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WHO Expert Committee on Biological Standardization

Thirty-sixth Report

World Health Organization
Technical Report Series
745

World Health Organization, Geneva 1987

ISBN 92 4 120745 0

ISSN 0512-3054

PRINTED IN SWITZERLAND

86/6958 – Schüler SA – 6500

CONTENTS

WHO EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION

Geneva, 12–18 November 1985

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WHO EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION

Thirty-sixth Report

The WHO Expert Committee on Biological Standardization met in Geneva from 12 to 18 November 1985. The meeting was opened on behalf of the Director-General by Dr Lu Rushan, Assistant Director-General.

GENERAL

Review of the work of the Expert Committee on Biological Standardization

The Committee reviewed the scope of the items covered in its recent meetings and in its current agenda, and noted that the work could be divided into two broad categories, namely requirements and standards. The Committee also noted that the range of topics had become very broad, and that the items associated with many of the disciplines included in the Committee's terms of reference were becoming increasingly complex. Consequently, problems were arising in drawing enough committee members (from the WHO Expert Advisory Panel on Biological Standardization) who had both the appropriate background to address adequately the items on the agenda and who represented a balanced geographical distribution. The Committtee therefore requested the WHO Secretariat to take appropriate steps to expand the membership of the Expert Advisory Panel, and invited the Director-General to consider increasing the number of experts who participated in the meetings of the Expert Committee on Biological Standardization, by forming subcommittees, or by other appropriate mechanisms.

Preparation of standards in ampoules

The Committee expressed concern that several candidate materials prepared in stoppered vials had been offered to WHO for establishment as international standards. In order to ensure

maximum stability of international standards, it has been the policy of the Committee to establish as standards only those materials that have been prepared in hard-glass ampoules, sealed by fusion of the glass (WHO Technical Report Series, No. 626, 1978, Annex 4). The Committee therefore reaffirmed the instructions given in the same report that only materials prepared in glass ampoules should be accepted for consideration as international standards. It also emphasized that this criterion should be verified before extensive collaborative studies were undertaken and before a candidate material was submitted to the Committee for establishment as a standard. The Committee urged anyone intending to prepare a candidate material to inform the WHO Secretariat in advance, and requested the Secretariat to take steps to ensure that, whenever possible, those intending to provide standard material are aware of the instructions given in the *Guidelines for the preparation and establishment of reference materials and reference reagents for biological substances* (WHO Technical Report Series, No. 626, 1978, Annex 4).

Vaccine quality

The Committee was informed that the WHO Secretariat was currently drafting a procedure that would allow WHO to evaluate the acceptability of vaccines in general (especially the acceptability of vaccines for use in immunization programmes) organized by WHO or other UN agencies and to check the quality of selected batches of vaccines. The Committee recommended that a working group be convened by WHO to discuss the technical elements of this process.

Hepatitis B vaccine produced by recombinant DNA techniques

The Committee recognized that there had been remarkable progress in the development of vaccines through the use of recombinant DNA techniques and reaffirmed the belief, expressed in its thirty-third report (WHO Technical Report Series, No. 687, 1983, p. 15), that these techniques provided new opportunities for improving the health of large numbers of people in the world, especially in developing countries. For example, recombinant DNA techniques are being used to produce alternatives to the currently available vaccines against hepatitis B virus, as well as for the