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*WORLD HEALTH ORGANIZATION*

*TECHNICAL REPORT SERIES*

No. 86

# EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION

## Seventh Report

WORLD HEALTH ORGANIZATION

PALAIS DES NATIONS

GENEVA

JUNE 1954

## EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION

**Seventh Session**

*Geneva, 26-31 October 1953*

*Members :*

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J. Gibbard, Chief, Laboratory of Hygiene, Department of National Health and Welfare, Ottawa, Canada

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Professor A. A. Miles, Director, Lister Institute of Preventive Medicine, London, England

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Dr. W. L. M. Perry, Director, Department of Biological Standards, National Institute for Medical Research, Mill Hill, London, England (*Rapporteur*)

Professor R. Prigge, Director, Paul Ehrlich Institute, State Institute for Experimental Therapy, Frankfurt-on-Main, Germany

Dr. A. W. Stableforth, Director, Ministry of Agriculture and Fisheries Veterinary Laboratory, Weybridge, Surrey, England

Professeur J. Tréfouël, Directeur de l'Institut Pasteur, Paris, France

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*FAO Representative :*

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*Secretariat :*

Dr. W. Aeg. Timmerman, Director, Division of Therapeutic Substances, WHO

Dr. E. M. Lourie, Chief, Biological Standardization Section, WHO

The report on the seventh session of this committee was originally issued in mimeographed form as document WHO/BS/252, 16 November 1953.

* Was unable to attend.

PRINTED IN SWITZERLAND

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## GENERAL



## ANNEX 1

# EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION

## Seventh Report *

The seventh session of the Expert Committee on Biological Standardization was held in Geneva from 26 to 31 October 1953.

The Director-General welcomed the experts and thanked them for the work that they had already done in preparation for a long and difficult agenda. Their work aimed at making it possible for the potency of therapeutic, prophylactic, and diagnostic substances to be measured and described in terms which are accepted throughout the world. This is essential for orderly progress in human and veterinary medicine. It can be achieved to its maximum potential only if there are efficient working arrangements not only at WHO headquarters and at the two International Centres, in Copenhagen and London respectively, but also at the national control centres of the individual countries. He therefore welcomed the fact that

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

The Executive Board

1. NOTES the seventh report of the Expert Committee on Biological Standardization;
2. THANKS the members of the committee for their work;
3. AUTHORIZES publication of the report;
4. ENDORSES the recommendations of the expert committee that:

(1) the term "national control centres" be replaced by "national laboratories for biological standards"; and

(2) the status, privileges, and functions of national laboratories for biological standards be those proposed in Annex I to the report, i.e.:

(*a*) National laboratories should have scientific staffs qualified to deal with biological standardization in their own countries.

(*b*) National laboratories should as far as possible encourage the use of international units and the establishment of subsidiary standards with international unitage.

(*c*) National laboratories shall be entitled to receive specimens of the international standards for purposes approved by the Expert Committee on Biological Standardization. The international standards shall be used mainly for the calibration of subsidiary standards, in order to conserve the supply of the international standards.

(*d*) National laboratories shall receive from WHO reports describing the work and data on which the establishment and use of the international biological standards are based.

(*e*) The national laboratories should inform the World Health Organization about the establishment of any local standard, whether or not there exists an international standard for that substance.

(Resolution EB13.R11, *Off. Rec. Wld Hlth Org.* **52**, 5)

the committee proposed to devote an important part of its time to considering means by which the system of national control centres, or national laboratories for biological standards, might be strengthened, so that all countries would be able to derive the fullest benefit possible from the international biological standards.

## IMMUNOLOGICAL

### 1. Blood-Typing Sera [1]

1.1 *Proposed International Standard for Anti-$Rh_0$ (Anti-D) Blood-Typing Serum*

The committee noted that the International Blood-Group Reference Laboratory, London, in consultation with the National Institute for Medical Research, London, had now completed the preparation of the proposed International Standard for Anti-$Rh_0$ (Anti-D) Blood-Typing Serum. The committee authorized the Statens Seruminstitut, Copenhagen, to establish this material as the International Standard for Anti-$Rh_0$ (Anti-D) Blood-Typing Serum and to assign a unitage to it on the basis of the results of the collaborative study.

1.2 *The International Blood-Group Reference Laboratory* [2]

The committee noted that the International Blood-Group Reference Laboratory had been established at the Medical Research Council's Blood-Group Reference Laboratory, London.

### 2. International Standard for Anti-Brucella abortus Serum [3, 4]

The International Standard for Anti-*Brucella abortus* Serum was established by the committee at its sixth session.[5] In the light of its decision to assign unitages to diagnostic sera (see section 15, page 13) and of the

[1] National Institute for Medical Research, Department of Biological Standards, London, unpublished working document WHO/BS/213

[2] Unpublished working document WHO/BS/240

[3] Statens Seruminstitut, Department of Biological Standards, Copenhagen, unpublished working document WHO/BS/223

[4] Stableforth, A. W., unpublished working documents WHO/BS/224, WHO/BS/228

[5] *Wld Hlth Org. techn. Rep. Ser.* 1953, **68**, 9

fact that the mean weight of ampoules has been determined, the committee decided that one International Unit for Anti-*Brucella abortus* Serum is contained in 0.091 mg of the International Standard. This will mean that there will be the convenient number of 1,000 International Units in each ampoule.

### 3. Cholera Antigens, Diagnostic Sera, and Vaccines [6]

The committee considered the results of the collaborative studies organized by the Statens Seruminstitut and established the International Reference Preparations of:

(*a*) Cholera Agglutinating Serum (Ogawa)
(*b*) Cholera Agglutinating Serum (Inaba)
(*c*) Cholera Antigen (Ogawa)
(*d*) Cholera Antigen (Inaba)
(*e*) Cholera Vaccine (Ogawa)
(*f*) Cholera Vaccine (Inaba).

The committee also asked the Statens Seruminstitut to arrange for a further collaborative examination of the two proposed International Reference Preparationsof Cholera Vaccines.

### 4. Clostridium Perfringens Antitoxins

The committee considered a suggestion from the Fifteenth International Veterinary Congress [7] that it should take steps towards establishing standards for *Clostridium perfringens* antitoxins, beta and epsilon, in

[6] Statens Seruminstitut, Department of Biological Standards, Copenhagen, unpublished working document WHO/BS/222

[7] The text of a resolution adopted at a plenary session of the Fifteenth International Veterinary Congress (held in Stockholm in August 1953) is as follows:

"Recognising the need for urgent action to establish international standards for biological products for veterinary use, the XVth International Veterinary Congress welcomes the extension of the work of the Committee on Biological Standardization of the World Health Organization to include such products. It suggests that this Committee be encouraged to extend as soon as possible its work towards the provision of international standards for other suitable veterinary substances, those meriting immediate attention being *Cl. welchii* (*Cl. perfringens*) antitoxins, beta and epsilon, and swine erysipelas antiserum. The XVth International Veterinary Congress also welcomes the work of the OIE [International Office of Epizootics] on the study of biological products for use in the control of animal diseases and suggests that the Office be encouraged to continue its activities on this subject."

addition to the existing International Standard for Gas-Gangrene Antitoxin (Perfringens). These new standards would be required mainly for therapeutic purposes in veterinary practice, and the committee requested the Veterinary Laboratory, Weybridge, Surrey, England, to obtain suitable batches of serum for both the proposed new standards. It was further agreed that the Weybridge Veterinary Laboratory should be asked to arrange for a collaborative examination by interested workers throughout the world of the suitability of these preparations as International Standards. It was suggested that an examination should be made of potency and monospecificity of the proposed new standards and of the existing one.

The committee also discussed the need for these and other *Cl. perfringens* antitoxins for diagnostic purposes and asked the Weybridge Veterinary Laboratory to set up a small working group to examine this question and to prepare a report for an early future session of the committee.

## 5. Diphtheria

### 5.1 *Proposed International Standard for Diphtheria Toxoid, Adsorbed* [8, 9, 10]

The committee asked the Paul Ehrlich Institute, Frankfurt-on-Main, to prepare material for the International Standard for Diphtheria Toxoid, Adsorbed, and requested the Statens Seruminstitut to arrange for further studies of the stability of diphtheria toxoids at different temperatures, using for this purpose both the International Standard for Diphtheria Toxoid, Plain, and the proposed International Standard for Diphtheria Toxoid, Adsorbed.

The committee also discussed the general need for, and interpretation of, accelerated degradation tests for stability of standard preparations and decided to study this question in detail.

### 5.2 *Schick-test toxin* [11, 12]

The committee noted that in the collaborative investigation of various selected Schick-test toxins a freeze-dried purified preparation had shown the most consistent results, and authorized the Statens Seruminstitut to

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[8] Greenberg, L. (1953) *Bull. Wld Hlth Org.* **9**, 829

[9] Statens Seruminstitut, Department of Biological Standards, Copenhagen, unpublished working document WHO/BS/193

[10] Prigge, R. (1953) *Bull. Wld Hlth Org.* **9**, 843

[11] Statens Seruminstitut, Department of Biological Standards, Copenhagen, unpublished working document WHO/BS/229

[12] Unpublished working document WHO/BS/247

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