

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, and endocrinological substances. The second part of the report, of particular relevance to manufacturers and national regulatory authorities, contains WHO recommendations and guidelines on Japanese encephalitis vaccine (inactivated), human regulatory preparedness for human pandemic influenza vaccines; and clinical evaluation of meningococcal C conjugate vaccines.

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.

WHO Expert Committee on Biological Standardization

Fifty-eighth report



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**World Health
Organization**

WHO Library Cataloguing-in-Publication Data

Fifty-eighth report/WHO Expert Committee on Biological Standardization.

(WHO technical report series ; no. 963)

1. Biological products - standards. 2. Vaccines - standards. 3. Reference standards.
4. Guidelines. I.World Health Organization. II.WHO Expert Committee on Biological
Standardization (2007: Geneva, Switzerland). III.Series.

ISBN 978 92 4 120963 2
ISSN 0512-3054

(NLM classification: QW 800)

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Design: WHP (Sophie Guetaneh Aguetant)

Layout: Interligar (<http://www.interligar.com.br>)

Printed in Italy

Contents

WHO Expert Committee on Biological Standardization	v
Introduction	1
General	5
Developments in biological standardization	5
Moving from biological to chemical reference materials	12
Development of tools for assessing implementation of WHO standards	14
Nomenclature for biological medicines	15
Regulatory evaluation of “biosimilars”/“follow-on biologics”	16
WHO Blood Regulators Network	18
International recommendations, guidelines, and other matters related to the manufacture and quality control of biologicals	21
Recommendations for inactivated Japanese encephalitis vaccine for human use	21
Regulatory preparedness for human pandemic influenza vaccines	21
Clinical evaluation of dengue vaccines	22
Recommendations for clinical evaluation of meningococcal C vaccines	23
Revision of guidelines for cell substrates	23
Proposed replacement seed stock for human diploid fibroblast MRC-5 cells for manufacture of biological medicines	24
Recommendations for the production and control of pneumococcal conjugate vaccines	25
In vitro diagnostic devices	26
Quality, safety and efficacy of antisera	28
Transmissible spongiform encephalopathies	29
Antibiotics	31
Amphotericin B – second International Standard	31
Nystatin – report on the third International Standard	31
Antigens and related substances	33
Tetanus toxoid – second International Standard	33
Diphtheria toxoid – second International Standard	34
Poliovirus, Sabin, type 1 – Progress report on replacement International Standard for the monkey neurovirulence test	35
Anti-measles serum – proposals for an ELISA value for the third International Standard	36
Anti-human papillomavirus type 16 serum – WHO Reference Reagent	37
Blood products and related substances	39
Protein C, concentrate – first International Standard	39
Heparin, low molecular weight (calibrant for molecular weight distribution) – second International Standard	39
Anti-thrombin concentrate – third International Standard	40
Anti-human platelet antigen 1a - first International Standard	41
Tissue plasminogen activator antigen in plasma – first International Standard	42

Cytokines, growth factors and endocrinological substances	45
Parathyroid hormone 1–34, recombinant, human	45
Tissue necrosis factor-related apoptosis-inducing ligand	45
Availability of standards for stem cell preparations	46
Diagnostic reagents	49
Anti-syphilitic plasma IgG (human) – first International Standard	49
Hepatitis A virus RNA for nucleic acid amplification test assay – new stability data on first International Standard	50
Hepatitis C virus RNA for nucleic acid amplification test assay – third International Standard	51
International Reference Preparations for the control of Chagas diagnostic tests	52
Proposed new Reference Preparation Projects	53
Proposed development of replacement WHO International Standards for antibiotics	53
Proposed development of new or replacement WHO International Standards or Reference Reagents for antigens and related substances	53
International Standard for acellular pertussis vaccine	54
International Standard for Japanese encephalitis vaccine, inactivated	54
Proposed development of new or replacement WHO International Standards or Reference Reagents for blood products and related substances	55
Proposed development of new or replacement WHO International Standards or Reference Reagents for diagnostic reagents	55
Discontinuation of WHO International Standards or Reference Reagents	56
Annex 1	
Recommendations for inactivated Japanese encephalitis vaccine for human use	57
Annex 2	
Regulatory preparedness for human pandemic influenza vaccines	117
Annex 3	
Recommendations for clinical evaluation of meningococcal C vaccine	225
Annex 4	
Biological substances – International Standards and Reference Reagents	239
Annex 5	
Recommendations and guidelines for biological substances used in medicine and other documents	241

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Geneva, 8–12 October 2007

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