



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 July 2011
EMA/HMPC/238586/2011
Committee on Herbal Medicinal Products (HMPC)

Overview of comments received on Community herbal monograph on *Achillea millefolium* L., flos (EMA/HMPC/143949/2010)

Table 1: Organisations and/or individuals that commented on the draft Community herbal monograph on *Achillea millefolium* L., flos as released for public consultation on 15.11.2010 until 15.02.2010.

	Organisations and/or individuals
1	European Scientific Cooperative on Phytotherapy - ESCOP
2	Association of the European Self-Medication Industry - AESGP
3	European Botanical Forum-EBF



Table 2: Discussion of comments

General comments to draft document

Interested party	Comment and Rationale	Outcome
ESCOP	ESCOP appreciates the draft for a Community Herbal Monograph on <i>Achillea millefolium</i> , flos, prepared by the Committee on Herbal Medicinal Products (HMPC). However, we consider the following modification necessary.	
AESGP	AESGP in principle welcomes the development of the above-mentioned Community herbal monograph which, by providing harmonised assessment criteria for <i>Millefolii flos</i> -containing products, should facilitate mutual recognition in Europe.	
EBF	<p>The policy of the precautionary principle to exclude all children/adolescents bellow age of 18 years of age in posology by the wording: „the use in children and adolescents under 18 years of age has not been established due to lack of adequate data.“</p> <p>Without any justification by only “not sufficient data” substantiation is inappropriate. The real impact is the practical exclusion of the whole category of this population from the benefits of phytotherapy self-medication as we have commented to previous monographs drafts.</p> <p>The EMA is aware about this problem with issuing draft EMA/HMPC/833398/2009: „Reflection paper on the necessity of initiatives to stimulate the conduct of clinical studies with herbal medicinal products in the paediatric population“, But since THMPD is about TU or WEU it seems unbelievable that in 127 cases no trace of TU in children is available as stems from the reflection paper Draft: “there are 128 indications for traditional use and 27 for well established use and only one indication (the traditional use for skin disorders and minor wounds of <i>Avenae fructus</i>) does not have any age restriction.”</p> <p>It is not clear if time and resources consuming Evidence Based Medicine</p>	<p>The proposal is accepted partially. The use of the herbal substance and comminuted herbal substance by adolescents were accepted taking in to consideration that liquid extract has been used traditionally by adolescents for more than 30 years and the fact that there is no significant difference in composition between a liquid extract prepared with liquor vine: ethanol 96 (V/V) 91:9 (m/m) and herbal tea preparation. Even the herbal tea contains lower amounts of ingredients. The cutaneous use for adolescents can be considered safe as well.</p> <p>A traditional indication for children under 12 years of age can not be accepted because 30-year-old data are not available for this age group.</p>

	solutions (i.e. to conduct clinical studies) are superior to a better collection and documentation of TU in children and the adolescent population within the Member States as Herbal Medicinal Products are having also a broad off-label use by paediatricians and paediatric physicians.	
--	---	--

SPECIFIC COMMENTS ON TEXT

Section number and heading	Interested party	Comment and Rationale	Outcome
4.1 Therapeutic Indications	AESGP	We propose to include the following indication: "Traditional herbal medicinal product for symptomatic treatment of minor spasms associated with menstrual periods". This indication is described in literature for <i>Achillea herba</i> and well as for Achillea flower [1] and should therefore be included in the monograph on <i>Achillea flower</i> as well.	The submitted reference is very recent (2008). However, Hagers Handbuch (1992) and Commission E monograph (1990) do not make the difference between the herb and the flower. As the herb consists of mainly flowers, the proposal can be accepted.
4.1 Therapeutic Indications	EBF	Indication 1) "Traditional herbal medicinal product used in temporary loss of appetite." Temporary loss of appetite seems to be more health claim than indication and therefore we propose "Dyspeptic disorders connected with temporary loss of appetite."	The proposal is not accepted because this is the standard wording for this indication.
4.2. Posology	EBF	To Indication 1) and 2) a) 2-4 g comminuted herbal substance as infusion three or four times daily between meals b) Expressed juice: 5 -10 ml twice or three times daily c) Liquid extract: 2-4 ml three times daily to be added for better efficacy: "in case of dyspeptic disorders connected with temporary loss of appetite, <i>the liquid is to be taken 30 minutes before meals</i> ".	The proposal can be accepted. For the indication "loss of appetite" the liquid preparations are supposed to be taken ½ hour before meal (See e.g. <i>Gentianae radix</i> monograph).

4.2. Posology	ESCOP	<p>We disagree with the restriction of use in adolescents: Although spasmodic gastrointestinal complaints including bloating and flatulence (indication 2) usually are no indication for adolescents between 12 and 18, in indication 1 (temporary loss of appetite) and 3 (treatment of small superficial wounds) THMPs from <i>Achillea millefolium</i>, flos, might be used for adolescents as well.</p> <p>Thus, we propose to delete “and adolescents under 18 years of age” and to use the standard wording “children under 12 years”</p>	Accepted (see above).
4.4.	ESCOP	The same applies as stated under 4.2.	Accepted (see above).
4.4 Special warnings and precautions for use	AESGP	<p>We suggest to delete the statement “The use in children and adolescents under 18 years of age has not been established due to the lack of adequate data” or – alternatively – in case the existing data for children under 12 years of age are not regarded to be sufficient, to replace “18 years” by “12 years”.</p> <p>The use of <i>Achillea</i> flower preparations in paediatric medicine has been described in literature [1] in the following indications: stomach disorders, wound healing, complaints associated with menstrual periods.</p> <p>As the indications</p> <p>loss of appetite</p> <p>gastrointestinal complaints</p> <p>small superficial wounds</p> <p>are also relevant for children and the indication minor spasms associated with menstrual periods also for adolescents, the use of <i>Achillea</i> flos preparations for the treatment of these complaints should not be excluded.</p>	<p>The proposal is accepted partially. The use of the herbal substance and comminuted herbal substance by adolescent were accepted taking in to consideration that liquid extract has been used traditionally by adolescents for more than 30 years and the fact that there is not significant difference in composition between a liquid extract prepared with liquor vine: ethanol 96 (V/V) 91:9 (m/m) and herbal tea preparation. Even the herbal tea contains lower amount of ingredients. The cutaneous use for adolescents can be considered safe as well.</p> <p>A traditional indication for children under 12 years of age can not be accepted because 30-year-old data are not available for this age group.</p>

AESGP Reference: Bühring U, Eil-Beiser H, Girsch M. Heilpflanzen in der Kinderheilkunde. Stuttgart: Sonntag, 2008: 108-109, 173, 276, 345, 348.