



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EMA/HMPC/573003/2018
Committee on Herbal Medicinal Products (HMPC)

Overview of comments received on European Union herbal monograph on *Ruscus aculeatus* L., rhizoma (EMA/HMPC/188804/2017)

Table 1: Organisations and/or individuals that commented on the draft European Union herbal monograph on *Ruscus aculeatus* L., rhizoma as released for public consultation on 15 March 2018 until 15 June 2018.

	Organisations and/or individuals
1	Joseph Shafer (European Public Health Alliance)
2	Viorica Cursaru (Myeloma Euronet)



Table 2: Discussion of comments

Specific comments on text

Section number and heading	Interested party	Comment and Rationale	Outcome
4.1	J Shafer (EPHA)	4.1 (under Indication 2) Delete the partial phrase: "after serious conditions have been excluded by a medical doctor" <i>The warning should not be included here, but later. Traditional use did NOT include a medical doctor's evaluation. The above was mentioned correctly in section 4.4.</i>	Not Endorsed. In reference to the guideline on the assessment of clinical safety and efficacy in the preparation of EU herbal monographs for well established and traditional herbal medicinal products (EMA/HMPC/104613/2005 – Rev. 1, 19 September 2017), "... a disease or condition that per se is not considered serious, but displays symptoms that are common to a serious disease, may be acceptable for a traditional herbal medicinal product provided that the patient is requested to consult a physician before use of the product to exclude that serious disease is causing the symptoms." This is the case of the condition related to indication 2.
4.4	V Cursaru (Myeloma Euronet)	With reference to the monograph on European Union herbal monograph on <i>Ruscus aculeatus</i> L. rhizome I suggest the following change of the section 4.4. - Special warnings and precautions for use – Traditional use The text "The use in children and adolescents under 18 years of age has not been established due to lack of adequate data" should be listed before Indication 1 and Indication 2. because 1 and 2 refer only to adults and therefore they should not be mixed up with some info about children. At the same time, given the lack	Endorsed. The sentence was placed ahead of indications.

Section number and heading	Interested party	Comment and Rationale	Outcome
		of sufficient reliable information, this remark must be clearly flashed on the top, to catch attention.	