20 November 2019
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Committee on Herbal Medicinal Products (HMPC)

Addendum to Assessment report on *Taraxacum officinale* Weber ex Wigg., folium

Rapporteur(s)	Milan Nagy
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HMPC decision on review of monograph Taraxaci folium adopted on<date>	20 November 2019
Call for scientific data (start and end date)	From 15.2.2019 to 15.5.2019
Agreed by Committee on Herbal Medicinal Products (HMPC)	September 2019 November 2019
Adoption by Committee on Herbal Medicinal Products (HMPC)	20 November 2019

Review of new data on *Taraxacum officinale* Weber ex Wigg., folium

Periodic review (from2009 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
- ☐ 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

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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 31 new references not yet available during the first/previous assessment were identified.

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

Seventeen references were considered to be relevant for the assessment.

No references justify a revision of the monograph.

No revision is considered required because all new relevant references describe either presence of secondary metabolites of dandelion or non-clinical studies (*in vitro* and *in vivo*), and one efficacy study with 17 volunteers. The limitations of this study design include lack of blinding, small numbers of

subjects, self-monitoring for fluid input/output, no correction for water content of food consumed, and limited baseline values of urine output. No new references were identified which are related to safety.

References

a) References relevant for the assessment:

Chagas-Paula DA, Oliveira TB, Faleiro DPV, Oliveira RB, Da Costa FB. Outstanding Anti-inflammatory Potential of Selected Asteraceae Species through the Potent Dual Inhibition of Cyclooxygenase-1 and 5-Lipoxygenase. Planta Med 2015; 81:1296-1307.

Clare BA, Conroy RS, Spelman K. The Diuretic Effect in Human Subjects of an Extract of *Taraxacum officinale* Folium over a Single Day. J Altern Compl Med 2009; 5:929-934.

Davaatseren M, Hur HJ, Yang HJ, Hwang J-T, Park JH, Kim H-J, *et al*. Taraxacum official (dandelion) leaf extract alleviates high-fat diet-induced nonalcoholic fatty liver. Food Chem Toxicol 2013; 58:30-36.

Esatbeyoglu T, Obermair B, Dorn T, Siems K, Rimbach G, Birringer M. Sesquiterpene Lactone Composition and Cellular Nrf2 Induction of *Taraxacum officinale* Leaves and Roots and Taraxinic Acid β-D-Glucopyranosyl Ester. J Med Food 2017; 20:1-8.

Flores-Ocelotl MR, Rosas-Murrieta NH, Moreno DA, Vallejo-Ruiz V, Reyes-Leyva J, Domínguez F, *et al*. *Taraxacum officinale* and Urtica dioica extracts inhibit dengue virus serotype 2 replication *in vitro*. BMC Complement Altern Med 2018; 18:95-104.

Ghale-Salimi MY, Eidi M, Ghaemi N, Khavari‐Nejad RA. Antiurolithiatic effect of the taraxasterol on ethylene glycol induced kidney calculi in male rats. Urolithiasis 2018; 46:419-428.

Giambanelli E, D'Antuono LF, Ferioli F, Frenich AG, Romero-González R. Sesquiterpene lactones and inositol 4-hydroxyphenylacetic acid derivatives in wild edible leafy vegetables from Central Italy. J Food Comp Anal 2018; 72:1-6.

González-Castejón M, García-Carrasco B, Fernández-Dacosta R, Dávalos A, Rodriguez-Casado A. Reduction of Adipogenesis and Lipid Accumulation by *Taraxacum officinale* (Dandelion) Extracts in 3T3L1 Adipocytes: An *in vitro* Study. Phytother Res 2014; 28:745-752.

Khan AS, Arif K, Munir B, Kiran S, Jalal F, Qureshi N, *et al*. Estimating Total Phenolics in Taraxacum offcinale (L.) Extracts. Pol. J Environ Stud 2019; 28:497-501.

Kurkin VA, Aznagulova AV. Constituents of the aerial part of *Taraxacum officinale*. Chem Nat Comp 2016; 52:711-712.

Laquale S, Avato P, Argentieri MP, Candido V, Perniola M, D'Addabbo T. Nematicidal potential of *Taraxacum officinale*. Environ Sci Pollut Res 2018; 25:30056-30065.

Maliakal PP, Wanwimolruk S. Effect of herbal teas on hepatic drug metabolising enzymes in rats. J Pharm Pharmacol 2001; 53:1323-1329.

Moriarty B, Pinney JH, Owen-Casey MP, Rustin MHA, Deroide F, Laing C, *et al*. A. Digital necrosis from dandelion tea. Br J Dermatol 2013; 169:227-229.

Paulsen E, Andersen KE. Clinical patterns of Compositae dermatitis in Danish monosensitised patients. Contact Dermatitis 2017; 78:185-193.

Shtangeeva I, Tesfalited S, Lövgren L. Comparison of nutrient concentrations in leaves of five plants. J Plant Nutr 2017; 40:239-247.

Yang Y, Li S. Dandelion Extracts Protect Human Skin Fibroblasts from UVB Damage and Cellular Senescence. Oxid Med Cell Longev 2015, Article ID 619560.

Zhang J, Kang M-J, Kim M-J, Kim M-E, Song J-H, Lee Y-M, Kim J-I. Pancreatic lipase inhibitory activity of *Taraxacum officinale in vitro* and *in vivo*. Nutr Res Pract 2008; 2:200-203.

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

HMPC agreed with Rapporteurs position that no monograph revision is needed because no new data of relevance were detected that would change the content of the monograph.

The HMPC decided by consensus not to revise the monograph, assessment report and list of references on Taraxaci folium.