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Committee on Herbal Medicinal Products (HMPC)

Opinion of the HMPC on a European Union herbal monograph on *Rhamnus purshiana* DC., 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 23 out of 24 votes a revised European Union herbal monograph on *Rhamnus purshiana* DC., cortex which is set out in Annex I.

The divergent position is 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 appendices.

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 2007.

Amsterdam, 6 May 2020

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Annex I: European Union herbal monograph (EMA/HMPC/726270/2016)

Appendix I: Assessment report (EMA/HMPC/909434/2019)

Appendix II: Divergent position

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

Divergent view on the *Rhamni purshianae* cortex well-established use

In the assessment report for *Rhamni purshianae* cortex in p. 4.2 there is concluded.

There are limited clinical studies with cascara bark as a single active ingredient (...). However, the clinical efficacy is generally assumed from the well-established and documented medicinal use in authoritative texts and monographs as reflected in the European Union Monographs for "*Aloe barbadensis* Mill." (EMA/HMPC/759585/2015) and "*Senna alexandrina* Mill." (EMA/HMPC/228759/2016).

This was confirmed in AR conclusions with justification for well-established use of cascara bark preparations in cases of occasional constipation

There are no recent clinical investigations available, which evaluate cascara bark alone, i.e. not in combination with other laxatives, in a representative study population.

There are no well-designed non-experimental descriptive studies with mono-preparations of cascara bark available that investigate the short-term use in occasional constipation. Evidence is obtained from pharmacological data, experts' reports and opinions and extensive clinical experiences as well as reference to related HAD-containing herbal preparations viz. senna leaf and aloe preparations.

Although *Rhamnus purshiana* bark contains also hydroxyanthracene derivatives, similarly like aloe preparations, but there are no commonly available published results of pharmacological studies indicating that the effects of the cascara and aloe preparations are the same (Assessment report, Table 4; Izzo *et al.*, 1996, 1997).

On a base of the presented assessment report, because of lack of bibliographic data on clinical reports on cascara preparations I cannot confirm that the criteria for its well-established medicinal use were fulfilled according to the art. 10, (a), (ii) of Directive 2001/83/WE.

Wojciech Dymowski, HMPC Member from Poland

Amsterdam, 6 May 2020