

Recent Publications

Ethical criteria for medicinal drug promotion

In May 1988, the Forty-first World Health Assembly adopted a Resolution endorsing ethical criteria for medicinal drug promotion based on a draft prepared by an international group of experts. Member States were urged to take these into account in developing measures to ensure that medicinal drug promotion supports the aim of improving health care through the rational use of drugs.

Reference: *Ethical criteria for medicinal drug promotion*, World Health Organization, Geneva. ISBN 92 4 154239 X (1988).

Good manufacturing practices of Japan: third edition

This compendium of information on good manufacturing practices, which is issued in a dual Japanese/English format, is produced by the Inspection and Guidance Division of the Japanese Pharmaceutical Affairs Bureau. Its scope is broader than might be assumed from its provenance and the previous editions. This volume contains not only the Japanese regulations on good practices in the manufacture and quality control of drugs which — as pointed out in the preface — remain consonant with the basic recommendations of WHO, but has also been considerably expanded to cover newly-introduced regulations relating to medical devices, *in vitro* diagnostics, and extracts of natural products contained in traditional Kampo prescription medicines. It also includes, by way of comparison and reference, the corresponding United States Good Manufacturing Practices Regulations for finished pharmaceutical products and medical devices. It will be of value to many regulatory authorities and pharmaceutical companies far removed from Japan.

Reference: *GMP Regulations of Japan*, Third edition. The Inspection & Guidance Division, Pharmaceutical Affairs Bureau, Ministry of Health and Welfare, Japan. ISBN4-8408-0129-0 C3047 (1988).

British Pharmacopoeia 1988

The new edition of the *British Pharmacopoeia*, which includes 2100 monographs for drug substances, finished dosage forms and other articles widely used in medicine, became effective in the United Kingdom as from 1 December 1988. The increasing trend toward integration of official standards throughout the European Economic Community is evident since a quarter of the entries — and over 40 per cent of those for drug substances — are edited versions of European Pharmacopoeia monographs and an injunction is contained in the introduction to indicate that "in the event of doubt of interpretation, recourse should be had to the English text published under the direction of the Council of Europe". The influence of the European Pharmacopoeia is, in fact, even wider than these figures indicate since its general monographs for tablets and other dosage forms apply to all specific monographs for dosage forms adopted within the Member States of the European Economic Community, whether or not the latter are themselves included in the European Pharmacopoeia.

The international character of the pharmaceutical manufacturing industry clearly demands a more international approach from pharmacopoeial authorities. The appointment of scientists from the National Biological Standards Laboratory in Australia and an officer from WHO Headquarters, Geneva, as corresponding members to the advisory committees of the British Pharmacopoeia Commission is another welcome indication of acceptance of the need for international harmonization of standards.

Reference: *British Pharmacopoeia*, 1988. Available from: HMSO Publications Centre, P.O. Box 276, London, SW8. ISBN 0 11 320837 5.