



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

31 January 2017
EMA/HMPC/748525/2016
Committee on Herbal Medicinal Products (HMPC)

Overview of comments received on European Union herbal monograph on *Glycine max* (L.) Merr., lecithinum (EMA/HMPC/220599/2016)

Final

Table 1: Organisations and/or individuals that commented on the draft European Union herbal monograph on *Glycine max* (L.) Merr., lecithin as released for public consultation on 27 July 2016 until 31 October 2016.

	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	AESGP welcomes the above-mentioned European Union herbal monograph which, by providing harmonised assessment criteria for lecithinum ex soya-containing products, should facilitate mutual recognition in Europe.	

Specific comments on text

Section number and heading	Interested party	Comment and Rationale	Outcome
2. Qualitative and quantitative composition	AESGP	<p>ii) Herbal preparations</p> <p>Please replace soya-bean lecithin (de-oiled, enriched phospholipids from soya bean) by Soya-bean lecithin (de-oiled, phospholipids from soya bean)</p> <p>Justification:</p> <p>As justified in the Draft Assessment report on <i>Glycine max</i> (L.) Merr., lecithin (EMA/HMPC/220598/2016), the therapeutic indication retained in the draft monograph (Traditional herbal medicinal product for the relief of temporary fatigue and sensation of weakness) is supported by a long-lasting use of the active substance 'De-oiled, phospholipids from soya beans'.</p> <p>The therapeutic indications approved for 'De-oiled, enriched</p>	Endorsed

Section number and heading	Interested party	Comment and Rationale	Outcome
		<p>phospholipids from soya beans' are:</p> <ul style="list-style-type: none"> • mild hypercholesterolemia, • hepatic problems, both not retained as therapeutic indication in the draft monograph. <p>As a consequence it is not appropriate to list under section 2 the active substance 'De-oiled, enriched phospholipids from soya beans'. The active substance to be listed should read 'De-oiled, phospholipids from soya beans'.</p>	