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SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

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

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 amarae* 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, 18 November 2020

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Annex I: European Union herbal monograph (EMA/HMPC/44543/2018)

Appendix I: Assessment report (EMA/HMPC/749723/2017)

Appendix II: Divergent position

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

The assessment report for the proposed monograph refers to the herbal tea combination tabel based on HMPC monographs which are chosen on a base of the therapeutic area 'loss of appetite'. It contains: *Millefolii herba*, *Absinthii herba*, *Centaurii herba*, *Cichorii radix*, *Gentianae radix*, *Menyanthidis folium*, *Marrubii herba* and *Taraxaci radix cum herba*. The included herbal substances are linked more to the former activity of the Committee than to the therapeutic or bitterness value. As a result some of herbal substances commonly used bitter combinations were not included, if they were not assessed yet by the HMPC (e.g. *Aurantii amari epicarpium et mesocarpium*, *Cnici benediti herba*); the others are included in spite of a weak bitterness. According to the tradition there were two types of herbal tea combinations, which were traditionally used for a required period both in the traditional categories *amara pura* and *amara aromatica*. In the proposed combinations they are mixed.

For an application on traditional herbal combination a national competent authority requires documentation on a traditional use of the combination product as such so the potential applicant used the proposed monograph will be required for the presentation of the evidence of use of the combination product (or corresponding product). If the combination is taken directly of the tabel, the application may not be accepted because, on a base of the art. 16c, p.1, (iv) in case of combinations, as referred to in Article 1(30) or Article 16a(2), it is required the information referred to in Article 16a(1)(e) relating to the combination as such. In our view, without clear guide or additional explanations this monograph should not be used.

Wojcieck Dymowski, HMPC Member from Poland

Amsterdam, 18 November 2020