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Committee on Herbal Medicinal Products (HMPC)

Public statement on *Tribulus terrestris* L., herba

Final

Discussion in Committee on Herbal Medicinal Products (HMPC)	May 2022 November 2022 January 2023 July 2023 September 2023 March 2024 May 2024
Adopted by HMPC for release for consultation	29 May 2024
Start of public consultation	15 June 2024
End of consultation (deadline for comments)[1].	15 September 2024
Re-discussion in HMPC	November 2024
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Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; European Union list entries; Public statements; *Tribulus terrestris* L., herba**,** Tribuli terrestris herba, puncture vine herb/caltrop herb

[1] No comments were received during the period of public consultation. Therefore, the final public statement is published together with the final assessment report and list of references, without an 'Overview of comments received during the public consultation'.

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Public statement on *Tribulus terrestris* L., herba

PROBLEM STATEMENT

The HMPC decided to prepare a European Union herbal monograph on *Tribulus terrestris* L., herba as announced in the May 2021 HMPC meeting report.

The herbal substance consists of dried, whole, or fragmented flowering and fruit bearing aerial parts of *Tribulus terrestris* L.

A comprehensive literature search was conducted and available data, including information on products on the market in the European Union (EU), were assessed in relation to the requirements laid down in Directive 2001/83/EC and its Annex I, in particular Article 10a and Chapter 2a.

The only preparation on the EU market derived from *Tribulus terrestris* L., herba is a dry extract (DER 35-45:1), extraction solvent methanol 80% V/V, containing not less than 45% of furostanol saponins calculated as protodioscin, approved in Bulgaria since 1981.

Although a period of 10 years medicinal use of the product has elapsed, data supporting an acceptable level of safety and a recognized efficacy are not available as published data.

Although the requirement of 30 years on the market is fulfilled, the extract is considered specific and therefore not appropriate to support the establishing of a EU herbal monograph based on traditional use. Sufficient information on traditional use of other *Tribulus terrestris* L., herba preparations has not been found in the searched literature.

Altogether, a European Union herbal monograph based on traditional use and/or well-established use cannot be established at present.

The HMPC is fully aware that there may be non-authorised/non-registered products with *Tribulus terrestris* L., herba on the EU market, however, these products may not be sufficiently characterised, and information about a long-standing safe medicinal use according to a specific indication, strength and posology is considered insufficient. This also includes the use of *Tribulus terrestris* L., herba based on a non-European tradition.

The HMPC concluded that the following requirements for the establishment of a European Union herbal monograph on traditional and/or well-established herbal medicinal products containing *Tribulus terrestris* L., herba are not fulfilled:

- the requirement laid down in Article 10a of Directive 2001/83/EC that the active substance has a recognised efficacy and an acceptable level of safety and that the period of well-established medicinal use has elapsed;

- the requirement laid down in Article 16a(1)(d) of Directive 2001/83/EC that "the period of traditional use as laid down on Article 16c(1)(c) has elapsed".

CONCLUSIONS

Based on the above-mentioned information, the HMPC is of the opinion that a European Union herbal monograph on *Tribulus terrestris* L., herba cannot be established.

To read more about the assessment carried out, a link is provided to the page where to access the assessment report on *Tribulus terrestris* L., herba and its list of references.

https://www.ema.europa.eu/en/medicines/herbal/tribuli-terrestris-herba