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Sixth Report

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EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION

Sixth Session

Geneva, 20-25 October 1952

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The report on the sixth session of this committee was originally issued in mimeographed form as document WHO/BS/183, 17 November 1952.

* Attended during the discussion of subjects of special interest to FAO.

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World Hlth Org. techn. Rep. Ser. 1953, **68**

EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION

Sixth Report [1]

The sixth session of the Expert Committee on Biological Standardization was held in Geneva from 20 to 25 October 1952.

The Deputy Director-General welcomed the experts and referred to the impressive and accelerating rate of increase in the number of international biological standards. This reflects an ever-increasing burden of responsibility, willingly shouldered by the committee and the other members of the expert panel. Without both their advisory and their technical activities it would be impossible for WHO to discharge its obligations to fullest effect in this vital field of work. WHO is therefore most grateful to them for their unremitting assistance.

An important development which the Deputy Director-General had noted was the increasing proportion of standards intended for diagnostic rather than for therapeutic purposes. Among these are several which are to be used in the diagnosis of zoonoses. This involves WHO in still closer co-operation with the Food and Agriculture Organization of the United Nations (FAO), a development which cannot fail to bring both organizations nearer to their common goal of increased human welfare. He wished therefore to express also to FAO the thanks of WHO for its continued co-operation in this work.

IMMUNOLOGICAL

ANTIGENS AND VACCINES

1. Tuberculins

Purified protein derivative (PPD) of mammalian tuberculin [2]

The committee considered the unitage to be assigned to the International Standard for Purified Protein Derivative of Mammalian Tuberculin.

[1] The Executive Board, at its eleventh session, adopted the following resolution:
The Executive Board
1. NOTES the sixth 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 EB11.R17, *Off. Rec. World Hlth Org.* **46**, 6)

[2] Statens Seruminstitut, Department of Biological Standards, Copenhagen, unpublished working document WHO/BS/173; Green, H. H., unpublished working document WHO/BS/181

The desirability of equating the unit of this material to the International Unit of Old Tuberculin, as far as it is possible to do this, was confirmed. The standard established last year,[3] prepared by Dr. Florence Seibert of the Henry Phipps Institute, Philadelphia, Pa., USA (by drying in ampoules a solution of PPD of mammalian tuberculin in phosphate buffer), includes a certain amount of non-specific material. In previously published work the unit of PPD of mammalian tuberculin has been regarded as 0.00002 mg of material which contains no buffer. Since the international standard does contain such buffer, the unit of the standard is somewhat larger and has been determined as 0.000028 mg. The committee decided that one International Unit is contained in 0.000028 mg of the International Standard for Purified Protein Derivative of Mammalian Tuberculin.

PPD of avian tuberculin [4]

The committee noted certain difficulties encountered in the preparation of the proposed International Standard for Purified Protein Derivative of Avian Tuberculin, and in the supply of stable cultures of strain D4 of *Mycobacterium tuberculosis* (avian). The Weybridge Laboratory, Surrey, United Kingdom, is continuing work on this problem and it is expected that these materials will be available for examination within the coming year.

2. Diphtheria Toxoids and Toxin

See below, under section 3, " Pertussis vaccine ".

3. Pertussis Vaccine

The committee considered the recommendations made in a memorandum submitted by the Chairman (Dr. G. S. Wilson) of the WHO Conference of Heads of Laboratories producing Diphtheria and Pertussis Vaccines, held in Dubrovnik, Yugoslavia, from 13 to 18 October 1952 : [5]

(*a*) *International Standard for Diphtheria Toxoid Adsorbed*

The committee noted the recommendation that such a standard preparation should be set up at an early date, and reported that considerable progress had already been made, along the lines proposed at its fifth session.[6]

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[3] *World Hlth Org. techn. Rep. Ser.* 1952, **56**, 6

[4] Green, H. H., unpublished working document WHO/BS/181

[5] *World Hlth Org. techn. Rep. Ser.* 1953, **61**

[6] *World Hlth Org. techn. Rep. Ser.* 1952, **56**, 5

(*b*) *International reference preparation for opacity*

The committee noted that the conference recommended the establishment of an international reference preparation for opacity, and reported that such a standard was about to be established (see section 4, below).

(c) Proposed reference preparation of Schick toxin

The committee noted the recommendation of the conference that the provision of such a reference preparation should be considered, and authorized the Statens Seruminstitut, Copenhagen, to investigate the possibility of obtaining suitable stable material for this purpose.

(*d*) *Proposed standard for pertussis vaccine*

The committee noted that the conference recommended the setting up of a standard for pertussis vaccine, and authorized the Statens Seruminstitut to continue its investigations into the possibilities of doing so.

(*e*) *Proposed standard for anti-pertussis serum*

The committee noted the recommendation of the conference that it should consider the provision of a reference standard agglutinating anti-pertussis serum, and authorized the Statens Seruminstitut to investigate the possibility of providing such a standard.

(*f*) *Proposed reference strain of virulent* Haemophilus pertussis

The committee noted that the conference recommended that the provision of a reference strain of virulent *Haemophilus pertussis* should be considered. The committee was, however, not convinced of the usefulness of providing such a reference strain and was of the opinion that the provision of virulent strains could be undertaken by consultation and the exchange of strains between laboratories interested in this problem.

4. Opacity Standard for Bacterial Suspensions [7]

The committee noted that the Statens Seruminstitut, Copenhagen, had collected opinions on the standard for opacity used by the National Institutes of Health, Bethesda Md., USA. Opinions were unanimous that this material is suitable for the International Reference Preparation for Opacity. The committee, therefore, authorized the Statens Serum-

[7] Statens Seruminstitut, Department of Biological Standards, Copenhagen, unpublished working document WHO/BS/172

institut, in consultation with the National Institutes of Health, Bethesda, to establish either the existing material or a new batch of equivalent material as the International Reference Preparation for Opacity, and to assign to it an opacity of 10 International Units per millilitre.

5. Smallpox Vaccines [8]

The committee noted a report by the Consultative Group on Laboratory Investigation of Dried Smallpox Vaccine, describing plans for the collaborative examination of a number of fluid and dried vaccines in order to determine the value of dried vaccines. As a first stage the work is now limited to observations in laboratory animals.

6. Cholera Vaccines and Antigens

Vaccines

The committee noted that examination of the proposed standard preparations for cholera vaccines is held up by the lack both of virulent cholera strains and of susceptible mice in the participating laboratories. The committee accepted the offer by the Pasteur Institute, Paris, and the Central Research Institute, Kasauli, India, to distribute virulent cholera vibrios, and the offer by the National Institutes of Health, Bethesda, to supply breeding colonies of susceptible mice to the participating laboratories.

Antigens for the preparation of diagnostic sera; diagnostic sera [9]

The committee noted that (*a*) dried preparations of cholera vibrios (Ogawa and Inaba respectively) prepared by the late Dr. P. B. Bruce White, National Institute for Medical Research, London, to be used for the production of diagnostic sera, and (*b*) monospecific Ogawa and Inaba agglutinating sera, prepared by Lieutenant-Colonel M. L. Ahuja, Central Research Institute, Kasauli, were now available at the Statens Seruminstitut, Copenhagen. The committee decided that these preparations should be accepted as international reference preparations, subject to an examination as to their suitability. The committee asked the Statens Seruminstitut and the Haffkine Institute, Bombay, to undertake this investigation in collaboration with other interested laboratories.

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[8] Consultative Group on Laboratory Investigation of Dried Smallpox Vaccine, unpublished working document WHO/Smallpox/3

[9] Statens Seruminstitut, Department of Biological Standards, Copenhagen, unpublished working document WHO/BS/167