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. 444

WHO EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION 6

Twenty-second Report

WORLD HEALTH ORGANIZATION

GENEVA

1970

© World Health Organization 1970

Publications of the World Health Organization enjoy copyright protection in accordance with the provisions of Protocol 2 of the Universal Copyright Convention. Nevertheless governmental agencies or learned and professional societies may reproduce data or excerpts or illustrations from them without requesting an authorization from the World Health Organization.

For rights of reproduction or translation of WHO publications in toto, application should be made to the Office of Publications and Translation, World Health Organization, Geneva, Switzerland. The World Health Organization welcomes such applications.

The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the Director-General of the World Health Organization concerning the legal status of any country or territory or of its authorities, or concerning the delimitation of its frontiers.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the World Health Organization in preference to others of a similar nature which are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

PRINTED IN SWITZERLAND

CONTENTS

							Page			
GENER	RAL						7			
Dryinger										
PHARMACOLOGICAL Antibiotics										
1	Viomycin						7			
	Viomycin						8			
	Methacycline						8			
	Polymyxin B						8			
	Nisin						9			
	Tetracycline						9			
	Pecilocin						10			
	Anti-tumour antibiotics — mithramycin and daunorubicin						10			
	Saramycetin						11			
	Doxycycline						11			
Hormo	nes and enzymes									
11.	Human growth hormone						11			
12.	Angiotensins and renins						12			
	Immunological									
Antiger										
_	noc .						12			
	Old tuberculin			•	•	•	13			
15.	D 11			•	•	•	14			
	Cholera vaccine			•	•	•	14			
	Diphtheria toxoid (plain)						14			
	Influenza virus haemagglutinin						15			
	Rinderpest vaccine (live)						15			
	Clostridium oedematiens (type A) toxoid (adsorbed)						16			
20.	cope 11) tokota (adsorbed) 1 1 1 1	•	·	•	•	•	10			
Antiboo	dies									
21.	Anti-Mycoplasma gallisepticum serum						16			
22.	Anti-Salmonella pullorum sera						17			
23.	Tetanus antitoxin						17			
24.	Diphtheria antitoxin for flocculation test						18			
25.	Rheumatoid arthritis serum						19			
	Naia antivenin						19			

	BIOLOGICAL REFERENCE REAGENTS	Page
27.	Enterovirus antisera	19
	REQUIREMENTS FOR BIOLOGICAL SUBSTANCES	
28.	Requirements for rinderpest cell culture vaccine (live) and rinderpest vaccine (live)	20
29.	Requirements for <i>Brucella abortus</i> strain 19 vaccine (live—for veterinary use)	20
30.	Development of a national control laboratory for biological substances (A guide to the provision of technical facilities)	21
31.	Stability of preservatives	21
32.	Requirements for yellow fever vaccine	21
	Miscellaneous	
33.	Cholera O group 1 serum	22
	Annexes	
Annex	1. Requirements for rinderpest cell culture vaccine (live) and rinderpest vaccine (live) (Requirements for biological substances No. 19)	23
Annex	2. Requirements for <i>Brucella abortus</i> strain 19 vaccine (live—for veterinary use) (Requirements for biological substances No. 20)	58
Annex	3. Development of a national control laboratory for biological substances (A guide to the provision of technical facilities)	71
Annex	4. Requirements for biological substances and other sets of recommendations	87
Annex	5. International biological standards and international biological reference preparations, 1970	89
Annex	6. International biological reference reagents	120
Annex	7. Proposed international biological standards, international biological reference preparations and international biological reference reagents	128
Annex	8. Discontinued international biological standards	131
INDEV		122

WHO EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION

Geneva, 30 September to 8 October 1969

Members: *

- Dr D. R. Bangham, Director, Division of Biological Standards, National Institute for Medical Research, London, England
- Dr H. H. Cohen, Director, Rijks Instituut voor de Volksgezondheid, Utrecht, Netherlands
- Dr J. Desbordes, Director, Microbiology Department, National Public Health Laboratory, Paris, France
- Dr M. R. Dhanda, Director, Commonwealth Bureau of Animal Health, Central Veterinary Laboratory, Weybridge, Surrey, England
- Dr L. Greenberg, Chief, Biologics Control Laboratories, Laboratory of Hygiene, Department of National Health and Welfare, Ottawa, Canada
- Dr Sutas Guptarak, Chief, Biological Division, The Government Pharmaceutical Organization, Bangkok, Thailand
- Dr Tanja B. Jablokova, Head, BCG and Tuberculin Laboratory, State Institute for the Control of Medical Biological Preparations (L. A. Tarasevič Institute), Moscow, USSR (Vice-Chairman)
- Dr R. Murray, Director, Division of Biologics Standards, National Institutes of Health, Bethesda, Md., USA
- Dr J. B. Shrivastav, Additional Director General of Health Services, Ministry of Health, New Delhi, India (Rapporteur)
- Dr J. Spaun, Deputy Director, Department of Biological Standardization, Statens Seruminstitut, Copenhagen, Denmark (Chairman)

Representatives of other organizations:

Food and Agriculture Organization of the United Nations:

Mr I. Davidson, Department of Biological Products and Standards, Central Veterinary Laboratory, Weybridge, Surrey, England

International Office of Epizootics:

Professor A. Florent, Director, National Institute for Veterinary Research, Brussels, Belgium

Dr R. Vittoz, Director, International Office of Epizootics, Paris, France Professor V. Zavagli, Director, Istituto Zooprofilattico Sperimentale, Rome, Italy

Dr P. Krag, Director, Department of Biological Standardization, Statens Serum-institut, Copenhagen, Denmark

Dr M. Kurokawa, Chief, Department of General Biologics Control, National Institute of Health, Tokyo, Japan

Professor A. Rafyi, Dean, Faculty of Veterinary Medicine, University of Teheran, Iran

^{*} Unable to attend:

Secretariat:

- Professor D. G. Evans, London School of Hygiene and Tropical Medicine, London, England (Consultant)
- Mr E. C. Hulse, Director, Department of Biological Products and Standards, Central Veterinary Laboratory, Weybridge, Surrey, England (Consultant)
- Dr A. N. Klimov, Director, Division of Biomedical Sciences, WHO, Geneva
- Mr J. W. Lightbown, Division of Biological Standards, National Institute for Medical Research, London, England (Consultant)
- Mr J. Lyng, Department of Biological Standardization, Statens Seruminstitut, Copenhagen, Denmark (Consultant)
- Dr A. S. Outschoorn, Chief Medical Officer, Biological Standardization, WHO, Geneva (Secretary)
- Dr Sophia S. Vrancheva, Chief, Laboratory for Control and Standardization of Bioproducts, Research Institute of Epidemiology and Microbiology, Sofia, Bulgaria (Consultant)
- Dr W. W. Wright, Acting Deputy Director, Division of Pharmaceutical Sciences, Bureau of Science, Food and Drug Administration, Washington, D.C., USA (Consultant)

WHO EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION

Twenty-second Report

The WHO Expert Committee on Biological Standardization met in Geneva from 30 September to 8 October 1969. Dr P. Dorolle, Deputy Director-General, on behalf of the Director-General, welcomed the members of the Committee. He also welcomed the representatives of the Food and Agriculture Organization of the United Nations (FAO) and of the International Office of Epizootics (OIE). This was the first time that representatives of OIE had attended a meeting of the WHO Expert Committee on Biological Standardization. A large proportion of the work of the Committee was concerned with items of veterinary interest, since the Organization now worked for the establishment of biological standards and the formulation of requirements for biological products within the sphere of interest of FAO. The collaboration of OIE was invaluable in providing expert advice and assistance in these tasks.

The Deputy Director-General observed that, as usual, the agenda contained items of varied application and interest. As he had mentioned on previous occasions, an important function of the Committee was to advise the Organization on the priorities for establishing biological standards and on the activities that would be of most use to countries in enabling them to use biological products of adequate efficacy and safety in prophylaxis and therapy. There were many countries that needed help and guidance in ensuring the necessary minimum level of quality. It was most opportune that one of the items before the Committee was the consideration of a guide to the development of laboratory facilities for the control of biological products. Since it was important to help promote the wider adoption of international standards and requirements for biological substances and their more effective application, he hoped the Committee would keep this aspect of the programme well in mind.

PHARMACOLOGICAL

ANTIBIOTICS

1. Viomycin

The Committee noted 1 the results of the limited collaborative assay, requested in its twenty-first report, 2 of the proposed second international

¹ Unpublished working document WHO/BS/69.984.

² Wld Hlth Org. techn. Rep. Ser., 1969, No. 413, p. 10.

reference preparation of viomycin. The Committee also noted ¹ that, in accordance with the authorization given in its twenty-first report, ² the National Institute for Medical Research, London, had established the second International Reference Preparation of Viomycin in replacement of the first international reference preparation and, on the basis of the results of the collaborative assay, had defined the International Unit for Viomycin as the activity contained in 0.0012285 mg of the International Reference Preparation of Viomycin.

2. Chlortetracycline

The Committee noted ³ that the collaborative assay of the proposed second international standard for chlortetracycline had been completed. The Committee also noted ³ that, in accordance with the authorization given in its twenty-first report, ⁴ the National Institute for Medical Research, London, had established the second International Standard for Chlortetracycline in replacement of the first international standard and, with the agreement of the participants, had defined the International Unit for Chlortetracycline as the activity contained in 0.001 mg of the International Standard for Chlortetracycline.

3. Methacycline

The Committee was informed that, in accordance with the authorization given in its twenty-first report,⁵ the National Institute for Medical Research, London, had established the International Reference Preparation of Methacycline and, on the basis of the results of the limited collaborative assay requested in the twenty-first report,⁵ had defined the International Unit for Methacycline as the activity contained in 0.001082 mg of the International Reference Preparation of Methacycline.

4. Polymyxin B

The Committee noted ⁶ that the collaborative assay of the proposed second international standard for polymyxin B had been completed and that, in accordance with the authorization given in its twenty-first report,⁷

预览已结束,完整报告链接和二维码如下:

https://www.yunbaogao.cn/report/index/report?reportId=5 30859



¹ Unpublished working document WHO/BS/69.984.

² Wld Hlth Org. techn. Rep. Ser., 1969, No. 413, p. 10.

³ Unpublished working document WHO/BS/69.983.

⁴ Wld Hlth Org. techn. Rep. Ser., 1969, No. 413, p. 11.

⁵ Wld Hlth Org. techn. Rep. Ser., 1969, No. 413, p. 12.

⁶ Unpublished working document WHO/BS/69.990.

⁷ Wld Hlth Org. techn. Rev. Ser., 1969, No. 413, n. 13.