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Eighth Report

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EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION

Eighth Session

Geneva, 18-23 October 1954

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* Was unable to attend.

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CONTENTS

IMMUNOLOGICAL

PHARMACOLOGICAL

Antibiotics

Hormones (and protamine)

Miscellaneous

General

Annex

EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION

Eighth Report *

The eighth session of the Expert Committee on Biological Standardization was held in Geneva from 18 to 23 October 1954.

The Deputy Director-General of the World Health Organization welcomed the members and thanked them for the preparatory work they had already done, and for being willing to work still further, towards making the session a success. He also expressed appreciation of the continued and valuable co-operation of the Food and Agriculture Organization of the United Nations in those aspects of the Committee's work which are the joint concern of veterinary and medical workers.

IMMUNOLOGICAL

1. Blood-Typing Sera

1.1 *Anti-Rh_0 (anti-D) blood-typing serum*

The proposed International Standard for Anti-Rh_0 (Anti-D) Blood-Typing Serum was prepared for the characterization of saline-agglutinating anti-Rh_0 (anti-D) sera for routine use. In view of the difficulties experienced by workers in obtaining such agglutinating sera and the relative ease with which albumin-agglutinating anti-Rh_0 (anti-D) sera can be obtained, the Committee authorized the Statens Seruminstitut, Copenhagen, in consultation with the International Blood-Group Reference Laboratory, London, to examine the practicability of preparing a standard anti-Rh_0 (anti-D) serum to be used with albumin or other activating substances.

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* The Executive Board, at its fifteenth session, adopted the following resolution:
The Executive Board

1. NOTES the eighth report of the Expert Committee on Biological Standardization;
2. THANKS the members of the Committee for their work; and
3. AUTHORIZES publication of the report.

(Resolution EB15.R4, *Off. Rec. Wld Hlth Org.* 1955, **60**, 2)

1.2 *Anti-Rh′ (anti-C) and anti-Rh″ (anti-E) blood-typing sera*

The Committee noted that the few contributions of anti-Rh′ (anti-C) and anti-Rh″ (anti-E) blood-typing sera sent to the International Blood Group Reference Laboratory, London, for international standards of these two sera were insufficient for making standard preparations. In view of the expected delay in the establishment of these standards, the Committee wished to draw attention to the alternative method of characterizing anti-Rh′ (anti-C) and anti-Rh″ (anti-E) sera, whereby the red cells of persons of the correct type who are readily available to the laboratories concerned can be authenticated by the International Blood Group Reference Laboratory, and used as " standard " antigens for the titration of routine anti-Rh′ (anti-C) and anti-Rh″ (anti-E) typing sera.

2. International Reference Preparations of Cholera Vaccines, Diagnostic Antigens, and Diagnostic Sera

The Committee asked Dr. P. M. Wagle of the Haffkine Institute, Bombay, in association with Dr. M. L. Ahuja of the Central Research Institute, Kasauli, India, and in consultation with the Statens Seruminstitut, Copenhagen, to arrange the further collaborative studies of the International Reference Preparations of Cholera Vaccines.[1]

The Committee endorsed for publication a memorandum on the preparations, their properties and the ways in which they may be used.[2]

3. International Reference Preparations of Clostridium Welchii (Perfringens) Antitoxins

The Committee noted that the Veterinary Laboratory, Weybridge, Surrey, England, had obtained a batch of serum for each of the proposed new International Standards for *Clostridium welchii* Antitoxins, Types B and D, and had carried out a collaborative examination [3] of the suitability of these batches as international standards.[4] The Committee adopted the

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[1] See *Wld Hlth Org. techn. Rep. Ser.* 1954, **86**, 7.

[2] Maaløe, O., unpublished working document WHO/BS/255

[3] Participants : Maaløe, O., Statens Seruminstitut, Denmark ; Mason, J. H., South African Institute for Medical Research, Union of South Africa ; Morgan, F. G., Commonwealth Serum Laboratories, Australia ; Prigge, R., Paul-Ehrlich Institute, Germany ; Stableforth, A. W., Ministry of Agriculture and Fisheries Veterinary Laboratory, England and Wales ; Wellcome Research Laboratories, England

[4] Statens Seruminstitut, Department of Biological Standards, Copenhagen, unpublished working document WHO/BS/281 ; Stableforth, A. W., unpublished working document WHO/BS/283

materials as International Reference Preparations of *Clostridium welchii* (Type B) Antitoxin and of *Clostridium welchii* (Type D) Antitoxin. The Committee decided that one provisional unit of beta antitoxin is contained in 0.0137 mg of the Type B Preparation and one provisional unit of epsilon antitoxin is contained in 0.0657 mg of the Type D Preparation. It is expected that, until further information is obtained about the properties of these antitoxins, they will be used to assay therapeutic sera and not for the identification of types of *Cl. welchii*.

The Committee recognized that the existing International Standard for Gas Gangrene Antitoxin (*perfringens*) is actually a *Cl. welchii* Type A antitoxin, and recommends that it be studied together with the international reference preparations with a view to assigning unitages to the three antitoxin preparations for the known toxic components of *Cl. welchii*. The Committee authorized the Veterinary Laboratory, Weybridge, and the Statens Seruminstitut, Copenhagen, to organize this collaborative examination.

4. Diphtheria Toxoid and Schick-Test Toxin

4.1 *Diphtheria toxoid, adsorbed*

The Committee noted that the batch of aluminium hydroxide adsorbed diphtheria toxoid prepared by the Paul-Ehrlich Institute, Frankfurt-on-Main, has now been sent to the Statens Seruminstitut, Copenhagen, and authorized that institute to establish it as the International Standard, subject to the approval of participants in a collaborative study of its potency and thermostability.

The Committee noted further evidence of the need for an international standard of this type in a report on assays of a large number of diphtheria toxoid preparations.[1]

4.2 *International Standard for Schick-Test Toxin (Diphtheria)*

The Committee considered reports[2] on collaborative studies[3] of a dried preparation of diphtheria toxin and established it as the International

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[1] Greenberg, L. (1955) *Bull. Wld Hlth Org.* **12**, 751

[2] Statens Seruminstitut, Department of Biological Standards, Copenhagen, unpublished working document WHO/BS/274; Prigge, R., unpublished working document WHO/BS/275 and Add. 1 and 2

[3] Participants: Barr, M., Wellcome Research Laboratories, England; Greenberg, L., Biologics Control Laboratories, Canada; Prigge, R., Paul-Ehrlich Institute, Germany; Rostock, O. and Schiebel, I., Statens Seruminstitut, Denmark

Standard for Schick-Test Toxin (Diphtheria). The Committee assigned to the Standard a unitage such that 900 International Units are contained in one ampoule of the Standard Preparation as at present issued.

The Committee agreed that there is no need to provide international standards for Schick-test control reagents.

5. Influenza Vaccines and Diagnostic Reagents

5.1 *Influenza vaccines*

The Committee considered the possibilities of providing a stable reference preparation of influenza vaccine, but emphasized that the technical difficulties appear at present to be insuperable.[1, 2]

The Committee recommended, however, that in any future field trial of influenza vaccines, concurrent laboratory assays of the vaccines used should be encouraged.

5.2 *Influenza diagnostic reagents*

The Committee considered the question raised by the WHO Expert Committee on Influenza concerning the desirability of providing standard reagents for the differentiation of types of influenza virus.[3] The Committee suggested that the Expert Committee on Influenza confirm that typing can be achieved with sufficient precision by means of reference sera alone. If this is so, the Committee will be pleased to give all possible assistance in establishing and distributing diagnostic reference sera for influenza-virus typing.

6. International Reference Preparation for Opacity

The Committee adopted a report[4] on the International Reference Preparation for Opacity as the memorandum for distribution with issues of this preparation.

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[1] National Institute for Medical Research, World Influenza Centre and Department of Biological Standards, London, unpublished working document WHO/BS/258

[2] Unpublished working document WHO/Influenza/18

[3] *Wld Hlth Org. techn. Rep. Ser.* 1953, **64**, 10; Payne, A. M.-M., unpublished working document WHO/BS/290

[4] Maaløe, O. (1955) *Bull. Wld Hlth Org.* **12**, 769