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Report of WHO Workshop on Regulation of Herbal Medicines in the European Region

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Contents

Introduction

The results from the WHO Traditional Medicine team (TRM) Global Survey on National Policy on Traditional/Complementary/Alternative Medicine and Regulation of Herbal Medicines show that the European herbal medicines market in developed countries, such as Switzerland, as well as in transitional countries, such as the Czech Republic, Turkmenistan and Bulgaria has nearly doubled in sales from 1999 to 2001. With growing demand for herbal medicines, the Newly Independent States (NIS) and countries in Central and Eastern Europe (CCEE) are striving to develop and incorporate national policies and programs for the regulation of herbal medicines where such policies are lacking or are in their initial stages.

Currently, with the growing demand for traditional medicine, Europe represents the single largest commercial market for medicinal plants and herbal medicines in the world. European countries are not just importers, they also have a large number of producers of medicinal plants and herbal medicines. European consumers often look to herbal medicines as a form of alternative treatment to conventional medicines. In addition, as many patients in Eastern Europe pay for health care themselves, the difficult economic conditions mean that they are often unable to afford the more expensive conventional medicines, leading them to seek alternative medicines, such as herbal products. European Union countries already have well-established national policies and programs to regulate and monitor herbal medicines. However, NIS and CCEE regions are in the process of developing and implementing such policies and programs, and are looking for specific guidance and experience in this area.

The results from the WHO-TRM Global Survey on National Policy on Traditional/Complementary/Alternative Medicine and Regulation of Herbal Medicines also showed that the challenges faced by the Eastern European countries relate primarily to their lack of research data and of education and training for national experts. Many countries lack a national policy and system of regulation of traditional and complementary medicine; and, if such a policy exists, it often excludes herbal medicines, which are instead grouped under conventional medicines. As herbal medicines are more complicated than conventional medicines, because they often contain more than one component, national drug authorities lack the knowledge and technical expertise to evaluate the safety, efficacy and quality of herbal products. In many countries in the NIS and CCEE regions, a safety monitoring system, if it exists, often does not include herbal medicines.

With these issues in mind, a workshop was conducted by WHO to share experiences and exchange ideas on development of regulatory systems and medicinal policies between participants from countries within the EURO region.

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Objectives of the workshop

In order to assist countries in meeting challenges and to identify proper approaches to regulating the safety and quality of herbal medicines discussed above, and to ensure their prudent use, WHO has developed a series of policy and technical documents. The objectives of the current workshop are to:

- Discuss the WHO Strategy for Traditional Medicine and other relevant WHO documents and guidelines for the development of regulatory systems for herbal medicines;
- Analyze the main issues and difficulties and share country experiences as regards the regulatory situation of herbal medicines;
- Discuss the minimum requirements for the regulation and registration of herbal medicine products for the participating countries.