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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Thirty-first Report

Annex 5

REQUIREMENTS FOR POLIOMYELITIS VACCINE (ORAL)

(Requirements for Biological Substances No. 7)
(Revised 1971)

Addendum 1980

CORRIGENDUM

Page 170, lines 4–5

Delete: ... Stored at 40 °C, the decanted medium may be used for further subcultivation of cells.

Insert: ... Stored at 4 °C, the decanted medium may be used for further subcultivation of cells.

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Geneva, 15–22 April 1980

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WHO EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION

Thirty-first Report

GENERAL

The WHO Expert Committee on Biological Standardization met in Geneva from 15 to 22 April 1980. The meeting was opened on behalf of the Director-General by Dr V. Fattorusso, Director, Division of Prophylactic, Diagnostic, and Therapeutic Substances.

The Committee has been unwilling for many years to set up biological standards for antibiotics used in the treatment of malignant tumours when the only known way of measuring their biological activity is a microbiological assay not involving mammalian cells, particularly for antitumour antibiotics that are complex mixtures of related biologically active components—e.g., bleomycin. However, with the development of analytical techniques that have allowed the composition of a given preparation to be measured precisely and the variability in composition of different batches to be maintained within acceptable limits, it was considered that an international reference material for bleomycin (bleomycin complex A_2/B_2) would serve a useful purpose. The International Reference Preparation of Bleomycin has now been established and it will be used for standardization in microbiological assay. Accelerated degradation studies of the International Reference Preparation of Bleomycin have demonstrated, however, that the reservations of the Committee on the value of microbiological assays of antitumour antibiotics were soundly based. Potencies of bleomycin preparations estimated by microbiological assays in terms of the international unit of activity are likely to provide relative measures of antitumour activity only if the component composition of each preparation has been shown by chemical analysis to be within acceptable limits. Such limits are included in Guidelines for the Quality Assessment of Antitumour Antibiotics adopted by the Committee.

These guidelines are intended as an interim measure until definitive international specifications for antitumour antibiotics are adopted. National authorities in countries that import antitumour antibiotics and their dosage forms should find the guidelines helpful in examining and judging the quality of batches of these materials. The guidelines provide information on the characteristic chemical, physical, and bio-