

(33) World Health Organization Scientific Group (1975)
Guidelines for Evaluation of Drugs for Use in Man
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Preamble

A copy of this report is available online at WHO (<http://apps.who.int/medicinedocs/documents/s22219en/s22219en.pdf>) It is also available in French, Russian, and Spanish. The WHO Technical Reports referred to in the *Aims* above are no. 287 (*Evaluation of dependence-producing drugs*), no. 341 (*Principles for Pre-clinical Testing of Drug Safety* (1966)), no. 364 (*Principles for the testing of drugs for teratogenicity* (1967)), no. 403 (*Principles for the Clinical Evaluation of Drugs* (1968)); see no. (18) above), no. 407 (*WHO Expert Committee on Drug Dependence, sixteenth report*), no. 425 (*International drug monitoring – the role of the hospital* (1969)), no. 426 (*Principles for the testing and evaluation of drugs for carcinogenicity* (1969)), no. 446 (*Clinical pharmacology – scope, organization, training* (1970)), no. 482 (*Evaluation and testing of drugs for mutagenicity – principles and problems* (1971)), no. 498 (*International drug monitoring – the role of national centres* (1972)), no. 524 (*Pharmacogenetics* (1973)), no. 536 (*Bioavailability of drugs – principles and problems* (1974)); and, no. 546 (*Assessment of the carcinogenicity and mutagenicity of chemicals* (1974).

Aims

The introduction of large numbers of new drugs during recent decades has caused concern among the medical profession, research workers in the drug field, and the public in regard to both safety and efficacy. But it was not until the tragic effects of thalidomide in the early 1960s that the procedures employed, which left evaluation of the safety and efficacy of drugs largely in the hands of the drug manufacturers and clinicians, were recognized as inadequate. The manner in which the World Health Organization can contribute to an improvement in drug evaluation has been discussed at various sessions of the governing bodies of WHO. The Seventeenth World Health Assembly (1964) adopted a resolution requesting the Director-General “to undertake, with the assistance of the Advisory Committee on Medical Research, the formulation of generally accepted principles and requirements for the evaluation of the safety and efficacy of drugs”. A number of scientific groups and meetings have been convened in compliance with this request and their reports have been published in the WHO Technical Report Series. The present Group was convened to consider all aspects of the evaluation and testing of drugs in the light of increasing knowledge and to formulate proposals and guidelines for present and future research in this field (Introduction, pages 7 and 8).

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References

Authors

The Chairman of the Scientific Group is Professor DR Laurence (Medical Unit, University College Hospital Medical School and Department of Pharmacology, University College, London, England). The Secretariat from Drug Evaluation and Monitoring (WHO, Geneva, Switzerland) is Dr H Nakajima (Scientist) and Dr BW Royall (Chief Medical Officer). The other members are Professor DL Azarnoff (Clinical Pharmacology Toxicology Center, the University of Kansas Medical Center, Kansas City, USA); Dr RA Chapman (formerly Assistant Deputy Minister, Food and Drug Directorate, Department of National Health and Welfare, Ottawa, Canada); Professor F Coulston (Director, Institute of Comparative and Human Technology, Albany Medical College, Union University, Albany, NY, USA); Professor L Dettle (Medical Clinic, Bürgerspital, Basle, Switzerland); Dr H Frohberg (Director, Institute of Toxicology, E Merck, Darmstadt, Federal Republic of Germany); Professor EE Galal (Director General, Drug Research and Control Centre, Cairo, and Visiting Head of Pharmacology Department, Azhar University, Cairo, Egypt); Professor S Garattini (Director, Istituto di Ricerche Farmacologiche "Mario Negri", Milan, Italy); Dr VC Lepakhin (Senior Scientific Worker, USSR Scientific Research Institute and Institute of Approbation of Medical Equipment, Moscow, USSR); Professor PN Magee (Courtauld Institute of Biochemistry, The Middlesex Hospital Medical School, London, England); Dr Y Omori (Department of Pharmacology, National Institute of Hygienic Sciences, Ministry of Health and Welfare, Tokyo, Japan); and, Dr GA Overbeek (Assistant Research Director, Organon International BV, Oss, Netherlands), representing the International Union of Pharmacology (IUPHAR).