



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Overview of comments received on European Union herbal monograph on *Eschscholzia californica* Cham., herba

Final

Table 1: Organisations and/or individuals that commented on the draft European Union herbal monograph on *Eschscholzia californica* Cham., herba as released for public consultation on 1 July 2014 - 31 October 2014.

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



Table 2: Discussion of comments

General comments to draft document

Interested party	Comment and Rationale	Outcome
AESGP	<p>Rationale for Traditional Use of the liquid extract prepared from <i>Eschscholzia californica</i> Cham., planta tota:</p> <p>Historically <i>Eschscholzia californica</i> tinctures (i.e. liquid extract) have been produced since at least 1950 by the homeopathic laboratories but their use was always a merely traditional herbal use, which is reflected also in the indication and in the fact that there is <u>no homeopathic use</u> for these tinctures. Therefore this liquid extract should be considered as traditional use in herbal medicine.</p> <p>This liquid extract from <i>Eschscholzia californica</i> Cham., planta tota, prepared by using ethanol 80 % m/m (DER 1: 1.2-1.8) is called “tincture” or “MT” in the medical literature from the laboratories.</p> <p>Its presence on the French market since 30 years as a herbal medicinal product, with a continuous use, appears in particular on:</p> <ul style="list-style-type: none"> - Excerpt from 1984 French Health ministry decision, showing that the liquid extract from <i>Eschscholzia californica</i>, planta tota, in the form of oral drops could be marketed by Laboratories Weleda as pharmaceutical products [1] - Product related documentation, i.e. sales catalogues or reference product catalogues from several Herbal medicinal products laboratories: Laboratoires Weleda 1999 [2], Laboratoires Lehning 1984 [3] and Laboratoires Dolisos 1993 [4]. <p>The use of the <u>underground part and the aerial part</u> (whole plant) of <i>Eschscholzia californica</i> Cham. as the herbal drug is actually described in several Phytotherapy handbook, from 1948 till today [5] [6] [7] [8] [9].</p> <p>The use of the whole plant as <u>liquid extract</u> is also described as a traditional use</p>	<p>Not endorsed.</p> <p>The provided data refers to <i>Eschscholzia californica</i> Cham., planta tota and not to <i>Eschscholzia californica</i> herba (aerial parts) for which the assessment report and herbal monograph have been developed.</p>

Interested party	Comment and Rationale	Outcome
	<p>[6] [8]. The proposed posology is 50 ml/day [8] or an equivalent to 2.5 g to 5 g of plant per day [6].</p> <p>All these handbooks indicate a potential effect of the whole plant as sedative, analgesic and hypnotic and a traditional use to treat sleep disturbance, anxiety or emotional disorders; main constituents being responsible for the activity are alkaloids [5] [6] [7] [8] [9]. This use of the whole plant complies with the traditional use from the draft European Union herbal monograph on <i>Eschscholzia californica</i>, herba: "Traditional herbal medicinal product for relief of mild symptoms of mental stress or to aid sleep" [11].</p> <p>Indeed, alkaloids are the main components in <i>Eschscholzia californica</i> and the main support of the activity [10]. Both underground part and aerial part contain alkaloids, the latter being richer than the former (up to 1.6% alkaloids in the roots ; 0.50-1.20 per cent of total alkaloids are in the herb) [10]. The presence of the underground part is then justified.</p>	

Specific comments on text

Section number and heading	Interested party	Comment and Rationale	Outcome
2. Qualitative and quantitative composition	AESGP	<p>Traditional use <i>Eschscholzia californica</i> Cham., herba or planta tota</p> <p>ii) Herbal preparations</p> <p>a) Powdered herbal substance</p> <p>b) Liquid extract from planta tota (DER 1:1.2-1.8) ; extraction solvent: ethanol 80% (m/m)</p> <p>The use of planta tota is justified in the former section "General comments to draft document".</p> <p>The use of liquid extract is justified in the former section "General comments to draft document".</p>	<p>Not endorsed.</p> <p>See rationale given above.</p>
3. Pharmaceutical form	AESGP	<p>Traditional use Herbal preparations in solid or liquid dosage forms for oral use.</p> <p>The use of liquid extract is justified in the former section "General comments to draft document".</p>	<p>Not endorsed.</p> <p>See rationale given above.</p>
4.2 Posology and method of administration	AESGP	<p>Traditional use</p> <p>Posology <i>Adults, elderly</i></p> <p>Indication 1)</p>	<p>Not endorsed.</p> <p>See rationale given above.</p>

Section number and heading	Interested party	Comment and Rationale	Outcome
		<p>Powdered herbal substance: Single dose: 480-600 mg Daily dose: 960-1500 mg Liquid extract: Daily dose: 25-50 ml</p> <p>Indication 2)</p> <p>Powdered herbal substance: Single dose: 480 mg Daily dose: 960–1500 mg</p> <p>Liquid extract: Daily dose: 25-50 ml</p> <p>2.5 g to 5 g of plant per day [6] = 25 ml - 50 ml liquid extract from planta tota (DER 1:1.2-1.8) /day</p>	