

# Recent Publications and Documents

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## International travel and health

The 1998 revised edition of *International travel and health: vaccination requirements and health advice* has now been issued and contains vital information on medical and personal health precautions needed for international travellers. The guide contains a country-by-country listing of vaccination requirements.

In view of the deteriorating malaria situation, relevant information is included for prophylaxis and treatment, including a recommended chemoprophylactic regimen for each malarious area. A section on multidrug-resistant malaria is also included.

Other sections of the guide provide information on health hazards commonly encountered in different parts of the world, such as risks posed by contaminated food and water, or diseases spread by insect bites.

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*International Travel and Health. Vaccination Requirements and Health Advice. Available from: World Health Organization, Geneva, Switzerland. ISBN 92 4 158023 2 Price: Sw.fr. 17 (Sw.fr. 11.90 in developing countries).*

## Guidance on the clinical investigation of medicinal products for treatment of schizophrenia

The Committee for Proprietary Medicinal Products (CPMP) of the European Union has approved a guidance document for the evaluation of drugs in the treatment of schizophrenia which comes into force in August 1998.

Although the guideline focuses mainly on antipsychotic products developed specifically for schizophrenia, comments are also made on related psychotic syndromes. In the past, products that demonstrated efficacy in schizophrenia were generally called neuroleptics. However, these products have also traditionally been used to treat psychotic symptoms such as those manifested in delusion disorder or substance-related disorder.

Antipsychotic agents have generally been used in three ways: in the acute phase to treat positive symptomatology, as maintenance therapy to control symptoms, and as long-term prophylactic treatment to prevent relapses or recurrence.

Initially, the effect of antipsychotic agents on positive symptoms in schizophrenic patients was attributed to the anti-dopamine effect of these compounds. Recently, so-called atypical antipsychotic agents have been developed which have shown, in vitro, more affinity for serotonergic receptors, though they also have an affinity for dopamine receptors.

The guideline also covers investigations concerning, use of placebo, potential negative symptoms, methods to assess efficacy, selection of patients, strategy, and safety aspects.

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*European Agency for the Evaluation of Medicinal Products. Note for guidance on the clinical investigation of medicinal products in the treatment of schizophrenia. CPMP/EWP/559/95, 1998.*

## Draft guidance for industry: container and closure integrity testing

The Food and Drug Administration has announced the availability of draft guidance for industry: *Container and closure integrity testing in lieu of sterility testing as a component of the stability protocol for sterile products.*

All sterile products are required to have adequate container and closure integrity and to remain free from contamination throughout the entire shelf-life. The guidance proposes methods that reliably confirm the integrity of the container and closure system in the final product.

It is intended to offer alternative methods for sterility testing to confirm the integrity of container and closure systems for sterile biological products, human and veterinary drugs, and medical devices. The guidance applies only to the replacement of the

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sterility test with an appropriate container and closure integrity test in the stability protocol. It is not offered as a replacement for the sterility test in product release.

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*Draft Guidance for Industry: Container and Closure Integrity Testing in lieu of Sterility Testing as a Component of the Stability Protocol for Sterile Products. Available from: Food and Drug Administration, Rockville, MD 20857, USA, or: "<http://www.fda.gov/cber/guidelines.htm>".*

## **Regulatory situation of herbal plants**

In many parts of the world, many people rely on medicinal plants and herbal medicines to deal with their health problems, and public interest in natural

therapies is increasing everywhere. Real benefits can be gained by the use of herbal medicines but most still need to be studied scientifically.

The evaluation of the safety and efficacy of these products is an important challenge and WHO has begun to document experience from countries around the world on the registration, regulation and national requirements for herbal medicines. Thus far, 52 countries have provided information, which is set out in a document produced by WHO's Traditional Medicine Unit. The document will be updated as more contributions become available.

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*Regulatory Situation of Herbal Medicines: A worldwide Review. WHO/TRM/98.1. Available from: Traditional Medicine, World Health Organization, Geneva, Switzerland.*