**The regulation of homeopathic and anthroposophic medicines in the EU**

Appropriate legislation and a regulatory framework that allow for a harmonised environment in the EU are essential to ensure Europe-wide availability of homeopathic and anthroposophic medicinal products which meet the highest standards of quality, safety and effectiveness.

Homeopathic and anthroposophic medicinal products are both part of a long-standing European tradition. The thousands of medicinal products used in homeopathy and anthroposophic medicine have been safely on the market in Europe for many decades. They have traditionally been regulated in several EU Member States since the 1970s, including Austria, France, Germany and the United Kingdom, allowing for a wide selection of these products to be available to prescribers and patients.

Since 1992, European legislation has been trying to create a common regulatory base in this field. However, we are still far from common legal provisions for homeopathic and anthroposophic medicines with therapeutic indications. Although more than twenty years since its adoption, the implementation and enforcement of European medicines legislation for this sector is far from complete. Divergent legal and regulatory approaches in the EU Member States mean that European citizens are confronted with differing products and varying availability in the 27 countries.

The regulatory burden means that it is not sustainable for companies to maintain registrations for the large range of substances and multiple finished medicinal products required for proper practice of these therapies. The regulatory environment, including assessment capacity and policy at national level, is not proportionate.

The current EU legal and regulatory framework means that citizens and prescribers are slowly being denied access to the medicines of their choice. Availability is threatened in some Member States by the lack of a workable registration process, and in others by an incomplete process for the renewal of existing registrations. It is often the case there is no functioning environment to meet the demand for products for self-medication.

Anthroposophic medicinal products which are homeopathically prepared in accordance with an official pharmacopoeia (the European Pharmacopoeia, the German Homeopathic Pharmacopoeia or the French Pharmacopoeia) are treated in the same way as homeopathic medicinal products. While some markets, in particular Austria, Denmark, Finland, Germany, Italy, Sweden, Switzerland, and United Kingdom, recognise some products, a considerable proportion of the range of anthroposophic medicinal products are unable to meet the general authorisation requirements prescribed by European legislation; in many Member States this leads to significant difficulties for manufacturers, prescribers and patients. There is no European regulatory framework for non-homeopathically prepared anthroposophic medicinal products.