



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

## Overview of comments received on Community herbal monograph on *Ononis spinosa* L., radix (EMA/HMPC/138317/2013)

Table 1: Organisations and/or individuals that commented on the final Community herbal monograph on *Ononis spinosa* L., radix as released for public consultation on 15 August 2013 until 15 December 2013.

	Organisations and/or individuals
1	European Botanical Forum



Table 2: Discussion of comments

### General comments on draft document

Interested party	Comment and Rationale	Outcome
N/A		

### Specific comments on text

Section number and heading	Interested party	Comment and Rationale	Outcome
4.  Clinical particulars  4.1.  Therapeutic indications	EBF	<p>„Traditional herbal medicinal product used to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary complaints.“</p> <p>Is proposed to be modified as follows:</p> <p>„Traditional herbal medicinal product used to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in cases of inflammation, renal gravel and other minor urinary complaints.“</p> <p>ESCOP Monographs ,Second Edition , Ononidis Radix, p. 351, Thieme, 2003</p>	<p>The proposal cannot be endorsed.</p> <p>The wording of the indication should express the plausible effect of the herbal medicinal product. There are not sufficient pharmacological data in cases of inflammation and renal gravel.</p> <p>The therapeutic indication of <i>Ononis spinosa</i> L., radix has been accepted in accordance with other approved Community monographs for traditional herbal medicinal products which have similar properties on urinary tract and therefore the use of the standard formulation in the monograph is preferred.</p>

#### References:

1. ESCOP Monographs 2<sup>nd</sup> ed. Ononidis radix - Restharrow root. European Scientific Cooperative on Phytotherapy, editor. Thieme, Stuttgart 2003, 351