



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 November 2024
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Committee on Herbal Medicinal Products (HMPC)

Overview of comments received on European Union herbal monograph on *Eucalyptus globulus* Labill.; *Eucalyptus polybractea* R.T. Baker; *Eucalyptus smithii* R.T. Baker, aetheroleum

Table 1: Organisations and/or individuals that commented on the draft European Union herbal monograph on *Eucalyptus globulus* Labill.; *Eucalyptus polybractea* R.T. Baker; *Eucalyptus smithii* R.T. Baker, aetheroleum as released for public consultation on 15.04.2024 until 15.07.2024.

	Organisations and/or individuals
1	AESGP - Association of the European Self-Medication Industry



Table 2: Discussion of comments

General comments to draft document

Interested party	Comment and Rationale	Outcome
AESGP	<p>AESGP highly appreciates the revision of the 'European Union herbal monograph on European Union herbal monograph on <i>Eucalyptus globulus</i> Labill.; <i>Eucalyptus polybractea</i> R.T. Baker; <i>Eucalyptus smithii</i> R.T. Baker, aetheroleum' and the publication of the respective draft (EMA/HMPC/320292/2023) together with the draft assessment report and the draft list of references.</p> <p>After extensive discussion of the draft monograph with the manufactures of herbal medicinal products, following suggestions will be provided.</p>	-

Specific comments on text

Section number and heading	Interested party	Comment and Rationale	Outcome
4.9 Overdose	AESGP	<p>Comment: We propose to add headings to the paragraphs in the chapter 4.9 overdose, as written in the former version i.e.:</p> <p><u>Cutaneous use</u> Accidental overdose of liniments or bath preparations may cause skin irritation.</p> <p><u>Inhalation</u> No case of overdose has been reported.</p> <p><u>Oromucosal use</u></p>	<p>Partially agreed.</p> <p>For cutaneous and oromucosal use the subheading is inserted. Since for inhalation no overdose is reported, this will not be inserted.</p>

Section number and heading	Interested party	Comment and Rationale	Outcome
		<p>Intake of doses larger than those recommended can provoke gastro-intestinal symptoms (such as abdominal pain, vomiting, diarrhoea, nausea); respiratory problems; central nervous problems (such as CNS depression, loss of consciousness, convulsions, ataxia), constricted pupils.</p> <p>Rational: The new sentence "<i>Intake of doses larger than those recommended can provoke gastro-intestinal symptoms (such as abdominal pain, vomiting, diarrhoea, nausea); respiratory problems; central nervous problems (such as CNS depression, loss of consciousness, convulsions, ataxia), constricted pupils.</i>" is similar to the respective sentence of the former version found under "oromucosal use". Now this sentence is written without a heading, indicating that it relates to the general use, and not specifically to oromucosal use. Without this reference, one could mistakeably interpret that the sentence applies to all types of use, including cutaneous use.</p>	