



20 November 2019
EMA/HMPC/514844/2019
Committee on Herbal Medicinal Products (HMPC)

Addendum to Assessment report on *Taraxacum officinale* Weber ex Wigg., radix cum herba

Rapporteur(s)	Milan Nagy
Peer-reviewer	Marie Heroutová

HMPC decision on review of monograph Taraxaci radix cum herba adopted on	20 November 2019
Call for scientific data (start and end date)	From 15.2.2019 to 15.5.2019
Agreed by Working Party on European Union monographs and list (MLWP)	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., radix cum herba

Periodic review (from 2009 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 Scopus, Web of Science, PubMed, Embase, MEDLINE, Cochrane Database of Systematic Reviews, HealLink, ToxNet, Micromedex, HerbMed, Central Register of Controlled Trials
- 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

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

An agency of the European Union



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)

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

Summary and conclusions on the review

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

Thirteen references were considered to be relevant for the assessment.

Four of them are related to the dandelion's diuretic action. One reference describes exact content of taraxinic acid D-glucopyranoside, known contact sensitizer. One reference describes dandelion tea (plant part not known) decreased activity of CYP1A2 and CYP2E, respectively. A Ph. Eur. monograph has been published for *Taraxaci radix cum herba*. There is an identification test based on thin-layer chromatography, microscopical, and macroscopical characterisation of herbal substance. General

pharmacognostical tests (loss on drying, total ash, ash insoluble in hydrochloric acid, extractable matter, and bitterness value) are also described. Analytical method for quantitative determination of an analytical marker has not been evaluated.

No clinical studies or new safety concerns related to the use of *Taraxacum officinale* Weber ex Wigg., radix cum herba were found. There are no new products on the EU market containing *Taraxacum officinale* Weber ex Wigg., radix cum herba.

No references justify a full revision of the monograph. To reflect a newly available Ph. Eur. monograph (without an assay method) as relevant quality standard, a correction should be introduced in the existing monograph on Taraxaci radix cum herba (footnote section 2).

No revision is considered required because all relevant references describe either presence of secondary metabolites of dandelion or non-clinical studies (*in-vitro* and *in vivo*). No new references were identified which are related to efficacy or safety.

References

a) References relevant for the assessment:

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.

European Pharmacopoeia. Dandelion root with herb (Taraxaci officinalis herba cum radice). Monograph 07/2012:1851.

Gerbino A, Schena G, Milano S, Milella L, Barbosa AF, Armentano F, *et al.* Spilanthol from Acmella Oleracea Lowers the Intracellular Levels of cAMP Impairing NKCC2 Phosphorylation and Water Channel AQP2 Membrane Expression in Mouse Kidney. *PLoS ONE* 2016; 11:e0156021.

Gerbino A, Russo D, Colella M, Procino G, Svelto M, Milella L, *et al.* Dandelion Root Extract Induces Intracellular Ca²⁺ Increases in HEK293 Cells. *Int J Mol Sci* 2018; 19:1112-1128.

Ghale-Salimi MY, Eidi M, Ghaemi N, Khavari-Nejad RA. Inhibitory effects of taraxasterol and aqueous extract of *Taraxacum officinale* on calcium oxalate crystallization: *in vitro* study. *Ren Fail* 2018a; 40:298-305.

Ghale-Salimi MY, Eidi M, Ghaemi N, Khavari-Nejad RA. Antirolithiatic effect of the taraxasterol on ethylene glycol induced kidney calculi in male rats. *Urolithiasis* 2018b; 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

Huber M, Triebwasser-Freese D, Reichelt M, Heiling S, Paetz C, Chandran JN, *et al.* Identification, quantification, spatiotemporal distribution and genetic variation of major latex secondary metabolites in the common dandelion (*Taraxacum officinale* agg.). *Phytochemistry* 2015; 115:89-98.

Jovanović M, Poljački M, Mimica-Dukić N, Bož P, Vujanović LJ, Đuran V, *et al.* Sesquiterpene lactone mix patch testing supplemented with dandelion extract in patients with allergic contact dermatitis, atopic dermatitis and non-allergic chronic inflammatory skin diseases. *Contact Dermatitis* 2004; 51:101-110.

Minciullo PL, Calapai G, Miroddi M, Mannucci C, Chinou I, Gangemi S, *et al.* Contact dermatitis as an adverse reaction to some topically used European herbal medicinal products – part 4: *Solidago virgaurea*–*Vitis vinifera*. *Contact Dermatitis* 2017; 77:67-87.

Moriarty B, Pinney JH, Owen-Casey MP, Rustin MHA, Deroide F, Laing C, *et al.* 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.

Yadava RN, Khan S. A New Flavonoidal Constituent from *Taraxacum officinale* (L.) Weber. *Asian J Chem* 2013; 25:4117-4118.

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 radix cum herba*.