The Importance of Injectables as used in Homeopathic and Anthroposophic Medicine

Background

Homeopathic and anthroposophic medicines for parenteral[1] administration are prescribed by large numbers of doctors and play an important role in the European homeopathic and anthroposophic tradition. Their track record of effectiveness and safety should be sufficient to ensure their future availability to practitioners and patients.

However, European legislation puts the future of injectables at risk, by seeking to regulate them differently to the majority of homeopathic and anthroposophic medicines. This puts a disproportionate burden on the manufacturers of these products that makes it unlikely they will be able to continue to supply these to their customers.

Therapeutic relevance

Homeopathic and anthroposophic literature documents the use of injectables for over 100 years. Today there are more than 90 million homeopathic/anthroposophic ampoules sold each year, prescribed by doctors for subcutaneous[2] or other parenteral administration. International medical umbrella organisations confirm the need of their members to continue to prescribe these products.

A recent study[3] of 1693 doctors experienced in the use of homeopathic/anthroposophic injectables showed that 94.2% chose subcutaneous administration because of its therapeutic effect. 99.5% desired these products to stay on the market and 89% would be severely or very severely limited in their profession if they were not available.

Safety

Pharmacovigilance data and therapeutic experience demonstrate the safety of the subcutaneous application of homeopathic/anthroposophic injectables whose low risk profile is similar to that of the oral route of administration of homeopathic/anthroposophic medicinal products.

The number of adverse reactions reported to three leading manufacturers[4] within a period of 10 years is lower than 1:5,000,000, which means less than one adverse reaction per 5 million subcutaneously applied single dosages. The reported adverse reactions were mostly harmless (about 98% concerned local redness, hematoma (bruising) or local pain).

A very small number of serious adverse reactions (anaphylactic reaction, feverish symptoms, aversion/anxiety against injections, and asthma) have been reported with products whose final concentration of the active ingredient/s was lower than 1:10,000.

---

[1] when the substance is given by routes other than the digestive tract, either by injection or infusion
[2] under the skin
[3] The Journal of Alternative and Complementary Medicine, Safety of Homeopathic Injectables for Subcutaneous Administration: A Documentation of the Experience of Prescribing Practitioners, Aug 2005, Vol. 11, No. 4 : 609 -616
[4] Homeopathic Injectables – Importance of the parenteral administration of homeopathic and anthroposophic remedies - Risks and Benefits; Dr Wilfrid Stock, Published by ECHAMP

office@echamp.be – www.echamp.org

Manufacturing
Homeopathic and anthroposophic injectables are sterile medicinal products, manufactured in accordance with current Pharmaocopoeia standards and Good Manufacturing Practice. These guarantee the quality and thus contribute to the safety of these medicinal products.

Regulatory
In accordance with Directive 2001/83 EC, homeopathic medicinal products can be registered under the 'simplified' registration procedure laid down in Articles 14 and 15. However EU regulations restrict European simplified registration to oral and external dosage forms of homeopathic medicinal products in a 'sufficient degree of dilution' and so without any justifiable reason, homeopathic medicinal products for subcutaneous use are required to undergo the procedure for marketing authorisation according to Article 16, even if they are on the market with a dilution higher than 1:10,000 and without indications.

Homeopathic and anthroposophic prescription is highly individualised and the industry produces a vast number of different medicinal products in very small batches to fulfil the needs of patients, making production relatively expensive and non economic. The cost of acquiring a marketing authorisation for all the medicinal products for subcutaneous use needed in homeopathy and anthroposophic medicine would be prohibitive.

ECHAMP Position
ECHAMP supports the need for Good Manufacturing Practice and all relevant quality assurance and control standards for all medicinal products. Its members apply these standards without question at their sterile production units, regardless of batch size or turnover.

For prescribers and patients in the EU however, it is necessary that homeopathic and anthroposophic injections for subcutaneous administration remain available. Only if the less costly homeopathic simplified registration procedure is applied to these products, can the homeopathic and anthroposophic industry afford to keep them on the market, ensuring their availability for prescribers and their patients.

For further information please see ECHAMP Position Paper 2003/02 'Injectables for Subcutaneous Administration as used in Homeopathic and Anthroposophic Medicine'.

office@echamp.be – www.echamp.org