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Introduction

The WHO Expert Committee on Biological Standardization met in Geneva from 7 to 11 October 1996. The meeting was opened on behalf of the Director-General by Dr F.S. Antezana, Assistant Director-General.

Dr Antezana explained that the shorter meeting that year followed the pattern established for other WHO Expert Committees. As recommended by the Committee in 1995, progress and development reports had been combined into a single agenda item so that attention could be directed to requirements and guidelines, reports of consultations and proposals for establishment and discontinuation of international reference materials.

He emphasized the importance of the work of the Committee to both developed and developing countries and the expansion of the field of biological products and its increasing diversity. Such diversification, together with the development of products derived by new biotechnologies, raised new and significant issues of safety, and he stressed that the challenge was to ensure public safety while not inhibiting the development of potentially important products through inappropriate or restrictive requirements.

Dr Antezana recalled the importance of obtaining international consensus regarding procedures for ensuring the safety and efficacy of new biological products. At the same time, it was necessary to ensure that requirements for existing products reflect scientific and technical advances. The role of well characterized reference materials, internationally established and supplied, was fundamental in contributing to the quality and safety of biological products.

Dr Antezana noted that a review of the scientific basis of the standardization and quality control of biological substances used in human medicine had been conducted recently for the National Biological Standards Board of the United Kingdom, which had responsibility for supervision of one of the WHO International Laboratories for Biological Standards. This review had been undertaken with the collaboration of WHO and the support of the European Medicines Evaluation Agency, the European Pharmacopoeia and the United States Food and Drug Administration. The report was to be presented during the meeting, and its conclusions had international implications that the Committee should consider.

He thanked the WHO International Laboratories for their important contribution to the programme of biological standardization, and

thanked the participants in WHO meetings and collaborative studies for the vital contribution they make to the international reputation and success of the programme.

The death of Dr D.I. Magrath, who served with distinction at WHO as Chief, Biologicals, from 1987 to 1994 was noted with deep regret.

General

Developments in biological standardization

The Committee was informed of the continued demand for international reference materials distributed by the International Laboratories for Biological Standards. As proposed by the Committee in 1995, work in progress in the various International Laboratories was summarized. Attention was drawn to a review of reference reagents for blood-typing sera; to a meeting planned for November 1996 to consider issues relating to immunoassays of cytokines; and to the need to review the requirements for antivenoms. In response to comments received concerning the measurement of antibodies, a WHO Informal Consultation would be held to prepare a report for consideration by the Committee in 1997.

The Committee discussed the importance of rapid dissemination of its decisions. National control authorities and manufacturers needed ready access to newly adopted guidelines and requirements, as well as information on the establishment of international reference materials. However, publication of the Committee's report could take longer than was ideal. Partly for these reasons, a summary of the major decisions of the 1995 meeting, including changes in the list of international reference materials, had appeared in the *Weekly epidemiological record*.[1] The Committee nevertheless urged WHO to seek other ways to speed up the dissemination of its decisions.

The Committee was informed of recent data concerning the presence of sequences of simian virus 40 (SV40) in certain human tumour tissues. It was also informed that simian virus 40 had not been present in poliomyelitis vaccine since the early 1960s and that tests to ensure its absence are performed routinely. The Committee requested the Secretariat to monitor developments.

The Committee was also informed that two WHO meetings had been held to discuss the public health implications of transmissible