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WORLD HEALTH ORGANIZATION

TECHNICAL REPORT SERIES

No. 413

WHO EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION

Twenty-first Report

WORLD HEALTH ORGANIZATION

GENEVA

1969

PRINTED IN SWITZERLAND

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Geneva, 30 September to 5 October, 1968

Members :

Dr N. K. Dutta, Director, Haffkine Institute, Bombay, India

Dr A. Lafontaine, Director, Institute of Hygiene and Epidemiology, Brussels, Belgium

Mr J. W. Lightbown, Division of Biological Standards, National Institute for Medical Research, London, England (*Chairman*)

Professor B. Lunenfeld, Director, Institute of Endocrinology, Tel-Hashomer Government Hospital and Bar Ilan University, Tel-Hashomer, Israel

Dr R. Murray, Director, Division of Biologics Standards, National Institutes of Health, Bethesda, Md., USA

Dr J. D. van Ramshorst, Chief, Laboratory of Biological Standardization, Rijks Instituut voor de Volksgezondheid, Utrecht, Holland (*Rapporteur*)

Dr J. Spaun, Deputy Director, Department of Biological Standardization, Statens Seruminstitut, Copenhagen, Denmark

Mr J. R. Thayer, Viral Products Section, National Biological Standards Laboratory, Parkville, Victoria, Australia (*Vice-Chairman*)

Dr G. V. Vygodčikov, Head, Department, Gamaleja Institute of Epidemiology and Microbiology, Moscow, USSR

Dr G. R. Zahnd, Chargé de Recherches, Policlinique universitaire de Médecine, Geneva, Switzerland

Representatives of other organizations :

Food and Agriculture Organization of the United Nations :

Mr I. Davidson, Central Veterinary Laboratory, Weybridge, Surrey, England

International Atomic Energy Agency :

Dr F. Antoni, Radiation Biology, International Atomic Energy Agency, Vienna, Austria

Secretariat :

Dr D. R. Bangham, Director, Division of Biological Standards, National Institute for Medical Research, London, England (*Consultant*)

Professor D. G. Evans, London School of Hygiene and Tropical Medicine, London, England (*Consultant*)

Mr E. C. Hulse, Director, Department of Biological Products and Standards, Central Veterinary Laboratory, Weybridge, Surrey, England (*Consultant*)

Dr A. N. Klimov, Director, Division of Biomedical Sciences, WHO

Dr P. Krag, Director, Department of Biological Standardization, Statens Seruminstitut, Copenhagen, Denmark (*Consultant*)

Dr A. S. Outschoorn, Chief Medical Officer, Biological Standardization, WHO (*Secretary*)

Professor A. E. Wilhelmi, Department of Biochemistry, Woodruff Medical Center of Emory University, Atlanta, Ga., USA (*Consultant*)

Dr W. W. Wright, Acting Deputy Director, Division of Pharmaceutical Sciences, Bureau of Science, Food and Drug Administration, Washington, D.C., USA (*Consultant*)

Wld Hlth Org. techn. Rep. Ser., 1969, No. 413

WHO EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION

Twenty-first Report

The WHO Expert Committee on Biological Standardization met in Geneva from 30 September to 5 October 1968. Dr P. Dorolle, Deputy Director-General, welcomed the members of the Committee on behalf of the Director-General. He also welcomed the representative of the Food and Agriculture Organization of the United Nations and the representative of the International Atomic Energy Agency.

The Deputy Director-General stated that this twenty-first meeting of the WHO Expert Committee on Biological Standardization should be regarded as an important anniversary because it brought to mind the long traditions of the Committee and the useful service it rendered. He pointed out that the subjects covered by the programme of biological standardization were increasing in scope and complexity, particularly in recent years. It was inevitable, therefore, that certain tasks of evident importance had to be left aside so that the Committee could undertake others of higher priority in relation to the overall programme of the World Health Organization.

In addition to the establishment of international standards for use as references in biological assays, the Expert Committee had in recent years been given the responsibility for reviewing and approving the various sets of requirements for biological substances formulated by the WHO Secretariat. These had proved of great value to Member States, especially when control activities over biological products were being developed.

GENERAL

The Committee gave further consideration to the problems arising from the estimation of hormones by the techniques of immunoassay, discussed in its twentieth report.[1] The information that had since been collected by the WHO Secretariat was taken into account.

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[1] *Wld Hlth Org. techn. Rep. Ser.*, 1968, **384**, 8.

The Committee was informed that for various reasons related to the species specificity of hormones, it would be desirable for international standards and reference preparations of protein and polypeptide hormones to be named so as to indicate the species of origin of the preparations and the use for which they were intended, i.e., for immunoassay or for bioassay. The Committee therefore recommended that this principle should be followed in the future and also decided to rename the existing international standards and reference preparations of hormones for bioassay accordingly.

The Committee was also informed that immunoassays of hormones had important implications in clinical medicine and research as well as in the national control of hormone preparations used in therapy. There was a need, therefore, to establish international standards as early as possible. Since the collaborative assays necessary for the establishment of international standards would inevitably take considerable time, the Committee agreed that suitable preparations could meanwhile serve usefully as international reference preparations. The Committee stressed, however, the importance of ensuring that minimum criteria for such preparations are satisfied before their establishment even as international reference preparations. The Committee requested the WHO Secretariat to obtain advice from appropriate experts on the minimum criteria desirable for this purpose in respect of each preparation. In addition, it was essential that all information regarding a particular preparation and the results of tests made should be circulated to interested workers so that any observations or suggestions that they wished to make could also be taken into account by the Committee when deciding whether or not the criteria had been fulfilled.

The Committee discussed various possible ways of specifying potency as determined by immunoassay and decided that it was advisable not to depart from the practice of specifying potency in international units. The international unit for an international standard (or reference preparation) used in immunoassay should be defined in the same way as the international unit for an international standard used in bioassay, i.e., as the activity contained in a stated amount (by weight) of the international standard (or reference preparation) for immunoassay.

In defining such an international unit it would be desirable to make this as nearly as possible equal to an existing international unit for bioassay, even when the latter is for a standard originating from another species. When a standard for immunoassay is replaced, the international unit should be defined by comparing the new standard with the previous standard by immunoassay. When a standard for immunoassay is the first standard established for a hormone, and a standard for bioassay for the hormone of the same species of origin is introduced later, the unit for bioassay should be assigned by bioassay against the existing standard for immunoassay. Ideally, for a hormone of any given species of origin the unit for the standard