

WHO Expert Committee on Biological Standardization

37th Report

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This report presents the work and recommendations of an expert committee concerned with establishing and maintaining international standards and reference reagents for vaccines and other biologicals.

The report has two main parts. The first announces changes in the status or development of international standards for 35 biologicals classified as antibiotics, antibodies, antigens, blood products and related substances, endocrinological and related substances, and a miscellaneous group of substances. Information includes the establishment of new international reference preparations and the recommended discontinuation of others, the need for replacement materials, and the need for new reference materials required for the development or testing of new biologicals.

The second and most extensive part provides detailed information on guidelines for establishing standards, on principles for evaluating the acceptability of vaccines proposed to United Nations agencies for use in immunization programmes, and on requirements for the manufacturing, testing, and quality control of selected vaccines. These include hepatitis B vaccines made by recombinant DNA techniques in yeast, live mumps vaccine, and inactivated rabies vaccine produced in continuous cell lines. Of particular practical interest is an extensive report on a WHO meeting concerned with the use of recombinant DNA techniques to produce hepatitis B vaccines.

The report also includes amendments to previous requirements for oral poliomyelitis vaccine and for diphtheria toxoid, pertussis vaccine, tetanus toxoid, and combined vaccines.

A copy of the above report is available in the MMA library.