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WHO Expert Committee on Biological Standardization

Geneva, 16–23 October 1990

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Introduction

The WHO Expert Committee on Biological Standardization met in Geneva from 16 October to 23 October 1990. The meeting was opened on behalf of the Director-General by Dr J. Idänpään-Heikkilä, Deputy Director, Division of Drug Management and Policies.

General

Growth factors and cytokines

At its thirty-ninth meeting (WHO Technical Report Series, No. 786, 1989, p. 12) the Committee discussed recombinant cytokines. More recently, polypeptide growth factors have assumed increasing importance. Taking this into account, the Committee discussed issues associated with the classification and standardization of various recombinant-DNA-derived products, including growth factors, cytokines and other biological response modifiers. It requested the WHO Secretariat to review the situation and evaluate how WHO should interact with other groups interested in the same issues.

The term "polypeptide growth factors" refers to polypeptides (of relative molecular mass up to 80 000) having a regulatory action on cell differentiation or proliferation through interaction with specific high-affinity cell-surface receptors, and active only at short range (as opposed to classic hormones which act on specific distant targets). Research in this field is expanding rapidly with the discovery both of new growth factors and of new effects of those already known; at the same time, there is increasing evidence of the complexity of the interactions between different growth factors.

The therapeutic and diagnostic potential of a number of growth factors is being investigated, and the need for international reference materials is becoming evident. The major potential therapeutic applications of such growth factors are as anticancer, anti-inflammatory, immunomodulatory and wound-healing agents, and these are currently being investigated. Priority is being given to: (i) *epidermal growth factor* (EGF), currently undergoing clinical trials as a wound-healing agent and being evaluated in cancer chemotherapy; (ii) *acidic and basic fibroblast growth factors* (aFGF, bFGF), a group of polypeptides with potential as wound-healing agents; and (iii) *platelet-derived growth factor* (PDGF) for use in wound-healing and the treatment of chronic ulcers (e.g., varicose, diabetic).

International reference preparations derived from materials of human origin

The Committee noted that the Guidelines for the Preparation, Characterization and Establishment of International and Other Standards

and Reference Reagents for Biological Substances, revised in 1989 (WHO Technical Report Series, No. 800, p. 181), required that, for safety reasons, biological materials of human origin being considered for the preparation of international reference materials should be tested to ensure the absence of infectivity markers for hepatitis B virus human immunodeficiency virus (HIV) and other pathogens.

In considering the establishment of new or replacement international reference materials derived from materials of human origin, and in reviewing the present status of candidate materials that may later be proposed for establishment, the Committee emphasized the need for the starting materials to be screened for hepatitis C virus antibody as well, since tests licensed for that purpose were now available.

Distribution of international reference materials by the four International Laboratories for Biological Standards

The Committee noted that the distribution of international reference materials by the four International Laboratories for Biological Standards had continued in 1989 (Table 1) (BS/90.1644).[1] It also noted that the proportions of recipient laboratories in different categories (national control authorities, manufacturers, research laboratories and universities) had been tabulated (Table 2). In view of the widespread use of, and increasing need for, international reference materials, particularly for the products of biotechnology, the Committee stressed the importance of the distribution of such materials in promoting the international standardization of biological products, thus facilitating their free circulation between countries, to the benefit of the health of the peoples of the world.

The Committee agreed that, in order to assign priorities, it would be useful to gather information, through a questionnaire circulated to recipients, on the ways in which the international reference materials are used. The Committee therefore requested the WHO Secretariat to obtain such information and to identify trends in the distribution and use of these materials.

WHO bank of Vero cells for the production of biologicals

The Committee was informed of progress in the distribution of ampoules from the WHO bank of Vero cells referred to in its fortieth report (WHO Technical Report Series, No. 800, 1990, p. 11), and noted that, since the cell bank was established in 1989, 26 requests for such ampoules had been received. The Committee was also informed that the WHO Secretariat planned to establish a WHO bank of BHK-21 cells.
