



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/HMPC/820644/2022
EMA/HMPC/M/H/0254
Committee on Herbal Medicinal Products (HMPC)

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

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 21 votes a European Union herbal monograph on *Species digestivae* 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 appendix.

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

Amsterdam, 30 March 2022

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Annex I: European Union herbal monograph (EMA/HMPC/180400/2018)

Appendix I: Assessment report (EMA/HMPC/607773/2017)

Appendix II: Divergent position

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

In Poland, in the national part of Farmakopea Polska, was established monograph for Species digestivae, defined as a combination of:

Cichorii radix 27 parts (as PBW),

Angelicae archangelicae radix 28 parts,

Carvi fructus 10 parts,

Gentianae radix 5.0 parts.

The monograph is based on Polish tradition, still valid and included in the national part of last editions of Farmakopea Polska.

Herbal medicinal products based on this monograph have been registered on a base of national pharmaceutical law before joining of Poland to the Union and still are on the pharmaceutical market.

This is the reason that different herbal combinations should not be used under the same name of Species digestivae in Poland. In the Farmakopea Polska is included also other national monograph Species cholagoge from the same therapeutic area which is covered by the assessment report for the HMPC monograph Species digestivae.

Any herbal combination product of the upper mentioned area, when applied for authorisation In Poland, should be assessed in terms of its individual tradition (art. 16c, 1, c, of the Directive 2001/83) and taking into account earlier existing national monographs in Poland.

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HMPC Member, Poland