

## **PL6. The regulatory framework for the quality and safe use of essential oils as herbal medicinal products. Selected examples from our Balkan “Neighbourhood”**

*Ioanna Chinou*<sup>1\*</sup>

*Keywords:* essential oils, regulatory, quality, safety, EU

All over the world medicinal plants and essential oils have been used therapeutically for centuries, and there are many conducted scientific studies that describe their remarkable healing properties. It is well known, that the chemistry of essential oils is influenced by the local geography, weather conditions, season and time of harvest, processing, packaging and storing conditions. The essential oils can be used mainly to be applied to the skin; to be inhaled; gargled and ingested, as well as bath additives. The methods of their administration result in absorption through the skin or oromucosa, and by inhalation.

The European Union has considered the medicinal use of essential oils as herbal products mainly through the Traditional Herbal Medicinal Products Directive (Directive 2004/24EC amending Directive 2001/83/EC as regards THMPs). The Herbal Medicinal Products Committee (HMPC) at the European Medicines Agency (EMA, London) has drafted and adopted guidelines which are intended to support assessment of THMPs considering their particular characteristics, while HMPC has established community monographs of herbal substances, and currently, about 13 monographs on essential oils (fennel, anise, peppermint, thyme, rosemary, lavender etc.), have been finalised and are available on EMA’s website. In these monographs, the accepted quality, as well as the finally adopted indications among EU countries, together with potential risks, adverse reactions and contraindications in their uses, are presented, based in their longstanding medicinal uses and European experience. A viewpoint of the regulatory Authorities Experience in EU will be discussed, in detail, through Selected Examples mainly coming from our Balkan “Neighbourhood” (essential oils and other aromatic plants from the Balkan Peninsula).

---

<sup>1</sup>Lab of Pharmacognosy and Chemistry of Natural Products, Faculty of Pharmacy, National and Kapodistrian University of Athens, University Campus of Zografou, 15771 Athens, Greece, Chair of the Monographs and List Working party of HMPC at European Medicines Agency (EMA).

\*Corresponding author: [ichinou@pharm.uoa.gr](mailto:ichinou@pharm.uoa.gr)