

Existing authorisations for Echinacea products in the UK

In this guide

[In this guide](#)

1. [The potential health effects of Echinacea in the maternal diet - Introduction and Background](#)
2. [Existing authorisations for Echinacea products in the UK](#)
3. [EMA assessment reports and conclusions](#)
4. [Health-based guidance values \(HBGV\)](#)
5. [Mechanism of action](#)
6. [Drug-herb interaction potential: effects on cytochrome P450 and P-glycoprotein](#)
7. [The potential health effects of Echinacea in the maternal diet -Toxicity Studies](#)
8. [Contaminants](#)
9. [The potential health effects of Echinacea in the maternal diet - Exposure Assessment](#)
10. [The potential health effects of Echinacea in the maternal diet - Risk Characterization](#)
11. [The potential health effects of Echinacea in the maternal diet - Conclusions](#)
12. [The potential health effects of Echinacea in the maternal diet - List of Abbreviations](#)
13. [The potential health effects of Echinacea in the maternal diet - References](#)
14. [TOX/2024/45 Annex A](#)
15. [TOX/2024/45 Annex B](#)

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

12. Herbal products containing *E. purpurea* (L.) Moench. (EMA 2014), *E. angustifolia* DC, radix (EMA 2012) and *E. pallida* (Nutt.) Nutt., radix have herbal medicinal licences in EU/EEA member states. In the UK, there are a range of *Echinacea* products holding a Traditional Herbal Registration (THR) from the MHRA under the THR scheme (for the list of products see Table 10 Annex B). These products have been approved for the relief of the common cold symptoms and influenza type infections, symptomatic relief of minor skin conditions such as spots, pimples, and blemishes and relief of minor urinary complaints associated with cystitis in women based on traditional use only in adults and children over 12 years for maximum duration of 10 days. None of these products are recommended for pregnant or lactating women. Although *Echinacea* dietary supplements are the focus of this paper, the products holding a THR are worth noting for reference to doses and preparations (for further information on doses and preparations of THR *Echinacea* products and EMA monographs please see Table 11 Annex B).

13. For a product to be granted a THR, it should meet the required standards relating to its 'quality, safety, evidence of traditional use and other criteria as set out in the Human Medicines Regulations 2012 (HMR, 2012)'. The evidence of traditional use relates to the product having been in traditional medicinal use for a continuous period of at least 30 years, of which at least 15 years must be within the European Union (Part 7 HMR, 2012). The safety requirements are a bibliographic review of safety data together with an expert report on safety (Schedule 12, HMR, 2012).

14. The MHRA confirmed in recent correspondence with the FSA that *Echinacea* products with THR are not recommended for use in pregnancy or lactation due to insufficient data available rather than any evidence of adverse effects. MHRA also stated that since there is no established threshold below which side effects are not expected to occur, they would expect any herbal product being marketed as a food supplement to carry the same warnings and precautions on the labelling as stated in the leaflet accompanying THR products. The MHRA have also stated that they don't actively monitor the market for products which should have a THR but are sold without one. Therefore, it is possible that there are *Echinacea* products on the market sold as food supplements but would be regarded as medicinal products and require a THR.