Introduction and Background

In this guide

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

Introduction

1. The Scientific Advisory Committee on Nutrition (SACN) last considered the maternal diet and nutrition in relation to offspring health in its reports on ‘The influence of maternal, foetal and child nutrition on the development of chronic

disease in later life' (SACN, 2011) and on 'Feeding in the first year of life' (SACN, 2018). In the latter report, the impact of breastfeeding on maternal health was also considered. In 2019, SACN agreed to conduct a risk assessment on nutrition and maternal health, focusing on maternal outcomes during pregnancy, childbirth and up to 24 months after delivery. Further information on the scope of the maternal health projects can be found in the Scope of the Nutrition and Maternal health project Annex.

2. SACN agreed that, where appropriate, other expert committees would be consulted and asked to complete relevant risk assessments. A provisional list of chemicals was proposed by SACN Members. However, this was subject to change following discussion by the COT. A scoping paper was presented to the Committee (TOX/2020/45) to define the scope of the work from a toxicological safety perspective and request their input on the selection of candidate chemicals or chemical classes that could be added or removed.

3. As part of this work, the Committee decided it would be useful to consider the use of dietary supplements during pregnancy. A scoping paper (TOX/2020/51) was presented, reviewing the dietary supplements commonly used during pregnancy. These supplements are not officially recommended by relevant health and regulatory authorities but are promoted by anecdotal evidence and unofficial sources as having various purported benefits.

4. The review, presented in the scoping paper, was confined to herbal dietary supplements which would be regulated under food law, as opposed to traditional herbal medicines, which are overseen by the Medicines and Healthcare Products Regulatory Agency (MHRA). Following this review, the COT suggested that *Echinacea* required further investigation, noting that both human and animal *in vitro* and **in vivo** data were available. The main areas of concern included general toxicity to the mother, effects on the development of the foetus or embryo and possible interactions with drugs.

5. Based on the COT's recommendations, a more extensive literature search was undertaken to evaluate the safety of Echinacea use during pregnancy, and the results are presented below (for full details of the search method, see Appendix A).

Background

Uses

6. *Echinacea* is a genus of herbaceous flowering plants, comprised of ten species and originally native to North America (Ahmadi et al., 2024). Three *Echinacea* species (*Echinacea purpurea, Echinacea pallida, and Echinacea angustifolia*) are used medicinally for the prevention and treatment of the common cold, influenza, and upper respiratory tract infections (Ardjomand-Woelkart and Bauer, 2015). *E. purpurea* is the most widely used and extensively studied of the three. Prior to 1968, *Echinacea angustifolia* and *Echinacea pallida* were considered to be different varieties of the same species until a revision of the genus described them as two separate species (WHO, 1999).

7. *Echinacea* herbal products are often sold as dietary supplements to enhance the immune function and to reduce the symptoms and duration of common cold and upper respiratory tract infections. These are popular products in North America and Europe, generating more than 300 million USD annually in the U.S. alone (Ahmadi et al., 2024).

8. *Echinacea* extracts are used for a broad range of ailments including respiratory infections (colds and flu, bronchitis, strep throat, toothache), urinary tract infections, skin disorders (Staphylococcus infections, cold sores, ulcers, wounds, burns, insect bites, eczema, allergies) and rheumatoid arthritis (Hudson, 2012). Between 0.5% (Heitmann et al., 2016) and 9.2% (Cuzzolin et al., 2010) of pregnant women report using *Echinacea* during pregnancy for the treatment of cold and flu, stimulating the immune system and the prevention of common cold (Cuzzolin et al., 2010; Holst et al., 2011).

Constituents and preparations

9. The fresh or dried aerial parts and the fresh pressed juice from the flowering tops of *E. purpurea*, as well as the whole plant, and the dried roots of *E. purpurea*, *E. pallida* and *E. angustifolia* are used medicinally. Different methods of extraction are used for preparing the *Echinacea* products and the final products can contain powdered plant parts, dry and liquid extracts, pressed and dried pressed juice (Barnes et al., 2010).

10. The composition of bioactive compounds varies across the three medicinally used species and their respective plant parts. It is generally considered that there is no single chemical or a clearly defined group of chemicals responsible for the activity of Echinacea. The combined effects of several groups of bioactive compounds, including alkylamides, caffeic acid derivatives, echinacoside, cichoric acid, cynarin, flavonoids, polysaccharides and alkenes, all contribute to the biological activity of Echinacea (Barnes et al., 2010).

There is also no consensus of which of the chemical constituent(s) should serve as a standardisation marker for Echinacea preprations.