

(37) The Association of the British Pharmaceutical Industry (1977)
Guidelines for Preclinical and Clinical Testing of New Medicinal Products,
Part 1: Laboratory investigations, Part 2: Investigations in Man
London: Association of the British Pharmaceutical Industry

Preamble

The two parts of these Guidelines are available online at the James Lind Library (www.jameslindlibrary.org/association-british-pharmaceutical-industry-1977). The Association of the British Pharmaceutical Industry (ABPI) published several guidelines covering aspects of research on animals and human subjects (some are available online at www.abpi.org.uk/publications). These appear to start in 1963 with the First Report of the Expert Committee set up by the ABPI into toxicity tests on experimental animals. The present two-part guidelines do not reference this report but they do refer to the Report by the Medico-Pharmaceutical Forum (1974; see no. (30) above), as well as the WHO Technical Reports nos. 425 (*International drug monitoring – the role of the hospital* (1969)), and, 563 (*Guidelines for Evaluation of Drugs for Use in Man*, 1975, see no. (33) above); the World Health Association Declaration of Helsinki (revised Tokyo, Japan, 1975); the Report of the Committee Appointed by the Royal College of Physicians of London on the *Supervision of the Ethics of Clinical Investigations in Institutions* (*BMJ* 1967;3; 429-430); and the ABPI *Report of the committee to investigate medical experiments on staff volunteers* (1970, updated 1984).

This report in turn referenced the WHO Technical reports TRS no. 341 (*Principles for Pre-clinical Testing of Drug Safety* (1966)) and TRS no. 403 (*Principles for the Clinical Evaluation of Drugs*, 1968; see no. (18) above), as well as ethical issues that were the subject of statements by the Medical Research Council (*Statement of the considerations which should in their opinion, govern the conduct of scientific investigations on human subjects* (Medical Research Council Annual report 1962-63 (Cmnd 2382, London: HMSO, 1964, pages 21 – 25), reprinted *BMJ* 1964:2:178-180).

There is also the ABPI report on *Bioavailability studies in drug development* (1977); the Medicines (Labelling) Regulations 1976 (S1 no.1726); the ABPI/RCGP/BMA *Code of Practice for the Clinical Assessment of Licensed Medicinal Products in General Practice* (1983); and, the ABPI *Guidelines on Compensation for Drug Induced Injury* (1983).

After 1983, that is, beyond the period covered by my article, there are the Royal College of Physicians of London *Guidelines on the Practice of Ethics Committees in Medical Research* (1984); the ABPI *Guidelines on Data Needed to Support the Administration of New Chemical Entities to Non-Patient Volunteers* (1985); the Royal College of Physicians report *Research on Healthy Volunteers* (1986). the ABPI *Statement on Good Clinical Research* (1986) updated as the ABPI: *Guidelines on good clinical research practice* (1988); the Medico-Pharmaceutical Forum booklet *A Report by the Forum's Working Party on Clinical Trials* (1987); Guidelines prepared by the ABPI Working Party on the handling of blood samples (1987); Medicines Commission advice to Health Ministers on healthy volunteer studies, Department of Health and Social Security (1987); the Joint Committee of ABPI, BMA, CSM and RCGP *Guidelines on Post-marketing Surveillance* (1988), and, the 1988: ABPI: *Guidelines for Medical Experiments in Non-Patient Human Volunteers* (1988).

Aims

These guidelines, which are published as separate pre-clinical (Part 1) and clinical (Part 2) sections, have been prepared for the Scientific and Technical Council by its Research and Development and Medical Committees. They represent the consensus views of the Committees' experts on good practice in the pre-clinical and clinical testing of new medicinal products for human use. As the title indicates, these documents are intended to provide guidance only and do not attempt to establish requirements for testing. The problems encountered in drug research demand a flexible approach and, depending on the precise nature of a new medicinal compound, it is appropriate to undertake evaluation by different methods or to different standards (Foreword, page 4 (part 1) and page 5 (part 2)).

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Foreword (PT Main)

General introduction

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Authors

The foreword was written by PT Main (Chairman of the Scientific and Technical Council); the members of the committees that produced the guidelines are not listed.