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WHO EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION

Fifty-fifth report

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 the production and quality control of candidate tetravalent dengue virus vaccines and recommendations for the preparation, characterization and establishment of international and other biological reference standards. Also included are a list of recommendations, guidelines and other documents for biological substances used in medicine, and of international standards and reference reagent for biological substances.

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Geneva, 15–18 November 2004

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