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Committee on Herbal Medicinal Products (HMPC)

Addendum to Assessment report on *Arctium lappa* L., radix

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HMPC decision on review of monograph *Arctium lappa* L., radix adopted on 16 September 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)	15 January 2020

Review of new data on *Arctium lappa* L., radix

Periodic review (from 2011 to 2019)

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: Pubmed (Using the search terms "*Arctium lappa*" and “Burdock root” from 2010 to 2019, Search date: September 2019, 244 hits and 65 hits, respectively), Embase (Using the search terms “*Arctium lappa*”, “*Arctium lappa*” and “root”, Search date: September 2019, 543 hits and 118 hits, respectively)

☐ 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)

New products identified during review:

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Active substance	**Indication**	**Pharmaceutical form** **Strength** **Posology** **Duration of use**	**Regulatory Status (date, Member State, Type of Marketing authorisation)**
Dry extract (DER 3-5:1); extraction solvent: ethanol 50% (V/V)	Traditional herbal medicinal product used in treatment of seborrheic skin conditions.	1 hard capsule contains 200 mg of dry extract (DER 3-5:1); extraction solvent: ethanol 50% (V/V) Posology: *Adults*: 1 capsule twice a day. Duration of use: 4 weeks	TU (1994, FR) *
Dry extract (DER 2-4:1); extraction solvent: ethanol 70% (V/V)	A traditional herbal medicinal product used to increase the amount of urine for the purpose of flushing the urinary tract to assist in minor urinary complaints. This is based on traditional use only.	1 hard capsule contains 399 mg of dry extract Posology: *Adults and elderly*: 2 capsules 3 times daily. Duration of use: if symptoms worsen or do not improve after 2 weeks, a doctor or a qualified healthcare practitioner should be consulted.	TU (2011, UK) **

* The dry extract does not have 30 years of tradition.

** No publicly available data supporting the required period of use.

☐ Referral

☒ Ph.Eur. monograph: no Ph.Eur monograph available.

☐ 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 / Updated Ph. 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	☐	☒

Summary and conclusions on the review

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

No references were provided by Interested Parties during the Call for data.

33 references were considered to be relevant for the assessment.

No references justify a revision of the monograph.

No revision is considered required because:

- There are no new clinical studies justifying the acceptance of new herbal medicinal products for WEU.
- There are no new preparations that fulfil the criteria for traditional use.
- There are no new data that justify the consideration of a list entry.
- There are no new clinical data that could justify the use by special patient populations.
- There are no new regulatory data that justify a change of the existing monograph.
- There are no new safety concerns.
- No inconsistencies are identified in the existing monograph.
- New references were retrieved between 2010 and 2019. These references deal with preclinical studies of *Arctium lappa radix* extracts or powder not relevant for the existing therapeutic indications in the monograph (2010):
  (1) *Traditional herbal medicinal product used to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary tract complaints.*
  (2) *Traditional herbal medicinal product used in temporary loss of appetite.*
  (3) *Traditional herbal medicinal product used in treatment of seborrhoeic skin conditions.*

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 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 *Arctium lappa* L., radix, by consensus.