



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EMA/HMPC/326670/2010
Committee on Herbal Medicinal Products (HMPC)

Overview of comments received on Community herbal monograph on *Filipendula ulmaria* (L.) Maxim., herba (EMA/HMPC/434881/2010)

Table 1: Organisations and/or individuals that commented on the draft Community herbal monograph on *Filipendula ulmaria* (L.) Maxim., herba as released for public consultation on 15 November 2010 until 15 April 2011.

	Organisation and/or individuals
1	Dr. Willmar Schwabe GmbH & Co. KG (SCHWABE)



Table 2: Comments

SPECIFIC COMMENTS ON TEXT			
Section number and heading	Interested party	Comment and Rationale	Outcome
1. Qualitative and quantitative composition	SCHWABE	<p>We suggest to add:</p> <p>ii) Herbal preparations</p> <p>c) Tincture (1:5), extract solvent ethanol 45%</p> <p>Rationale: (s. 3.2)</p>	Endorsed, see 3.2
2. Pharmaceutical Form	SCHWABE	<p>We suggest to add:</p> <p>Herbal preparation in liquid dosage form.</p> <p>Rationale: (s. 3.2)</p>	Endorsed, see 3.2
3.2 Posology and method of administration	SCHWABE	<p>We suggest to add:</p> <p>Posology</p> <p>c) Tincture (1:5), extract solvent ethanol 45%:</p> <p>single dose: 2-4 ml</p> <p>daily dose: 6-12 ml</p> <p>Rationale:</p> <p>The use of Filipendula as a tincture was first mentioned by Madaus in 1938 (Madaus, 1938). However, the kind of the extract solvent was not given. The use of an alcoholic tincture for diuretic therapy was described by Leclerc (Leclerc, 1966). Furthermore, an alcoholic tincture of Filipendula was mentioned</p>	<p>Endorsed, only for indication 2, see 3.2</p> <p>Liquid preparations are mentioned in the British Herbal Pharmacopoeia of 1974. However, these preparations were not included in the draft monograph because no liquid product has been reported to be on the market by Member States.</p> <p>A wide variety of tinctures or possible tincture-based</p>

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	<p>in the British Herbal Pharmacopoeia (British Herbal Pharmacopoeia, 1983) and in the British Herbal Compendium (British herbal compendium, 1992), specified as a liquid extract 1:1 in 25% alcohol or a tincture 1:5 in 45% alcohol, daily dose 6-12 ml. This tincture was also recently mentioned (Barnes, 2007). Additionally, in some countries of the EU food supplements containing alcoholic extracts of Filipendula used in medicinal indications are available on the market. For instance in Benelux the product "Spirea ulmaria herbal tincture" from "Biover" used for the maintenance of flexible joints and for the relief of tired muscles. The product contains an alcoholic extract of Filipendula (solvent 61% ethanol). In UK two tinctures "Meadowsweet tincture" from "Organic" (indication: traditionally used for treatment of heartburn and acid reflux) and "Meadowsweet tincture" from "G Baldwin & Co." are available. Both contain extracts with 21% alcohol. In Italy a product named "Spirea ulmaria" with an alcoholic extract with 44% alcohol and in San Marino the product "Spirea ulmaria" from "Erba Vita" containing an extract with 25% ethanol are available. The medicinal use of the alcoholic extracts of Filipendula has been described for more than 30 years. The extract specified above was known for nearly 30 years in the EU. Furthermore, some products containing alcoholic extracts are on the EU market. Therefore it seems to be reasonable to add the alcoholic extract to the monograph.</p> <p><u>Literature:</u></p> <p>Bradley PR British Herbal Compendium Vol 1. British Herbal Association, Bournemouth 1992, 158-160</p>	<p>products are reported to be on the market somewhere in the Community as food supplements.</p> <p>Partly endorsed because only the use for indication 2 is mentioned the British Herbal Pharmacopoeia of 1974.</p>

SPECIFIC COMMENTS ON TEXT			
		<p>Barnes J, Anderson LA, Phillipson JD, Herbal Medicines 3rd ed. Pharmaceutical Press, London 2007, 432-424</p> <p>British Herbal Pharmacopoeia, British Herbal Association, Bournemouth 1983, 91-92</p> <p>Leclerc C, Précis de phytothérapie, 5. Ed., Masson er Cie, Éditeurs Libraires de l'académie de Médecine 120, Bd Saint-Germaion, Paris VI, 1966, 55-56</p>	