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, endocrinological substances and in vitro diagnostic devices. The second part of the report, of particular relevance to manufacturers and national regulatory authorities, contains revised WHO Recommendations for production and control of live attenuated influenza vaccines and for production and control of pneumococcal conjugate vaccines. New WHO Guidelines on the regulatory evaluation of similar biotherapeutic medicines are also provided.

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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# WHO Expert Committee on Biological Standardization

Sixtieth report

World Health Organization

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# WHO Expert Committee on Biological Standardization

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World Health Organization

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19 to 23 October 2009

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[1] The decisions of the Committee were taken in closed session with only members of the Committee present. Each Committee member had completed a declaration of interests form before the meeting. These were assessed by the WHO Secretariat and no declared interests were considered to be a conflict for full participation in the meeting.

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