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Principles for the clinical evaluation of drugs
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Preamble
Unfortunately, this report in the WHO Technical Report Series is not available online at the WHO website.

Aims
In recent years widespread concern about the safe use of drugs has been developing amongst medical and other scientific workers and the general public. The development and surveillance of drugs affect the welfare and rights of both the individual and society, and encompass scientific, ethical and legal matters of extraordinary complexity. These factors may at times lead to conflict, and the goal of the responsible parties must be a judicious balance of these needs and values. The ways and means by which WHO can contribute to the promotion of the efficacy and safety of drugs have been discussed extensively in various sessions of the governing bodies of the Organization. As a result, the Seventeenth World Health Assembly (1964) adopted a resolution requesting the Director-General, inter alia, "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". In compliance with this request several meetings of experts have been convened and their reports published. The present Group was convened to review and to formulate some principles for the clinical evaluation of drugs, whether new or old, and whether used for a new indication or in a new physical form or combination. (Introduction, pages 5 and 6).

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[Sub-sub-headings omitted]

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