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WHO Expert Committee on Specifications for Pharmaceutical Preparations

Twenty-sixth Report

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WHO EXPERT COMMITTEE ON SPECIFICATIONS FOR PHARMACEUTICAL PREPARATIONS

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CORRIGENDA

Page 46, line 12

Delete : **Ethanol (950 g/l) TS**
Insert : **Ethanol (750 g/l) TS**

Page 46, line 13

Delete : **Ethanol (900 g/l) TS**
Insert : **Ethanol (710 g/l) TS**

Page 46, line 15

Delete : **Ethanol (500 g/l) TS**
Insert : **Ethanol (375 g/l) TS**

Page 46, line 17

Delete : **Ethanol (200 g/l) TS**
Insert : **Ethanol (150 g/l) TS**

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WHO EXPERT COMMITTEE ON SPECIFICATIONS FOR PHARMACEUTICAL PREPARATIONS

Geneva, 25–30 April 1977

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WHO EXPERT COMMITTEE ON SPECIFICATIONS FOR PHARMACEUTICAL PREPARATIONS

Twenty-sixth Report

The WHO Expert Committee on Specifications for Pharmaceutical Preparations met in Geneva from 25 to 30 April 1977. The meeting was opened on behalf of the Director-General by Dr Ch'en Wen-chieh, Assistant Director-General. He recalled that in its twenty-fifth report the Expert Committee had proposed revised texts of " Good practices in the manufacture and quality control of drugs " and " Certification scheme on the quality of pharmaceutical products moving in international commerce ".[1] He informed the Committee that the Twenty-eighth World Health Assembly, in resolution WHA28.65,[2] had adopted those texts and had recommended Member States to apply the revised requirements. WHO had so far received 14 positive replies from countries agreeing to apply the certification scheme. Cyprus, Egypt, France, Italy, New Zealand, Poland, Portugal, and the Syrian Arab Republic had given positive replies without reservations or comments. Australia, Japan, Norway, Sweden, the United Kingdom and the USA had given positive replies with reservations or comments.

1. ANALYTICAL CRITERIA FOR DRUG QUALITY ASSESSMENT

Specifications are an important element in a drug quality assurance system, forming a basis for the laboratory examination of drugs. The selection of standards and associated methods of analysis depends partly on the intended area of application of the specification.

There are two principal considerations—one concerns the types of criteria for judging drug quality (e.g., standards and tests for identity

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[1] WHO Technical Report Series, No. 567, 1975, Annex 1, pp. 16–32.

[2] WHO Handbook of Resolutions and Decisions, Vol. II, second edition, 1977, p. 52.

and purity, standards and assays of strength, and standards and tests of performance for dosage forms) and the other concerns the use of criteria in quality specifications (e.g., pharmacopoeial monographs, manufacturer's batch release specifications, government regulations).

In the belief that an examination of various aspects of the analytical criteria used for drug quality assessment would be useful to all involved in drug regulatory activities, the Committee carried out a review of these criteria, which is published in Annex 1.

2. REVISION OF THE INTERNATIONAL PHARMACOPOEIA

In resolution WHA28.66,[1] the Twenty-eighth World Health Assembly requested the Director-General " to continue to develop activities related to the establishment and revision of international standards, requirements and guidelines for prophylactic and therapeutic substances in consultation, as appropriate, with relevant governmental and non-governmental organizations in official relations with WHO ".

It was recommended in the twenty-fifth report [2] of the Expert Committee that the Secretariat, working with members of the Expert Advisory Panel and with other specialists, should establish specifications for raw materials (comprising active and inactive ingredients) in pharmaceutical products and general methods and tests necessary to support such specifications.

Following these recommendations, work was started on the revision of the general methods of analysis contained in the International Pharmacopoeia. Drafts of a number of general methods of analysis to be used in the third edition of the International Pharmacopoeia were produced with the help of specialists and circulated to all members of the Expert Advisory Panel and to national and regional pharmacopoeia commissions. On the basis of the comments received revised drafts of those methods were prepared. Work was also started on the revision of specifications for the third edition of the International Pharmacopoeia.

The Committee welcomed the progress that had been made and requested the Secretariat to continue the process of revision of the International Pharmacopoeia, giving priority to those substances that are most widely used in general health care.

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[1] WHO Handbook of Resolutions and Decisions, Vol. II, second edition, 1977, p. 51.

[2] WHO Technical Report Series, No. 567, 1975.

3. INTERNATIONAL CHEMICAL REFERENCE SUBSTANCES

3.1 Reports from the WHO Centre

Reports from the WHO Collaborating Centre for Chemical Reference Substances were received by the Committee.[1]

3.1.1 *Establishment of new reference substances*

The Committee noted that in accordance with the authorization given in its previous reports the following new International Chemical Reference Substances had been established :

Chloramphenicol Palmitate
Chloramphenicol Palmitate (polymorph A)
Dicloxacillin Sodium
Fluphenazine Hydrochloride
Phenoxymethylpenicillin Potassium
Tolnaftate

3.1.2 *Replacement of current reference substances*

The Committee also noted that replacement batches of the following International Chemical Reference Substances had been introduced :

Carbenicillin Sodium
Ergotamine Tartrate
Oxacillin Sodium
Riboflavin
Vitamin A Acetate

3.1.3 *Future work*

The Committee was informed that work had been initiated to replace the following International Chemical Reference Substances since stocks of them were nearing depletion :

Digitoxin
Digoxin
Ergometrine Maleate
Folic Acid

It was noted that the Centre had, in consultation with the Secretariat, prepared a tentative list of new International Chemical Reference Substances to be established in the next few years. This list had been sent to a number of other organizations known to be concerned with the establishment of reference materials, together with an invitation to collaborate on substances of mutual interest.

[1] Unpublished documents WHO/PHARM/75.485, WHO/PHARM/76.488, and WHO/PHARM/77.491.