

This report presents the recommendations of a WHO expert committee commissioned to coordinate activities leading to the adoption of international recommendations for the production and control of vaccines and other biologicals and the establishment of international biological reference materials.

The report starts with a discussion of general issues brought to the attention of the Committee and provides information on the status and development of reference materials for various antibodies, antigens, blood products and related substances, cytokines, growth factors, endocrinological substances and in vitro diagnostic devices. The second part of the report, of particular relevance to manufacturers and national regulatory authorities, contains revised WHO Recommendations for production and control of live attenuated influenza vaccines and for production and control of pneumococcal conjugate vaccines. New WHO Guidelines on the regulatory evaluation of similar biotherapeutic medicines are also provided.

Also included are a list of Recommendations, Guidelines and other documents for biological substances used in medicine, and of International Standards and Reference Reagent for biological substances.

WHO Expert Committee on Biological Standardization

Sixtieth report



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**World Health
Organization**

WHO Library Cataloguing-in-Publication Data:

WHO Expert Committee on Biological Standardization, sixtieth report.

(WHO technical report series ; no. 977)

1. Biological products - standards. 2. Vaccines - standards. 3. Reference standards.
4. Guideline. I. World Health Organization. II. WHO Expert Committee on Biological
Standardization (2009: Geneva, Switzerland). III. Series.

ISBN 978 92 4 120977 9

(NLM classification: QW 800)

ISSN 0512-3054

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Printed in Italy

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WHO Expert Committee on Biological Standardization

19 to 23 October 2009

Members¹

Dr M.M.F. Ahmed, National Organisation for Drug Control and Research (NODCAR), Agousa, Egypt

Dr J. Epstein, Center for Biologics Evaluation and Research, Food and Drug Administration, Rockville, MD, USA

Dr E. Griffiths,² Health Canada, Ontario, Canada

Mrs T. Jivapaisarnpong, Division of Biological Products, Ministry of Public Health, Nonthaburi, Thailand (*Rapporteur*)

Dr H. Klein, National Institutes of Health, Bethesda, MD, USA (*Vice-Chairman*)

Dr J. Löwer, Paul-Ehrlich-Institute, Langen, Germany

Dr P. Minor, National Institute for Biological Standards and Control, Potters Bar, England (*Chairman*)

Dr L.S. Slamet, National Agency of Drug and Food Control, Jakarta, Indonesia

Dr P. Strengers, Sanquin, Amsterdam, the Netherlands

Professor H. Yin, State Food and Drug Administration, Beijing, China

Representatives from other organizations

AdvaMed

Dr B. Marchlewicz, Abbott Park, IL, USA

Chinese Pharmacopoeia Commission

Mr H. Xiaoxu, Beijing, China

Council of Europe, European Department for the Quality of Medicines and HealthCare

Dr K.H. Buchheit, Strasbourg, France

Mr J-M. Spieser, Strasbourg, France

Developing Country Vaccine Manufacturers' Network

Dr A. Homma, Bio-Manguinhos/Fiocruz, Rio de Janeiro, Brazil

Dr S. Jadhav, Serum Institute of India, Pune, India

¹ The decisions of the Committee were taken in closed session with only members of the Committee present. Each Committee member had completed a declaration of interests form before the meeting. These were assessed by the WHO Secretariat and no declared interests were considered to be a conflict for full participation in the meeting.

² Unable to attend.

European Diagnostic Manufacturers Association (EDMA)

Dr C. Giroud, Marnes-la-Coquette, France

European Generic Medicines Association

Ms S. Kox, Brussels, Belgium

European Medicines Agency

Mr P. Richardson, London, England

European Society of Human Genetics

Dr M. Morris, Geneva, Switzerland

International Association of Biologicals

Dr A. Eshkol, La Rippe, Switzerland

International Federation of Clinical Chemistry and Laboratory Medicine

Professor J-C. Forest, Quebec, Canada

International Federation of Pharmaceutical Manufacturers & Associations

Ms A-M. Autere, Welwyn Garden City, England

Dr M. Duchêne, GSK Biologicals, Wavre, Belgium

Dr M.P. Fletcher, Pfizer, New London, CT, USA

Dr A. Sabouraud, Sanofi Pasteur, Marcy l'Etoile, France

International Generic Pharmaceutical Alliance

Dr M. Schiestl, Kundl, Tirol, Austria

International Organization for Standardization

Mr T. Hancox, Geneva, Switzerland

International Plasma Fractionation Association (IPFA)

Dr R. Perry, Amsterdam, the Netherlands

International Society on Thrombosis and Haemostasis (ISTH)

Professor K. Mertens, Chapel Hill, NC, USA

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