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

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Geneva, 27 September–3 October 1983

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WHO EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION

Thirty-fourth Report

GENERAL

The WHO Expert Committee on Biological Standardization met in Geneva from 27 September to 3 October 1983. The meeting was opened on behalf of the Director-General by Dr B. Sankaran, Director, Division of Diagnostic, Therapeutic, and Rehabilitative Technology.

International standards and international reference preparations

In the past, two categories of standard preparations with defined international units of activity have been established, namely, international biological standards and international biological reference preparations. The need for two categories, both serving the same function, had been questioned and was examined by the Committee.

The category of international biological reference preparations was first introduced during a period of rapid development in the antibiotic field. Because the establishment of an international standard, with its defined unit of activity, was a lengthy procedure, it was considered necessary to make internationally accepted reference preparations available as quickly as possible, to avoid the confusion arising from a multiplicity of national units. The stated intention was "to temporarily satisfy a need which, at a later date, could be met by replacement of such international reference preparations by international standards" (WHO Technical Report Series, No. 172, 1959, p. 6). At that period an international reference preparation did not define an international unit of activity. Later, however, the Committee decided that an international unit could be assigned not only to an international standard, but also to an international reference preparation (WHO Technical Report Series, No. 259, 1963, p. 6). This procedure was followed, for example, for the International Reference Preparation of Amphotericin B and the International Reference Preparation of Vancomycin (WHO Technical Report

Series, No. 274, 1964, p. 8). Subsequently, many international reference preparations defining international units of activity were established on the basis of collaborative assays. They have served their intended function satisfactorily but have not been reclassified as international standards.

The Committee, at its present meeting, agreed that it was no longer necessary for international reference preparations with defined units of activity to constitute a separate category, and that all such materials could be considered functionally to be international standards. The question of whether it would be desirable to rename the international biological reference preparations already established as international biological standards was discussed, and it was agreed that to do so would probably cause confusion because of the extensive scientific literature in which their existing names had been used.

The Committee decided that, in the future, a single category of standard preparations would be established for the purpose of defining international units of activity, namely, international biological standards. It would, nevertheless, remain necessary to designate certain materials as international biological reference preparations, but that designation would be restricted to preparations that did not define international units of activity.

The Committee agreed that all international standards and international reference preparations with defined units of activity on which the World Health Assembly had not yet made a recommendation should be presented to the Health Assembly as soon as possible. This procedure was necessary to ensure the continued international acceptance of the various international units of biological activity.

Paper discs

In Part A, section 5.2.1 of the *Requirements for antimicrobic susceptibility tests. I. Agar diffusion tests using antimicrobic susceptibility discs* (WHO Technical Report Series, No. 673, 1982, pp. 156–159) it is stated that for *assays of content* of blank discs suitable paper should be used to prepare standard discs; that is, discs impregnated with standard antimicrobic agents. Whether the blank discs to be used routinely by a control laboratory are suitable may be determined by comparing how they perform in the assay system with the performance of blank discs of known suitability.