EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Addendum to Assessment report on *Cichorium intybus* L., radix

Rapporteur(s)	B. Kroes
Peer-reviewer	M. Příhodová / M. Heroutová

HMPC decision on review of monograph *Cichorium intybus L.*, radix, adopted on 15 January 2013	13 January 2021
Call for scientific data (start and end date)	From 01 February 2021 to 30 April 2021
Adoption by Committee on Herbal Medicinal Products (HMPC)	26 January 2022

Review of new data on *Cichorium intybus* L., radix

Periodic review (from 2013 to 2021)

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

☒ Pharmacovigilance data (e.g. data from EudraVigilance, VigiBase, national databases).
EudraVigilance was searched for adverse reactions on January 19, 2022. Vigilyze search was performed on January 5, 2022. No new safety information was found.

☒ Scientific/Medical/Toxicological databases: Medline database through PubMed(NIH). Embase was searched for term "*Cichorium*" from 2012 to present, on November 8, 2021, and 124 results were revealed.

☐ 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

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☐ 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 / 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

Market overview

Information on herbal medicinal product marketed in Poland:

Active substance	**Indication**	**Pharmaceutical form** **Strength (where relevant)** **Posology** **Duration of use**	**Regulatory status (date, Member State, type of marketing authorisation / registration where possible)[1]**
Cichorii intybi radix, comminuted herbal substance for herbal tea, decoction	Traditional herbal medicinal product to relieve symptoms of digestive disorders such as the feeling of fullness, flatulence, slow digestion and in a periodic lack of appetite	Herbal tea, decoction. 3 g (corresponding to level teaspoon) pour with a 250 ml of water, heat to boil and keep boiling 3 minutes, then step away and strain. Drink once a day the fresh prepared decoction. In digestive disturbances drink the decoction half an hour before meal. If the symptoms persist for more than two weeks, please consult the doctor.	First registration certificate was edited 01 October 1992 (on a base of national act of law from 1987) PL. TUR 18 June 2017

The active substance, indication and posology of the Polish herbal medicinal product are in accordance with the monograph that was adopted in 2013.

Scientific data

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

During the review 124 new references not yet available during the previous assessment were identified. The majority of the publications were related to plant biosynthesis and plant growth, 17 publications were on isolation and identifications of plant constituents, 14 on the ethnomedical use in the middle east, 12 on hepatoprotective activities, four on (*in vitro*) anticancer activity, and four on antidiabetic activity.

None of these references was considered to be relevant for the assessment and to justify a revision of the monograph.

Only one traditional herbal medicinal product is registered in the EU. The active substance, indication and posology of this herbal medicinal product are in accordance with the monograph that was adopted in 2013. Available scientific data do not justify a revision of the monograph. In view of this no revision of the monograph is proposed.

[1] The information on the regulatory status of the herbal medicinal products may preferably include the nature of the marketing authorisation (MA) granted for accessing 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 (TU), 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.

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 *Cichorium intybus* L., radix by consensus.