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WHO EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION

Eighteenth Report

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WHO EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION

Geneva, 27 September - 2 October 1965

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Dr H. H. Cohen, Director, National Institute of Public Health, Utrecht, Netherlands

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Representative of the Food and Agriculture Organization of the United Nations :

Mr H. I. Field, Director, Central Veterinary Laboratories and Veterinary Investigation Services, Weybridge, Surrey, England

Secretariat :

Professor D. G. Evans, London School of Hygiene and Tropical Medicine, London, England (*Consultant*)

Mr E. C. Hulse, Director, Department of Biological Standards, Central Veterinary Laboratory, Weybridge, Surrey, England (*Consultant*)

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Dr A. S. Outschoorn, Chief Medical Officer, Biological Standardization, WHO, Geneva (*Secretary*)

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Dr W. W. Wright, Deputy Director, Division of Antibiotics and Insulin Certification, Bureau of Scientific Standards and Evaluation, Food and Drug Administration, Washington, USA (*Consultant*)

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Dr J. H. S. Gear, Director, South African Institute for Medical Research, Johannesburg, South Africa ; Dr P. de Goes, Director, Institute of Microbiology, University of Brazil, Rio de Janeiro, Brazil ; Dr P. A. Versilova, Institute of Epidemiology and Microbiology (N. F. Gamaleja), Moscow, USSR.

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WHO EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION

Eighteenth Report

The WHO Expert Committee on Biological Standardization met in Geneva from 27 September to 2 October 1965.

Dr P. Dorolle, Deputy Director-General, on behalf of the Director-General, welcomed the members of the Committee, as well as the representative of the Food and Agriculture Organization of the United Nations.

Recalling the long traditions of the work on biological standardization, the Deputy Director-General stated that most of the members of the Committee had had long association with it and could be depended on to maintain the high standard expected of the Committee. Referring briefly to the agenda before the Committee, he observed that with successive Expert Committees the topics to be considered appeared to increase both in number and in scope. The increasing responsibility taken by these Committees for the formulation of international requirements for biological substances was one of their most important progressive developments.

The Deputy Director-General also referred to a resolution of the Eighteenth World Health Assembly [1] recommending that Member States of WHO should recognize officially certain international standards and units enumerated in the resolution, this list superseding a similar list included in a resolution of a previous World Health Assembly [2]. These resolutions indicated the interest and recognition by member countries of the work of biological standardization. The use and application of biological standards and of requirements for biological substances were important nationally in medical and public health practice, and had international implications as well, for example in large-scale eradication programmes against communicable diseases and in certain aspects of international quarantine.

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[1] *Off. Rec. Wld Hlth Org.*, 1965, **143**, 5 (Resolution WHA18.7).

[2] World Health Organization (1963) *Handbook of resolutions and decisions of the World Health Assembly and the Executive Board*, 7th ed., Geneva, p. 13 (Resolution WHA3.8).

PHARMACOLOGICAL

ANTIBIOTICS

1. Novobiocin

The Committee noted [1] that in accordance with the authorization in its sixteenth report [2] the National Institute for Medical Research, London, had established the International Standard for Novobiocin, which replaces the International Reference Preparation, and with the agreement of the participants had defined the International Unit for Novobiocin as the activity contained in 0.001031 mg of the International Standard for Novobiocin.

2. Ristocetin

The Committee noted [3] that the manufacture of ristocetin had been discontinued and concluded that the collaborative assay of the International Reference Preparation of Ristocetin, requested in its seventeenth report,[4] was now unnecessary.

3. Nystatin

The Committee noted [5] that the stability studies of the International Standard for Nystatin, requested in its sixteenth report,[2] had not so far revealed any undue instability.

4. Paromomycin

The Committee noted [6] that in accordance with the authorization in its seventeenth report [4] the International Reference Preparation of Paromomycin had been established.

The Committee requested the National Institute for Medical Research, London, to organize a limited collaborative study since the material was part of a batch serving as the only existing national standard. The Committee authorized the National Institute for Medical Research to define the international unit with the agreement of the participants.

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[1] Unpublished working document WHO/BS/766.
[2] *Wld Hlth Org. techn. Rep. Ser.*, 1964, **274**.
[3] Unpublished working document WHO/BS/759.
[4] *Wld Hlth Org. techn. Rep. Ser.*, 1964, **293**.
[5] Unpublished working document WHO/BS/777.
[6] Unpublished working document WHO/BS/761.

5. Rolitetracycline

The Committee noted [1] the results that had been obtained when the preparation of rolitetracycline referred to in its seventeenth report [2] was compared with two national standards and requested that it be compared with other national standards.

6. Colistin

The Committee noted [3] that a sufficient quantity of the batch of colistin sulfate referred to in its seventeenth report [2] had been obtained and that in accordance with the authorization in that report the material had been established as the International Reference Preparation of Colistin and that a collaborative assay would be arranged.

7. Colistin Methane Sulfonate

The Committee noted [3] that the sample of colistin sodium methane sulfonate referred to in its seventeenth report [2] had been compared with a number of other samples obtained from the two countries in which colistin sodium methane sulfonate is made. The Committee was informed that there were only minor differences between the various samples tested and that only one international reference preparation would be required. The Committee therefore requested the National Institute for Medical Research, London, to obtain a sufficient quantity of the material originally examined, and to distribute the material into ampoules. The Committee authorized the National Institute for Medical Research to establish the material as the International Reference Preparation of Colistin Methane Sulfonate and to arrange a collaborative assay.

8. Procaine Benzylpenicillin in Oil with Aluminium Monostearate

The Committee noted [4] the progress of the collaborative study, requested in its seventeenth report,[2] of the material intended to replace the International Reference Preparation of Procaine Benzylpenicillin in Oil with Aluminium Monostearate. The Committee authorized the National Institute for Medical Research, London, to establish this material as the second International Reference Preparation of Procaine Benzylpenicillin in Oil with Aluminium Monostearate on the basis of the results of the collaborative study.

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[1] Unpublished working document WHO/BS/760.

[2] *Wld Hlth Org. techn. Rep. Ser.*, 1964, **293**.

[3] Unpublished working document WHO/BS/764.

[4] Unpublished working document WHO/BS/765.

The Committee also noted [1] that studies of the stability of benzylpenicillin in serum samples were in progress.

9. Tylosin

The Committee noted [2] that in accordance with the authorization in its seventeenth report [3] the International Reference Preparation of Tylosin had been established. On the basis of the results of the collaborative assay the Committee defined the International Unit for Tylosin as the activity contained in 0.001 mg of the International Reference Preparation of Tylosin.

10. Hygromycin B

The Committee noted [4] that in accordance with the authorization in its seventeenth report [3] the International Reference Preparation of Hygromycin B had been established. On the basis of the results of the collaborative assay, the Committee defined the International Unit for Hygromycin B as the activity contained in 0.0008928 mg of the International Reference Preparation of Hygromycin B.

11. Cefalotin

The Committee noted [5] that in accordance with the request in its seventeenth report [3] the National Institute for Medical Research, London, had obtained a quantity of sodium cefalotin suitable to serve as an international reference preparation.

The Committee established this material as the International Reference Preparation of Cefalotin and requested the National Institute for Medical Research to organize a limited collaborative study, since the material was part of a batch serving as the only existing national standard.

The Committee authorized the National Institute for Medical Research to define the international unit with the agreement of the participants.

12. Lincomycin

The Committee noted [5] that in accordance with the request in its seventeenth report [3] the National Institute for Medical Research, London, had obtained a quantity of lincomycin hydrochloride suitable to serve as an international reference preparation.

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[1] Unpublished working document WHO/BS/765.
[2] Unpublished working document WHO/BS/785.
[3] *Wld Hlth Org. techn. Rep. Ser.*, 1964, **293**.
[4] Unpublished working document WHO/BS/786.