



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28 March 2017
EMA/HMPC/81744/2017
Committee on Herbal Medicinal Products (HMPC)

Overview of comments received on European Union herbal monograph on Species diureticae (EMA/HMPC/224755/2016)

Final

Table 1: Organisations and/or individuals that commented on the draft European Union herbal monograph on Species diureticae as released for public consultation on 28 October 2016 until 31 January 2017.

	Organisations and/or individuals
1	Bernat Vanaclocha, Sociedad Española de Fitoterapia (SEFIT)



Table 2: Discussion of comments

Specific comments on text

Section number and heading	Interested party	Comment and Rationale	Outcome
Table 3, Mate folium	ESCOP	In the table, on page 3 of the monograph, in the line concerning mate folium, I think it would be more convenient to put 20% in the range of combinations (excluding excipients), if, as I suppose, the percentage of the drugs in this formula has been calculated including the excipients (surely it is a lyophilized compound, because the maximum possible of ingredients is of 50%).	Not endorsed. Mate folium (comminuted leaves, not a lyophilised herbal preparation) has evidence of traditional medicinal use only in a single herbal tea combination, where the amount was exactly 10% in the mixture (see table 2, entry n. 26 in the Assessment report). Therefore a change of the amount in herbal tea combinations is not justified.