



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EMA/HMPC/370682/2019
Committee on Herbal Medicinal Products (HMPC)

Overview of comments received on European Union herbal monograph on *Rhamnus frangula* L., cortex (EMA/HMPC/726261/2016)

Final

Table 1: Organisations and/or individuals that commented on the draft European Union herbal monograph on *Rhamnus frangula* L., cortex as released for public consultation on 15/02/2019 until 15/05/2019.

	Organisations and/or individuals
1	AESGP



Table 2: Discussion of comments

General comments to draft document

Interested party	Comment and Rationale	Outcome

Specific comments on text

Section number and heading	Interested party	Comment and Rationale	Outcome
2. Qualitative and quantitative composition ii) Herbal preparations	AESGP	<p>The draft of the monograph only covers standardised comminuted herbal substance. In the existing monograph, however, herbal preparations have so far also been included: "Standardised herbal substance or herbal preparation for oral use in solid or liquid dosage forms".</p> <p>From the assessment report it becomes clear that herbal preparations like extracts usually have been used, too. Moreover, there is a European Pharmacopoeia monograph (1214) Frangula bark dry extract, standardized. Since both herbal teas and other herbal preparations are standardised to 10–30 mg hydroxyanthracene derivatives, calculated as glucofrangulin A, there is from our point of view no reason to exclude certain preparations from the use. Several examples for products which contain Frangula extracts are attached.</p> <p>Proposal:</p> <p>"Comminuted herbal substance or herbal preparations thereof,</p>	Endorsed

Section number and heading	Interested party	Comment and Rationale	Outcome
		standardised"	
3. Pharmaceutical form		<p>The draft of the monograph only covers standardised comminuted herbal substance as herbal tea for oral use. However, from the assessment report it becomes clear that also liquid and solid pharmaceutical forms have usually been used.</p> <p>Proposal:</p> <p>Standardised comminuted herbal substance as herbal tea for oral use.</p> <p>Standardised herbal preparations in liquid or solid dosage forms for oral use.</p>	Endorsed