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929

WHO EXPERT COMMITTEE ON SPECIFICATIONS FOR PHARMACEUTICAL PREPARATIONS

Thirty-ninth report

This report presents the recommendations of an international group of experts convened by the World Health Organization to consider matters concerning the quality assurance of pharmaceuticals and specifications for drug substances and dosage forms. Of particular relevance to drug regulatory authorities and pharmaceutical manufacturers, this report discusses the monographs on antiretrovirals proposed for inclusion in *The International Pharmacopoeia* and specifications for radiopharmaceuticals, quality specifications for antituberculosis drugs and the revision of the monograph on artemisinin derivatives, as well as quality control of reference materials, good manufacturing practices (GMP), inspection, distribution and trade and other aspects of quality assurance of pharmaceuticals, and regulatory issues.

The report is complemented by a number of annexes, including an amendment to good manufacturing practices: main principles regarding the requirement for the sampling of starting materials, guidelines on good manufacturing practices regarding water for pharmaceutical use, guidelines on the sampling of pharmaceutical products and related materials and draft guidelines for registration of fixed-dose combination medicinal products.

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World Health Organization
Geneva

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WHO Expert Committee on Specifications for Pharmaceutical Preparations

Geneva, 25–29 October 2004

Members[*]

Professor I. Addae-Mensah, Professor of Chemistry, University of Ghana, Legon, Accra, Ghana

Ms K. Bremer, Director, Pharmaceutical Department, Norwegian Medicines Agency, Oslo, Norway

Dr S. Haghighi, Head, Pharmaceutical and Microbiology Department, Pasteur Institute of Iran, Tehran, Islamic Republic of Iran

Professor J. Hoogmartens, Faculty of Pharmaceutical Sciences, Laboratory for Pharmaceutical Chemistry and Drug Analysis, Leuven, Belgium (*Chairperson*)

Dr R. Jachowicz, Head, Department of Pharmaceutical Technology and Biopharmaceutics, Faculty of Pharmacy, Jagiellonian University Medical College, Medyczna, Kraców, Poland

Professor Jin Shaohong, Deputy Director-General, National Institute for the Control of Pharmaceutical and Biological Products, Ministry of Public Health, Beijing, People's Republic of China

Dr J.A. Molzon, Associate Director for International Programs, Center for Drug Evaluation and Research, US Food and Drug Administration, Rockville, MD, USA

Ms Metta Treebamroong, Bureau of Drug and Narcotics, Department of Medical Sciences, Ministry of Public Health, Nonthaburi, Thailand (*Co-Chairperson*)

Mr R.W. Tribe, Holder, ACT, Australia (*Rapporteur*)

Representatives of other organizations[†]

European Medicines Evaluation Agency (EMEA)
Mr B. Cuddy, Inspections Sector, London, England

European Pharmacopoeia/European Directorate for the Quality of Medicines
Dr J.H. McB. Miller, Head of Division III (Laboratory), Council of Europe, Strasbourg, France

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[*] Unable to attend: Professor Kim Kil-Soo, Chief, Institute of Pharmaceutical Sciences, College of Pharmacy, Ewha Woman's University, Seoul, Republic of Korea; Dr J.-L. Robert, Service du Contrôle des Médicaments, Laboratoire National de Santé, Luxembourg.

[†] Unable to attend: Argentinian Pharmacopoeia, Buenos Aires, Argentina; Brazilian Pharmacopoeia, Santa Maria RS, Brazil; Chinese Pharmacopoeia, Beijing, People's Republic of China; Commonwealth Pharmaceutical Association (CPA), London, England; European Chemical Industry Council (CEFIC), Brussels, Belgium; Indian Pharmacopoeia, New Delhi, India; Japanese Pharmacopoeia, Tokyo, Japan; Pharmaceutical Inspection Co-operation Scheme (PIC/S), Geneva, Switzerland; Russian Pharmacopoeia, Moscow, Russian Federation; The World Bank, Washington, DC, USA; United Nations Development Programme (UNDP), New York, NY, USA; United Nations Industrial Development Organization (UNIDO), Vienna, Austria; World Customs Organization (WCO), Brussels, Belgium; World Intellectual Property Organization (WIPO), Geneva, Switzerland; World Self-Medication Industry (WSMI), Ferney-Voltaire, France; World Trade Organization (WTO), Geneva, Switzerland.

International Pharmaceutical Federation (FIP)
Dr A.P. Sam, The Hague, The Netherlands

International Atomic Energy Agency (IAEA)
Dr K. Solanski, Division of Human Health, Department of Nuclear Sciences and Applications, Vienna, Austria

International Federation of Pharmaceutical Manufacturers Associations (IFPMA)
Mrs J. Ramsbotham, Vice President Global Quality Assurance, Solvay Pharmaceuticals, Weesp, The Netherlands

International Generic Pharmaceutical Alliance (IGPA)
Dr N. Cappuccino, Chair, Science Committee, Sandoz, Inc., Princeton, NJ, USA

International Pharmaceutical Excipients Council (IPEC)
Mr A. Bone, Chair, IPEC Europe, Basingstoke, England
Professor H. de Jong, Vice Chair, IPEC Europe, Servier, Courbevoie, France
Mr F. Milek, Chair, GDP Committee, IPEC Europe, Stuttgart, Germany

Korean Pharmacopoeia
Dr Myoengsin Choi, Department of Drug Evaluation, Korea Food and Drug Administration, Central Pharmaceutical Affairs Council, Seoul, Republic of Korea

United Nations Children's Fund (UNICEF)
Dr P.S. Jakobsen, Pharmaceutical Quality Assurance Officer, UNICEF Supply Division, Copenhagen, Denmark

United States Pharmacopeia
Dr T. Cecil, Rockville, MD, USA

Secretariat*

Dr R. Balocco, Quality Assurance and Safety: Medicines, Department of Medicines Policy and Standards, WHO, Geneva, Switzerland

Dr M. Couper, Quality Assurance and Safety: Medicines, Department of Medicines Policy and Standards, WHO, Geneva, Switzerland

Professor T.G. Dekker, Scientific Support, Research Institute for Industrial Pharmacy, North-West University (Potchefstroom Campus), Potchefstroom, South Africa *(Temporary Adviser)*