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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, as amended, and as set out in the appended assessment report, establishes, by a majority of 24 out of 29 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 agrees 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 appendix.

The European Union herbal monograph and assessment report will be published on the European Medicines Agency website. They replace those adopted on 31 March 2011.

London, 24 November 2015

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Annex I: European Union herbal monograph (EMA/HMPC/586888/2014)

Appendix I: Assessment report (EMA/HMPC/586887/2014)

Appendix II: Divergent positions

Two members 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 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.

Linda Anderson, HMPC member

Marisa Delbò, HMPC member

London, 24 November 2015

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 *Hederae helicis* as having well-established medicinal use and recognised efficacy as required by Article 10a of Directive 2001/83/EC. There is no convincing evidence due to serious methodological flaws and lack of placebo controls in the studies presented as evidence.

Moreover, the studies 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

London, 24 November 2015

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

In my view the data on use in children below 6 years are not sufficient to demonstrate WEU. They may be sufficient for regarding them as an evidence of tradition. Moreover, the difference of use of the preparations in paediatric patients is that in a view of our paediatricians the use of the Hedera helix , leaves preparations have to be consulted until the age of 5 years (in the monograph is 4). Solid forms were not advised for children until the age of 4 years because of a risk of choking (liquid forms were preferred). Eventually, the use in individual child in this age have to be consulted with a doctor.

Wojciech Dymowski, HMPC member

London, 24 November 2015

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

1. Procedure

A 'light' revision can create some confusion because no detailed revision is done of the posology of a wide variety of extracts and its translation to the monograph. Furthermore it should be clearly stated in the final conclusions on which base well-established use was adopted for the different extracts. I would recommend to move directly to a complete revision of the monograph and assessment report.

2. Details

2.1. Type of the extracts

Extracts with different concentrations of ethanol are listed in the actual assessment report (pp. 12-23). It is suggested to make a comprehensive table to demonstrate which extracts are taken into the monograph in which doses (single and maximal daily dose). The actual version can lead to discrepancies with when completely revising the documents.
Extract (a) can be taken as an example. In the assessment report an extract 4-8:1 with ethanol 30% m/m (pp. 12-14) and an extract 6-4:1 with ethanol 30% V/V (pp. 21-23) is mentioned. Apparently the latter one is also included into the monograph. Posology of the extracts under (a) has to be re-checked.

2.2. Galenic form

Losenges for children are mentioned in the assessment report. The monograph on *Sisymbrium officinalis herba* (published in October 2014) mentions:
… The oromucosal use in children under 6 years of age is not recommended … (Section 4.2.) and *… The oromucosal use in children under 6 years of age is not recommended because of the pharmaceutical form (solid dosage form) and due to lack of adequate data …* (Section 4.4.). It is not clear whether changing to well-established use only is the reason, for not mentioning this precaution in the *Hedera helix* monograph.

Gert Laekeman, HMPC member

London, 24 November 2015