



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

## Overview of comments received on Public statement on *Paeonia lactiflora* Pallas, radix (Paeoniae radix alba) (EMA/HMPC/150787/2015)

Table 1: Organisations and/or individuals that commented on the Public statement on *Paeonia lactiflora* Pallas, radix (Paeoniae radix alba) for public consultation on 16 February 2016 until 15 May 2016.

	Organisations and/or individuals
1	Department of Chinese Medicine and Pharmacy, Ministry of Health and Welfare, Taiwan, ROC



Table 2: Discussion of comments

**General comments to draft document**

None

**Specific comments on text**

Section number and heading	Interested party	Comment and Rationale	Outcome
Assessment Report, chapter 1.1. Description of the herbal substance(s), herbal preparation(s) or combinations thereof	Department of Chinese Medicine and Pharmacy, Ministry of Health and Welfare, Taiwan, ROC	The text of the <i>Paeoniae radix alba</i> monograph in Taiwan Herbal Pharmacopeia PAEONIAE ALBA RADIX/ 白芍 /Bai Shao should be included in the AR.	Chapter 1.1 and 2.2 of the assessment report contains the information that the drug is also described in the Taiwan Herbal Pharmacopoeia.  The detailed text of this pharmaceutical monograph is not included in the HMPC assessment report, as pharmaceutical monographs are not part of the HMPC assessment report.
Assessment Report, chapter 6. Overall conclusions (benefit-risk assessment)	Department of Chinese Medicine and Pharmacy, Ministry of Health and Welfare, Taiwan, ROC	<i>Paeoniae radix rubra</i> is used in Traditional Chinese medicines. The herbal substance is described in the Taiwan Herbal Pharmacopeia 2nd. In Taiwan, there are 1054 drug license containing <i>Paeoniae radix rubra</i> issued by the Ministry of Health and Welfare.	The comment refers to <i>Paeoniae radix rubra</i> , which has no relevance for the monograph of <i>Paeoniae radix alba</i> . No efficacy and safety for specific European mono-preparation and indications for establishing a HMPC-monograph can be concluded from the information.  The overall conclusion is not changed.