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WHO Expert Committee on Biological Standardization

Thirty-sixth Report

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Geneva, 12–18 November 1985

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1. The first part of the paper discusses the importance of understanding the underlying mechanisms of the observed phenomena. This involves a thorough review of the existing literature and a clear identification of the research gaps. The authors emphasize the need for a multidisciplinary approach to address these complex issues.

2. The second part of the paper presents the methodology used in the study. This includes a detailed description of the data collection process, the statistical models employed, and the validation techniques used to ensure the reliability of the results. The authors provide a clear and concise explanation of the research design and the steps taken to minimize potential biases.

3. The third part of the paper presents the results of the study. This section includes a detailed analysis of the data, highlighting the key findings and their implications. The authors discuss the statistical significance of the results and provide a clear interpretation of the findings in the context of the research objectives.

4. The fourth part of the paper discusses the limitations of the study and suggests directions for future research. The authors acknowledge the constraints of the current study and provide a clear roadmap for further investigations. This section is crucial for providing a balanced view of the research and for guiding the next steps in the field.

5. The final part of the paper is a conclusion that summarizes the main findings and the overall contribution of the study. The authors reiterate the importance of the research and provide a clear statement of the key takeaways. This section serves as a concise summary of the entire paper and is essential for the reader's understanding of the study's impact.

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 Committee 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

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