



18 November 2020
EMA/HMPC/487394/2020
Committee on Herbal Medicinal Products (HMPC)

Addendum to Assessment report on *Lavandula angustifolia* Mill. (*L. officinalis* Chaix), flos

| | |
|---------------|----------------------------------|
| Rapporteur(s) | Gert Laekeman |
| Assessor(s) | Patricia Bodart (Eudravigilance) |
| Peer-reviewer | Jacqueline Wiesner |

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|--|----------------------------------|
| HMPC decision on review of monograph <i>Lavandula angustifolia</i> Mill. (<i>L. officinalis</i> Chaix), flos adopted on 27 March 2012 | 15 January 2020 |
| Call for scientific data (start and end date) | From 1 March 2020 to 31 May 2020 |
| Adoption by Committee on Herbal Medicinal Products (HMPC) | 18 November 2020 |

Review of new data on *Lavandula angustifolia* Mill. (*L. officinalis* Chaix), flos

Periodic review (from 2012 to 2020)

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

- Pharmacovigilance data (e.g. data from EudraVigilance, VigiBase, national databases)
- Scientific databases: Embase and PubMed searched on *Lavandula* AND flos, Lavender AND flower
- 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

Consistency (e.g. scientific decisions taken by HMPC)

- Public statements or other decisions taken by HMPC

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- 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"/> | X |
| New clinical safety data likely to lead to a relevant change of the monograph | <input type="checkbox"/> | X |
| New data introducing a possibility of a new list entry | <input type="checkbox"/> | X |
| 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"/> | X |
| New clinical studies introducing a possibility for new WEU indication/preparation | <input type="checkbox"/> | X |
| Other scientific data likely to lead to a relevant change of the monograph | <input type="checkbox"/> | X |
| <i>Regulatory practice</i> | Yes | No |
| New herbal substances/preparations with 30/15 years of TU | X | <input type="checkbox"/> |
| New herbal substances/preparations with 10 years of WEU | <input type="checkbox"/> | X |
| Other regulatory practices likely to lead to a relevant change of the monograph | X | <input type="checkbox"/> |
| Referrals likely to lead to a relevant change of the monograph | <input type="checkbox"/> | X |
| New / Updated Ph. Eur. monograph likely to lead to a relevant change of the monograph | <input type="checkbox"/> | X |
| <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"/> | X |
| Relevant inconsistencies with other monographs within the therapeutic area that require a change of the monograph | <input type="checkbox"/> | X |
| Other relevant inconsistencies that require a change of the monograph | <input type="checkbox"/> | X |

MARKET OVERVIEW

Country: Germany

| Active substance | Indication | Pharmaceutical form Strength (where relevant) Posology Duration of use | Regulatory Status (date, Member State, Type of Marketing authorisation/regist ration where possible) ¹ |
|---|--|--|---|
| TU | | | |
| <i>Lavandula angustifolia</i> Mill. (<i>L. officinalis</i> Chaix), flos. | For the treatment of functional circulatory disturbances | Bath additive Single dose 10-50 g/10 l water Daily dose 10-50 g/10 l water | 1986, DE, Standard Marketing Authorisation according to section 36 of the German Medicinal Products Act |

Contraindications

Bath: major skin injuries, acute skin disease, severe febrile and infectious diseases, cardiac insufficiency and high blood pressure.

EUDRAVIGILANCE DATABASE

A search in the EudraVigilance database was done from 1996 until 2020. It resulted in 6 hits on '*Lavandula angustifolia*'. For 3 cases, *Lavandula angustifolia* was mentioned without other precision and was administered with 3-10 other herbal drugs. The 3 other cases concerned a herbal tea containing several constituents including *Lavandula angustifolia* flower. The pharmacovigilance information obtained does not reveal any need to revise the monograph on *Lavendulae flos* for safety reasons.

Summary and conclusions on the review

During the review 8 new references not yet available during the first/previous assessment were identified.

0 references were provided by Interested Parties during the Call for data.

3 references were considered to be relevant for the assessment.

- Farshbaf-Khalili A, Kamalifard M, Namadian M. Comparison of the effect of lavender and bitter orange on anxiety in postmenopausal women: A triple-blind, randomized, controlled clinical trial. *Complementary therapies in clinical practice* 2018, 31: 132-138
- Kamalifard M, Khalili A F, Namadian M, Herizchi S, Ranjbar Y. Comparison of the effect of lavender and bitter orange on depression in menopausal women: A triple-blind randomized

¹ The information on the regulatory status of the products may preferably include the nature of the marketing authorisation (MA) granted for the product to access the market (MA based on full or mixed application, MA based on bibliographic application as per Article 10a of Directive 2001/83/EC (WEU), traditional use registration, etc.) to establish the period of medicinal use; for TU: at least 30 years of medicinal use including at least 15 years in the EU; for WEU: at least 10 years of MA in the EU.

controlled trial. *International Journal of Women's Health and Reproduction Sciences* 2017, 5:3 224-230

- Chen S L, Chen C H. Effects of Lavender Tea on Fatigue, Depression, and Maternal-Infant Attachment in Sleep-Disturbed Postnatal Women. *Worldviews on evidence-based nursing / Sigma Theta Tau International, Honor Society of Nursing* 2015, 12:6 370-379

No revision is considered required because no new data/findings of relevance for the content of the monograph.

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 *Lavandula angustifolia* Mill. (*L. officinalis* Chaix), flos, by consensus.