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Clinical pharmaceutical evaluation in drug control: report on a symposium convened by the Regional Office for Europe of the World Health Organization, Heidelberg, 27-30 November 1972 (EURO 7406)

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Preamble

This report, which is also available in French and Russian, includes lists of the temporary advisers, observers, and staff at WHO headquarters. It references two reports in the World Health Organization Technical Report Series, no. 403 (*Principles for the Clinical Evaluation of Drugs*, see (18) above), and no. 446 (*Clinical pharmacology – scope, organization, training* (1970)).

This was the first of a series of reports with the title *Clinical Pharmacological Evaluation in Drug Control* published annually by the WHO Regional Office for Europe, each one based on a symposium. The full reports were published in English, French and German with summaries appearing in the *European Journal of Clinical Pharmacology*. The second symposium (EURO 7407, 1974; Heidelberg, 24 to 27 September 1973) continued the objectives of the first, while the third (EURO 7408, 1975); Heidelberg, 5 to 8 November 1974) considered the operation of drug control authorities and drug registration. The fourth (ICP/SQP 004, 1976; Deidesheim, 11 to 14 November 1975) considered drug utilization, registration, responsibilities for providing drugs, and assessment of herbal and traditional remedies; the fifth (ICP/PHA 003, 1977; Deidesheim, 26 to 29 October 1976) considered antihypertensive and anti-inflammatory drugs as well as adverse drug reactions. The sixth (ICP/PHA 004; 1978; Deidesheim, 22 to 25 November 1977) considered the role of clinical pharmacology and of clinical pharmacologists in drug development. For the seventh symposium see no. (48) below.

Aims

During the last few decades the production and use of drugs has increased in all parts of the world. There has been an increasing awareness that the specificity, potency and growing variety of drugs now available aggravate the difficulty of ensuring optimum results without undue risk. It is also generally recognised that efficient control must be exercised over the efficacy, safety and pharmaceutical quality of drugs, as well as over information on their indications and use. In a resolution adopted in 1971, the World Health Assembly noted that the continuous development of medical science and of the pharmaceutical industry leads to the appearance of new and more effective drugs, that there is an increasing need for the prescribing physician to know and fully understand the effects, side reactions and possible interactions of drugs, and that the World Health Organization has a responsibility to assist in keeping the national health authorities and the medical profession abreast of such developments through expanded facilities for information on pharmacotherapy and for continuing education in clinical pharmacology. In the field of drugs, as in other fields, decision-taking at the national level belongs to individual governments, which have the power and the means to select a proper course of action on the basis of advice from scientists and physicians and taking due account of all the factors involved. In implementing control measures designed to ensure that drugs are adequately tested and evaluated for safety and efficacy, the national health authorities require the assistance of qualified staff within the

administration and the advice of non-governmental experts. The aim of the European Symposium on Clinical Pharmacological Evaluation in Drug Control was to review the importance of clinical pharmacology in decisions relating to drug control and to consider the degree to which this discipline is used in practice (Introduction, page 1).

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Authors

The report was prepared by the Regional Office for Europe of the World Health Organization for distribution to the governments of Member States in the Region (Note, page ii). The participants at the Symposium were Dr A Harrestrup Andersen (Chairman, Danish Drug Registration Board, National Health Service of Denmark, Copenhagen, Denmark); Professor LK Böttiger (Head, Pharmacotherapeutic Division, Department of Drugs, National Board of Health and Welfare, Stockholm, Sweden); Mr F Clapuyt (Secretary, Drugs Committee, Ministry of Public Health and the Family, Brussels, Belgium); Professor D Dobrescu (Head of the Chair of Pharmacodynamics and Dean of the Faculty of Pharmaceutics, Bucarest, Romania); Dr Ingeborg Eichler (Director, Federal Institute for Experimental, Pharmacological and Balneological

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