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WORLD HEALTH ORGANIZATION

TECHNICAL REPORT SERIES

No. 222

EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION

Fourteenth Report

WORLD HEALTH ORGANIZATION

GENEVA

1961

EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION

Geneva, 26 September - 1 October 1960

Members :

Dr D. G. Evans, Director, Department of Biological Standards, National Institute for Medical Research, London, England

Dr P. de Góes, Director, Institute of Microbiology, University of Brazil, Rio de Janeiro, Brazil (*Vice-Chairman*)

Dr P. Krag, Director, Department of Biological Standards, Statens Serum-institut, Copenhagen, Denmark (*Chairman*)

Dr A. S. Outschoorn, Head, Division of Pharmacology, Medical Research Institute, Colombo, Ceylon (*Rapporteur*)

Dr C. Purannanda, Director, Queen Saovabha Memorial Institute, Bangkok, Thailand

Dr Soemiatno, Director, Pasteur Institute, Bandung, Indonesia

Dr J. Tréfouël, Director, Institut Pasteur, Paris, France

Dr V. L. Troitski, Institute of Epidemiology and Microbiology (N.F. Gamaleja), Moscow, USSR

Dr W. G. Workman, Division of Biologics Standards, National Institutes of Health, Bethesda, Md, USA

Representative of the Food and Agriculture Organization :

Dr A. W. Stableforth, Director, Veterinary Laboratories and Veterinary Investigation Service, Central Veterinary Laboratory, Weybridge, Surrey, England

Secretariat :

Dr N. K. Jerne, Chief Medical Officer, Biological Standardization, WHO (*Secretary*)

Dr C. A. Morrell, Director, Food and Drug Divisions, Department of National Health and Welfare, Ottawa, Canada (*Consultant*)

PRINTED IN SWITZERLAND

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EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION

Fourteenth Report

The Expert Committee on Biological Standardization met in Geneva from 26 September to 1 October 1960.

Dr N. I. Grashchenkov, Assistant Director-General, on behalf of the Director-General, welcomed the members of the Committee and the representative of the Food and Agriculture Organization of the United Nations.

Reviewing the standardization work accomplished by the thirteen Expert Committees on Biological Standardization that have met under the auspices of the World Health Organization, and surveying the extensive agenda of the present Committee, the Assistant Director-General asked the members to aim both at continuity in the performance of this work and at results that will be as useful as possible to those who look to WHO for assistance and who are working in their national spheres under a great variety of conditions.

GENERAL

The Committee discussed the scope and the usefulness of the work that is being conducted under its responsibility; it was generally agreed that the provision of International Standards and International Reference Preparations of biological substances, as well as the formulation of International Requirements for the manufacture and control of biological products were tasks that are of importance for orderly progress in human and veterinary medicine.

The Committee considered its procedures for the establishment, custody and distribution of the International Standards and International Reference Preparations. It was of the opinion that the elaborate and careful way in which numerous laboratories throughout the world contributed to the work of establishing International Standards and Reference Preparations, both by generous gifts of material and by the participation, without charge, in extensive collaborative studies, ensured a satisfactory basis for international biological standardization.

The International Laboratories for Biological Standards in the Statens Seruminstitut, Copenhagen, and in the National Institute for Medical

Research, London, have been the custodians of the standards for more than thirty-five years. In view of the expansion of its work, particularly in respect of substances of veterinary importance, the Committee requested the Secretariat to consult with the Food and Agriculture Organization concerning the possibility of nominating a third International Laboratory for Biological Standards with responsibility for the custody and distribution of those International Standards and International Reference Preparations that are primarily of veterinary importance.

As for the distribution of the International Standards and International Reference Preparations by the custodians, the Committee reiterated its opinion, stated in the seventh report,[1] that national governments should designate National Laboratories for Biological Standards qualified to deal with biological standardization in their own countries. These National Laboratories are entitled to receive supplies of the international standards and international reference preparations on request from the custodians in order to make these available to manufacturers and research workers in their countries. They should, nevertheless, be encouraged to prepare national standards when the demands for standard materials are large. The Committee recognized, however, that in some countries such National Laboratories cannot, at the present time, be designated or function adequately, and considered that the International Laboratories for Biological Standards should attempt to satisfy directly requests from individual laboratories in these countries.

The Committee was informed of the technical discussions that took place in connexion with the Thirteenth World Health Assembly,[2] and noted that these discussions, though they had acknowledged the usefulness of international biological standardization and of the formulation of international requirements in the control of vaccines and other biological products, had clearly indicated the difficulties which the responsible authorities in many countries experience in trying to establish appropriate laboratory control procedures. The Committee also noted the suggestion, made in the report on these discussions, that it would be of great value if the World Health Organization could assist in making facilities available for the control testing of vaccines on an international basis.

The Committee was of the opinion that each country should proceed with the establishment of a National Laboratory for Biological Standards which could control the biological preparations of medical importance made and offered to the public in its country, and it stressed that this is an important part of any national public health programme. The Committee realized, however, that many countries needed international assistance while such a system was being developed and it therefore asked the Secre-

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[1] *Wld Hlth Org. techn. Ser.*, 1954, **86**, Annex I

[2] Unpublished working document A13/Technical Discussions/5

tariat to consult with laboratories qualified in the control testing of various biological preparations and to compile a list of those that are willing to assist.

PHARMACOLOGICAL

ANTIBIOTICS

1. Leucomycin

The Committee noted that the National Institute for Medical Research, London, had reassessed the need for an international reference preparation of leucomycin.[1] In view of the fact that leucomycin is not, at the present time, in widespread clinical use the Committee decided not to establish an international reference preparation of leucomycin, and asked the National Institute for Medical Research to distribute the material held to interested workers on request.

2. Neomycin B

The Committee noted that the National Institute for Medical Research, London,[2] in collaboration with other laboratories, was continuing the examination of samples of neomycin but had not yet been able to obtain a preparation of neomycin B sufficiently pure to serve as an international standard and to replace the existing International Reference Preparation of Neomycin.

3. Novobiocin

The Committee noted that the collaborative assay of the International Reference Preparation of Novobiocin had been completed,[3] and that the international standard of novobiocin would be established and the international unit defined by the National Institute for Medical Research, London, with the agreement of the participants in the collaborative assay.

4. Nystatin

The Committee noted that the collaborative assay of the International Reference Preparation of Nystatin was in progress,[4] and authorized the

[1] Unpublished working document WHO/BS/520
[2] Unpublished working document WHO/BS/522
[3] Unpublished working document WHO/BS/521
[4] Unpublished working document WHO/BS/524

National Institute for Medical Research, London, to establish the international standard for nystatin and to define the international unit with the agreement of the participants in the collaborative assay.

5. Oleandomycin

The Committee noted that the collaborative assay of the International Reference Preparation of Oleandomycin had been completed,[1] and that the international standard for oleandomycin would be established and the international unit defined by the National Institute for Medical Research, London, with the agreement of the participants in the collaborative assay.

6. Penicillin : Unit Notation

The Committee reiterated its decision not to change the definition of the International Unit of Penicillin, which is the activity of 0.0005988 mg of the International Standard for Penicillin. In view of the fact that, for the purpose of clinical dosage, some workers desire to change the expression of potency of penicillin preparations from International Units to terms of weight, the Committee stated that, for all practical clinical purposes, the International Unit of Penicillin may be regarded as equivalent to 0.0006 mg of pure sodium benzylpenicillin or to 0.00056 mg of pure benzylpenicillin acid.[2]

7. Ristocetin

The Committee noted that the National Institute for Medical Research, London, had now obtained a quantity of ristocetin suitable for serving as an international reference preparation.[3] The Committee established this material as the International Reference Preparation of Ristocetin, and asked the National Institute for Medical Reserach to assess the need for establishing an international standard for ristocetin and, if the need is evident, to arrange collaborative assays.

8. Other Antibiotics

The Committee considered a number of antibiotics that had been brought to its notice by the Expert Committee on Antibiotics and by other workers in the antibiotics field.[4]

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[1] Unpublished working document WHO/BS/521
[2] Unpublished working document WHO/BS/529
[3] Unpublished working document WHO/BS/518
[4] Unpublished working document WHO/BS/530