This report contains the collective views of an international group of experts and does not necessarily represent the decisions or the stated policy of the World Health Organization.

WORLD HEALTH ORGANIZATION

TECHNICAL REPORT SERIES

No. 594

WHO EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION

Twenty-seventh Report

WORLD HEALTH ORGANIZATION

GENEVA

1976

ISBN 92 4 120594 6

PRINTED IN SWITZERLAND

CONTENTS

WHO EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION

Geneva, 2–8 December 1975

Members : *

Mr Chou Hai-chun, Deputy Director of the Revolutionary Committee of the Peking Institute for the Control of Pharmaceutical and Biological Products, Peking, China

Dr H. H. Cohen, Director, National Institute of Public Health, Bilthoven, Netherlands (*Chairman*)

Professor S. G. Dzagurov, Director, Tarasevič State Institute for the Standardization and Control of Medical Biological Preparations, Moscow, USSR

Professor D. G. Evans, Director, National Institute for Biological Standards and Control, London, England

Dr L. Higy-Mandić, Chief, Department of Biological Standardization, Institute of Immunology, Zagreb, Yugoslavia (*Rapporteur*)

Mr J. Lyng, Department of Biological Standardization, State Serum Institute, Copenhagen, Denmark

Dr Harry M. Meyer, Jr., Director, Bureau of Biologics, Food and Drug Administration, Bethesda, MD, USA

Dr H. Mirchamsy, Associate Director, Razi State Institute of Serum and Vaccine Production, Karaj, Iran

Dr R. Murata, Director, Second Department of Bacteriology, National Institute of Health, Tokyo, Japan (*Vice-Chairman*)

Dr J. B. Shrivastav, Director General of Health Services, Ministry of Health, New Delhi, India

Secretariat :

Mr I. Davidson, Head, Biological Products and Standards Department, Central Veterinary Laboratory, New Haw, Weybridge, Surrey, England (*Consultant*)

Dr J. W. Lightbown, Head, Division of Antibiotics, National Institute for Biological Standards and Control, London, England (*Consultant*)

Dr F. T. Perkins, Chief, Biological Standardization, WHO, Geneva, Switzerland (*Secretary*)

Dr J. Spaander, Director-General, National Institute of Public Health, Bilthoven, Netherlands (*Consultant*)

Mr Tsou Pang-chu, Chief, Vaccine Section, Peking Institute for the Control of Pharmaceutical and Biological Products, Peking, China (*Consultant*)

Dr W. W. Wright, Deputy Associate Director, Pharmaceutical Research and Testing, Bureau of Drugs, Food and Drug Administration, Washington, DC, USA (*Consultant*)

---

* Unable to attend : Dr E. C. Gotschlich, Associate Professor and Physician, The Rockefeller University, New York, NY, USA ; Dr J. Spaun, Director, Department of Biological Standardization, State Serum Institute, Copenhagen, Denmark.

WHO EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION

Twenty-seventh Report

The WHO Expert Committee on Biological Standardization met in Geneva from 2 to 8 December 1975. The meeting was opened on behalf of the Director-General by Dr D. Tejada-de-Rivero, Assistant Director-General, who spoke of the emphasis that was now being placed on the application of standards and of the increased use of the biological standardization programme in a more practical way, especially in the developing countries. He asked the Committee to pay particular attention to the type of meetings needed in the future and to consider whether the format used at the twenty-sixth meeting of the Committee, in which a single group of substances was discussed, should be repeated.

GENERAL

The Committee was of the opinion that in future all requests from various organizations for the establishment of international biological standards, reference preparations, and reference reagents should be channelled through the World Health Organization. The Committee considered that priority should be given to substances used in prophylaxis, therapy or diagnosis of human diseases and for which, by use of international standards and reference preparations, a designation of activity could be made in quantitative terms. There may be occasions, however, when the Committee will have to consider biological reference reagents for use in qualitative procedures, and for which the assignment of a unit of measurement is not applicable. In such cases a careful selection will have to be made of those substances that could serve as international reference reagents on the basis of their need and value in diagnosis. On the other hand, the Committee considered that the establishment of standards, reference preparations or reference reagents for biological substances used only for research purposes should not be the concern of the Committee.

There are also occasions when WHO technical units ask the Committee to give international recognition to certain biological materials which those units have themselves obtained and investigated. Previous examples of such occasions are the diagnostic sera for viruses and lepto-

spires. The Committee considered that this was a valuable service and one that should be continued in future. The biological substances concerned must be of the high quality required by the Committee.

The Committee was of the opinion that its work should continue to advance on a broad front and where a special subject called for treatment in depth this could be done by holding a workshop prior to a meeting of the Expert Committee. As a result of such a workshop, the formulation of requirements and the establishment of international standards, reference preparations, or reference reagents could be recommended to the Expert Committee. The Committee agreed that such a procedure might be adopted in the case of blood products and related substances before its next meeting. The Committee concluded, therefore, that the procedure followed at its twenty-sixth meeting of devoting the whole agenda to a single special subject should not be repeated.

SUBSTANCES

ANTIBIOTICS

1. Doxycycline

The Committee noted the results [1] of the collaborative study referred to in its twenty-fourth report.[2] The Committee also noted that in accordance with the authorization in its twenty-fifth report[3] the National Institute for Biological Standards and Control, London, on the basis of the results of the collaborative assay had established the International Reference Preparation of Doxycycline and with the agreement of the participants in the collaborative assay had defined the International Unit for Doxycycline as the activity contained in 0.0011494 mg of the International Reference Preparation of Doxycycline.

2. Neomycin

The Committee noted the results [4] of the collaborative study of the proposed second International Reference Preparation of Neomycin. The Committee also noted that in accordance with the authorization in its

[1] Unpublished working document WHO/BS/75.1099.
[2] WHO Technical Report Series, No. 486, 1972, p. 9.
[3] WHO Technical Report Series, No. 530, 1973, p. 5.
[4] Unpublished working document WHO/BS/75.1097.