



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 *Cistus creticus* L., herba (EMA/HMPC/150763/2015)

Table 1: Organisations and/or individuals that commented on the draft European Union herbal monograph on *Cistus creticus* L., herba as released for public consultation on 15 August 2024 until 15 November 2024

	Organisations and/or individuals
1	Finzelberg GmbH & Co. KG, Koblenzer Str. 48-56, 56626 Andernach, Germany



Table 2: Discussion of comments

General comments to draft document

Interested party	Comment and Rationale	Outcome
Finzelberg GmbH & Co. KG (herbal extract manufacturer, Germany)	Enclosed is an updated search report on Traditional medicinal use of a tea infusion of the herb of <i>Cistus creticus</i> L. or <i>Cistus incanus</i> L. in the field of indication cough and colds. Based on this additional data a traditionally use of the tea is also given for gastrointestinal discomfort / diarrhoea (high content of polyphenols act as tannins) as well for tonsillitis (Polyphenols act as antinflammatory actives).	Thank you for your interest and results provided through your search on traditional use for <i>Cistus creticus</i> L., herba. The comment is not endorsed as only for the indication proposed in the MO there is adequate information on posology.

Specific comments on text

Section number and heading	Interested party	Comment and Rationale	Outcome
2.1.1. Information about products on the market (assessment report)	Finzelberg GmbH & Co. KG (herbal extract manufacturer, Germany)	Under table 1 is cited the 1st THMP conform dry extract of herba <i>Cistus incanus</i> L. – synonym to <i>Cistus creticus</i> L., which is relevant for the actual monograph: Dry extract from Cisti incani herba (4-9:1), extraction solvent: water. The DER range 4-9:1 (average 7:1) stand for an extractive matter of rd 14.2%. This corresponds to yields for classical herbal tea preparations (=maceration), instead an industrial exhaustive extraction yields are in a range of 25-50% (= DER native 2-4:1). In conclusion a tea-analogue extraction is the base. Furthermore the used raw material is correct mentioned as	Not endorsed. The referred dry extract from <i>Cisti incani herba</i> (4-9:1), extraction solvent: water, has been registered under National procedures since 2015 and cannot be further evaluated for traditional use. So, in fact only <i>Cistus creticus</i> L. in the form of herbal tea is included in the developed by HMPC monograph developed therefore, based to existing data fulfilling the 30 years.

Section number and heading	Interested party	Comment and Rationale	Outcome
		Cistus incanus L., because traditionally this variety used only available. The marketing driven change to a description "Cistus x incanus L. Pandalis" was possible, since the protection of a special sort / variety in 2017 was given. This was related to products containing the brand name Cystus® mainly. However, this cannot conceal the former historical use of Cistus incanus L., which is why tea analogue extracts with DER 4-9:1 from Cistus incanus L. can also be included in the monograph. The known indications would be cough and cold.	