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Committee on Herbal Medicinal Products (HMPC)

## Opinion of the HMPC on a European Union herbal monograph on *Rhamnus frangula* L. cortex

### 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 24 out of 25 votes a revised European Union herbal monograph on *Rhamnus frangula* L. cortex which is set out in Annex I.

The divergent position is 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, and Norway, together with its Annex I and appendix.

The revised European Union herbal monograph and assessment report will be published on the European Medicines Agency website. They replace those adopted on 7 September 2006.

London, 25 September 2019

## **Annex I: European Union herbal monograph (EMA/HMPC/726261/2016)**

## **Appendix I: Assessment report (EMA/HMPC/483550/2018)**

## Appendix II: Divergent position

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

In the assessment report for Frangulae cortex there was concluded that no recent clinical investigations available which evaluate the herbal substance alone, i.e. not in combination with other laxatives, in a representative study population. Also there are no well-designed non-experimental descriptive studies with mono-preparations of frangula bark available that investigate the short-term use in occasional constipation. The evidence for medical medicinal use is obtained from pharmacological data, experts' reports and opinions and extensive clinical experiences.

The Committee suggested also the reference to other hydroxyanthracene-containing herbal preparations, like senna leaf and aloe preparations. But the senna leaf and aloe are preparations are more clinical data justifying their well-established medicinal use unlike for Frangulae cortex. The fact that for other herbal preparations are available clinical data must not justify the efficacy of frangula bark preparations for which the clinical data were absent.

However Frangula bark contains a fraction of hydroxyanthracene derivatives, which may be even stronger purgative than other derivatives present in aloe preparations but we have no published results of clinical trials required for justifying of well-established medicinal use.

In a view of above I feel that the monograph Frangulae cortex is not enough justified.

Wojciech Dymowski, HMPC Member from Poland

Amsterdam, 25 September 2019