agreed with the Rapporteur's position that the wording in section 4.7. should be corrected in the current monograph due to an oversight.