WHO Technical Report Series
993

WHO Expert Committee on Biological Standardization

Sixty-fifth report

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

WHO Library Cataloguing-in-Publication Data:

WHO Expert Committee on Biological Standardization, sixty-fifth report.

(WHO technical report series ; no. 993)

1.Biological Products - standards. 2.Vaccines - standards. 3.Blood - standards. 4.Anti-Bacterial Agents - standards. 5.Reference Standards. 6.Diagnostic Test Approval. I. World Health Organization. II. WHO Expert Committee on Biological Standardization (2014: Geneva, Switzerland). III. Series.

ISBN 978 92 4 120993 9 (NLM classification: QW 800)
ISBN (PDF) 978 92 4 069409 5
ISSN 0512-3054

Printed in Italy

Contents

WHO Expert Committee on Biological Standardization

13 to 17 October 2014

Committee members[1]

Professor K. Cichutek, Paul-Ehrlich-Institut, Langen, Germany

Dr J. Epstein, Center for Biologics Evaluation and Research, Food and Drug Administration, Rockville, MD, United States of America (USA) (*also Blood Regulators Network (BRN) representative*)

Dr E. Griffiths, Kingston-upon-Thames, England (*Chairman*)

Dr S. Hindawi, Blood Transfusion Services, Jeddah, Saudi Arabia

Mrs T. Jivapaisarnpong, Institute of Biological Products, Ministry of Public Health, Nonthaburi, Thailand

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

Dr P. Minor, National Institute for Biological Standards and Control, Potters Bar, England

Dr J. Petricciani, Palm Springs, CA, USA (*Rapporteur*)

Mr V.R. Reddy,[2] South African National Blood Service, Weltevreden Park, South Africa

Dr L.S. Slamet, Technical Adviser and Consultant to the National Agency of Drug and Food Control, Jakarta, Indonesia

Dr Y. Sohn, Ministry of Food and Drug Safety, Chungcheongbuk-do, Republic of Korea

Dr J. Wang, National Institutes for Food and Drug Control, Beijing, China

Professor H. Yin,[2] China Food and Drug Administration, Beijing, China

Dr K. Zoon, National Institutes of Health, Bethesda, MD, USA

Representatives of other organizations

Advanced Medical Technology Association

Dr R. Enns, Consultant to Cepheid, Sunnyvale, CA, USA

Bill & Melinda Gates Foundation

Dr N. Wairagkar, Bill & Melinda Gates Foundation, Seattle, WA, USA

[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 prior to the meeting. These were assessed by the WHO Secretariat and no declared interests were considered to be in conflict with full meeting participation.

[2] Unable to attend.

Council of Europe, European Directorate for the Quality of Medicines & HealthCare
Dr K-H. Buchheit, Official Medicines Control Laboratories Network and HealthCare, Strasbourg, France

Dr E. Charton, European Pharmacopoeia Department, Strasbourg, France

Developing Country Vaccine Manufacturers Network[3]
Dr S. Gairola, Serum Institute of India Ltd., Pune, India

Dr V. Paradkar, Biological E. Limited, Hyderabad, India

International Federation of Clinical Chemistry and Laboratory Medicine
Professor P. Gillery, American Memorial Hospital, Reims, France

International Federation of Pharmaceutical Manufacturers & Associations[3]
D. Colette, GlaxoSmithKline Vaccines, Wavre, Belgium

Dr C. Saillez, GlaxoSmithKline Vaccines, Wavre, Belgium

Dr M. English,[4] Merck, West Point, PA, USA

Mr M. McGoldrick,[4] Merck, West Point, PA, USA

Dr D. Schmalzing,[4] Merck, West Point, PA, USA

Dr S. Pluschkell, Pfizer Inc., Groton, CT, USA

Dr L. Mallet, Sanofi Pasteur, Marcy L'Etoile, France

International Generic Pharmaceuticals Alliance
Dr S. Kox, European Generic Medicines Association, Brussels, Belgium

International Plasma Fractionation Association
Dr P. Strengers, Amsterdam, Netherlands

International Society of Blood Transfusion
Dr C. Bianco, Amsterdam, Netherlands

International Society on Thrombosis and Haemostasis
Dr P. Lenting, Le Kremlin-Bicêtre, France

Pharmaceutical and Medical Device Regulatory Science Society of Japan
Dr T. Murai, Osaka, Japan

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

United States Pharmacopeial Convention
Dr F. Atouf, Rockville, MD, USA

---

[3] A maximum of two representatives of the DCVMN and two representatives of the IFPMA were present in the meeting room during discussion of any one agenda item.

[4] Participated via teleconference.

United States Pharmacopeial Convention–India
Dr R. Chakrabarti, Hyderabad, India

Temporary advisers

Ms S. Boucher, Bacterial and Combination Vaccines Division, Health Canada, Ottawa, Ontario, Canada

Dr K. Chumakov,[5] Center for Biologics Evaluation and Research, Food and Drug Administration, Bethesda, MD, USA

Dr C. Conrad, Paul-Ehrlich-Institut, Langen, Germany

Dr S. Gagneten,[5] Center for Biologics Evaluation and Research, Food and Drug Administration, Rockville, MD, USA

Dr A. Hubbard, National Institute for Biological Standards and Control, Potters Bar, England (*Rapporteur for the blood products and in vitro diagnostics track*)

Dr M. Lennon, Horning, England

Dr H. Meyer, Paul-Ehrlich-Institut, Langen, Germany

Dr M. Nübling, Paul-Ehrlich-Institut, Langen, Germany (*Rapporteur for the blood products and in vitro diagnostics track*)

Dr A. Padilla, Madrid, Spain (*Lead for the blood products and in vitro diagnostics track*)

Dr R. Sheets, Silver Spring, MD, USA

Dr A.L. Waddell, Stanley, England

Mr M. Welin, Medical Products Agency, Uppsala, Sweden

Dr T. Wu, Bacterial and Combination Vaccines Division, Health Canada, Ottawa, Ontario, Canada

Participants

Dr F. Agbanyo, Biologics and Genetic Therapies Directorate, Health Canada, Ottawa, Ontario, Canada (*also BRN representative*)