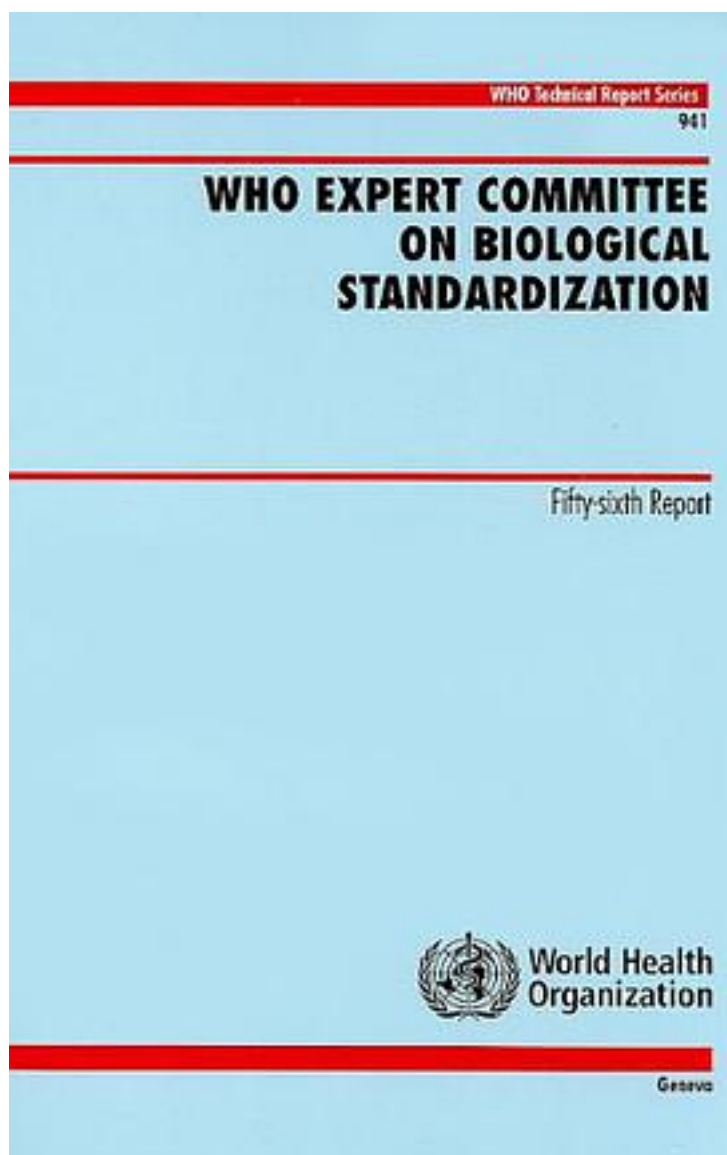


# WHO Expert Committee on Biological Standardization



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This report presents the recommendations of a WHO Expert Committee commissioned to coordinate activities leading to the adoption of international recommendations to assure the quality, safety and efficacy of vaccines, blood products and other biological medicines, and the establishment of international biological reference standards for these products and related diagnostic devices. The report, of particular relevance to manufacturers and national regulatory authorities, starts with a discussion of general issues brought to the Committee's attention. The second part of the report contains written specifications that establish international regulatory expectations for the following products; DNA vaccines, pertussis (whole cell) vaccine, plasma (human) for fractionation, rabies vaccine, and rotavirus vaccine. The report also provides a risk assessment and defines conditions for the safe production of pandemic strain influenza vaccines. The third part of the report provides information on the status and development of international reference materials for various antibodies, antigens, blood products and related substances, and in vitro diagnostic devices.

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