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**COMMITTEE ON HERBAL MEDICINAL PRODUCTS
(HMPC)**

DRAFT

PUBLIC STATEMENT ON *CENTELLA ASIATICA* (L.) URBAN, HERBA

DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	May 2009 July 2009 September 2009
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REDISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	
ADOPTION BY HMPC	

Comments should be provided using this [template](#) to hmpc.secretariat@emea.europa.eu
Fax: +44 20 75 23 70 51

KEYWORDS	Herbal medicinal products; HMPC; Community herbal monographs; well-established use; traditional use; <i>Centella asiatica</i> (L.) Urban; <i>Centella asiatica</i> herba; <i>Hydrocotyle asiatica</i> L., herba; Gotu kola; TECA (titrated extract of <i>Centella asiatica</i>); TTFCA (total triterpenoid fraction of <i>Centella asiatica</i>); TTF (total triterpenic fraction); CATTF (<i>Centella asiatica</i> total triterpenic fraction); ETCA (Estratto Titolato di <i>Centella asiatica</i>)
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PUBLIC STATEMENT ON *CENTELLA ASIATICA* (L.) URBAN, HERBA

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 purification¹ 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 CATTFF are different acronyms to designate the same extract, commercially known as Madecassol® or Centellase® or Blastostimulina®, containing 40% of asiaticoside and 60% of asiatic acid and madecassic acid.

TECA is a highly purified extract, fractionated and enriched in triterpenic acid and triterpenic sugar ester fractions to reach about the 40% of asiaticoside and about the 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 the microcirculation and the 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 an 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.

No information about the type of preparations and extent of use of unlicensed products is available. Should such information be provided, a monograph could be prepared.

¹ HMPC Draft 'Reflection paper on level of purification of extracts to be considered as herbal preparations' (EMA/HMPC/186645/2008)

<http://www.emea.europa.eu/htms/human/humanguidelines/quality.htm#herbal>