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Clinical Pharmacological Evaluation in Drug Control

Report on the Seventh European Symposium, Deidesheim, Germany, 14 – 17 November 1978

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Preamble

This report was also issued in French and Russian. It references the World Health Organization Technical Report Series (TRS) no. 168, 1959 (First report of the Expert Committee on Cardiovascular Diseases and Hypertension, meeting held Geneva, 13-18 October 1958, Hypertension and coronary heart disease: classification and criteria for epidemiological studies); Report of an Expert Committee, WHO TRS no. 231, 1962 (Arterial hypertension and ischaemic heart disease: preventive aspects); WHO Report of a Scientific Group, TRS no. 341, 1966 (Principles for Pre-clinical Testing of Drug Safety); Report of a WHO Scientific Group, WHO TRS no. 403, 1968 (Principles for the Clinical Evaluation of Drugs, see no. (18) above); WHO TRS no. 498 (International drug monitoring – the role of national centres, 1972); Report of a WHO Scientific Group, WHO TRS no. 563 (Guidelines for Evaluation of Drugs for use in man, 1975 (see no. (33) above; WHO Working Group on the Harmonization of Guidelines for Clinical Trials and Drugs - Antihypertensive Drugs, Uppsala, 24-25 April 1978; and, Clinical Pharmacological Evaluation in Drug Control, Report on a Symposium, 1977 (ICP/PHA 004).

The series of reports under the heading Clinical Pharmacological Evaluation in Drug Control continued with the ninth (EURO reports and studies 50, 1981; Schlangenbad, 18 to 21 November 1980), on the control of drugs for the elderly; the tenth (EURO reports and studies 66, 1982; Schlangenbad, 27 to 30 October 1981), on drugs for infants and children; and the eleventh (EURO reports and studies 91, 1985; Schlangenbad, 19 to 22 October 1982) on drugs in general practice. Beyond that the series continued for several years.

Aims

The Symposium was the seventh in a series of meetings on clinical pharmacological evaluation in drug control, convened annually since 1972 by the WHO Regional Office for Europe, with sponsorship by the Federal Republic of Germany, initially at Heidelberg and later at Deidesheim. The meetings have provided a forum for scientific discussion of the clinical problems and procedures associated with drug control in the broadest sense. The work of each meeting has supplemented that of earlier ones and concrete recommendations on general and specific matters have been produced. An innovation in the agenda this year was the discussion of draft guidelines for the evaluation of hypertensive drugs in man (Introduction, page 1).

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Annex I. Guidelines for evaluation of antihypertensive drugs in man

Annex II. List of participants

Participants

The Symposium was attended by forty-one participants from twenty-six countries as well as twenty temporary advisers and regular staff of WHO, and ten representatives of other organizations. The forty-one participants were Dr H Abdelkader (Institute of Pharmacology, University of Lausanne, Switzerland); Dr E Alhava (Chief, Department of Pharmacology and Microbiology, National Laboratory for the Control of Drugs and Pharmaceuticals, Helsinki, Finland); Professor L Blumenbach (Director, Institute of Drugs, Federal Health Office, Berlin (West), Federal Republic of Germany); Professor A Danysz (Department of Pharmacology, Institute for Drug Research and Control, Warsaw, Poland); Dr I Eichler (Federal Institute for Experimental Pharmacology and Balneology, Vienna, Austria); Dr K Fäller (Deputy Director, National Institute of Pharmacy, Budapest, Hungary); Professor H Friebel (Drug Commission of the German Medical Profession, Cologne, Federal Republic of Germany); Mr P Grech (Assistant to the Director, Directorate of Pharmacy ans Medicine, Ministry of Health and Family Welfare, Paris, France); Mr A Grímsson (Chief, Pharmaceutical Division, Ministry of Health and Social Security, Reykjavik, Iceland); Mr Ferreira del Almeida (Directorate-General of Hospitals, Lisbon, Portugal); Mr P Fischer (Director, Intercantonal Office of Drug Control, Bern, Switzerland); Dr M Godinho de Matos (Director, Pharmacy

Services, Directorate-General of Health, Lisbon, Portugal); Dr M Hassar (Agrégé in Clinical Pharmacology, Faculty of Medicine, Rabat, Morocco); Dr G Hitzenberger (Head, Division of Clinical Pharmacology, Faculty of Medicine, University of Vienna, Austria); Mr H Hovgaard (Chief, Administrative Department, Pharmaceutical Laboratory of the National Health Service, Brønshø, Denmark); Professor H Hüller (Head, Department of Clinical Pharmacology, Ernst-Moritz-Arndt University, Griefswald, German Democratic Republic); Mr MB Huyghe (Inspector-General of Pharmacy, Ministry of Public Health and Family Welfare, Brussels, Belgium); Professor EF Hvidberg (Department of Clinical Pharmacology, University Hospital, Copenhagen, Denmark); Dr G Lones (Principal Medical Officer, Medicines Division, Department of Health and Social Security, London, United Kingdom); Professor H Kewitz (Steglitz Clinic, Institute for Clinical Pharmacology, Free University of Berlin, Berlin (West), Federal republic of Germany); Professor H Kleinsorge (Neustadt, Federal Reublic of Germany); Dr A Kristinsson (Chairman, Icelandic Committee on Medicines, University Hospital, Reykjavik, Iceland); Dr VK Lepakhin (Ministry of Health of the USSR, Moscow, USSR); Dr I Lunde (National Centre for Medicinal Products, Oslo, Norway): Professor L von Manger-Koenig (Special Consultant on Medical Affairs, Federal Ministry for Youth, Family Affairs and Health, Bad Honnef-Rhondorf, Federal Republic of Germany); Dr PJ Neuvonen (Reader in Clinical Pharmacology, Department of Clinical Pharmacology, University of Helsinki, Finland); Dr TV O'Dwyer (Senior Medical Officer, Department of Health, Dublin, Ireland); Dr L Offenhaus (Health Inspector, Directorate-General of Public Health, Ministry of Public Health and Environmental Protection, Leidschendam, Netherlands); Professor G Olive (National Institute of Health and Medical Research, Paris, France); Professor R Presig (Director and Chairman, Department of Clinical Pharmacology, University of Bern, Switzerland); Dr J Reuse (Professor Pharmacology, Faculty of Medicine and Pharmacy, Free University of Brussels, Belgium); Professor HJ Richter (Director, Institute for Drugs and Drug Control of the German Democratic Republic, Berlin, German Democratic Republic); Professor J Setekleiv (Department of Pharmacology, University of Oslo, Norway); Professor K Strandberg (Department of Drugs, Pharmacotherapeutic Division, National Board of Health and Welfare, Uppsala, Sweden); Dr S Szucsova (Assistant Lecturer, Institute for Postgraduate Medical and Pharmaceutical Studies, Bratislava, Czechoslovakia); Dr E Tschöpe (Institute for Drugs, Federal Health Office, Berlin (West), Federal Republic of Germany); Professor W Tsourouksoglou (Director, First Department of Internal Medicine, Faculty of Medicine, University of Salonika, Greece); Dr K Türker (Professor of Pharmacology, Faculty of Medicine, University of Ankara, Turkey; Dr B Vrhovac (Clinical Pharmacologist, Internal Medicine Clinic, Faculty of Medicine, University of Zagreb, Yugoslavia); Professor E Weber (Professor of Pharmacology and Toxicology, Head, Clinical Pharmacology Division, University Medical Clinic, Heidelberg, Federal Republic of Germany); Miss J Weydert (Head, Division of Pharmacy and Drugs, Inspectorate of Pharmacies, Directorate of Public Health, Luxembourg).