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Public statement on *Glycine max* (L.) Merr., semen

Final

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Public statement on *Glycine max* (L.) Merr., semen

PROBLEM STATEMENT

The HMPC/MLWP decided to prepare a European Union herbal monograph on *Glycine max* (L.) Merr., semen, as announced in the 2014 MLWP work programme.

A comprehensive literature search was conducted and available data, including information on products on the market in the European Union, were assessed in relation to the requirements laid down in Directive 2001/83/EC and its Annex I, in particular Article 1, Article 10a and Chapter 2a.

During the assessment of *Glycine max* (L.), Merr., semen, HMPC noted that it would be more appropriate to develop a separate monograph on soya lecithin (Lecithinum ex soya) (see EU monograph EMA/HMPC/220599/2016) and a separate monograph on soya oil (Soiae oleum raffinatum) (see EU monograph EMA/HMPC/338914/2016). Hence, this public statement excludes these herbal preparations. The herbal preparations from *Glycine max* (L.), Merr., semen, covered in this public statement are:

- Dry extract from the soya bean germ (hypocotyl) (DER 100-400:1), extraction solvent ethanol 60%-70% V/V.
  The extract contains 40% isoflavones calculated as the sum of isoflavones (26% isoflavones calculated on genistein).
- Dry extract from the soya bean germ (hypocotyl) (DER 47.61-190.47:1), extraction solvent methanol 80% V/V.
  The extract contains 26% isoflavones calculated as the sum of isoflavones.
- Dry extract from the soya bean germ (hypocotyl) (DER 43-53:1), extraction solvent ethanol 60% V/V.
  The extract contains 10% isoflavones calculated as the sum of isoflavone glucosides.
- Dry extract from the soya bean germ (hypocotyl) (DER 50-70:1), extraction solvent ethanol 60% V/V.
  The extract contains 30% isoflavones calculated as the sum of isoflavone glucosides.

The HMPC/MLWP concluded that the following requirements for the establishment of a European Union herbal monograph on traditional or well-established herbal medicinal products containing *Glycine max* (L.) Merr., semen are not fulfilled:

- the requirement laid down in Article 10a of Directive 2001/83/EC that the active substance has a recognised efficacy
- the requirement laid down in Article 16a(1)(d) of Directive 2001/83/EC that “the period of traditional use as laid down on Article 16c(1)(c) has elapsed”.

CONCLUSIONS

Based on the above-mentioned information, the HMPC is of the opinion that a European Union herbal monograph on *Glycine max* (L.) Merr., semen, cannot be established.

To read more about the assessment carried out, a link is provided to the page where to access the draft assessment report on *Glycine max* (L.) Merr., semen and its list of references.

http://www.ema.europa.eu/ema/index.jsp?curl=/pages/medicines/landing/herbal_search.jsp&murl=menus/medicines/medicines.jsp&mid=WC0b01ac058001fa1d