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Twenty-third Report

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Geneva, 17 to 25 November 1970

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WHO EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION

Twenty-third Report

The WHO Expert Committee on Biological Standardization met in Geneva from 17 to 25 November 1970. Dr L. Bernard, Assistant Director-General, welcomed the members of the Committee on behalf of the Director-General. He recalled the traditional tasks that the Committee undertook and pointed out that, although the items on the agenda related mainly to the control of biological substances, the subjects before the Committee have increased in recent years, both in number and complexity. Certain new elements therefore have appeared, such as blood coagulation substances, and immunological reagents. It was evident that the Committee had to consider an increasing number of items that were of interest to other programmes of WHO. Over the years, the reports of the WHO Expert Committee on Biological Standardization had provided useful guidance to national authorities concerned with the control of biological products.

GENERAL

Since the days of the WHO Interim Commission, it has been envisaged [1] that each Member State of WHO would develop its own national laboratory for biological substances, which would provide the technical facilities for the control of biological products either manufactured in or imported into that country. Many countries, however, have not yet formally designated national centres for biological standards or national laboratories for the control of biological products, although some functions of control may in fact be performed by individual workers.

It is desirable that national control authorities be advised of the value of setting up laboratory facilities for the control of biological substances, even though they are initially on a modest scale and perhaps only for some selected products. These laboratories, besides fulfilling the needs for control of biological products in the country, could also perform valuable

[1] *Off. Rec. Wld Hlth Org.*, 1948, **11**, 10 (Second report of the Expert Committee on Biological Standardization).

functions in diagnosis and research. The Committee in its twenty-second report [1] adopted certain recommendations that could be used in developing such national control laboratories for biological substances.

The Committee was informed that where such laboratories or facilities exist, demands for international biological standards and reference preparations are sometimes made on the erroneous assumption that these materials are available for routine day-to-day use. Further, the international laboratories for biological standards in Copenhagen, London and Weybridge, often receive requests for international preparations from laboratories that are not directly concerned with the national control of biological products. Such laboratories include research institutes, university and hospital laboratories, and manufacturing and testing institutions. As many as possible of such demands are met, provided the requests appear to be made for some reasonable purpose. In this way the international laboratories for biological standards continue the principles enunciated at the Intergovernmental Conference on Biological Standardization, held in Geneva in October 1935. This Conference recommended that international standards should be freely distributed,[2] which has always been interpreted as meaning free of charge and as widely as possible.

The Committee emphasized, however, that international standards and reference preparations should be conserved for the primary purpose for which they are intended, namely for the calibration of national standards and reference preparations or working standards. It is these national preparations that may be used for the routine day-to-day biological assay of preparations to be tested. Serious problems would arise if international standards and reference preparations were distributed indiscriminately in response to all requests, since this would result in stocks becoming exhausted in a short time. Materials for establishment as international preparations have always been obtained as donations—first, by the League of Nations and later by the Interim Commission and WHO. Such materials, however, are sometimes rare and often expensive to produce, and their characterization may demand much work. In addition, before the preparations can be established, or replaced, as international standards or reference preparations, international collaborative assays are made that are often extensive and may take several months or years to complete.

Although national control laboratories can obtain WHO international standards and reference preparations wherever needed for the calibration of national standards and reference preparations, it is the responsibility of the national control laboratories to prepare or obtain their own national

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[1] *Wld Hlth Org. techn. Rep. Ser.* 1970, No. 444, Annex 3 : *Development of a national control laboratory for biological substances (A guide to the provision of technical facilities).*

[2] *Bull. Hlth Org. L. of N.* 1935, **4**, 631. These recommendations were later adopted by the Council of the League of Nations in 1936 and brought to the notice of Member Governments.

reference materials. In some special instances, however, materials suitable for use as national standards may be difficult to produce and characterize. An example of a national institution providing such material, as a service, occurred when the third International Standard for Corticotrophin, Porcine, for Bioassay, was established in 1962.[1] The National Institute for Medical Research, London, when setting up the international standard, prepared several additional lots of material, which were calibrated and made available free of charge to laboratories for use in routine assays. In other instances, where the materials for national use may even be easily produced, the facilities available to a national laboratory may be inadequate to permit suitable preparations to be made. An example of working material of this kind being provided as an international service to such laboratories is the cholera O group 1 serum, which was prepared and made available by the Statens Seruminstitut, Copenhagen.[2]

It has not been the practice for WHO to provide national standards for biological substances or working standards for routine use to national control laboratories. Since, however, some laboratories experience difficulties in obtaining working materials in certain circumstances, WHO should consider the possibility of arranging for the supply of suitable preparations to those laboratories that need them. Laboratories that are willing to assist may be invited to contribute materials and to provide facilities for training personnel. In order, however, to avoid excessive demands on a particular laboratory, the means of providing assistance should preferably be co-ordinated on a group or area basis.

The Committee studied the report [3] of a Panel on Radiation Sensitivity of Toxins and Animal Poisons, which was organized by the International Atomic Energy Agency and met in Bangkok from 19 to 22 May 1969. The Panel had made recommendations for research on certain microbial toxins, animal poisons and venoms, antitoxins and antivenins. The Committee noted those recommendations that were related to the standardization of biological substances, comprising a number of toxoids, antitoxins and antivenins that have already been included in the biological standardization programme for several years. Newer methods of preparing toxoids, e.g., by radiation of toxins, could be of interest, in relation to the establishment of standards and the formulation of requirements. The Committee restated its interest [4] in the preparation of venom fractions and in the identification and characterization of these fractions, since these may be of value in the estimation of potency of antivenins.

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[1] *Wld Hlth Org. techn. Rep. Ser.*, 1963. No. 259, p. 13.

[2] *Wld Hlth Org. techn. Rep. Ser.*, 1970, No. 444, p. 22.

[3] *Radiation sensitivity of toxins and animal poisons*, Vienna, IAEA, 1970 (*Panel Proceedings Series* STI/PUB/243).

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