

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.

Following a brief introduction, the report summarizes a number of general issues brought to the attention of the Committee. The next part of the report, of particular relevance to manufacturers and national regulatory authorities, sets out revised WHO Guidelines on the quality, safety and efficacy of candidate dengue tetravalent vaccines (live, attenuated), along with revised WHO Recommendations in relation to the production and quality control of bacille Calmette–Guérin (BCG) vaccines and of acellular pertussis vaccines. In addition, a generic protocol for the calibration of seasonal and pandemic influenza antigen working reagents is included. Revised WHO Guidelines for thromboplastins and plasma used to control oral anticoagulant therapy with vitamin K antagonists are then presented. Finally, new WHO assessment criteria for national blood regulatory systems are provided.

Subsequent sections of the report then provide information on the current status and proposed development of international reference materials in the areas of antibiotics; biotherapeutics other than blood products; blood products and related substances; in vitro diagnostic device reagents; and vaccines and related substances.

A series of annexes are then presented which include an updated list of WHO Recommendations, Guidelines and other documents on biological substances used in medicine (Annex 1), followed by a series of WHO Recommendations and Guidelines adopted on the advice of the Committee (Annexes 2–7). All additions made during the meeting to the list of International Standards and Reference Reagents for biological substances maintained by WHO are then summarized in Annex 8, and are also available at: <http://www.who.int/biologicals>.



WHO Expert Committee on Biological Standardization

Sixty-second report

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17 to 21 October 2011

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