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SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

## Opinion of the HMPC on a European Union herbal monograph on *Species sedativae*

### 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 22 votes a European Union herbal monograph on *Species sedativae* 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 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.

Amsterdam, 18 November 2020

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# **Annex I: European Union herbal monograph (EMA/HMPC/438183/2017)**

# Appendix I: Assessment report (EMA/HMPC/438185/2017)

# Appendix II: Divergent positions

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

The criteria used for the assessment of herbal combination exclude the true existing herbal combinations which are in use over a required period of 30 years traditional use (presence on a market of EU country or bibliographic evidence).

According to the tradition of prescribing every traditional herbal tea combinations should contain following components: *basis*, *adjuvans* and *excipients*. This rule could be seen in a bibliography. However in the monograph it was proposed to reduce a combination content only to the selected active herbal ingredients, naming them „combination partners“; the others are regarded as additives. The „partners“ are chosen among the monographs prepared by the Committee rather than be based on documented tradition. As a result of the proposed Monographs seems to be not based on a documented use of known products. On a base of a given tables it is difficult to identify the original herbal medicinal products or their corresponding products. If any applicant wanted to use the proposed monograph on a base of the art. 16c, p.1, (iv) in case of combinations, as referred to in Article 1(30) or Article 16a(2), it is required the information referred to in Article 16a(1)(e) relating to the combination as such. For an application for traditional herbal combination a national competent authority require documentation of traditional use of the whole combination as such, not only for a part of arbitrary named active ingredients. Also a period of use of a product as such should be well documented. The chosen „partners“ group contains both the substances possessing pharmacological activities, like *Valerianae radix*, *Passiflorae herba*, *Lupuli flos* and possessing only the tradition of use in a corresponding indications, like *Melissae folium*. The dosage of the proposed fixed combination should be individually justified for every combination, with adjusting the dose to the weight of components. In Poland Species Sedativae are described in Polish Pharmacopoeia in a national monograph. It contains: *Valerianae radix* 30.0 p.; *Crataegi folium cum flore* 20.0 p; *Melissae folium* 15.0 p.; *Lupuli flos* 15.0 p.; *Menthae piperitae folium* 10.0 p.; *Matricariae flos* 10.0 p. This combination is based on a national tradition.

Wojcieck Dymowski, HMPC Member from Poland

Amsterdam, 18 November 2020

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

I cannot accept the reasoning why *Crataegi folium cum flore* cannot be included as combination partner. The 30 years of use is proved, it does not matter that now only one product which contains it can fulfil this requirement. There are also other products registered in Poland.

Zsuzsanna Borone Sandor, HMPC Member from Hungary

Amsterdam, 18 November 2020