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## Homoeopathy

### **Moderators: Dr Harald G. Schweim, Germany, and Ms Yupin Lawanprasert, Thailand**

Many drug regulatory authorities have little knowledge about homoeopathic principles, and are unsure how to evaluate the safety of these highly diluted products, how to carry out meaningful stability testing, or how to assess new homoeopathic products. Recent reports of adverse effects of homoeopathic treatment have raised concerns about how to ensure safety. The objectives of this session were to allow DRAs to exchange their knowledge and experience of regulation of homoeopathic medicines, discuss how to ensure quality control of the highly diluted products, and consider how to educate consumers in their proper use.

### **Registration criteria for homoeopathic medicinal products in the United Arab Emirates**

#### **Dr Sassan Behjat, United Arab Emirates**

An increasing demand for homoeopathic treatment by the people of the United Arab Emirates (UAE) and a strong political will for regulation of complementary medicines have led to the establishment of a registration system for homoeopathic medicinal products under the Office of Complementary and Alternative Medicines of the Ministry of Health.

The objectives are to make available homoeopathic medicines within a legal framework that ensures consumer protection by guaranteeing that homoeopathic medicines imported into the UAE are of high quality, and that, for homoeopathic medicines sold directly to the public, adequate information is provided to allow informed decisions and to ensure safety of consumers.

Assessment is based on the safety and quality of the homoeopathic products. Manufacturers must be licensed and conform to GMP. Manufacturing processes should be in accordance with one of the internationally recognized pharmacopoeias. Restrictions are placed on advertisements, labelling and the dosage forms of the products. At the same time, homoeopathic practitioners are regulated and homoeopathic products can only be prescribed by licensed practitioners.

Continuing education of practitioners and pharmacists, and awareness programmes for the public, are of key importance.

### **The regulatory framework for homoeopathic medicinal products in Germany and in the European Union** **Dr Konstantin Keller, Germany**

Homoeopathy was founded in Germany by Dr Samuel Christian Hahnemann in 1796. It forms a substantial part of the health care system in Germany. Homoeopathic products are used in all member states of the European Union (EU), with Germany, France, Belgium and Austria accounting for 90% of the total estimated market of about US\$ 230 million.

Homoeopathic products fall into the WHO definition of traditional medicine. Homoeopathy is fully integrated into the European pharmaceutical legislation. Under Council Directive 2001/83/EEC, homoeopathic products without any therapeutic claims may be registered through a simplified marketing authorization, whereas a full marketing authorization is required for those with indication claims.

Registration requirements include compliance with GMP and pharmacopoeias, evidence of homoeopathic tradition, mandatory labelling of the homoeopathic nature, and restrictions on the degree of dilution and dosage forms. Additional toxicological data or bibliographical data on the traditional use of the homoeopathic products may be required for full marketing authorization. Nonetheless, the directive allows member states to implement specific rules to address the national tradition and the particularities of homoeopathy for medicinal products with indication claims.

The European Pharmacopoeia is an important tool in the area of quality. It sets out clear definitions and monographs for homoeopathic preparations and the manufacturing procedures. The variety of starting materials of botanical, zoological, chemical and microbial origin warrants adequate assessment of safety, especially viral contamination. The safety of homoeopathic products is often overlooked, since they are perceived as being always highly diluted. However, this is not necessarily true and homoeopathic products may contain toxic substances in considerable quantities.

## **Regulation of homoeopathic products in the United Kingdom**

### **Dr Ian Hudson, United Kingdom**

Homoeopathic products are commonly used in the United Kingdom. About 20% of the UK population have used homoeopathic products and the sales are reported to be about £25 million per year.

Registration of homoeopathic products in the UK dates back to 1971 when the Medicines Act was first implemented. Existing homoeopathic products were issued with Product Licences of Right. They are subject to labelling and advertising restrictions and are constantly reviewed for conformity with current safety and quality standards.

In 1994, the Special Simplified Registration Scheme was implemented, which avoids considerations of efficacy. Restrictions are placed on the route of administration, degree of dilution, therapeutic claims and the use of trade names. Assessment is based on issues of quality, safety and labelling. If expert opinions are necessary, an application will be referred to the Advisory Board on the Registration of Homoeopathic Products.

Recent challenges in the regulation of homoeopathic products include pressure from consumers for more information on their use. In addition, debates have been stirred up on how to deal with products not previously used in traditional UK homoeopathy, and on the problems in quality and safety evaluations owing to the high dilution.

One future goal is the establishment of specific national rules in the UK for those homoeopathic products not eligible for the simplified scheme. More collaboration and harmonization within member states of the EU are also necessary.

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## Recommendations

1. In collaboration with Member States, WHO should harmonize definitions of homoeopathic products and practices in order to allow classification and identification of homoeopathic products at national level.
2. WHO should cooperate with governmental institutions to establish recommendations for safe degrees of dilutions of homoeopathic preparations.
3. In collaboration with Member States, WHO should promote the exchange of information. A reference list of information resources on homoeopathic medicines, including official pharmacopoeias should be made available. WHO should develop systems to collect and provide information to consumers on the safe use of homoeopathic medicines.
4. WHO should provide guidance to governments and NGOs for training of homoeopathic medicine providers.
5. Progress should be reported back to the ICDRA.