



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

## Opinion of the HMPC on a European Union herbal monograph on *Crataegus spp.*, folium cum flore

### 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 17 out of 26 votes a European Union herbal monograph on *Crataegus spp.*, folium cum flore 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 appendices.

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

London, 5 April 2016



# Annex I: European Union herbal monograph (EMA/HMPC/159075/2014)

## Appendix I: Assessment report EMA/HMPC/159076/2014)

## Appendix II : Divergent positions

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

The indication "Traditional herbal medicinal product used to relieve symptoms of temporary nervous cardiac complaints (e.g. palpitations, perceived extra heart beat due to mild anxiety) after serious conditions have been excluded by a medical doctor. The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.", is not considered suitable for safe use in self-care by a patient or consumer. The validation of the traditional use, regarding this specific indication remains questionable.

The specification of cardiac symptoms as part of the indication, are not acceptable for a Traditional herbal medicinal product.

Emiel van Galen, HMPC member from the Netherlands

London, 5 April 2016

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 European Union Monograph for *Crataegus spp.*, folium cum flore because the indication "used to relieve symptoms of temporary nervous cardiac complaints (e.g. palpitations, perceived extra heart beat due to mild anxiety) after serious conditions have been excluded by a medical doctor" is not considered acceptable for a traditional herbal medicinal product according to the following reasons:

- cardiac complaints cannot be treated without medical supervision as provided for therapeutic traditional indication;
- palpitations (perceived extra heart beat) are generally a benign symptom in healthy subjects, not in patients;
- palpitations are not exclusively due to mild anxiety but they are also a clinical sign of cardiac arrhythmia, thyroid disorders, anaemia and other serious diseases; it is not easy for patients to distinguish between benign and not benign palpitations.

Gioacchino Calapai, Co-opted member of the HMPC

London, 5 April 2016

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 monograph for *Crataegus spp.*, folium cum flore based on concerns regarding the potential safe use of this herbal substance for self-medication "to relieve symptoms of temporary nervous cardiac complaints (e.g. palpitations, perceived extra heart beat due to mild anxiety) after serious conditions have been excluded by a medical doctor" as outlined in the first indication. Therefore, in my view this indication is not acceptable for a traditional herbal medicinal product in line with Directive 2004/24 EC.

Ioanna Chinou, HMPC member from Greece

London, 5 April 2016

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

There are concerns regarding the potential safe use of this herbal substance for self-medication "to relieve symptoms of temporary nervous cardiac complaints (e.g. palpitations, perceived extra heart beat due to mild anxiety) after serious conditions have been excluded by a medical doctor" as outlined in the first indication. Therefore, the view is that this indication is not acceptable for a traditional herbal medicinal product in line with Directive 2004/24 EC.

Furthermore, the use of *Crataegus spp.*, folium cum flore as a traditional herbal medicinal product for relief of mild symptoms of mental stress and to aid sleep in adolescents, 12 – 18 years, is not considered acceptable.

The data to support the proposed use in this age group are insufficient and it is considered that treatment should be under medical supervision.

Linda Anderson, HMPC member from the United Kingdom

London, 5 April 2016



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

The indication 1) of the monograph for TU of *Crataegus spp.*, folium cum flore cannot be accepted for the following reason:

- the requirement of the article 16a (1)(a) of the Directive 2001/83/EC, as amended is not fulfilled, as the symptoms related with cardiovascular disorders should be monitored by a medical doctor.

Maria Helena Pinto Ferreira, Co-opted member of the HMPC

London, 5 April 2016

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 monograph for ***Crataegus spp.*, folium cum flore** based on concerns regarding the potential safe use of this herbal substance for self-medication "to relieve symptoms of temporary nervous cardiac complaints (e.g. palpitations, perceived extra heart beat due to mild anxiety) after serious conditions have been excluded by a medical doctor" as outlined in the first indication. Therefore, in my view this indication is not acceptable for a traditional herbal medicinal product in line with Directive 2004/24 EC.

Furthermore the following preparation cannot be considered as medicinal product because sweet wine with no further specification cannot be accepted as an extraction solvent and the herbal preparation do not differ from common alcoholic beverages, freely sold in wine shops;

Liquid extract (DER 1: 19.2-20), extraction solvent: sweet wine.

Marisa Delbò, HMPC member from Italy

London, 5 April 2016

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

We have concerns regarding the potential safe use of this herbal substance in the following indication "Traditional herbal medicinal product used to relieve symptoms of temporary nervous cardiac complaints (e.g. palpitations, perceived extra heart beat due to mild anxiety) after serious conditions have been excluded by a medical doctor". In our view this indication is not acceptable for a traditional herbal medicinal product in line with Directive 2004/24/EC.

In addition we do not support the indication for relief of mild symptoms of mental stress and to aid sleep in children and adolescents (12-18 years) as this is not appropriate for self-medication in this population.

Una Mockler, HMPC member from the Ireland

London, 5 April 2016

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

Primary pharmacodynamic does not indicate any sedative abilities of *Crataegi flos* preparations, what is inconsistent with monograph. Primary pharmacodynamics justifying the use the preparations in "nervous cardiac complaints" (positive influence on inotropic effect, effects on myocardial perfusion, effects on ischemia and reperfusion induced arrhythmias, inhibition of cardiac hypertrophy) were classified as secondary pharmacodynamics, what seem incompatible with the indications. In overall conclusions on clinical effects positive effects on cardiovascular system were also not referred, not in clinical pharmacology not in clinical efficacy there was not objective summary of positive aspects on patients with mild symptoms of first stages of cardiovascular insufficiency.

However products containing *Crataegi flos* and *folium* preparations have been used in patients with minor complaints (on the level I and II in NYHA scale) in overview of comments the mentioned NYHA scale was substituted by another scale, focused on more serious clinical symptoms of heart failure. Changing view on of cardiovascular symptoms classification and putting starting point of the new scale in place where more serious clinical symptoms are forming starting point, the mild functional symptoms are neglected. In America both scales are used complementary, both the old functional scale and the one based on heart failure classification. The NYHA-scale hasn't been rejected.

Wojciech Dymowski, HMPC member from Poland

London, 5 April 2016

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

In the case of indication 1) - traditional herbal medicinal product used to relieve symptoms of **temporary** nervous cardiac complaints (e.g. palpitations, perceived extra heart beat due to mild anxiety) after serious conditions have been excluded by a medical doctor- the duration of use is too long. Patients cannot wait for **two weeks** if their symptoms persist more than two weeks, a medical investigation is necessary whether there is need for other treatment or not.

Zsuzsanna Biróné Dr Sándor, HMPC member from Hungary  
London, 5 April 2016