WHO Technical Report Series
904

WHO EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION

Fiftieth Report

World Health Organization
Geneva 2002

WHO Library Cataloguing-in-Publication Data

WHO Expert Committee on Biological Standardization (1999 : Geneva, Switzerland)
WHO Expert Committee on Biological Standardization : fiftieth report.

(WHO technical report series ; 904)

1.Biological products — standards 2.Vaccines — standards 3.Blood 4.Cytokines — standards
5.Reference standards 6.Guidelines I.Title II.Series

ISBN 92 4 120904 6 (NLM classification: QW 800)
ISSN 0512-3054

Typeset in Hong Kong
Printed in Singapore
2001/13779 — SNPBest-set/SNPSprint — 6000

Contents

WHO Expert Committee on Biological Standardization

Geneva, 25–29 October 1999

Members

Dr D.H. Calam, European Coordinator, National Institute for Biological Standards and Control, Potters Bar, Herts., England

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 (*Vice-Chairman*)

Dr F. Ofusu, Department of Pathology and Molecular Medicine, McMaster University, Hamilton, Ontario, Canada

Dr D.J. Wood, National Institute for Biological Standards and Control, Potters Bar, Herts., England (*Rapporteur*)

Professor Zhou Hai-jun, Director Emeritus, National Institute for the Control of Pharmaceutical and Biological Products, Temple of Heaven, Beijing, China

Dr K. Zoon, Director, Center for Biologics Evaluation and Research, Food and Drug Administration, Rockville Pike, MD, USA (*Chairwoman*)

Representatives of other organizations

Council of Europe

Dr J.-M. Spieser, European Department for the Quality of Medicines, Council of Europe, European Pharmacopoeia Commission, Strasbourg, France

European Association of the Plasma Products Industry (EAPPIA)

Dr I. Van Hoegen, Brussels, Belgium

International Association of Biologicals (IABS)

Dr A. Eshkol, Ares-Serono International SA, Plan-les-Ouates, Switzerland

International Federation of Clinical Chemistry (IFCC)

Professor J. Thijssen, Department of Endocrinology, University Hospital of Utrecht, Utrecht, Netherlands

International Federation of Pharmaceutical Manufacturers Associations (IFPMA)

Dr J.-C. Vincent-Falquet, Pasteur Mérieux Connaught France, Marcy l'Etoile, France

Dr M. Duchêne, SmithKline Beecham Biologicals, Rixensart, Belgium

International Society on Thrombosis and Haemostasis (ISTH)

Dr D. Thomas, North Green, Kirtlington, Oxford, England

Secretariat

Dr W.G. van Aken, Central Laboratory of the Netherlands Red Cross Blood Transfusion Service, Amsterdam, Netherlands (*Temporary Adviser*)

Dr A. Bristow, National Institute for Biological Standards and Control, Potters Bar, Herts., England (*Temporary Adviser*)

Dr P. Folb, Department of Pharmacology, University of Cape Town, Groote Schuur Hospital Observatory, Cape Town, South Africa (*Temporary Adviser*)

Dr J. Furesz, Ottawa, Ontario, Canada (*Temporary Adviser*)

Dr E. Griffiths, Coordinator, Quality Assurance and Safety: Biologicals, World Health Organization, Geneva, Switzerland (*Secretary*)

Dr T. Kurata, Deputy Director-General, National Institute of Infectious Diseases, Tokyo, Japan (*Temporary Adviser*)

Dr H. Kurz, Federal Ministry of Health and Consumer Protection, Department of Blood and Blood Products, Vienna, Austria (*Temporary Adviser*)

Professor J. Leikola, Director, Finnish Red Cross, Helsinki, Finland (*Temporary Adviser*)

Dr I. Levenbook, Northbrook, IL, USA (*Temporary Adviser*)

Dr J. Löwer, Paul Ehrlich Institute, Langen, Germany (*Temporary Adviser*)

Dr A. Padilla, Quality and Safety of Plasma Derivatives and Related Substances, World Health Organization, Geneva, Switzerland

Dr F. Reigel, Director, Division of Biologicals, Swiss Federal Office of Public Health, Bern, Switzerland (*Temporary Adviser*)

Dr G. Schild, Director, National Institute for Biological Standards and Control, Potters Bar, Herts., England (*Temporary Adviser*)

Introduction

The WHO Expert Committee on Biological Standardization met in Geneva from 25 to 29 October 1999. Dr M. Scholtz, Executive Director of the Health Technology and Pharmaceuticals cluster at WHO, opened the meeting on behalf of the Director-General.

Dr Scholtz explained that WHO was emerging from a period of considerable restructuring over the previous 12 months under the leadership of the new Director-General. The main goal was to foster better coordination and cooperation at all levels of the Organization. Strengthening activities in the field of biological standardization was an important objective, and additional resources were being sought to support that work. WHO was grateful to organizations that had supported biological standardization work at WHO through staff secondments to help with special projects.

The Committee would consider a large number of topics, which reflected the increasing complexity of the field of biologicals. Indeed, the number of new biological medicines was likely to outstrip the number of new chemical medicines coming to the market in the next few years. The challenge faced by manufacturers and national control authorities alike was to ensure the quality and safety of new and existing biologicals and the Committee had an important role to play in this regard.

General

Independent review of WHO's remit and activities in the field of biologicals

The 1997 World Health Assembly resolution (WHA 50.20) on the quality of biologicals moving in international commerce called for an independent review of WHO's remit and activities in this field, particularly of the Organization's Biologicals unit and the way in which it interacted with other groups within and outside WHO. The review was to recommend action to assist in the harmonization of standards and requirements, minimize duplication of activities, and enable WHO to respond to scientific developments in a timely manner.

The review team consulted widely and submitted its report to WHO in November 1998. There was a clear consensus on the continued importance of WHO's work on standardization and control of biologicals for public health programmes worldwide. Indeed, this was a constitutional obligation of WHO. The review team recommended

that the Biologicals unit should be renamed to reflect its responsibilities more accurately and that staff and resources at WHO dedicated to biological standardization should be substantially increased. The review also recommended that a clear focus should be established for policy on biological substances used in medicine, to ensure that there was "one voice for biologicals" within WHO. Finally the review also recommended that the transparency, openness, and effectiveness of the standard-setting process should be improved.

The response from WHO had taken place within the context of the wider restructuring of the Organization under the new Director-General. The former Biologicals unit, following a name change to Quality Assurance and Safety: Biologicals (QSB), had been integrated into the Vaccines and other Biologicals department in the Health Technology and Pharmaceuticals cluster. Quality and Safety of Plasma Derivatives and Related Substances (QSD) had been given greater visibility, and was located in the Blood Safety and Clinical Technology department in the same cluster. QSB and QSD would continue to work very closely together as a cross-cutting biologicals team within the cluster and would provide a clear focus for biologicals activities within WHO. The advantages of this arrangement were the necessary degree of independence for the standard-setting process, greater access to funds for priority projects, and increased potential for collaboration on quality issues that affect all types of biological medicines.

WHO also proposed that the Expert Committee on Biological Standardization should be restructured by establishing three subcommittees that covered vaccines, blood products and related substances, and biological therapeutics. The objective was to ensure greater transparency and efficiency of the standard-setting process. The WHO Informal Consultation on Cytokine Standards, already in existence, provided a successful model for the subcommittees. The possibility of a fourth subcommittee on diagnostics was under consideration, but this required wide consultation with interested parties and no decision had yet been reached.

The Committee endorsed the new management structures and the priority that WHO had placed on the importance of quality and safety in all types of medicines. The Committee encouraged WHO to ensure that responses to matters such as transmissible spongiform encephalopathies, which potentially affected all types of medicines, were