WHO Technical Report Series

822

WHO EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION

Forty-second Report

World Health Organization

Geneva *1992*

WHO Library Cataloguing in Publication Data

WHO Expert Committee on Biological Standardization
WHO Expert Committee on Biological Standardization : forty-second report.

(WHO technical report series ; 822)

1. Biological products – standards I. Series

ISBN 92 41208228 (NLM Classification: QW 800)
ISSN 0512-3054

Printed in Switzerland
9219248 – Benteli – 6000

Contents

WHO Expert Committee on Biological Standardization

Geneva, 22–29 October 1991

Members

Dr D.H. Calam, Head, Chemistry Division, National Institute for Biological Standards and Control, Potters Bar, Herts., England (Rapporteur)

Professor E. M. Essien, Director, National Institute for Medical Research, Yaba, Lagos, Nigeria

Dr J. Furesz, Director, Bureau of Biologics, Ottawa, Ontario, Canada

Professor I. Gust, Director, Research and Development, CSL Ltd., Victoria, Australia (Chairman)

Dr Z. Khan, Principal Scientific Officer, Quality Control Division, National Institute of Health, Islamabad, Pakistan

Mr J. Lyng, Head, Laboratory of Biological Standardization, State Serum Institute, Copenhagen, Denmark

Professor N. V. Medunitsin, Director, Tarasevich State Institute for the Standardization and Control of Medical Biological Preparations, Moscow, USSR (Vice-chairman)

Dr H. Mirchamsy, Associate Director, Razi State Institute of Sera and Vaccines, Teheran, Islamic Republic of Iran

Dr W. W. Wright, Senior Scientist, Drug Standards Division, United States Pharmacopeia, Rockville, MD, USA

Mr Zhou Hai-jun, Director, National Institute for the Control of Pharmaceutical and Biological Products, Beijing, China

Representatives of other organizations

Council of Europe

Mr J.-M. Spieser, European Pharmacopoeia Commission, Council of Europe, Strasbourg, France

International Federation of Pharmaceutical Manufacturers Associations (IFPMA)

Dr H.-G. Lehmann, IFPMA, Geneva, Switzerland

Secretariat

Dr E. Esber, Associate Director for Research and Regulatory Coordination, Center for Biologics Evaluation and Research, Food and Drug Administration, Bethesda, MD, USA (Temporary *Adviser*)

Dr D. Magrath, Chief. Biologicals, WHO: Geneva, Switzerland (Secretary)

Dr P. L. Storring, Scientist, Department of Endocrinology, National Institute for Biological Standards and Control, Potters Bar, Herts., England (Temporary Adviser)

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

Dr H. J. M. van de Donk, Head, Control of Bacterial Vaccines, National Institute of Public Health and Environmental Protection, Bilthoven, Netherlands (Temporary Adviser)

Introduction

The WHO Expert Committee on Biological Standardization met in Geneva from 22 to 29 October 1991. The meeting was opened on behalf of the Director-General by Dr Hu Ching-Li, Assistant Director-General.

Dr Hu emphasized the importance of the biological standardization programme for countries with developing health programmes and stressed the need for the Committee, in making recommendations, to take account of the procedures essential for assuring the safety and efficacy of biological products, but to avoid specifying unnecessarily stringent or restrictive conditions.

General

Good manufacturing practices for biological products

The Committee noted that the WHO Secretariat had prepared a document entitled "Good manufacturing practice for biological products" (BS/91.1656),[1] intended to provide guidance for biological products supplementary to that given in the more general "Good manufacturing practices for pharmaceutical products" (WHO Technical Report Series, No. 823, 1992, Annex 1). After making some modifications to the draft text, the Committee agreed that the document should be annexed to its report (Annex 1).

Distribution of International Biological Standards and Reference Reagents

The Committee noted the distribution of international reference materials by the four main International Laboratories for Biological Standards during 1990 (Table 1) (BS/91.1677). It noted a slight decline in the number of standards distributed by comparison with 1989 (WHO Technical Report Series, No. 814, 1991, p. 3) and requested that for distributions made during 1991 a more detailed analysis by product category be provided. The Committee also requested the WHO Secretariat to obtain similar information on the distribution of international reference materials held and distributed on behalf of WHO by other cooperating laboratories.

The Committee was informed that, in accordance with the request made in

[1] References prefixed "BS/..." are to unpublished working documents of the World Health Organization. They are not issued to the general public, but a limited number of copies may be available to professionally interested persons on application to Biologicals, World Health Organization, 1211 Geneva 27, Switzerland.

Table 1
International Biological Standards and Reference Reagents distributed in 1990 by the International Laboratories for Biological Standards[a]

WHO region	Number of items distributed by International Laboratories for Biological Standards					
	Amsterdam	Copenhagen	Potters Bar	Weybridge	Total	% of total for all regions
Africa	31	12	68	6	117	0.9
Americas	134	354	979	12	1 479	11.0
Eastern Mediterranean	0	126	14	5	145	1.1
Europe	2 612	1 545	6 171	131	10 459	77.9
South-East Asia	7	132	599	9	747	5.6
Western Pacific	84	123	258	13	478	3.6
Total	2 868	2 292	8 089	176	13425	

[a] Central Laboratory of the Netherlands Red Cross Blood Transfusion Service, Amsterdam, Netherlands: items distributed during the calendar year 1990. State Serum Institute, Copenhagen, Denmark: items distributed during the calendar year 1990. National Institute for Biological Standards and Control, Potters Bar, Herts., England: items distributed between 1 March 1990 and 30 April 1991. Central Veterinary Laboratory, Weybridge, Surrey, England: items distributed during the calendar year 1990.

its forty-first report (WHO Technical Report Series, No. 814, 1991, p. 2), the WHO Secretariat had obtained some information on the ways in which international reference materials were used. Many users had stressed the key role played by international reference materials in harmonizing the quality of biologicals at both national and international levels. The Committee emphasized that standardization and control of biologicals could not be fully achieved without the provision of internationally accepted reference materials, and that in the present era of vanishing borders and increased demands for international harmonization, the role of international biological reference materials was even more important