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WHO Expert Committee on Specifications for Pharmaceutical Preparations

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1. Introduction

The WHO Expert Committee on Specifications for Pharmaceutical Preparations met in Geneva from 10 to 15 December 1990. The meeting was opened on behalf of the Director-General by Dr Hu Ching-Li, Assistant Director-General, who informed those present that WHO's revised drug strategy – which devolved from the Conference of Experts on the Rational Use of Drugs convened in Nairobi in 1985 – fully acknowledged the important role of the Expert Committee. He emphasized that the strategy was entirely consonant with the established philosophy of the Expert Committee in that it advocated a comprehensive approach to quality assurance, which, while retaining adequate rigour, had to be adaptable to the needs and economic circumstances of developing countries.

Pivotal to this approach was the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce, which provided a simple administrative procedure that enabled importing countries to obtain information on the registration status of a product in its country of origin and to obtain a declaration that the manufacturing facility had been inspected and was operating in compliance with WHO's requirements for good manufacturing practices (GMP). The Certification Scheme had been initially promulgated in 1969 and revised in 1975, and now had the endorsement of 132 participating countries. In 1988 it had been amended to bring within its ambit not only finished dosage forms but drug substances and products of public health relevance intended for veterinary use. Provision had also been made to include complete product information as approved in the country of origin, together with its date of approval.

Dr Hu stressed the importance of giving substance and credibility to the Certification Scheme and to other aspects of quality assurance, especially since the World Health Assembly had in 1988 requested the Director-General "to initiate programmes for the prevention and detection of the export, import and smuggling of falsely labelled, spurious, counterfeited or substandard pharmaceutical preparations". It was for this reason that the Expert Committee was being asked to give priority in the agenda of the present meeting to a consideration of guidelines for the use of the Certification Scheme and of several associated matters, including revised requirements for good manufacturing practices and guidelines for the procedures to be followed in pharmaceutical inspection.

It was evident, none the less, that the certification of imported products and the harmonization of control procedures – important as they were – did not, of themselves, provide a complete assurance of quality. Adequate facilities and technically competent staff to undertake pharmacopoeial analyses remained indispensable. Members were assured that, in maintaining *The international pharmacopoeia* as a compendium of standards founded on classical methods of analysis, the Expert Committee remained strongly identified with the needs of developing countries.

2. Good practices in the manufacture of pharmaceutical products

Several national and regional drug regulatory authorities have already issued guidelines that reflect the ongoing elaboration of the concept of GMP. It is important that these developments be reflected in WHO's requirements for good manufacturing practices, the original text of which was adopted by the Twenty-eighth World Health Assembly in 1975 in resolution WHA28.65 under the title "Good practices in the manufacture and quality control of drugs". The GMP text provides the technical basis for the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce (henceforth referred to in this report as the Certification Scheme). Unless the text is revised to reflect advances in pharmaceutical manufacturing technology, including developments in biotechnology, the Certification Scheme will cease to retain global relevance.

The Committee reviewed the proposed revision of the GMP text in the light of comments received from interested parties. It considered that the material could be presented in a more logical sequence if the format of the document were changed, and the definitive document, as subsequently approved by the members of the Committee, is set out in Annex 1, under the new title "Good manufacturing practices for pharmaceutical products".

3. Guidelines on inspection of pharmaceutical manufacturers

The Committee accepted in principle a proposal from the Secretariat that guidelines be developed for official inspections of drug manufacturing facilities to assess compliance with GMP requirements. It acknowledged that these would be of value, particularly to authorities in countries that had only recently engaged in the formulation of finished dosage forms, and that they would strengthen and facilitate the implementation of the WHO Certification Scheme.

The Committee invited comments from governments on the provisional guidelines set out in Annex 2 and recommended that the definitive guidelines be published.

4. The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce