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SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

## Overview of comments on draft Community herbal monograph on *Lavandula angustifolia* Miller, aetheroleum (EMA/HMPC/143181/2010)

Table 1: Organisations and/or individuals that commented on the draft Community herbal monograph entry on *Lavandula angustifolia* Miller, aetheroleum as released for public consultation on 15 February 2011 until 15 August 2011

	Organisations and/or individuals
1	AESGP, Brussels, Belgium
2	ESCOP, Exeter, United Kingdom
3	Dr. Willmar Schwabe GmbH & Co.KG, Karlsruhe, Germany



Table 2: Discussion of comments

### General comments to draft document

Interested party	Comment and Rationale	Outcome
AESGP	AESGP in principle welcomes the development of the above-mentioned Community herbal monograph which, by providing harmonised assessment criteria for <i>Lavandula aetheroleum</i> -containing products, should facilitate mutual recognition in Europe. We have the following specific comments.	
ESCOP	ESCOP welcomes the draft Community herbal monograph on Lavender oil prepared by the Committee on Herbal Medicinal Products (HMPC). ESCOP would like to comment on one particular issue of this monograph and herewith raise a general point with regard to posology and information on the number of drops recommended for essential oils.	
Schwabe	<p>We agree that the peroral well-established use of Lavender oil is assessed to be not acceptable, however for formal reasons only. In the <i>Assessment Report</i> [Doc. Ref. EMA/HMPC/143183/2010], thus, rejection of well-established use of Lavender oil should be explained by the fact that the essential formal factors to be taken into account in order to establish a well-established medicinal use are not fulfilled here: (1) Based on systematic and documented risk-benefit-evaluation only one marketing authorization was granted on June 26th 2009 (in Germany in fact, 80 mg lavender oil/capsule). I.e. neither a) the quantitative aspects of perorally used Lavender oil nor b) the degree of scientific interest in the use of the substance (reflected in the published scientific literature) is adequate to establish a well-established medicinal use.</p> <p>(2) The minimum time period required for establishing a well-established medicinal use of an active substance is one decade from the first systematic and documented use of that substance as a medicinal product in the Community. This period is not covered here.</p> <p>Proposed change [Draft Assessment report, page 43/45]:</p>	The suggested changes are taken into consideration. However the quality of the clinical studies is also a factor in the granting of a well-established use.

	<p><i>"4.3. Overall conclusion on clinical pharmacology and efficacy</i>  <i>The anxiolytic activity ..... to positively influence anxiety and stress-related restlessness. However, the peroral use of lavender oil should not be accepted as well-established anyway, as the essential factors to be taken into account in order to establish a well-established medicinal use [acc. to Annex I Directive 2001/83/EC] are not fulfilled here. So only for completeness, this assessment report</i>  <i>presents also one of the most recent studies (Woelk &amp; Schläfke, 2010), where patients with general anxiety disorder are included. The study ..... Furthermore no</i>  <i>placebo arm was included. Therefore it is not possible to grant a well-established use</i>  <i>for lavender....</i>  <i>Lavender oil has been .... might be too diverse."</i>  The clause <i>"Therefore it is not possible to grant a well-established use for lavender."</i> should be deleted, as the facts referred to by this clause are not deciding for rejection of well-established use of Lavender oil.</p>	
Schwabe	<p>As already pointed out in our comment of March 7th 2011, to our knowledge the longstanding oral use of <i>lavender oil</i> is only covered by taking a few drops e.g. onto a lump of sugar (as described also in the German Commission E monograph). This comment complies with the information meanwhile provided in the draft <i>Assessment Report</i> [Doc. Ref. EMA/HMPC/ 143183/2010] section 1.2.: no product listed here fulfils <i>Article 16c(2) Directive 2001/83/EC</i> i.e. on the European market no "corresponding product" is available which may be referred to when traditional use of peroral dosage form of lavender oil is discussed.</p> <p>So we like to emphasize here again:  (1) The long-standing oral use of <i>lavender oil</i> is only covered by taking a few drops e.g. onto a lump of sugar (as described also in the German Commission E monograph), which just for theoretical reasons first of all results in oromucosal</p>	Lavender oil incorporated in a capsule is considered as a solid dosage form. Further specification in the monograph, e.g. oral drops on a lump of sugar, is not considered as necessary.

	<p>absorption of Lavender oil. Only this dosage form and method of administration has been safely used throughout a long time period.</p> <p>(2) As confirmed by the German authority [in the marketing authorization procedure for our peroral lavender oil product with 80 mg lavender oil / capsule], the safety profile of <i>lavender oil</i> administered as drops (e.g. onto a lump of sugar) cannot be transferred to peroral dosage forms. For peroral dosage forms specific safety data should be provided.</p> <p>Conclusion: With regard to the oral traditional use of <i>lavender oil</i>, we propose changes in section “</p> <p>3. Pharmaceutical form” and “4.2. Posology and method of administration” to lay down this information in accordance with the long-standing oral use of <i>lavender oil</i> as drops, only, e.g. onto a lump of sugar. This long term use resulted in the German Commission E monograph many years ago and, thus, is confirmed explicitly. The proposed changes should be done to be on the safe side, as no other (peroral) <i>lavender oil</i> application form has been traditionally and safely used throughout a long time period.</p> <p>Following, please, find the proposed changes in detail.</p>	
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## SPECIFIC COMMENTS ON TEXT

Section number and heading	Interested party	Comment and Rationale	Outcome
3. Pharmaceutical form	AESGP	<p>Traditional use: Herbal preparation in liquid dosage form for oral use and as a bath additive.</p> <p>Proposed change: Herbal preparation in liquid dosage form for oral use, for cutaneous use and as a bath additive.</p> <p><u>Comment:</u> <i>Justification for traditional use since 1887.</i></p> <p><u>References:</u> Köhler's (1887/1888), Dragendorff (1898), Kroeber (1935), Madaus (1938), Fischer (1939), Pelikan (1963), Weleda (1968b), Gessner (1974), Hoppe (1975), BGA (1978), Weleda (1930), Weleda (1936), Weleda (1949), Weleda (1954), Weleda (1956), Weleda (1958a), Weleda (1958b), Weleda (1961), Weleda (1963), Weleda (1968a), Weleda (1976), BGA (1978), BfArM-Amis (2009), Weleda (1986), Weleda (1988), BGA (1990a), BGA 1990b), Weleda (1993), Weleda (1994), Weleda (1995), Weleda (1996), Weleda (1998), Weleda UK (1998), Weleda UK (1999), Weleda (1999), Weleda (2000a), Weleda (2000b), Weleda (2002), Weleda (2004a), Weleda (2005), Weleda (2007), Rote Liste (2008), Weleda (2009b).</p>	<p>Cutaneous use of lavender oil preparations belongs indeed to the herbal tradition. Complementary historical information provided by AESGP is incorporated in the assessment report.</p> <p>For the incorporation in the monograph: see comments under 4.1. Therapeutic indications and 4.2. Posology and method of administration</p>

<p>3. Pharmaceutical form Traditional use</p>	<p>Schwabe</p>	<p>Referring to the method of long-standing oral use of <i>lavender oil</i> (see our preceding comment), the wording should be laid down correspondingly to exclude any other application form. Proposed change: <i>“ Herbal preparation as oral drops and as bath additive.”</i></p>	<p>Recently Silexan® has been investigated in a clinical study<sup>1</sup>. Silexan® is considered as a solid dosage form. The monograph does not consider this preparation. The actual phrasing excludes solid forms as it reads: ... <i>Herbal preparation in liquid dosage form for oral use.</i></p>
<p>4.1 Therapeutic indications</p>	<p>AESGP</p>	<p>Traditional use: Traditional herbal medicinal product for relief of mild symptoms of mental stress and exhaustion and aid to sleep.</p> <p>The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.</p> <p>Proposed change: For oral use and bath additive Traditional herbal medicinal product for relief of mild symptoms of mental stress and exhaustion and aid to sleep.</p> <p>For cutaneous use: Traditional herbal medicinal product used for supportive treatment in conditions of nervous or physical tension which can show as restlessness difficulties falling asleep gastro-intestinal (abdominal) complaints, eg. cramps and wind (flatulence) periodic pains The product is a traditional herbal medicinal product for use in the specified indications exclusively based upon long-standing use in anthroposophic medicine.</p>	<p>Extensive additional information about cutaneous use is welcomed. See further comments below.</p>

<sup>1</sup> Woelk H, Schläfke S. A multi-center, double-blind, randomised study of the Lavender oil preparation Silexan in comparison to Lorazepam for generalized anxiety disorder. *Phytomedicine* 2010; 17: 94-99.aph

		<p><u>Comment:</u> <i>Justification is included in the following references.</i></p> <p><u>References:</u> <i>Köhler's (1887/1888), Dragendorff (1898), Kroeber (1935), Madaus (1938), Fischer (1939), Pelikan (1963), Weleda (1968b), Gessner (1974), Hoppe (1975), BGA (1978), Haag (1985), BGA (1990a), BGA (1990b), Kooperation Phytopharmaka (1991), Weleda (1995), Weleda (1996), Weleda (1998), Weleda (1999), Weleda (2000a), Weleda (2002), Weleda (2004a), Weleda (2004b), Weleda (2005), Weleda (2007), WHO (2007b), GAÄD (2008), Weleda (2009b).</i></p>	
4.2 Posology and method of administration	AESGP	<p>Posology and use in children</p> <p>External use We propose to delete the recommendation not to use the preparation in children under 12 years of age and to insert a dosage recommendation instead:</p> <p>As bath additive: 5-10 drops per bath, depending on the age (see below)</p> <p><u>Reasons:</u> The use of Lavender oil in children is well-known.</p> <p>Schilcher [1] describes the use of Lavender oil in children and recommends 5 to 10 drops essential oil per bath, emulsified with milk or cream.</p> <p>Furthermore, there are several cosmetic preparations (bathes, oils to be applied on the skin) in the market which do not</p>	<p>Referring to Schilcher, the information is not exactly the same as proposed in the suggestion. For the bathmilk (7,5-20% g/g) it reads: <i>... Zum Vollbad 1-2 Esslöffel nach dem Einlaufen des Wassers zusetzen, für Teilbäder entsprechend weniger.</i></p> <p>The posology is expressed as 1-2 big spoons. There is indeed no restriction on age but there are also no instructions according to different ages of children. As a consequence interpretation remains questionable.</p> <p>The specific products cited do not exclude children either, but precise instructions are needed.</p> <p>Conclusion: the suggestion cannot be taken to the monograph without sourced specifications</p>

		<p>exclude children from the use, such as</p> <p>Kneipp® Badeperlen Sanfter Ausklang Mondwurz Lavendel  Kneipp® Sprudelbad Lavendel  Kneipp® Hautöl Lavendel  Kneipp® Badekristalle Lavendel  Kneipp® Gesundheitsdusche Harmonie Pur  Kneipp® Aroma-Pflegebad Wildrose Lavendel</p>	
4.2 Posology and method of administration	AESGP	<p>Traditional use:  We propose to include the following use under 'posology':</p> <p>Cutaneous use as a 10% solution: 5 drops 1-2 times a day.</p> <p>With children from 1 to 5 years of age, do not rub lavender oil 10% on the skin but only use it on a compress.</p> <p>Lavender oil should not be used for babies younger than one year old.</p> <p><u>Reasons:</u>  There are publications in which children of different ages have been treated topically with lavender oil mainly within aromatherapy (<i>American Botanical Council 2005; Denner 2009; Lipton et al. 2008; Sheppard 2009</i>).</p> <p><i>Field et al. (2008)</i> investigated the effect of lavender bath oil in very young children (age 1 week to 4½ months). The authors reported that the bath reduces stress and crying and enhances sleep in the babies.</p> <p>There exists a written protocol data survey of anthroposophic physicians on the efficacy of lavender oil 10 % in children</p>	<p>With regard to paediatric use, there is a restrictive passage in the WHO monograph (2007): ... <i>Owing to a lack of safety data, the essential oil should be administered internally only under the supervision of a health-care provider.</i></p> <p>AESGP cites several references.</p> <p><i>American Botanical Council 2005</i>  No detailed instructions on paediatric use.</p> <p><i>Denner 2009</i>  Citation: ... <i>the Monograph from National Standard does not recommend use younger than 18 years, stating sufficient available data. However other authors indicate lavender's gentleness and safe use as an aromatic for children.</i></p> <p>Again no posology is mentioned.</p> <p><i>Lipton et al. 2008</i>  The authors wrote an extensive review on insomnia in childhood. No posology is mentioned for lavender oil (only: '<i>inhalation</i>')</p>



		<p>under 12 years old, according to which 93% (= 104) of the physicians reported positive experience (efficacy) with the application of the product. Furthermore, the safety of the product has been confirmed by all physicians. Regarding dosage, 99% (= 103) of the physicians, who had positive experience with the product in children under 12 years of age, considered the envisaged dosage (rub several times daily) as also being suitable for children under 12 years old. (<i>Weleda AG</i>).</p> <p>According to another written data survey of anthroposophical physicians on the efficacy in children under 12 years old, 81% (= 98) of the physicians included (= 121) reported positive experience (efficacy) with the application of a bath product which contains lavender oil (<i>Weleda Lavendel Bademilch</i>; 7.5 g lavender oil per 100 g). Furthermore, the safety of the product has been confirmed by all physicians except one who reported "hypersensitivity against lavender" as contraindication. Regarding dosage, 100% (= 98) of the physicians, who have positive experience with the product in children under 12 years of age, considered the envisaged dosage as also being suitable for children under 12 years old (<i>Weleda AG</i>).</p>	<p><i>Sheppard 2009</i> This is a reference from the International Chiropractic Pediatric Association (ICPA). It deals with essential oils in general. The information cannot be granted.</p> <p><i>Field et al. (2008)</i> Although this study has been carried out with 3 parallel groups of at least 70 children, no information is given on the amount of oil added to the bath.</p> <p>The anthroposophical complementary information in the column at the left does not contain the information needed for the monograph.</p> <p>Conclusion: The use in children and babies remains a qualitative issue that cannot be translated into the monograph.</p>
	AESGP	<p>Method of administration</p> <p>...</p> <p>Cutaneous use: Rub 2 x 3 times daily 3 to 5 drops slightly over the affected areas into the skin or use as a compress. If used as a compress, 5 to 15 drops will be put on a piece of gauze or a nettle cloth which covers the chest, the abdomen or the area to be treated. In cases of restlessness and difficulties falling asleep apply on chest region. In cases of abdominal complaints, apply on abdomen.</p>	<p>As far as cutaneous use is concerned, there exists indeed a lot of written protocol data survey of cutaneous anthroposophic practice. This practice goes back more than 30 years and can be considered as traditional. The translation into exact instructions seems however to be of a more recent date. AESGP provided many historical WELEDA documents. The first document mentioning a detailed use of the 10% lavender oil diluted with olive oil dates from 1999 (<i>Antrag auf Verlängerung des Zulassung eines Arzneimittels</i>). Under part 6 <i>Dosierung</i> (Posology) it</p>

	<p>In cases of physical tensions, apply on affected area.</p> <p>To use as a compress apply the drops of lukewarm oil on a gauze or bandage, put it on the affected area, cover it with a warm cotton or woollen cloth. Cover with blanket. Leave the compress for approximately 30 minutes. The application should be done at a warm and comfortable temperature that does not lead to sweating.</p> <p><u>Comment</u> According to the monograph (Commission C) the recommended dose is "several times daily" without an exact information about the quantity of drops to be used per dose. For safety reasons it is in general necessary to give accurate dosage recommendations.</p> <p>In Germany the product was registered in 1999 with the following recommendation: rub 2 x 3 times daily 3 to 5 drops slightly over the affected areas into the skin or use as a compress.</p> <p>If used as a compress, 5 to 15 drops will be put on a piece of gauze or a nettle cloth which covers the chest, the abdomen or the area to be treated. Before applying the compress will be slightly warmed. This moist heat supports the effect by additional relaxation and tranquillization as well as relaxation of the muscles.</p> <p>The different sites of application (chest region, abdomen and affected area) are traditionally grown. In general, it can be assumed that the distance to the affected area or organ should be minimised. It has to be emphasised, however, that there are no valid investigations available with respect to the efficacy</p>	<p>reads:</p> <p><i>Soweit nichts anders verordnet, 2-3 mal täglich 3-5 Tropfen Öl über den betroffenen Bereichen leicht in die Haut einreiben oder als Wickel anwenden.</i></p> <p><i>Bei vegetativen Gleichgewichtsstörungen, Einschlafstörungen und bei funktionellen Herz-Kreislaufstörungen erfolgt die Einreibung im linken Brustbereich,</i></p> <p><i>bei Blähungen auf dem Bauch im Uhrzeigersinn, bei Regelstörungen im Bauch- und Lendenbereich.</i></p> <p><i>Bei Säuglingen und Kleinkindern bis zum Alter von 5 Jahren wird Oleum aethereum Lavandulae 10% nicht in die Haut eingerieben sondern nur als Wickel angewendet.</i></p> <p>See page 9 of the assessment report.</p> <p>This information specifies the places where to rub the skin with the diluted (10%) lavender oil. It is even specified that in case of flatulence the rubbing should be done clockwise. There also does not seem to be an age limit.</p> <p>With regard to the dose used for compresses the number of drops to be put on the gauze cannot be retrieved in a written source.</p> <p>Conclusion: there is a long lasting tradition for cutaneous use. However the modalities cannot yet be considered as traditional, especially not for children.</p>
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		<p>in relation to the site of application, but it appears plausible to use the product in the region of the affected area as it is administered locally.</p> <p><u>Reference</u> BfArM (1986/1991)</p>	
4.2. Posology and method of administration	ESCOP	<p>We suggest to delete "1-4 drops" under posology because as compared to the posology given in mg (20-80 mg), this is not precise enough. Although the corresponding amount as drops has also been given in the ESCOP monograph, we think that there is a general need to reflect the correctness of a correlation between mg/ml and drops. The weight per drop depends on the essential oil itself as well as on the dropper used. We have explained this problem in the attached document with several examples (encl. 1) and a further statement (encl. 2).</p> <p>For this reason we suggest to leave out the number of drops in general but in order to achieve patients' compliance, to leave it up to the manufacturer of the individual product to calculate the respective number of drops taking also into consideration the dropper used for the individual product. This is in line with the Ph.Eur. general monograph "Liquid preparations for oral use" (0672), indicating that for the category of preparation "Oral drops", the labelling states the number of drops per millilitre of preparation or per gram of preparation if the dose is measured in drops.</p>	<p>The suggestion is relevant and constructive. The number of drops is deleted in the monograph and it is up to the manufacturer to convert the weight into a number of drops.</p> <p>The text is changed accordingly: Daily dose: 20 to 80 mg</p>
4.2. Posology and method of administration Traditional use	Schwabe	<p>As <i>lavender oil</i> should be orally administered as drops, the number of drops should have priority over the corresponding weights.</p> <p>Proposed change: " <i>Posology</i> ..."</p>	<p>This cannot be granted as ESCOP demonstrated the variability according to the droplet counter and the oil itself. A footnote is added: <i>It is expected that for the finished product, the amount will be expressed in a number of drops. As this number depends upon the droplet counter and the oil itself, it is up to the</i></p>

		<p><i>Oral use:</i> <i>Daily dose: 1 – 4 drops (20 – 80 mg)</i></p>	<p><i>applicant to convert the weight in a number of drops.</i></p>
4.2. Posology and method of administration Traditional use	Schwabe	<p>The daily dose should be given including the recommendation to take it e.g. onto a lump of sugar. This traditional way of intake should be laid down explicitly to be generally accepted without any further justification.</p> <p>Proposed change: “ <i>Posology ...</i> <i>Oral use:</i> <i>Daily dose: 1 – 4 drops (20 – 80 mg) e.g. onto a lump of Sugar</i> <i>.....</i>”.</p>	<p>Taking the oil on a lump of sugar is only one of the ways to administer the oil. For reasons given above, specifying the weight is sufficient. ... Daily dose: 20 to 80 mg The footnote above is added.</p>
4.4 Special warnings and precautions for use	AESGP	<p>As stated above, the recommendation not to use the preparation in children under 12 years of age should be deleted for the external use and for use as a bath additive.</p>	<p>See remarks above.</p>
4.8 Undesirable effects	AESGP	<p>We propose adding the following:</p> <p>Cutaneous use: In very rare cases (effects less than 1 user in 10,000) skin irritation may occur after application of ... which disappears after removal.</p> <p><u>Reference:</u> <i>WHO (2007b)</i></p>	<p>In the WHO monograph (2007) it reads under ‘Adverse reactions’: ... <i>allergic contact dermatitis has been reported in patients previously exposed to the essential oil</i>. As there is no information on frequency the suggested change cannot be taken to the monograph. The risk is sufficiently covered under 4.3. Contraindications: ... <i>Hypersensitivity to the active substance(s)</i>.</p>
5.3 Preclinical safety data	AESGP	<p>Traditional use</p> <p>Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended, unless necessary for the safe use of the product.</p> <p>Tests on genotoxicity, carcinogenicity and reproductive toxicity of lavender oil have not been performed.</p>	<p>Bickers et al. (2003) dealt with linalool and related esters. Whereas Evrandi et al. (2005) reported on test done with lavender oil. It is a pity that tests performed with the oil do not comply with the standards for a list entry, as only 2 <i>Salmonella typhimurium</i> and 1 <i>Escherichia coli</i> strains are used.</p> <p>The references and a summary of their content is</p>

		<p>Proposed change: Based on the literature available, we propose to change into: "Lavender oil showed no mutagenic activity in Salmonella typhimurium TA 98 and TA 100 strains and in Escherichia coli WP2 uvrA strain, with and without metabolic activation. Linalool and linalyl acetate showed no mutagenic activity in different Salmonella typhimurium strains with and without metabolic activation."</p> <p><u>Comments:</u> Literature research showed absence of mutagenity in different tests (see references below).</p> <p><u>References:</u> <i>Evrandi et al. (2005), Bickers et al. (2003)</i></p>	<p>added to the assessment report.</p>
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