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Committee on Herbal Medicinal Products (HMPC)

Public statement on *Cannabis sativa* L., flos

Draft

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Public statement on *Cannabis sativa* L., flos

PROBLEM STATEMENT

In order to foster a more harmonised approach in the presentation and manufacturing of Cannabis-derived medicinal products, the European Commission (EC) requested the Committee on Herbal Medicinal Products (HMPC) a compilation of terms and definitions[1] and also suggested to explore whether it was feasible to establish a European Union (EU) herbal monograph on *Cannabis sativa* L., flos. A first document, adopted on 22 September 2021, summarises existing scientific and legislative terminology that are of relevance in the context of evaluation of Cannabis-derived medicinal products, taking into account EU legislation on medicinal products, pharmaceutical quality guidelines and standards of the European Pharmacopoeia (Ph. Eur.). In addition, HMPC has commenced a procedure to investigate the possible establishment of an EU herbal monograph on *Cannabis sativa* L., flos as announced in the January 2023 HMPC meeting report[2].

A call for data[3] was launched in February 2023, which included an annex with information on the essential legal requirements on data suitability for the HMPC assessment regarding well-established use (WEU) and traditional use (TU) monographs. This annex intended to explain the legislative tasks of HMPC and clarified that it is not within the mandate of the HMPC to assess data relevant for other types of applications, e.g. stand-alone or mixed application (Article 8(3) of Directive 2001/83/EC), where safety and efficacy data derives from the pharmaceutical company's own development or a combination of own studies and bibliographic data.

According to the information provided by national competent authorities (NCAs) in the EU Member States, no preparations of Cannabis flowering tops as a single herbal substance are authorised as medicinal products in the EU. Some EU Member States allow the use of magistral formulas or preparations; however, there are no Cannabis-derived medicinal products for which efficacy and safety in any specific indication with a specific posology has been either assessed or approved by any NCA. Of note, as mentioned in the call for data, Cannabis-derived medicinal products based on isolated constituents, e.g. purified cannabinoids, are out of the scope of this evaluation. The only authorised Cannabis-derived medicinal product in the EU is a combination product consisting of two soft extracts from Cannabis leaf and flower, approved in several EU Member States since 2011.

Different preparations obtained from *Cannabis sativa* L., flos can be found in some EU Member States since 2003 as magistral formula. Although "medicinal use" in the context of WEU does not exclusively mean "use as an authorised medicinal product", data generated from magistral formula cannot replace the requirement to demonstrate a systematic and documented use for that 10-year period in the Union for the product in question. Given the preparations are different, a singular product with defined and consistent specifications and quality measurements was not available for assessment of efficacy and safety and therefore the HMPC did not consider the requirements of WEU as being met.

Following the review of information submitted on products containing a given herbal substance and preparations thereof or a combination of herbal substances/preparations marketed in the EU member states (as per EMA/HMPC/84530/2010), it is concluded that no authorised Cannabis-derived medicinal products (single-ingredient) are available on the EU market.

Overall, based on the comprehensive literature search conducted and the available data received, including information on Cannabis-derived medicinal products on the market in the EU, a scientific

[1] Compilation of terms and definitions for Cannabis-derived medicinal products
[2] HMPC meeting report on European Union herbal monographs, guidelines and other activities
[3] Call for scientific data for use in HMPC assessment work on *Cannabis sativa* L., flos (Cannabis sativa flowering tops)

assessment is not considered possible to carry out within the legal mandate of HMPC, according to the requirements laid down in Directive 2001/83/EC and its Annex I, in particular in Article 1, Article 10a, Chapter 2a.

Thus, an EU herbal monograph on *Cannabis sativa* L., flos as a single herbal preparation cannot be established based on the data received by the HMPC as part of the call for data procedure and given the relevant regulatory requirements thereof were not met.

The HMPC concluded that the following requirements for the establishment of a European Union herbal monograph on traditional and/or well-established herbal medicinal products containing *Cannabis sativa* L., flos are not fulfilled:

- the requirement laid down in Article 10a of Directive 2001/83/EC that the active substance has a recognised efficacy and an acceptable level of safety and that the period of well-established medicinal use has elapsed;

- the requirement laid down in Article 16a(1)(a) of Directive 2001/83/EC that the indications are "exclusively appropriate to traditional herbal medicinal products which, by virtue of their composition and purpose, are intended and designed for use without the supervision of a medical practitioner for diagnostic purposes or for prescription or monitoring of treatment";

- the requirement laid down in Article 16a(1)(b) of Directive 2001/83/EC that the herbal substance or herbal preparation is "exclusively for administration in accordance with a specified strength and posology";

- the requirement laid down in Article 16a(1)(d) of Directive 2001/83/EC that "the period of traditional use as laid down on Article 16c(1)(c) has elapsed";

- the requirement laid down in Article 16a(1)(e) of Directive 2001/83/EC that "the data on the traditional use of the medicinal product are sufficient; in particular the product proves not to be harmful in the specified conditions of use and the pharmacological effects or efficacy of the medicinal product are plausible on the basis of long-standing use and experience".

CONCLUSIONS

Considering all the above, the HMPC is of the opinion that it is not possible to establish a European Union herbal monograph on *Cannabis sativa* L., flos, at present. In summary, no conclusions can be drawn due to the absence of medicinal products with single herbal preparations from *Cannabis sativa* L., flos on the EU market. For the aforementioned reasons, the HMPC discontinues the assessment procedure. This document reflects only the conclusions of the HMPC and is without prejudice to the possibility of applications for marketing authorisation for Cannabis-derived medicinal products, e.g. in a stand-alone or mixed application (Article 8(3) of Directive 2001/83/EC).

The following link provides access to more information on *Cannabis sativa* L., flos.
https://www.ema.europa.eu/en/medicines/herbal/cannabis-flos