

Recent Publications and Documents

Measures to combat counterfeit drugs

There is no simple or standard solution in dealing with counterfeiting of medicinal products. Each country has to develop a strategy based on its own situation taking into account the infrastructure and availability of resources. Counterfeiting of medicines is a shared problem and solutions must be found by all the concerned parties.

The factors facilitating the occurrence of counterfeit drugs vary from country to country. However, it is known that counterfeiting affects both developed and developing countries alike and that the problem is more pronounced in those countries where medicines are less regulated and enforcement is weak.

Guidelines for the Development of Measures to Combat Counterfeit Drugs have been prepared within the framework of a WHO Joint Project on Counterfeit Drugs which operated between 1995 and 1997. They are the outcome of extensive consultation and have been developed for use by governments, drug regulatory authorities, law enforcement agencies, importers, distributors, professional associations, consumers and the pharmaceutical industry.

The Guidelines focus on specific measures to be undertaken, including investigation of possible counterfeiting operations, effective inspection procedures, test methods for suspected counterfeit products, and development of training programmes.

Guidelines for the Development of Measures to Combat Counterfeit Drugs. Department of Essential Drugs and Other Medicines, World Health Organization, Geneva. WHO/EDM/QSM/99.1

Monographs for medicinal plants

During the past decade, traditional systems of medicine have become more popular and many people in developed countries have begun to turn to alternative or complementary therapies, including the use of medicinal herbs. In developing countries,

a large proportion of the population relies heavily on traditional medicine to meet primary health care needs.

Few plant species have been scientifically evaluated for their medical application, and safety and efficacy data are only available for very few plant extracts and active ingredients. In many countries the market is poorly regulated and few herbal products are registered or controlled. Assurance of the safety, quality and efficacy of medicinal plants and herbal products has now become a key issue.

In order to provide independent authoritative information on the safety and efficacy of medicinal products, WHO has now published the first volume of WHO *Monographs on Selected Medicinal Plants* containing monographs on the quality control and traditional and clinical use of 28 medicinal plants.

Monographs are provided for a number of phyto-medicines traditionally used to treat common complaints such as diarrhoea, constipation, headache, loss of appetite, sleep disorders, fatigue, mild respiratory disorders, and gastrointestinal and skin conditions. Additional medical applications range from the lipid-lowering potential of garlic powder preparations to the possible antiplasmodial activity of *Fructus bruceae*, and the role of curcumin in promoting healing of peptic ulcer and reducing associated abdominal pain.

In preparing and publishing these monographs, WHO aims to encourage standardized approaches to ensuring the safety, quality and efficacy of medicinal plants and their products. The monographs were finalized following review by over 100 experts in 40 countries. Some 1400 references to the literature are included. This book is an impressive and complete collection of information on medicinal plants which will be of interest to a large and varied public.

WHO Monographs on Selected Medicinal Plants. Volume 1. World Health Organization, Geneva. Price Sw.fr. 92.- (Sw.fr. 64.40 developing countries). ISBN 92 4 154517 8

Stability testing of drug substances and drug products

The purpose of stability testing is to provide evidence on how the quality of a drug substance or drug product varies with time under the influence of a variety of environmental factors such as temperature, humidity and light. Stability testing permits the establishment of recommended storage conditions, retest periods, and shelf lives.

Information on the stability of drug substances under defined storage conditions is an integral part of the systematic approach to evaluation. Stress testing helps to determine the intrinsic stability characteristics of a molecule by establishing degradation pathways to identify likely products of degradation and to validate the stability-indicating power of the analytical procedures used.

Draft Guidance for Industry in the Stability Testing of Drug Substances and Drug Products is intended as a comprehensive document to provide information on all aspects of stability data generation and use. It references and incorporates substantial text from selected International Conference on Harmonization (ICH) guidelines. The guidance document is being distributed for comment purposes only at this stage.

Draft Guidance for Industry in the Stability Testing of Drug Substances and Drug Products. Office of Communication, Center for Drug Evaluation and Research, Food and Drug Administration, MD 20852-1448, USA. <http://www.fda.gov/cber/guidelines.htm>