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, outlines the discussions held on the development of revised WHO Recommendations and Guidelines for a number of vaccines, blood products and related substances. Specific discussion areas included the development of WHO guidance on the quality, safety and efficacy of poliomyelitis vaccines; recombinant malaria vaccines; diphtheria vaccines; tetanus vaccines; combined vaccines based on diphtheria and tetanus vaccines; and Japanese encephalitis vaccines.

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

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.

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WHO Library Cataloguing-in-Publication Data

WHO Expert Committee on Biological Standardization, sixty-third report.

(WHO technical report series ; no. 980)

1. Biological products - standards. 2. Vaccines - standards. 3. Reference standards.
4. Guideline. I.World Health Organization. II.WHO Expert Committee on Biological Standardization (2012: Geneva, Switzerland). III.Series.

ISBN 978 92 4 1209802 (NLM classification: QW 800)
ISSN 0512-3054

Printed in Italy

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15 to 19 October 2012

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