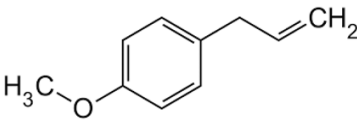
Estragole

HMPC PUBLIC STATEMENT: CHALLENGE POSED BY MEDICINAL PRODUCTS CONTAINING ESTRAGOLE



Background

Estragole is a component of numerous plants used in medicinal products. In March 2022, the HMPC published its updated public statement on herbal medicinal products (HMPs) containing estragole. Based on the evidence of genotoxic carcinogenicity, the HMPC recommends that the exposure to estragole from HMPs should be kept as low as practically achievable. The HMPC recommends a guidance value of 0.05 mg/day for adults with doses for children reduced accordingly.

Strategic evaluation

Application of the public statement in regulatory practice by the regulatory authorities not only has far-reaching consequences for the existing market of approved and registered phytopharmaceuticals, but also for chemically defined drugs with estragole-containing excipients (e.g., essential oils of fennel, anise, star anise). Following a toxicological evaluation based on the specified or empirically determined content of estragole in a medicinal product, it will be necessary to change formulations in many cases, including adaptation of analytical methods, acquisition of new stability data and implementation in the regulatory dossier.

Analysis and stability testing

PhytoLab has highly sensitive methods (GC-MS) at its disposal, which are capable of analysing even minute amounts of estragole in a finished drug product. As estragole can also be carried over into extracts and tea infusions, the analysis of such preparations constitutes an important building block in a data-based safety assessment of your medicinal products. PhytoLab combines analytical expertise with ICH stability testing competence in a package that offers you an optimized solution for the granting and maintenance of marketing authorizations.

Need for action

The EMA CMDh is demanding implementation of appropriate measures for all medicinal products containing estragole within 2 years.

We provide comprehensive advice on strategic, regulatory, analytical and toxicological issues. Talk to us:

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