EMA assessment reports and conclusions

In this guide

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This is a paper for discussion. This does not represent the views of the Committee and should not be cited.

15. The EMA has published detailed assessment reports on three medicinally used species: E. purpurea (L.) Moench. (EMA, 2014), E. angustifolia DC, radix (EMA, 2012) and E. pallida (Nutt.) Nutt., radix (EMA, 2018). PubMed and Toxline were searched for E. purpurea and E. pallida, whilst the search strategy for E. angustifolia is not specified. There were 1,325 references identified for E. purpurea, screened manually and the relevant ones were included in the assessment report (EMA, 2014). For E. pallida there was a total of 54 references identified and all were included in the assessment report (EMA, 2018).

16. Tests on reproductive toxicity, genotoxicity and carcinogenicity had not been performed for preparations of E. pallida (EMA, 2018) or E. angustifolia (EMA, 2012) at the time the EMA reports were written. In the absence of these data, the use of these species in pregnancy and lactation was not recommended by EMA. Due to the lack of genotoxicity data, the EMA did not recommend the addition of E. pallida (EMA, 2018) and E. angustifolia (EMA, 2012) to the Community list of herbal substances, herbal preparations and combinations thereof for traditional medicinal products. There was also insufficient clinical data to support the criteria for well-established medicinal use of E. angustifolia and E. pallida roots, in accordance with Directive 2001/83/EC. The traditional use of E. angustifolia and E. pallida root extracts for the relief of common cold symptoms was deemed as acceptably safe due to longstanding history of use without reports of serious adverse effects.

17. *E. purpurea* is on the Community list of herbal substances, herbal preparations and combinations thereof for traditional medicinal products based on traditional topical use for the treatment of small superficial wounds (HMPC, 2007). The benefit-risk assessment, conducted by EMA, concluded that there was sufficient clinical evidence to support the well-established medicinal use, in accordance with Directive 2001/83/EC, of expressed juice preparations from *E. purpurea* fresh herb for the short-term prevention (maximum 10 days) and treatment of common cold in adults and children over the age of 12 (EMA, 2014).

18. No genotoxic or mutagenic effects have been observed in bacterial reverse mutation tests, human lymphocyte assay and micronucleus assay with lyophilised *E. purpurea* (EMA, 2014). There was limited epidemiological data suggesting no adverse effects associated with oral *E. purpurea* use and pregnancy outcomes (EMA, 2014). However, EMA did not recommend its use (both topical and oral) during pregnancy and lactation due to the lack of guideline conforming preclinical data on reproductive and developmental toxicity.