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Introduction

The WHO Expert Committee on Biological Standardization met in Geneva from 17 to 21 November 2003. The meeting was opened by Dr Vladimir Lepakhin, Assistant Director-General, Health Technology and Pharmaceuticals, WHO, on behalf of the Director-General.

Dr Lepakhin emphasized the importance to Member States of the work of the Committee in preparing recommendations for biological products and for the development, establishment and distribution of reference materials for biologicals. During the meeting, a number of proposals for reference materials and draft recommendations would be considered. Dr Lepakhin informed the Committee that the World Health Assembly had endorsed many resolutions on the subjects of quality, safety and efficacy of medicines, blood products, vaccines and other biologicals. Despite considerable progress made both by WHO and its Member States in the implementation of such directives, urgent action was needed to sustain and expand basic normative regulatory functions underpinning public health efforts to assure access to quality biological medicines. Furthermore, as a result of rapidly changing global environments, increased international trade and the opening of borders, many biological medicines, including blood products, were circulating more freely than ever. Unless they were subject to control, biological medicines such as those derived from blood and plasma could be vehicles for the transmission of infectious diseases and/or other emerging agents. Dr Lepakhin reminded the Committee that the establishment and functioning of national regulatory systems with reference to WHO recommendations, norms and standards was essential to protect patients and public health from fraudulent practices and economic waste. WHO was therefore seeking political commitment and support from Member States to sustain and increase capacity building and training in all aspects of regulatory functions, including the efficient implementation of good regulatory practices. Finally, Dr Lepakhin reminded the Committee that its decisions should be based on sound science and common sense and not on partisan considerations.

General

Developments in biological standardization

The Committee was informed of the organizational changes that had taken place at WHO headquarters. The two teams concerned with

biological standardization work on an integrated programme although based in different clusters. The outcomes of the standardization programme include recommendations for quality standards, provision of reference materials, development of consensus on quality-related issues for biologicals and building technical capacity for biologicals in the different WHO Regions. The role of the International Laboratories in the development of this programme was acknowledged. The plans for further development of laboratory support for biological standardization by broadening geographical representation and improving working relationships with existing laboratories through regular meetings and better definition of priorities were outlined. A review of the Expert Advisory Panel on Biological Standardization had shown the need for more even geographical and gender representations and for the identification of more experts currently working the field. The need to enhance support for the Expert Committee had also been recognized and this could usefully be addressed through the greater use of Working Groups to prepare and review proposals for reference materials and recommendations. Consideration was also being given to how the work and operation of the Expert Committee might evolve to meet future needs in a more timely and efficient manner.

The place of standardization of vaccines within the Immunization, Vaccines and Biologicals department was outlined. Establishment of norms and standards is a critical early stage in the development of new vaccines. There is increasing appreciation by users of the norms and standards of the impact of standardization on global public health and trade, leading to increased support, both in terms of financial and human resources, and also to increased demand for standardization activities. These demands are likely to require innovative ways of providing support. As an example, the generous support of the Government of the Republic of Korea, through staff secondment from the Korean Food and Drug Administration, was acknowledged. The priorities for vaccine standardization for the next 2 years had