16 January 2019
EMA/HMPC/554898/2018
Committee on Herbal Medicinal Products (HMPC)

Addendum to Assessment report on *Potentialla erecta* (L.) Raeusch., rhizoma

Rapporteur(s)	R Länger
Peer-reviewer	I Chinou

HMPC decision on review of monograph *Potentialla erecta* (L.) Raeusch., rhizoma adopted on 25 November 2010	30 January 2018
Call for scientific data (start and end date)	From 31 March 2018 to 30 June 2018
Agreed by Working Party on European Union monographs and list (MLWP)	September 2018
Adoption by Committee on Herbal Medicinal Products (HMPC)	16 January 2019

Review of new data on *Potentilla erecta* (L.) Raeusch., rhizoma

Periodic review (from 2010 to 2018)

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, PubMed. Keywords: tormentil, Potentilla erecta; search date: 6 August 2018.
- ☐ 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)

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	☐	☒
Other	Yes	No
None	☐	☐

Summary and conclusions on the review

During the review thirty three new references not yet available during the previous assessment were identified.

No reference was provided by Interested Parties during the Call for data.

Eighteen references were considered to be relevant for the assessment.

No references justify a revision of the monograph.

No revision is considered required because the new relevant references include only results on chemistry of secondary metabolites of tormentil, together with some non-clinical studies (*in vitro* and *in vivo*) related mainly to its anti-inflammatory, antioxidant, antithrombotic and vasoconstrictive properties. No new references are related to efficacy or safety.

Based on the feedback from EU member states and Interested Parties no new medicinal products containing tormentil as the single active substance or in combination which fulfil the legal requirements of traditional use or WEU can be included.

References

a) References relevant for the assessment:

Anheyer D, Frawley J, Koch AK, Lauche R, Langhorst J, Dobos G, *et al*. Herbal medicines for gastrointestinal disorders in children and adolescents: A systematic review. *Pediatrics* 2017, 139(6): art. no. E20170062

Asgari Z, Selwyn BJ, Vonville H, DuPont HL. A systematic review of the evidence for use of herbal medicine for the treatment of acute diarrhea. *Nat Prod J* 2012, 2(1):1-8

Fecka I, Kucharska AZ, Kowalczyk A. Quantification of tannins and related polyphenols in commercial products of tormentil (Potentilla tormentilla). *Phytochem Anal* 2015, 26(5):353-366

Gau J, Prévost M, Van Antwerpen P, Sarosi M-B, Rodewald S, et *al.* Tannins and Tannin-Related Derivatives Enhance the (Pseudo-)Halogenating Activity of Lactoperoxidase. *J Nat Prod* 2017, 80(5):1328-1338

Hoffmann J, Casetti F, Bullerkotte U, Haarhaus B, Vagedes J, *et al*. Anti-inflammatory effects of agrimoniin-enriched fractions of *Potentilla erecta*. *Molecules* 2016, 21(6):art. no. 792

Ke F, Yadav PK, Ju LZ. Herbal medicine in the treatment of ulcerative colitis. *Saudi J Gastroenterol* 2012, 18(1):3-10

Langhorst J. Complementary and alternative medicine treatments in inflammatory bowel diseases [Naturheilkunde und Komplementärmedizin bei chronisch entzündlichen Darmerkrankungen]. *J Gastroenterologische und Hepatologische Erkrankungen* 2016, 14(1):9-16

Langhorst J, Wulfert H, Lauche R, Klose P, Cramer H, *et al*. Systematic review of complementary and alternative medicine treatments in inflammatory bowel diseases. *J Crohn's and Colitis* 2015, 9(1):86-106

Marcinczyk N, Jarmoc D, Leszczynska A, Zakrzeska A, Kramkowski K, *et al.* Antithrombotic potential of tormentil extract in animal models. *Frontiers in Pharmacol* 2017, 8(AUG):534

Mari A, Eletto D, Pizza C, Montoro P, Piacente S. Integrated mass spectrometry approach to profile proanthocyanidins occurring in food supplements: Analysis of *Potentilla erecta* L. rhizomes. *Food Chem* 2013, 141(4):4171-4178

Mazurek S, Fecka I, Węglińska M, Szostak R. Quantification of active ingredients in Potentilla tormentilla by Raman and infrared spectroscopy. *Talanta* 2018, 189:308-314

Piwowarski JP, Granica S, Zwierzyńska M, Stefańska J, Schopohl P, et *al.* Role of human gut microbiota metabolism in the anti-inflammatory effect of traditionally used ellagitannin-rich plant materials. *J Ethnopharmacol* 2014, 155(1):801-809

Piwowarski JP, Kiss AK, Kozłowska-Wojciechowska M. Anti-hyaluronidase and anti-elastase activity screening of tannin-rich plant materials used in traditional Polish medicine for external treatment of diseases with inflammatory background. *J Ethnopharmacol* 2011, 137(1):937-941

Tomczyk M, Latté KP. *Potentilla*-A review of its phytochemical and pharmacological profile. *J Ethnopharmacol* 2009, 122(2):184-204.

Tomczyk M, Sosnowska K, Pleszczyńska M, Strawa J, Wiater A, Grochowski DM, *et al*. Hydrogel containing an extract of tormentillae rhizoma for the treatment of biofilm-related oral diseases. *Nat Prod Comm* 2017, 12(3):417-421 (abstract only)

Triantafyllidi A, Xanthos T, Papalois A, Triantafillidis JK. Herbal and plant therapy in patients with inflammatory bowel disease. *Ann Gastroenterol* 2015, 28(2):210-220.

Wan P, Chen H, Guo Y, Bai A-P. Advances in treatment of ulcerative colitis with herbs: From bench to bedside. *World J Gastroenterol* 2014, 20(39):14099-14104.

Wölfle U, Hoffmann J, Haarhaus B, Rao Mittapalli V, Schempp CM. Anti-inflammatory and vasoconstrictive properties of *Potentilla erecta* – A traditional medicinal plant from the northern hemisphere. *J Ethnopharmacol* 2017, 204:86-94.

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 *Tormentillae* rhizoma.