EMA/HMPC/769686/2017
EMA/HMPC/M/H/0216
Committee on Herbal Medicinal Products (HMPC)

Opinion of the HMPC on a European Union herbal monograph on *Hedera helix L.*, folium

Opinion

The HMPC, in accordance with Article 16h(3) of Directive 2001/83/EC, and as set out in the appended assessment report, establishes by a majority of 20 out of 26 votes a European Union herbal monograph on *Hedera helix L., folium* which is set out in Annex I.

The divergent positions are appended to this opinion.

The Norwegian HMPC member does agree with the above-mentioned recommendation of the HMPC.

This opinion is forwarded to Member States, to Iceland and Norway, together with its Annex I and appendices.

The European Union herbal monograph and assessment report will be published on the European Medicines Agency website.

London, 21 November 2017

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Annex I: European Union herbal monograph (EMA/HMPC/7685/2013)

Appendix I: Assessment report (EMA/HMPC/7686/2013)

Appendix II: Divergent positions

The member of the HMPC mentioned below did not agree with the HMPC's opinion for the following reason:

I do not support the proposed Union Monograph for *Hedera helix* folium.

The evidence does not support the position of Hedera helix folium as having well-established medicinal use and recognised efficacy as required by Article 10a of Directive 2001/83/EC.

The studies presented as evidence have not been conducted on patients with the proposed indication as an expectorant in productive cough. The studies have been conducted in patients with more serious conditions including bronchitis, COPD and bronchial asthma.

Furthermore, the treatment times stated in the studies are generally longer than that proposed in the monograph. The evidence in support of this indication and the proposed posology is considered inadequate.

The data to support use in children below 12 years of age is not sufficient to demonstrate safe use.

Linda Anderson, HMPC member

London, 21 November 2017

The member of the HMPC mentioned below did not agree with the HMPC's opinion for the following reason:

I do not support the proposed Union Monograph for *Hedera helix* folium.

The evidence does not support the position of Hedera helix folium as having well-established medicinal use and recognised efficacy as required by Article 10a of Directive 2001/83/EC.

The studies presented as evidence have not been conducted on patients with the proposed indication as an expectorant in productive cough. The studies have been conducted in patients with more serious conditions including bronchitis, COPD and bronchial asthma.

Furthermore, the treatment times stated in the studies are generally longer than that proposed in the monograph. The evidence in support of this indication and the proposed posology is considered inadequate.

The data to support use in children below 12 years of age is not sufficient to demonstrate safe use.

Rachel Cox, HMPC Member from Ireland

London, 21 November 2017

The member of the HMPC mentioned below did not agree with the HMPC's opinion for the following reason:

I do not support the proposed Union Monograph for *Hedera helix* folium.

Current assessment report for revision of monograph on Hedera helix is based on a key publication: A. Schaefer, M.S. Kehr, B.M. Giannetti, M. Bulitta, C. Staiger. Randomized, controlled, double-blind, multi-center trial to evaluate the efficacy and safety of liquid containing ivy leaves dry extract (EA 575Ÿ) vs. placebo in the treatment of adults with acute cough, in Pharmazie 2016 (71):504-509. The publication was performed on request of sponsor from industry and there is no description of randomisation. In case of other assessment report lack of description of randomisation was a reason of disqualification of clinical data what was finalised with public statement.

The use of similar criteria may explain my reservation in this case.

Wojciech Dymowski, HMPC Member from Poland

London, 21 November 2017

The member of the HMPC mentioned below did not agree with the HMPC's opinion for the following reason:

I do not support the proposed Union Monograph for *Hedera helix* folium.

The evidence does not support the position of Hederae helicis as having well-established medicinal use and recognised efficacy as required by Article 10a of Directive 2001/83/EC.

The studies presented as evidence have not been conducted on patients with the proposed indication as an expectorant in productive cough. The studies have been conducted in patients with more serious conditions including bronchitis, COPD and bronchial asthma.

Furthermore, the treatment times stated in the studies are generally longer than that proposed in the monograph. The evidence in support of this indication and the proposed posology is considered inadequate. The data to support use in children below 12 years of age is not sufficient to demonstrate safe use.

Eeva Sofia Leinonen, HMPC Member from Finland

London, 21 November 2017

The member of the HMPC mentioned below did not agree with the HMPC's opinion for the following reason:

The evidence does not support the position of the HMPC for the following preparations of Hedera Helix L., folium, as having well-established medicinal use and recognised efficacy as required by Article 10a of Directive 2001/83/EC in the indication "Herbal medicinal product used as an expectorant in case of productive cough":

- Dry extract (DER 6-7:1), extraction solvent ethanol 40% m/m

- Dry extract (DER 3-6:1), extraction solvent ethanol 60% m/m

- Liquid extract (DER 1:1), extraction solvent ethanol 70% V/V

- Soft extract (DER 2.2-2.9:1), extraction solvent ethanol 50% V/V: propylene glycol (98:2)

The methodology of the clinical studies included in the assessment report was poor due to small sample size, inclusion criteria and clinical endpoints not in line with the proposed indication.

Alessandro Assisi, HMPC Member from Italy

London, 21 November 2017

The member of the HMPC mentioned below did not agree with the HMPC's opinion for the following reason:

I express my divergent opinion because the data to support the well-established use in children are insufficient and so do not fulfil the requirement of Article 10a of Directive 2001/83/EC.

Silvia Girotto, Co-opted member of the HMPC

London, 21 November 2017