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Introduction

The WHO Expert Committee on Biological Standardization met in Geneva from 27 to 31 October 1997. The meeting was opened on behalf of the Director-General by Dr F.S. Antezana, Assistant Director-General.

Dr Antezana welcomed the representatives of nongovernmental organizations and the European Pharmacopoeia Commission of the Council of Europe and also welcomed and introduced the new Committee members.

He underlined the fact that 1997 marked the 50th anniversary of the Committee, which started its activities in June 1947. However, work on international biological standardization and the provision of International Standards had already been going on for 25 years before that under the League of Nations through its Commission on Biological Standardization. The work of the Committee had had a significant impact on improving public health globally. Nevertheless, the increasing complexity and sophistication of biologicals, as well as the increasing number of biological products, presented a considerable challenge, especially for the developing world. Noting these developments, the World Health Assembly in May 1997 had adopted a resolution on the quality of biological products moving in international commerce. The resolution recognized that standardization activities need to be strengthened to meet the challenges of the 21st century and requested that an independent review be undertaken of WHO's activities in this field. Dr Antezana announced that this review was now under way and would recommend steps to strengthen the leadership of WHO in promoting the quality, safety and efficacy of biological and biotechnological products.

He noted that a number of items on the agenda reflected the expansion and increasing diversity of the field of biologicals. In some instances traditional products were being replaced by equivalents derived by recombinant DNA technology; in addition, new possibilities for diagnostics were emerging, such as the use of genome amplification techniques for the viral safety testing of blood and blood products. New approaches were also being explored for control testing, with molecular-based techniques promising a possible reduced reliance on testing in animals. This complexity underlines the importance of the Committee for the exchange of information, and as a source of expertise, on a global scale. Dr Antezana emphasized the need for its decisions and advice to be based on sound scientific principles and common sense.

Finally, he thanked institutions, manufacturers and individuals who donate candidate reference materials for their continued contributions, through their support of WHO's activities in international biological standardization, to global public health.

General

Developments in biological standardization

The Committee stressed that the timely dissemination of its work was essential. Some progress had been made through the publication of summaries of its meetings in the *Weekly epidemiological record*, in scientific journals and on the WHO web site on the Internet (www.who.int). The Committee recommended that the use of other WHO publications such as *WHO drug information* should be investigated, as this would permit a wider dissemination of the Committee's decisions.

The Committee also recognized the need for a more targeted distribution of its reports and recommendations. WHO was encouraged to consider developing a biologicals information publication for this purpose. Concern was also expressed about the premature use of draft requirements and guidelines. The Committee emphasized that these documents have no status until they are formally adopted. In future, such documents will be watermarked with the world "draft" to clarify their status. The Committee also expressed the need for clarification as to when its requirements, guidelines and recommendations "come into effect". The Secretariat explained that the Committee's report contained recommendations, not mandatory requirements, and could therefore be considered effective as soon as adopted. Requirements published by WHO are scientific and advisory in nature and become binding only when adopted by a national control authority as the basis of national regulations.

At the 1996 meeting the Committee had considered draft requirements for acellular pertussis vaccines; these had been adopted as "guidelines" since there was a lack of consensus about the antigenic composition of the vaccines, no unequivocal immunological correlates of protection had yet been demonstrated nor had a generally accepted animal model been validated. It had been recommended that a working group should continue discussion of related issues, such as developments in assay methods and reference preparations, as