22 September 2021
EMA/HMPC/363594/2021
Committee on Herbal Medicinal Products (HMPC)

Overview of comments received on European Union herbal monograph on *Orthosiphon aristatus* (Blume) Miq. var. *aristatus*, folium (EMA/HMPC/486551/2020)

Table 1: Organisations and/or individuals that commented on the draft European Union herbal monograph on *Orthosiphon aristatus* (Blume) Miq. var. *aristatus*, folium as released for public consultation on 01 February 2021 until 30 April 2021.

	Organisations and/or individuals
1	The Association of the European Self-Care Industry (AESGP)

Table 2: Discussion of comments

Specific comments on text

Section number and heading	Interested party	Comment and Rationale	Outcome
2. Qualitative and quantitative composition Column "Traditional use" page 3/7	AESGP	Please add the following extract traditionally used in France: h) Liquid extract (DER 1:10), extraction solvent: ethanol 65% m/m	Not endorsed. In France, the tincture (1:10), extraction solvent: ethanol 65% V/V was on the market until the end of 2019, as mother tincture used for a homeopathic medicinal product. The manufacturing process of this tincture was in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia. Therefore, this preparation complies with the characteristics of the homeopathic stocks. Furthermore, no data regarding the specified use according to TU requirements of Directive 2001/83/EC and no references were provided.
4.2 Posology and method of administration	AESGP	The herbal medicinal product "Arkogélule Orthosiphon" (325 mg per capsule of powdered leaf of orthosiphon - posology: 4 to 5 capsules/day) has been commercialized in France since 1989. The herbal medicinal product has been on the market for more than 30 years and should therefore be included in the monograph. In the HMPC's assessment report of 11 March 2010 [EMA/HMPC/135701/2009], page 9, it is clearly mentioned:	Not endorsed. The product "Arkogélule Orthosiphon" was initially registered in France in 1989 as capsules containing 250 mg powdered leaf. The daily approved posology was 3-6 capsules, maximum 9 capsule, meaning 750 up to 2250 mg herbal substance/day. Since 1997, is registered as TUR with the following posology: single dose: 650 mg and daily dose: 1300-1625 mg.

Section number and heading	Interested party	Comment and Rationale	Outcome
		"Powder: 250 to 500mg, 3 to 4 times daily (which corresponds to a daily dosage of 750 to 2000mg)". As a consequence, we propose to extend the dose range as follows: *Single dose: 250 to 500 mg* *Daily dose: 750 mg to 2000 mg*	
4.2. Posology and method of administration column "Traditional use" page 4/7	AESGP	Please add the following posology: h) Liquid extract (DER 1:10), extraction solvent: ethanol 65% m/m Single dose: 2.5 mL Daily dose: 7.5 mL	Not endorsed. See above.