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WHO EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION

Fifty-sixth Report

BIOLOGICAL STANDARDIZATION

This report presents the recommendations of a WHO Expert Committee commissioned to coordinate activities leading to the adoption of international recommendations for the production and control of vaccines and other biologicals and the establishment of international biological reference materials.

The report starts with a discussion of general issues brought to the attention of the Committee and provides information on the status and development of reference materials for various antibodies, antigens, blood products and related substances, cytokines, growth factors, and endocrinological substances. The second part of the report, of particular relevance to manufacturers and national regulatory authorities, contains guidelines on quality, safety and efficacy of live attenuated rotavirus vaccines; DNA vaccines; a biosafety risk assessment for production and quality control of human influenza pandemic vaccines; recommendations for inactivated rabies vaccines produced in cell substrates and embryonated eggs; for whole cell pertussis vaccine; and for production, control and regulation of human plasma for fractionation.

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