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WHO Technical Report Series

840

WHO EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION

Forty-third Report

World Health Organization

Geneva 1994

WHO Library Cataloguing in Publication Data

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

(WHO technical report series ; 840)

1. Biological products — standards I. Series

ISBN 92 4 120840 6 (NLM Classification: QW 800)
ISSN 0512-3054

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Printed in Switzerland
93/9716 – Benteli – 6500

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Geneva, 13–20 October 1992

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Introduction

The WHO Expert Committee on Biological Standardization met in Geneva from 13 to 20 October 1992. The meeting was opened on behalf of the Director-General by Dr Hu Ching-Li, Assistant Director-General.

Dr Hu emphasized the importance of WHO's 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

Needs for expert advice

The Committee identified an urgent need for additional expert assistance to enable it to fulfil its obligations in view of the rapid development of new biologicals, such as vaccines and therapeutic products prepared by recombinant DNA technology. It therefore requested the Secretariat to explore the organizational and financial means of establishing expert advisory groups for this purpose.

The Committee was informed that, in response to requests made in its thirty-eighth and fortieth reports (WHO Technical Report Series, No. 771, 1988, pp. 11-12, and No. 800, 1990, pp. 11-12), the WHO Secretariat had evaluated the need for reference materials for clinical diagnostic tests. It had concluded that a large number of such materials were required to ensure the accuracy and comparability of tests used for diagnosis, in the treatment of patients and for collecting epidemiological data.

In view of the vast number of diagnostic assays available and the need to conserve resources and avoid duplication of effort, the Committee recommended that WHO should consider convening a meeting of relevant units within the Organization and professional groups with expertise in the field, to advise the Committee on priorities for action and to recommend procedures for establishing reference materials for such tests.

The Committee was also informed that the number of cytokines and growth factors of clinical importance had continued to increase. Since 1988 an ad hoc committee of international experts has been assessing the need for, and overseeing provision of, international reference materials for these products. The Committee recommended the more formal establishment of an expert advisory group to review the results of international collaborative studies and to make recommendations to the Committee.

Distribution of International Biological Standards and Reference Reagents

The Committee noted the distribution of international reference materials by the International Laboratories for Biological Standards and other collaborating laboratories during 1991 (Table 1, BS/92.1693[1]) as well as the product categories and the categories of organization receiving materials. The Committee agreed that the programme was essential for the establishment of standards for biological products, which both national control authorities and manufacturers relied on to fulfil their responsibilities.

The Committee noted with concern the reductions made by WHO to the budgets of the International Laboratories and emphasized the continuing and increasing importance of their work. The Committee recognized with gratitude the efforts that the International Laboratories were making, from their own resources, to maintain their contribution to the biological standardization programme and the considerable support that they received from individual governments.

The Committee strongly recommended that the programme for International Biological Standards and Reference Reagents should be among WHO's priorities, but was also of the opinion that manufacturers and control authorities should be encouraged to contribute to its support.

Bovine spongiform encephalopathy

The Committee noted a report on a WHO meeting on public health issues related to animal and human spongiform encephalopathies (*Bulletin of the World Health Organization*, 1992, 70(2):183-190), which reviewed existing knowledge of the spongiform encephalopathies and evaluated the pathways of transmission and associated hazards. The possible implications of the animal diseases, especially bovine spongiform encephalopathy, with regard to the use of animal tissues as animal feed and human food and in the preparation of medicinal and other products for human use were discussed in the report, and recommendations made to national health authorities on appropriate measures to minimize the consequences of bovine spongiform encephalopathy for public and animal health.

The Committee agreed that bovine thromboplastin posed a theoretical risk to manufacturers and users in laboratories, and recommended that its use should be discouraged since rabbit thromboplastin was available as an alternative. The Committee further recommended that, wherever satisfactory alternatives existed, the use of products of bovine origin as international reference materials should be discouraged.

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