27 March 2018
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Committee on Herbal Medicinal Products (HMPC)

Addendum to Assessment report on *Avena sativa* L., herba and *Avena sativa* L., fructus

Rapporteur(s)	Gert Laekeman
Peer-reviewer	Linda Anderson

HMPC decision on review of monograph *Avena sativa* L., herba and *Avena sativa* L., fructus adopted on 4 April 2008	05 April 2016
Call for scientific data (start and end date)	From 15 June 2016 to 15 September 2016
Agreed by Working Party on European Union monographs and list (MLWP)	January 2018
Adoption by Committee on Herbal Medicinal Products (HMPC)	27 March 2018

Review of new data on *Avena sativa* L., herba and fructus

Periodic review (from 2010 to 2017)

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

☐ Pharmacovigilance data (e.g. data from EudraVigilance, VigiBase, national databases)

☒ Scientific/Medical/Toxicological databases: Embase; PubMed; literature search was performed on 1 November 2017. The following key-words were used (solo or combinations): *Avena* / *Avena sativa* / *oat(s)* / *herb* / *clinical* / *use*.

☒ Other: Dewaele S, Mees E. Master thesis pharmaceutical sciences: KULeuven 2015

Regulatory practice

☒ Old market overview in AR (i.e. products fulfilling 30/15 years on the market)

☒ New market overview

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☐ Referral

☐ 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 (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	☐	☒
New clinical safety data likely to lead to a relevant change 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 likely to lead to a relevant change of the monograph	☐	☒
New clinical studies introducing a possibility for new WEU indication/preparation	☐	☒
Other scientific data likely to lead to a relevant change 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	☐	☒
Other regulatory practices likely to lead to a relevant change of the monograph	☐	☒
Referrals likely to lead to a relevant change of the monograph	☐	☒
New/UpdatedPh.Eur. monograph likely to lead to a relevant change of the monograph	☐	☒
Consistency	Yes	No
New or revised public statements or other HMPC decisions likely to lead to a relevant change of the monograph	☐	☒
Relevant inconsistencies with other monographs within the therapeutic area that require a change of the monograph	☐	☒
Other relevant inconsistencies that require a change of the monograph	☐	☒
Other	Yes	No
Authorised or registered herbal medicinal products currently in EU according to WEU or TU provisions	☐	☒

Summary and conclusions on the review

During the review 89 new references not yet available during the first/previous assessment were identified.

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

Sixty three references were considered to be relevant for the assessment but no revision is considered required. Twenty three new references reported results of clinical studies. The main topics were dermatological conditions, plasma lipids and diabetic parameters. However, there are no medicinal products with *Avena sativa* L., herba or fructus in the EU with the indications reported in these new studies. Therefore, the new clinical studies do not introduce the possibility for a well-established use monograph.

The remaining new references consisted of reviews, covering the usefulness of clinical applications, preclinical investigations on mechanisms of action and phytochemical investigations on *Avena* species.

There are no new safety concerns related to the use of *Avena sativa* L., herba or fructus.

References

a) References relevant for the assessment:

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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 position 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 monographs, assessment report and list of references on Avenae herba and Avenae fructus by consensus.