



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 November 2009
EMA/HMPC/400536/2009
Committee on Herbal Medicinal Products (HMPC)

Overview of comments received on Community herbal monograph on *Taraxacum officinale* Weber ex Wigg., radix cum herba (EMA/HMPC/212895/2008)

Table 1: Organisations and/or individuals that commented on the draft Community herbal monograph on *Taraxacum officinale* Weber ex Wigg., radix cum herba as released for public consultation on 14 January 2009 until 15 May 2009.

	Organisations and/or individuals
1	Association of the European Self-Medication Industry (AESGP)
2	Dr Václav Bažata, Industrial Pharmacist



Table 2: Discussion of comments

General comments to draft document

Interested party	Comment and Rationale	Outcome
AESGP	<p>AESGP welcomes, in principle, the development of the above-mentioned Community herbal monograph which, by providing harmonised assessment criteria for <i>Taraxacum officinale</i>-containing products, should facilitate mutual recognition in Europe.</p> <p>We also welcome publication of the draft assessment report in parallel to the draft monograph because it provides useful background information on the preparation of the HMPC draft.</p>	Endorsed.
Dr Bažata	The wording of therapeutic indications in Community Herbal Monographs is generally too soft in case of traditional use to distinguish it from herbal non-medicinal products	<p>Not endorsed.</p> <p>According to Directive 2002/46/EC, Article 6(2): "The labelling, presentation and advertising must not attribute to food supplements the property of preventing, treating or curing a human disease, or refer to such properties".</p> <p>This definition clearly distinguishes herbal non-medicinal products from herbal preparations with a traditional medicinal use.</p>
Dr Bažata	Policy of precautionary principle to exclude all children bellow age of 12 years of age in Posology without any justification or only "lack of data" substantiation is dubious and may be harmful to SME businesses	<p>Not endorsed.</p> <p>According to EMA/HMPC guidance, if the clinical safety has not been demonstrated, use of a herbal preparation is not recommended for children under 12 years.</p>

SPECIFIC COMMENTS ON TEXT

Section number and heading	Interested party	Comment and Rationale	Outcome
2. Qualitative and quantitative composition	AESGP	We agree with the inclusion of a liquid extract (0.75:1), extraction solvent: ethanol 30% (m/m). This extract is a component of the medicinal product "Paverysat L Bürger, Flüssigkeit" which is available in the German market (1 g liquid contains 0.266 g of liquid extract).	Endorsed.
4.1. Therapeutic indications	AESGP	<p>We suggest to add the indications "lack of appetite" and "bile flow disorders".</p> <p>Comment:</p> <p>The above-mentioned product "Paverysat L Bürger", Flüssigkeit which contains the liquid extract (0.75:1), extraction solvent: ethanol 30% (m/m), was authorised according to Art. 10.1 (a)(ii) of Directive 2001/83/EC as amended (bibliographical application) in 2007. The marketing authorisation holder is Johannes Bürger Ysatfabrik GmbH, Bad Harzburg, Germany. The indication is: "...used in lack of appetite and bile flow disorders with digestive disorders such as flatulence and feeling of abdominal fullness (dyspeptic disorders)" (in German: "angewendet bei Appetitlosigkeit und Störungen des Galleflusses mit Verdauungsbeschwerden wie Blähungen und Völlegefühl (dyspeptische Beschwerden)").</p> <p>As the product has been authorised according to Art. 10.1 (a)(ii) of Directive 2001/83/EC, it might from our point of view</p>	<p>Partially endorsed.</p> <p>Bile flow disorders may be caused by serious gall-bladder/liver diseases (e.g. hepatitis, AIDS cholangiopathy, liver cirrhosis or fibrosis,...). Also many gastrointestinal diseases associated with long-term lack of appetite (tumors of GI tract, pancreatitis, GI bleeding,...) are serious conditions. These diseases must not be treated with traditional herbal medicines as a physician's diagnosis, therapy with regular controls are needed.</p> <p>Adapted sentence in Community monograph:</p> <p>Indication a) Traditional herbal medicinal product for the relief of symptoms related to mild digestive disorders (such as feeling of abdominal fullness, flatulence, and slow digestion) and temporary loss of appetite</p> <p>Partially endorsed.</p>

Section number and heading	Interested party	Comment and Rationale	Outcome
		be eligible for the “well-established medicinal use”. However, if this is not accepted in the HMPC monograph, the indication should be included for the “lower level”, the traditional use.	Clinical studies could not be found. Therefore only the use as a traditional herbal medicinal product is proposed.
4.1. Therapeutic indications	Dr Václav Bažata	<p>Comments:</p> <p>Indication a) is not reflecting the totality of evidence, f.i. ESCOP Monograph TARAXACI RADIX , where is given at heading Therapeutic indications: Restoration of hepatic and biliary function, dyspepsia, loss of appetite (EMEA draft of Herbal Monograph is mentioning only mild dyspeptic/gastrointestinal disorders, despite in Inventory of herbal substances for assessment – Alphabetical order , Doc.Ref.EMEA/HMPC/494079/2007 are ESCOP both herbal monographs on Taraxaci off. planta tota listed on page 13)</p> <p>Proposed change (if any):</p> <p>To include “Restoration of hepatic and biliary function, dyspepsia, loss of appetite” with deleting the word “mild”</p>	<p>Partially endorsed.</p> <p>Bile flow disorders may be caused by serious gall-bladder/liver diseases (e.g. hepatitis, AIDS cholangiopathy, liver cirrhosis or fibrosis,...). Also many gastrointestinal diseases associated with long-term lack of appetite (tumors of GI tract, pancreatitis, GI bleeding,...) are serious conditions. These diseases must not be treated with traditional herbal medicines as a physician's diagnosis and therapy with regular controls are needed.</p> <p>Adapted sentence in Community monograph:</p> <p>Indication a) Traditional herbal medicinal product for the relief of symptoms related to mild digestive disorders (such as feeling of abdominal fullness, flatulence, and slow digestion) and temporary loss of appetite</p>