

# Recent Publications and Documents

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## International Travel and Health

This annual guide issues authoritative advice on the medical and personal precautions needed to protect the health of international travellers. Information is provided on general precautions as well as recommended and legally required vaccinations. Extensive information is given on malaria including epidemiological data for endemic areas, geographical and seasonal distribution and the recommended chemoprophylactic regimen for each area.

Other chapters are dedicated to arthropod-borne, food-borne and water-borne diseases and other common health hazards. Advice is offered to travellers on how to protect themselves from the risks of contaminated food and water. Advice is also offered on immunization of HIV-infected travellers and on the risk of tuberculosis transmission during air travel.

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*International Travel and Health; Vaccination Requirements and Health Advice. Available from: Marketing and Dissemination, World Health Organization, 1211 Geneva 27, Switzerland. ISBN 92 4 158025 9 Price: Sw.fr. 17.-*

## WHO Expert Committee on Drug Dependence

The role of the WHO Expert Committee on Drug Dependence is to evaluate selected psychoactive substances and recommend an appropriate level of control under the international conventions on narcotic drugs and psychoactive substances. When making its recommendations, the Committee balances consideration of a drug's therapeutic usefulness against data on its pharmacological and toxicological properties, evidence of its dependence potential and likelihood of abuse, and provides an assessment of the corresponding risk to public health.

The Committee's Thirty-first report sets out the criteria used to review data on psychoactive substances and recommends the level of control in scheduling. In this report, the Committee also provides comments on a proposal to extend inter-

national control to the isomers, esters, ethers and pharmacological analogues of controlled substances in response to the growing problem of clandestine synthesis of psychoactive drugs.

Pre-reviews are presented of six psychoactive substances, including benzodiazepines, to determine the need for critical review. Given WHO's intention to develop an International Framework Convention for tobacco control, a critical review of tobacco was not recommended.

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*WHO Expert Committee on Drug Dependence. Thirty-first report. Technical Report Series No. 687, 1999. Available from: World Health Organization, 1211 Geneva 27, Switzerland. ISBN 92 4 120887 2 Price: Sw.fr. 14.-*

## Correct handling and distribution of propylene glycol

Starting materials used in the manufacture of pharmaceutical products often change hands many times before reaching the end user. Along the distribution, packaging and trade chain there are many opportunities for the starting material to be altered or become unsafe. Propylene glycol of pharmaceutical quality is a high purity product having various applications. Contamination or mislabelling could have serious consequences on the quality of the product and the health of the end user. Intermediate handling should therefore be subject to strict conditions.

The European Chemical Industry Council (CEFIC) has developed safe handling guidelines based on good manufacturing practices. Six major European producers of monopropylene glycol USP/EP (pharmaceutical grade) have jointly committed to enforce compliance with these guidelines in their own facilities and in downstream distribution chains by intensive auditing. CEFIC recommends that these guidelines be adopted as a code of practice by all parties involved in the distribution of propylene glycol (pharmaceutical grade). End users should also consider these guidelines for their own handling and storage purposes and impose them on their own contractors. All suppliers should operate

in compliance with this code of practice with full traceability and transparency as to the origin of materials through a certificate of origin.

The guidelines are available in English, French, German, Spanish and Italian and are posted on the CEFIC website at <http://www.cefig.org>.

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*Guidelines for Handling and Distribution of Propylene Glycol USP/EP. Available from the Propylene Oxide/Propylene Glycols Sector Group of CEFIC, European Chemical Industry Council (CEFIC), Brussels, Belgium.*

## Reporting adverse drug reactions

Compiled at the request of the pharmaceutical industry, this book responds to the urgent need for standard international terminology that is specific to adverse reaction reporting and procedures for post-marketing surveillance. Definitions are set out for over 180 terms commonly used for the reporting of adverse drug reactions to regulatory authorities and drug manufacturers.

The book is intended to facilitate the work of drug regulatory authorities and the drug safety departments of pharmaceutical companies. The terms, definitions and criteria are the result of more than a decade of meetings and consultations involving over 160 experts.

The terms are grouped according to 21 disorders using the standard WHO Adverse Reaction Terminology (WHO-ART). These are also reproduced on a CD-ROM which accompanies the publication.

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*Reporting of Adverse Drug Reactions. Definitions of Terms and Criteria for their Use. Available from: CIOMS, 1211 Geneva 27, Switzerland. ISBN 92 9036 071 2. Price: Sw.fr. 24.50.*

## Preparing core safety information

In 1995, the Council for International Organizations of Medical Sciences (CIOMS) Working Group III report was drafted in response to the need to harmonize core drug safety information. It has been widely endorsed by pharmaceutical manufacturers as a standard for preparation of information for data sheets, package inserts and product labelling.

The complementary *Guidelines for Preparing Core Clinical-Safety Information on Drugs* include recom-

mended safety information for drugs undergoing investigation, development of core safety information to be included in investigator's brochures, and information to support product approval. Relevant information is provided to researchers on the 7-day and 15-day global reporting requirements.

A new and important proposal is set out on the threshold requirements and assessment of risk benefit of a marketed product when a significant new safety signal is identified. The Guidelines conclude with the text of the European Union *Summary of Product Characteristics* and the US Food and Drug Administration *General Requirements on Content and Format of Labelling for Human Prescription Drugs*.

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*Guidelines for Preparing Core Clinical-Safety Information on Drugs, Including New Proposals for Investigators Brochures. Report of CIOMS Working Groups III and V. Available from: CIOMS, 1211 Geneva 27, Switzerland. ISBN 92 9036 070 4 Price: Sw.fr. 15.-*

## Good pharmaceutical procurement

Improper procurement practices lead not only to high prices and poor quality, but can also result in shortages of life-saving drugs. Ideally, the most cost-effective drugs should be bought in appropriate quantities from reputable suppliers at the lowest possible cost. However, procurement can go off track when a number of different agencies are involved, making the process highly complex and vulnerable to inefficiency and waste. Other problems — such as lack of transparency — lead to higher prices and poor quality. Irregular and limited funding can greatly hinder efforts to secure timely delivery.

The Guideline on Operational Principles for Good Pharmaceutical Procurement aims to assist governments, donor agencies and other organizations involved in drug procurement to obtain lower priced, better quality essential drugs and more reliable delivery. The Interagency Pharmaceutical Coordination (IPC) Group which devised the guidelines is made up of pharmaceutical advisers from UNICEF, UNFPA, the World Bank and WHO.

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*Operational Principles for Good Pharmaceutical Procurement. WHO/EDM/PAR/99.5. Available from Department of Essential Drugs and Medicines Policy, World Health Organization, Geneva.*