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Committee on Herbal Medicinal Products (HMPC)

Public statement on *Centella asiatica* (L.) Urban, herba

Final

This document was valid from 25 November 2010 until March 2022. It is now superseded by a new version adopted by the HMPC on 30 March 2022 and published on the EMA website.

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Problem statement

The HMPC/MLWP decided to prepare a Community herbal monograph on *Centella asiatica* (L.) Urban, herba according to the MLWP 2009 work programme. Starting the assessment on products containing *Centella* preparations available on the market, a major issue related to the level of purification[1] of extracts in these products has been identified as described below.

Medicinal products containing *Centella asiatica* (L.) Urban refined extracts are authorised and have been marketed in Europe in several Members States: Belgium, France, Greece, Italy, Portugal and Spain and the time elapsed since the first marketing authorisation is longer than 30 years.

Literature reports studies on the following extracts: TECA (titrated extract of *Centella asiatica*), TTFCA (total triterpenoid fraction of *Centella asiatica*) and TTF (Total Triterpenic Fraction) and, where the name of the commercial extract is mentioned, Madecassol® (titrated extract of *Centella asiatica*) or Centellase® (total triterpenoid fraction of *Centella asiatica*).

Information coming from literature and licensed medicinal products confirms that all the above mentioned TECA, TTFCA, TTF as well as ETCA and CATTF are different acronyms to designate the same extract, commercially known as Madecassol® or Centellase® or Blastoestimulina®, containing 40% of asiaticoside and 60% of asiatic acid and madecassic acid.

TECA is a highly purified extract, fractioned and enriched in triterpenic acid and triterpenic sugar ester fractions to reach about 40% of asiaticoside and about 60% of the triterpenic genins: asiatic acid and madecassic acid. The purification steps are extreme and involve chemical treatments that remove the herbal matrix so that the final extract is a recombination of a highly refined extract with an isolated constituent and the natural proportion of the components is not maintained.

The medicinal use of TECA for a period of 30 years has been established on the basis of published literature and decisions taken by National Competent Authorities to grant marketing authorisations.

Other products containing preparations from *Centella asiatica* are also available in several EU Countries with medicinal claims related to microcirculation and tissue draining. The traditional use of some of these *Centella asiatica* preparations may date back to more than the 30 years required by Directive 2004/24/EC.

Conclusions

Based on the information on manufacturing process, the HMPC is of the opinion that TECA extract cannot be classified as a herbal preparation due to the manufacturing steps and composition.

Therefore, despite the existing data on the safety and efficacy and the historical use within the Community of products containing TECA extract, it is not possible to propose any monograph for *Centella asiatica* preparations at this stage, because all the data do not refer to a herbal preparation.

Although some data are available on other herbal preparations, these data were not found sufficient and consistent according to requirements of Article 16a(1) of Directive 2001/83/EC. Should such information be provided, a monograph could be prepared.

1 HMPC 'Reflection paper on level of purification of extracts to be considered as herbal preparations' (EMA/HMPC/186645/2008) http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2011/01/WC500100375.pdf

To read more about the data situation for Centella, a link to the page where access to the assessment report is provided.

Link:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/herbal/medicines/herbal_med_000046.jsp&murl=menus/medicines/medicines.jsp&mid=WC0b01ac058001fa1d