WHO EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION

Fifty-first Report



World Health Organization

Geneva

The World Health Organization was established in 1948 as a specialized agency of the United Nations serving as the directing and coordinating authority for international health matters and public health. One of WHO's constitutional functions is to provide objective and reliable information and advice in the field of human health, a responsibility that it fulfils in part through its extensive programme of publications.

The Organization seeks through its publications to support national health strategies and address the most pressing public health concerns of populations around the world. To respond to the needs of Member States at all levels of development, WHO publishes practical manuals, handbooks and training material for specific categories of health workers; internationally applicable guidelines and standards; reviews and analyses of health policies, programmes and research; and state-of-the-art consensus reports that offer technical advice and recommendations for decision-makers. These books are closely tied to the Organization's priority activities, encompassing disease prevention and control, the development of equitable health systems based on primary health care, and health promotion for individuals and communities. Progress towards better health for all also demands the global dissemination and exchange of information that draws on the knowledge and experience of all WHO's Member countries and the collaboration of world leaders in public health and the biomedical sciences.

To ensure the widest possible availability of authoritative information and guidance on health matters, WHO secures the broad international distribution of its publications and encourages their translation and adaptation. By helping to promote and protect health and prevent and control disease throughout the world, WHO's books contribute to achieving the Organization's principal objective — the attainment by all people of the highest possible level of health.

The WHO Technical Report Series makes available the findings of various international groups of experts that provide WHO with the latest scientific and technical advice on a broad range of medical and public health subjects. Members of such expert groups serve without remuneration in their personal capacities rather than as representatives of governments or other bodies; their views do not necessarily reflect the decisions or the stated policy of WHO. An annual subscription to this series, comprising about 10 such reports, costs Sw. fr. 132.– (Sw. fr. 92.40 in developing countries).

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

WHO Technical Report Series

910

WHO EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION

Fifty-first Report



World Health Organization

Geneva 2002

The World Health Organization welcomes requests for permission to reproduce or translate its publications, in part or in full. Applications and enquiries should be addressed to the Office of Publications, World Health Organization, Geneva, Switzerland, which will be glad to provide the latest information on any changes made to the text, plans for new editions, and reprints and translations already available.	
© World Health Organization 2002	
Publications of the World Health Organization enjoy copyright protection in accordance with the provisions of Protocol 2 of the Universal Copyright Convention. All rights reserved.	
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 Secretariat of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries.	
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	

that are not mentioned. Errors and omissions excepted, the names of proprietary products are distin-

Typeset in Hong Kong Printed in Singapore 2001/14230 — SNPBest-set/SNP — 6500

guished by initial capital letters.

WHO Library Cataloguing-in-Publication Data

Contents

Introduction	1
General Developments in biological standardization Comparability of biotechnology products DNA vaccines Working reference materials Smallpox Stability testing of vaccines WHO Consultation on International Biological Standards for in vitro Diagnostic Procedures	2 2 3 3 4 5 5
International guidelines, requirements and other matters related to the manufacture and quality control of biologicals Poliomyelitis vaccines Recommendations for the production and control of poliomyelitis vaccine (oral) Recommendations for the production and control of poliomyelitis vaccine (inactivated) Guidelines for the production and control of Japanese encephalitis vaccine (live) for human use Guidelines for the production and control of inactivated oral cholera vaccines Requirements for diphtheria, tetanus, pertussis and combined vaccines Mouse protection models for acellular pertussis vaccines Guidelines on evaluation of preclinical and clinical testing of vaccines Meningococcal vaccines Serogroup B meningococcal protein-based vaccines Serogroup A, C meningococcal conjugate vaccines Standardization and validation of serological assays for the evaluation of immune responses to pneumococcal conjugate vaccines Guidelines on viral inactivation procedures for plasma and plasmaderived medicinal products Good manufacturing practices for the collection of source materials for the production of plasma derivatives Aide memoire Bovine spongiform encephalopathy and the safety of biologicals	6 6 6 7 8 8 9 10 11 12 12 12 13 14 14 15 15
International reference materials Biological substances: international standards and reference reagents Review of stocks of oral poliovirus vaccine seeds and neurovirulence reference materials WHO Working Group on International Reference Materials for Diagnosis and Study of Transmissible Spongiform Encephalopathies	17 17 18
Antigens Tetanus toxoid Diphtheria toxoid	19 19 20

Diagnostic kits for detecting hepatitis B surface antigen and antibodies	20
to hepatitis C and human immunodeficiency virus in blood	20
Antibodies to hepatitis C virus, genotype 1	20
Standardization of unfractionated heparin	21
Tissue plasminogen activator, recombinant	21
Fibrinogen concentrate	22
Blood coagulation factor VIII concentrate, human	23
Human parvovirus B19 DNA	23
Cytokines, growth factors and endocrinological substances	24
Biological therapeutics	24
Follicle-stimulating hormone and luteinizing hormone, human, urinary	25
Somatropin	25
Inhibin B	26
Insulin-like growth factor I	26
Annex 1	
Recommendations for the production and control of poliomyelitis vaccine (oral) (revised, Addendum 2000)	28
Annex 2 Recommendations for the production and central of policy vaccine	
Recommendations for the production and control of poliomyelitis vaccine (inactivated)	32
(mactivated)	02
Annex 3	
Guidelines for the production and control of Japanese encephalitis	00
vaccine (live) for human use	66
Annex 4	
Recommendations and guidelines for biological substances used in	00
medicine and other documents	99
Annex 5	
Biological substances: International Standards and Reference Reagents	103

WHO Expert Committee on Biological Standardization

Geneva, 30 October-3 November 2000

Members

- Dr D.H. Calam, European Coordinator, National Institute for Biological Standards and Control, WHO International Laboratory for Biological Standards, Potters Bar, Herts., England (*Rapporteur*)
- Dr M. de los Angeles Cortés Castillo, Director, Quality Control, National Institute of Hygiene, Mexico City, Mexico
- Dr R. Dobbelaer, Head, Biological Standardization, Scientific Institute of Public Health, Brussels, Belgium
- Dr V. Grachev, Deputy Director, Institute of Poliomyelitis and Viral Encephalitides, Moscow, Russian Federation
- Dr J.G. Kreeftenberg, Bureau for International Cooperation, National Institute of Public Health and Environmental Protection, Bilthoven, Netherlands
- Dr F.A. Ofosu, Department of Pathology and Molecular Medicine, McMaster University, Hamilton, Ontario, Canada
- Professor Zhou Hai-jun, Director Emeritus National Institute for the Control of Pharmaceutical and Biological Products, Temple of Heaven, Beijing, China (*Vice-Chairman*)
- Dr K. Zoon, Director, Center for Biologics Evaluation and Research, Food and Drug Administration, Rockville, MD, USA (*Chairwoman*)

Representatives of other organizations

Council of Europe

Mr J.-M. Spieser, Head, Biological Standardization, European Department for the Quality of Medicines, European Pharmacopoeia Commission, Council of Europe, Strasbourg, France

European Plasma Fractionation Association

Dr T. Evers, Executive Director, Amsterdam, Netherlands

International Association for Biologicals

- Dr A. Eshkol, Senior Scientific Adviser, Ares-Serono International, Geneva, Switzerland
- Dr J.C. Petricciani, President, International Association for Biologicals, Geneva, Switzerland

International Federation of Pharmaceutical Manufacturers Associations

Dr M. Dûchene, Director, Quality Control and Regulatory Affairs, SmithKline Beecham Biologicals, Rixensart, Belgium

Dr J-C. Vincent-Falguet, Aventis Pasteur, Marcy l'Etoile, France

International Society on Thrombosis and Haemostasis

Dr D. Thomas, Kirtlington, Oxford, England

Professor I. Peake, Division of Genomic Medicine, University of Sheffield, Royal Hallamshire Hospital, Sheffield, England

Plasma Protein Therapeutics Association
Dr I. von Hoegen, Director, Regulatory Affairs, Brussels, Belgium

Secretariat

- Dr W.G. van Aken, Medical Director, Central Laboratory of the Netherlands Red Cross Blood Transfusion Service, Amsterdam, Netherlands (*Temporary Adviser*)
- Dr A. Bristow, Division of Endocrinology National Institute for Biological Standards and Control, Potters Bar, Herts., England (*Temporary Adviser*)
- Dr W. Egan, Center for Biologics Evaluation and Research, Food and Drug Administration, Rockville, MD, USA (*Temporary Adviser*)
- Dr F. Fuchs, Drugs Agency, Lyon, France (Temporary Adviser)
- Dr J. Furesz, Ontario, Canada (Temporary Adviser)
- Dr E. Griffiths, Coordinator, Quality Assurance & Safety: Biologicals, World Health Organization, Geneva, Switzerland (*Secretary*)
- Dr K. Haslov, Statens Seruminstitut, WHO International Laboratory for Biological Standards, Copenhagen, Denmark (*Temporary Advise*r)
- Dr B. Horowitz, New Rochelle, NY, USA (Temporary Adviser)
- Dr T. Kurata, Deputy Director-General National Institute of Infectious Diseases, Tokyo, Japan (*Temporary Adviser*)
- Dr J. Kurz, Blood Products Inspection Cooperation, Federal Ministry of Health and Consumer Protection, Vienna, Austria (*Temporary Adviser*)
- Dr Lei Dianliang, National Institute for the Control of Pharmaceutical and Biological Products, Temple of Heaven, Beijing, China (*Temporary Adviser*)
- Dr Chung Keel Lee, International Vaccine Institute, Seoul National University Campus, Seoul, Republic of Korea (*Temporary Adviser*)
- Dr J. Leikola, Director, Finnish Red Cross Blood Transfusion Service, Helsinki, Finland (*Temporary Adviser*)
- Dr J. Löwer, Acting Director, Paul Ehrlich Institute, Langen, Germany (*Temporary Adviser*)

Dr.D. Miner Head Division of Vivolence Netional Institute for Dislocated Otendards

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 30439



