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.

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Members[1]

Dr J. Epstein, Director, Office of Blood Research and Review, Center for Biologics Evaluation and Research, Food and Drug Administration, Rockville, MD, United States of America (USA)

Dr E. Griffiths, Director-General, Biologics and Genetic Therapies, Health Canada, Ottawa, Ontario, Canada (*Chairman*)

Mrs T. Jivapaisarnpong, Director, Institute of Biological Products, Department of Medical Sciences, Ministry of Public Health, Bangkok, Thailand

Dr H. Klein, Chief, Department of Transfusion Medicine, National Institutes of Health, Bethesda, MD, USA

Dr P. Minor, Head, Division of Virology, National Institute for Biological Standards and Control, Potters Bar, England

Dr F.M. Moftah, Director-General, National Blood Transfusion Service, Ministry of Health, Giza, Egypt

Dr J. Petricciani, Palm Springs, CA, USA (*Rapporteur*)

Dr L.S. Slamet,[2] Deputy for Therapeutic Products, Narcotic, Psychotropic and Addictive Substance Control, Directorate General of Food and Drug Control of the Republic of Indonesia, Jakarta, Indonesia

Dr P. Strengers, Medical Director, Division of Plasma Products, Sanquin, Amsterdam, the Netherlands

Professor H. Yin, Deputy Director, Center for Drug Evaluation, State Food and Drug Administration, Beijing, China

Representatives of other organizations

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