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Contents

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Geneva, 21–25 April 1997

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1. Introduction

The WHO Expert Committee on Specifications for Pharmaceutical Preparations met in Geneva from 21 to 25 April 1997. The Director-General of WHO, Dr Hiroshi Nakajima, in his keynote address to open the meeting, stressed the need for continued international support to developing countries for ensuring drug quality. In a rapidly changing world, the globalization of economic forces, the expansion of travel and trade, and the trend towards privatization, together with new technologies, changing life-styles, and demographic shifts, had immediate implications for public health. In response, WHO had been engaged since 1995 in a revision of its health-for-all strategy. The goal of health for all in the 21st century presented WHO and its partners with an unprecedented challenge. It would be of the utmost importance for WHO to maintain its normative role if it was to meet the needs and expectations of its Member States. In addition, WHO would have to concentrate its resources on targeted areas of health work: essential drugs, for example, were recognized as having a high priority. Developing countries, in particular, would need international support in assuring drug and vaccine quality. WHO's normative activities had become increasingly important to its Member States as they strived towards regional and global harmonization of standards for production, quality control, safety, certification, and trade in pharmaceuticals and biologicals. WHO guidelines and publications were thus a valuable resource for countries establishing and strengthening their own regulatory systems. The goal of the Expert Committee was to maximize the value and availability of these resources. There was an increased need for the exchange of information and for harmonization at an international level, and for the appropriate use of available technical expertise within countries.

At the World Health Assembly in 1996, concern had been expressed about persistent problems in ensuring the quality of medicines. The Assembly had urged Member States to support mechanisms for monitoring and controlling the efficacy, quality and safety of drugs. In particular, the growing incidence of production, distribution and sale of counterfeit, spurious or substandard pharmaceutical products in developed and developing countries was a matter of concern for WHO. The Assembly had also called on WHO in resolution WHA49.14 "to continue the development, harmonization and promotion of standards to enhance drug regulatory and quality control mechanisms" and "to promote vigorously the use of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce".

The Director-General informed the participants that quality assurance had been extensively discussed at the Eighth International Conference of Drug Regulatory Authorities held in November 1996 in Manama, Bahrain. Those discussions showed clearly that WHO normative guidelines were appreciated throughout the world. The Conference had also reviewed progress made in the international harmonization of regulatory requirements, and collaboration between WHO and the International Conference on Harmonisation (ICH). WHO had participated as an observer since the establishment of the ICH process in 1990. WHO's objective in doing so was to provide a bridge between the 17 countries actively involved in the ICH process and the rest of WHO's Member States. As the World Health Assembly had asserted in May 1992 in resolution WHA45.28, WHO's role was to ensure that harmonization benefited all concerned.

2. *The international pharmacopoeia* and related issues

2.1 Quality specifications for drug substances and dosage forms

The Committee received a report of a worldwide survey on the use of *The international pharmacopoeia*, and noted with satisfaction its widespread use in virtually all areas of the world. The report clearly indicated that *The international pharmacopoeia* plays a major role in defining the specifications of pharmaceutical products. It also provides a valuable tool in the quality assurance of imported products. It was suggested that manufacturers in exporting countries should be encouraged to include an indication of compliance with *The international pharmacopoeia*, wherever appropriate, in the product information, to make it easier for developing countries to check the quality of imported products.

The Committee was informed that Volume 5 of *The international pharmacopoeia* would shortly be submitted for publication. Monographs for Volume 6 were in preparation. In cases where there was insufficient information from official sources, the monographs would be prepared with the assistance of pharmaceutical manufacturers.

Texts on general methods to be included in *The international pharmacopoeia* were approved for bacterial endotoxins, the visual inspection of particulate matter and extractable volume for parenteral prepara-