



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/HMPC/642021/2015
EMA/HMPC/M/H/174
Committee on Herbal Medicinal Products (HMPC)

Opinion of the HMPC on a European Union herbal monograph on *Serenoa repens* (W. Bartram) Small, fructus

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 25 out of 29 votes a European Union herbal monograph on *Serenoa repens* (W. Bartram) Small, fructus 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, 24 November 2015



Annex I: European Union herbal monograph (EMA/HMPC/280079/2013)

Appendix I: Assessment report (EMA/HMPC/137250/2013)

Appendix II : Divergent positions

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

We do not support the proposed European Union herbal monograph on *Sabalıs serrulatae fructus* based on the consideration reported below.

The evidence does not support the position of *Sabalıs serrulatae fructus* as having well-established medicinal use and recognised efficacy for the symptomatic treatment of benign prostatic hyperplasia as required by Article 10a of Directive 2001/83/EC. The data are insufficient to support a well-established use indication in accordance with Annex 1 of 2001/83/EC, as amended.

The efficacy of *Sabalıs serrulatae fructus* has not been sufficiently and consistently proven.

Linda Anderson, HMPC member

Zsuzsanna Biróné Dr Sándor, HMPC member

Emiel van Galen, HMPC member

Annamarie O'Sullivan, HMPC member

London, 24 November 2015