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Contents

WHO Expert Committee on Specifications for Pharmaceutical Preparations

Geneva, 28 November – 2 December 1994

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1. Introduction

The WHO Expert Committee on Specifications for Pharmaceutical Preparations met in Geneva from 28 November to 2 December 1994. The meeting was opened on behalf of the Director-General by Dr F. S. Antezana, Assistant Director-General, who emphasized the comprehensive role of the Expert Committee in dealing with a wide range of issues relating to the overall quality assurance of pharmaceutical products. In addition to the important task of elaborating and updating appropriate specifications for *The international pharmacopoeia,* he drew attention to other areas of the Expert Committee's work intended to assist WHO's Member States, especially developing countries. These included strengthening the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce, advice on the establishment and management of drug testing laboratories, and recommendations on the function and structure of a small drug regulatory authority.

In May 1994, the World Health Assembly adopted resolutions WHA47.11-WHA47.17 related to drugs and pharmacy. It reaffirmed the principles embodied in the Expert Committee's documents concerning the role and functions of a small national drug regulatory authority and the WHO Certification Scheme, and approved the text on good manufacturing practices. It also requested the Director-General to continue the normative activities that provided standards to assure the quality, safety and efficacy of pharmaceutical and biological products. In this context, Dr Antezana drew attention to the complex issue of the registration of multisource products. He was confident that the Expert Committee would be able to offer advice in what was an area of great importance to many national drug regulatory authorities.

The Committee confirmed that the overall objective of its broad range of activities was to provide a foundation on which Member States could build a comprehensive approach to the quality assurance of pharmaceutical products. It believed that its role was to provide Member States with a technically sound but flexible model to serve as both a target and a framework for their regulatory activities. Member States would, of course, need to adapt specific elements of that model to local circumstances. A step-by-step approach to the implementation of individual guidelines was frequently advisable. Proper allowance could then be made for the stage of development of a particular regulatory system and the locally determined needs and priorities. The Committee emphasized that the aim was to assist Member States to develop an appropriate and sustainable quality assurance infrastructure in order to optimize the use of available resources. International and regional organizations should be encouraged to provide appropriate local training on the implementation of WHO guidance (developing strategies, adapting guidelines) and assistance in operating WHO schemes.

2. *The international pharmacopoeia* and related activities

2.1 Quality specifications for drug substances and dosage forms

The Committee was pleased to be informed that Volume 4 of *The international pharmacopoeia* had been published in English in 1994 and recommended that every effort should be made to expedite publication in other official languages of WHO since this would greatly enhance its usefulness. That it was widely used was evident from the preliminary response received to the user questionnaire. The Secretariat was encouraged to continue to collect and analyse information on the use of *The international pharmacopoeia* in order to target the specification work more precisely.

The Committee considered monographs on a range of drug substances, medicinal gases, and tablets, and recommended their inclusion in future volumes. It suggested that, to avoid delays in making approved texts available, more frequent publication of smaller collections of monographs should be considered.

Progress was noted on the preparation of additional monographs for substances on the WHO Model List of Essential Drugs (*1*) and for the associated dosage forms. The Committee confirmed the principle of paying due regard to the toxicity of the reagents specified in tests as mentioned in its twenty-ninth report (*2*) and in Volume 3 of *The international pharmacopoeia* (*3*).

2.2 Test methodology

With respect to dissolution testing, the Committee approved the text describing the basket and paddle methods for inclusion in *The international pharmacopoeia*. In view of the considerable number of comments received, consultation on the accompanying advisory notes would need to be extended. A careful approach would be adopted, however, in incorporating dissolution requirements in the individual monographs for tablets and capsules in *The international pharmacopoeia*. Any further considerations should be based on comparative information on published specifications compiled by the Secretariat.

Following consideration of a preliminary discussion text, the Committee agreed that inclusion of a test for bacterial endotoxins was appropriate for *The international pharmacopoeia*. It advised, however, that finalization of such a text should await the outcome of current initiatives being pursued within national and regional pharmacopoeial programmes with respect to the reference endotoxin and the methodology. It was hoped, in particular, that it might thus be possible to extend the method to