This report contains the collective views of an international group of experts and does not necessarily represent the decisions or the stated policy of the World Health Organization

WHO Expert Committee on Biological Standardization

Twenty-eighth Report

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CONTENTS

WHO EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION

Geneva, 16–22 November 1976

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WHO EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION

Twenty-eighth Report

The WHO Expert Committee on Biological Standardization met in Geneva from 16 to 22 November 1976. The meeting was opened on behalf of the Director-General by Dr Ch'en Wen-chieh, Assistant Director-General, who observed that much of the agenda of the meeting would be concerned with human blood components and derivatives. A WHO Working Group on the Standardization of Human Blood Products and Related Substances had met in Geneva from 5 to 10 July 1976, and the report of the Group was to be considered in detail as it contained a number of important recommendations. In addition to the establishment of a number of standards and reference preparations, a particular recommendation was the need for the formulation of requirements for the manufacture and control of blood products.

Antibiotics, said Dr Ch'en, were also to be considered and the requirements for antibiotic susceptibility discs would fulfil an urgent need. The increase in antibiotic resistance of organisms was causing concern in many countries and it was essential to be able to compare these findings between countries. The List of Biological Substances had been brought up to date and the substances listed alphabetically within each category in order to facilitate reference. Reference reagents had been reintroduced into the list because of many inquiries concerning the availability of those preparations.

GENERAL

The Committee noted the report of the WHO Working Group on the Standardization of Human Blood Products and Related Substances and considered that the treatment of one particular field in depth by a group of specialists in this manner had been most productive. When necessary, problems in other fields could with advantage be approached in a similar way. The Committee agreed that the report of the Working Group should be annexed to this report (Annex 1).

The use of international units to specify the potency of blood typing sera should be strongly encouraged since international standards have now been established for the four blood typing sera of the greatest practical importance—namely, those for A, B, D and c antigens. The use of the international units will lead to more accurate quantification in the control of potency of blood typing sera, and the use of titres—the traditional way of describing the strength of these sera—should be discouraged. The prophylaxis, monitoring, and treatment of haemolytic disease of the newborn has concentrated particular effort on the quantification of anti-D antibodies. The use of automated instruments for measuring the potency of sera has extended the working dilution range several hundredfold and, as a result, numerical values of endpoint " titres " are cumbersome. The production of sera is now more extensive than ever before, and standardization for their control (for potency, specificity, and stability) is necessary.

The Committee recalled the resolutions of the World Health Assembly that countries should adopt international units to express the potency of biological materials.[1] It is important that this be done widely and rapidly following the establishment of international standards. In those instances where national units differ from the international units the repercussions could be hazardous in clinical practice and cause difficulties in the international exchange of materials and information. It is important, therefore, that national authorities inform WHO of any decision not to use established international units and report the reasons for the decision.

The Fisher-Race nomenclature for Rh blood typing is becoming more widely accepted, and the Committee agreed that it should be universally adopted in the interests of simplicity and uniformity (Annex 1, Part B, section 1). The Committee was informed that studies were in progress to determine whether this system could conveniently be used with computers.

With regard to the collaboration of international scientific organizations with the Expert Committee on Biological Standardization (Annex 1, Part C), the Committee agreed that contact with such specialist organizations could facilitate the rapid dissemination and implementation of WHO recommendations on biological standardization. It could also ensure the availability of specialized help with particular problems and with the establishment of international reference materials. To avoid

[1] See, for example, WHO Handbook of Resolutions and Decisions, Volume II, first edition, 1975, p. 16 (Resolution WHA26.32).