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**OVERVIEW OF COMMENTS RECEIVED ON
'COMMUNITY HERBAL MONOGRAPH ON
BETULA PENDULA ROTH; BETULA PUBESCENS EHRH., FOLIUM'
(EMEA/HMPC/260019/2006)**

Table 1: Organisations providing comments on the draft 'Community herbal monograph on Betula pendula Roth; Betula pubescens Ehrh., folium' as released for consultation on 8 May 2007 until 15 August 2007.

	Organisation
1	Europlant Phytopharm sp. z.o.o., Poland
2	The European Scientific Cooperative on Phytotherapy (ESCOP)
3	The Association of the European Self-Medication Industry (AESGP)
4	Kooperation Phytopharmaka, Germany

Table 2: Discussion of comments

GENERAL COMMENTS TO DRAFT DOCUMENT		
An interested party in principle welcomes the preparation of the above-mentioned Community herbal monograph which may provide harmonised assessment criteria for herbal medicinal products. The interested party has published a monograph on <i>Betulae folium</i> in 1996 and a revised version in 2003.		
2. QUALITATIVE AND QUANTITATIVE COMPOSITION		
Paragraph no. line no.	Comment and Rationale	Outcome
Paragraph no. 2., ii) Herbal preparations	<p>An interested party: Stabilised juice (1:1, 50 - 60 % (V/V) ethanol) from fresh leaves in liquid dosage form should be added to the list of herbal preparations.</p> <p>Tradition of stabilised juices has in Poland very long tradition. (Stabilised juice (<i>Succi stabilisatae</i>)) are obtained from fresh herbal crude drugs, usually after preliminary inactivation of the enzymes, differently from expressed juices.</p> <p>The inhibitor which is most often used is ethanol. Fresh crude drug, previously cleaned and comminuted, is subjected to stabilisation with 96% ethanol vapours in autoclaves under 0.2 MPa for 1–4 h. Stabilised juice is obtained from thus prepared crude drug by its maceration with the solvent prepared from ethanolic extract fluid (obtained after stabilisation), 96% ethanol and water, in a ratio ensuring that the content of ethanol in the finished product is about 50-60 % (V/V). The maceration time is differentiated – depending on the chemical nature of the active substances and on the plant part constituting the crude drug (root, rhizome, herb). The crude drug is subjected to pressing and the fluid extract obtained is combined with the fluid from the elution process. The product obtained is subjected to the sedimentation process and the time of seasoning depends on the preparation. After filtration, the juice is dosed into bottles.</p> <p>Due to quite different manufacturing processes the name of stabilised juice is proposed to distinguish from expressed juices.</p>	<p>Accepted.</p> <p>The stabilised juice of <i>Betulae folium</i> (<i>Succus Betulae folii recens</i>) for oral use, is presented on the Polish pharmaceutical market since 1956 (over 50 years). In the Community herbal monograph on <i>Betulae folium</i> the stabilised juice prepared from fresh birch leaves is mentioned as the liquid extract from fresh leaves stabilised by 96% ethanol vapours (1:1, 50-60% (V/V) ethanol). The obtaining of the herbal preparation is described in AR.</p>

Paragraph no. line no.	Comment and Rationale	Outcome
Paragraph no. 2., ii) Herbal preparations	<p>Two interested parties suggest adding “Pressed juice from fresh leaves”</p> <p>This preparation is relevant in some markets, e.g. Germany (“Schoenenberger naturreiner Heilpflanzensaft Birke”)</p>	<p>Not accepted.</p> <p>The detailed adequate information about „Pressed juice from fresh leaves“ is not available and has not been sent to the Rapporteur. The mentioned pressed juice from fresh leaves is fully different than stabilised juice from fresh leaves, described in previous section (see comment from an interested party on page 2).</p>
3. PHARMACEUTICAL FORM		
Paragraph no. line no.	Comment and Rationale	Outcome
	<p>An interested party:</p> <p>Stabilized juice in liquid dosage form, for oral use, should be added to the list of herbal preparations.</p> <p>Stabilised juice of <i>Succus Betulae folii recens</i> for oral use, is presented on the Polish pharmaceutical market since 1987 (Registration Certificate of <i>Succus Betulae</i>).</p> <p>Stabilised juices are obtained from fresh herbal crude drugs, usually after preliminary inactivation of the enzymes, differently from expressed juices. They exist as a pharmaceutical form of herbal medicinal products in Poland for several dozen years. The technology of stabilized juice was described in 1973 by Lutomski in “Technology of Herbal Drug” PZWL Warszawa (Lutomski & Małek 1973) and then in consecutive edition of “ Farmacja stosowana” by Janicki et al. in 1996, 1998, 2000, 2001 and 2006.</p> <p>According to bibliographic data it can be assumed that since 1956 domestic industry supplies the following juices for use in therapy: Hyperici succus and the following since 1980: Plantaginis succus, Taraxaci succus and Urticae succus, Echinacea succus, Betulae succus and Bardanae succus (Lutomski, Małek 1973; Janicki, Fiebig 1996).</p>	<p>See Outcome for comment on section 2.</p>

4.1. THERAPEUTIC INDICATIONS

Paragraph no. line no.	Comment and Rationale	Outcome
Well-established use	<p>Three interested parties suggest taking into consideration the well-established medicinal use as well. The indication is supported by bibliographic data and a field study.</p> <p>"Irrigation of the urinary tract, especially in cases of inflammation and renal gravel, and as an adjuvant in the treatment of bacterial infections of the urinary tract" [Schilcher 1984, 1987, 1990, Müller 1999, ESCOP 2003].</p> <p>In a field study 1066 patients received a dry aqueous extract of birch leaf (4-8:1) at various doses (between 180 and more than 1080 mg daily) for irrigation of the urinary tract. 73.8% of the patients suffered from inflammations of the urinary tract, 14.2% from irritable bladder, 9.3% from stones, and 2.7% had miscellaneous complaints. In most of the cases (63%) the treatment period was 2-4 weeks. After treatment symptoms disappeared in 78% of the first group, in 65% of the second group and 65% of the third group. In the first group, 56% of the patients were additionally treated with antibiotics. Symptoms disappeared in 80% of the patients treated with and in 75% without antibiotics. Both physicians and patients, considered efficacy to be „very good“ (39% and 48% respectively) or „good“ (52% and 44% respectively) [Müller 1999].</p>	<p>Not accepted.</p> <p>The clinical investigations are not sufficient for well-established medicinal use because of the lack of a control group and a too short period of observation (See Assessment Report). More clinical investigations would be necessary.</p>

4.2. POSOLOGY AND METHOD OF ADMINISTRATION

Paragraph no. line no.	Comment and Rationale	Outcome
	<p>The interested party also suggests adding for the “Stabilised juice (1:1, 50 - 60 % (V/V) ethanol) from fresh leaves”</p> <p>Adults, elderly Single dose Stabilised juice from fresh leaves (1:1), 50-60% ethanol (v/v) 2.5ml. Maximum daily dose Stabilised juice from fresh leaves (1:1), 50-60% ethanol (v/v) 7.5ml.</p>	<p>Accepted.</p>

4.4. Special warnings and precautions for use		
Paragraph no. line no.	Comment and Rationale	Outcome
Paragraph no. 1.	Three interested parties recommend not excluding children and adolescents below the age of 18 years of age. In case children have to be excluded, they suggest excluding “children below the age of 12 years”.	Accepted. New version: ‘The use in children under 12 years of age is not recommended because of the lack of available experience.’ It is harmonized now with the similar monographs on <i>Equisetum arvense</i> (herba) and <i>Solidago virgaurea</i> (herba).
4.8. UNDESIRABLE EFFECTS		
Paragraph no. line no.	Comment and Rationale	Outcome
Paragraphs no. 1. and 2.	Three interested parties propose “None reported” because from their point of view, there are no reports on undesirable effects available.	Not accepted. There are some reports on undesirable effects of preparations containing <i>Betulae folium</i> (See Assessment Report).