



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

## Overview of comments received on European Union herbal monograph on *Herniaria glabra* L., *H. hirsuta* L., *H. incana* Lam., herba (EMA/HMPC/554043/2018)

Table 1: Organisations and/or individuals that commented on the draft European Union herbal monograph on *Herniaria glabra* L., *H. hirsuta* L., *H. incana* Lam., herba as released for public consultation on 19 December 2019 until 15 March 2020.

	Organisations and/or individuals
1	LABORATORIOS DEITERS S.L



Table 2: Discussion of comments

### General comments to draft document

Interested party	Comment and Rationale	Outcome
LABORATORIOS DEITERS S.L	Report and studies concerning traditional knowledge and folk uses of <i>Herniaria glabra</i> L. (Caryophyllaceae) related to the genitourinary system, concretely in the prevention and treatment of minor renal stones based on a traditional use recognized in The Spanish Inventory of Traditional Knowledge related to Biodiversity and in the database on Catalan ethnobotany.	<p>The submitted references are acknowledged. However, the assessment report is not intended to give a complete overview on published data on a medicinal plant but to support the content of the related EU herbal monograph.</p> <p>The submitted references were checked in that regard and found to be of no additional value for the assessment and the EU herbal monograph.</p>

### Specific comments on text

Section number and heading	Interested party	Comment and Rationale	Outcome
2	LABORATORIOS DEITERS S.L	<p>I) Herbal substance. Not applicable</p> <p>II) Herbal preparations</p> <p>a) Comminuted herbal substance</p> <p>b) Dry extract (DER 4:1), extraction solvent: water: ethanol (50:50)</p> <p>c) Dry extract (DER 4:1), extraction solvent: water: ethanol (50:50)</p>	<p>Not endorsed.</p> <p>The interested party did not submit references regarding corresponding medicinal products for the proposed dry extracts (which are in fact identical) which is required according to Dir. 2001/83 as amended.</p>
3	LABORATORIOS	Indication 2)	Not endorsed.

Section number and heading	Interested party	Comment and Rationale	Outcome
	DEITERS S.L	Herbal preparation in liquid or solid dosage forms for oral use. - Herbal tea - Liquid extract - Lozenges	Rationale: see above Contradiction to the proposal for section 2 (no liquid extract).
4.1	LABORATORIOS DEITERS S.L	Add new traditional indication: Indication 2) Prevention and relief of symptoms related to small kidney stones and grit	Not endorsed. No reference justifying the safe traditional medicinal use in this indication is provided.
4.2	LABORATORIOS DEITERS S.L	Indication 2) Posology Adults and Elderly a) Herbal tea: 1.0 g of comminuted herbal substance in 150 ml of boiling water as a herbal infusion or in 150 ml water as decoction 2-4 times daily. Maximum daily dose: 4 g. b) Liquid extract: Single doses: 470 mg (10 ml) in 250 ml of water 1-2 times daily. Maximum daily dose: 940 mg c) Oral dosage form: single doses: 470 mg with 2 glasses of water 1-2 times daily. Maximum daily dose: 940 mg The use in children and adolescents under 18 years of age is not recommended (see	Not endorsed. See above. No references submitted which would justify the proposal.

Section number and heading	Interested party	Comment and Rationale	Outcome
		<p>section 4.4 'Special warnings and precautions for use').</p> <p>Duration of use</p> <p>If the symptoms persist longer than 2 weeks during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>Method of administration</p> <p>Oral use</p>	

Comments regarding the submitted references:

Title	Authors	Bibliographic data	Comment
<b>Non-clinical research</b>			
Antiuro lithiasic effect of a plant formulation of <i>Herniaria glabra</i> , <i>Agropyron repens</i> , <i>equisetum arvense</i> and <i>sambucus nigra</i> (HERBENSURINA®) in the prevention of experimentally induced nephrolithiasis in rats.	Anna Crescenti, Francesc Puiggròs, Arnau Colomé, Josep Antón Poch, Antoni Caimari, Josep Maria del Bas, Noemí Boqué and Lluís Arola	Urolithiasis 2015, 68(10):739-749	Combination product, not relevant for the monograph
<i>In Vitro</i> and <i>in Vivo</i> Antilithiasic Effect of Saponin Rich Fraction Isolated From <i>Herniaria hirsuta</i>	Atmani Fouada, Slimani Yamina, Mbark Addi Nait, Bnouham Mohammed, Ramdani Abdlekrim	J Bras Nefrol Volume XXVIII - nº 4 - Dezembro de 2006	Perliminary non-clinical investigation of fractions regarding prevention and cure of urolithiasis. No influence on the monograph.
Reinvestigation of <i>Herniaria glabra</i> L. saponins and their biological activity	Solomiia Kozachok, Łukasz Pecioa, Ilkay Erdogan Orhanc, Fatma Sezer Senol Denizc, Svitlana Marchyshynb,	Phytochemistry 169 (2020) 112162	12 new saponins were isolated. No significant activity in selected <i>in vitro</i> models.

<b>Title</b>	<b>Authors</b>	<b>Bibliographic data</b>	<b>Comment</b>
	Wiesław Oleszeka		No influence on the monograph.
<b>Overview articles</b>			
Medical management of urolithiasis, what opportunity for phytotherapy?	Fouad Atmani	Frontiers in Bioscience 8, s507-514, May 1, 2003	Overview article. Reference to <i>Herniaria</i> rat studies and ethnomedicinal use. No influence on the monograph.
Pharmacological importance of <i>Herniaria glabra</i> and <i>Herniaria hirsuta</i> - a review	Ali Esmail Al-Snafi	Indo Am. J. P. Sci, 2018; 05(04)	Review article containing information on constituents and non-clinical effects. No influence on monograph.
<b>Ethnomedicinal use</b>			
Inventario español de los conocimientos tradicionales relativos a la biodiversidad	Editors: M Padro de Santayana, R Morales, J Tardic, L Aceituno, M Molina	Madrid 2018	Reference to ethnomedicinal use. No influence on the monograph.
Traditional knowledge in semi-rural close to industrial areas: ethnobotanical studies in western Gironès (Catalonia, Iberian Peninsula)	Airy Gras, Ginesta Serrasolses, Joan Vallès and Teresa Garnatje	J Ethnobiol Ethnomed 2019, 15:19	Ethnomedicinal use of medicinal plants. No influence on monograph.
Contribution to the knowledge of the pharmaceutical ethnobotany of La Segarra region (Catalonia, Iberian Peninsula)	Dolors Raja, Cesar Blanche, Joan Valles Xirau	Journal of Ethnopharmacology 57 (1997) 149-160	Ethnomedicinal use of medicinal plants. No influence on monograph.
Studies on pharmaceutical ethnobotany in the regions of L'Alt Emporda` and Les Guilleries (Catalonia, Iberian Peninsula)	M. Angels Bonet, Montserrat Parada, Anna Selga, Joan Valles	Journal of Ethnopharmacology 68 (1999) 145-168	Ethnomedicinal use of medicinal plants. No influence on monograph.

Title	Authors	Bibliographic data	Comment
Pharmaceutical ethnobotany in the Montseny biosphere reserve (Catalonia, Iberian Peninsula). General results and new or rarely reported medicinal plants	M. Angels Bonet and Joan Valles	J Pharm Pharmacol 2003, 55:259-270	Ethnomedicinal use of medicinal plants. No influence on monograph.