

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>.

WHO Expert Committee on Biological Standardization

Sixty-third report



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Contents

Abbreviations	xi
1. Introduction	1
2. General	4
2.1 Current directions	4
2.1.1 Strategic directions in biological standardization: WHO priorities	4
2.1.2 Vaccines and biological therapeutics: recent and planned activities in biological standardization	4
2.1.3 Blood products and related in vitro diagnostics: recent and planned activities in biological standardization	6
2.2 Reports	6
2.2.1 Report from the WHO Blood Regulators Network	6
2.2.2 Report from the WHO collaborating centres for biological standards	7
2.3 Issues	8
2.3.1 Scientific issues identified by custodians of WHO biological reference preparations	8
2.3.2 Issues shared with the WHO Expert Committee on Specifications for Pharmaceutical Preparations	11
2.4 Feedback from other WHO committees	12
2.4.1 Request from the Strategic Advisory Group of Experts (SAGE) on Immunization for guidance on off-label use of vaccines	12
2.4.2 Request from the WHO Immunization Practices Advisory Committee (IPAC) to establish harmonized standards for the labelling of vaccines	13
3. International Recommendations, Guidelines and other matters related to the manufacture and quality control of biologicals	14
3.1 Vaccines and related substances	14
3.1.1 Recommendations to assure the quality, safety and efficacy of poliomyelitis vaccines (oral, live, attenuated)	14
3.1.2 Guidelines on the quality, safety and efficacy of recombinant malaria vaccines targeting the pre-erythrocytic and blood stages of <i>Plasmodium falciparum</i>	15
3.1.3 Recommendations to assure the quality, safety and efficacy of diphtheria vaccines (adsorbed)	16
3.1.4 Recommendations to assure the quality, safety and efficacy of tetanus vaccines (adsorbed)	17
3.1.5 Recommendations to assure the quality, safety and efficacy of DT-based combined vaccines	19
3.1.6 Recommendations to assure the quality, safety and efficacy of Japanese encephalitis vaccines (live, attenuated) for human use	19
3.1.7 In vitro assay system to replace the histamine sensitization test for acellular pertussis vaccines	20
3.2 Blood products and related substances	21
3.2.1 Strategies to promote the availability and safety of blood products	21
3.2.2 Blood components as essential medicines	22
3.2.3 Residual risk in recovered plasma to be used as an active pharmaceutical ingredient for fractionation	24

3.2.4	National strategies for plasma-derived medicinal products	25
3.2.5	Calibration of secondary reference materials	26
3.2.6	Assessment of commutability in WHO collaborative studies	26
4.	International reference materials – vaccines and related substances	28
4.1	WHO International Standards and Reference Reagents – vaccines and related substances	28
4.1.1	First WHO International Standard for anti-human papillomavirus type 18 serum	28
4.1.2	First WHO Reference Reagent for bacille Calmette–Guérin vaccine of Moreau-RJ substrain	28
4.1.3	First WHO International Standard for human diphtheria antitoxin	29
4.1.4	Second WHO International Standard for antibody to influenza H1N1pdm virus	30
5.	International reference materials – blood products and related substances	31
5.1	WHO International Standards and Reference Reagents – blood products and related substances	31
5.1.1	Fourth WHO International Standard for factor II and factor X concentrates	31
5.1.2	Second WHO International Standard for factor VII concentrate	31
5.1.3	Second WHO International Standard for fibrinogen concentrate	32
5.1.4	First WHO Reference Reagent for activated blood coagulation factor XI (human)	33
5.1.5	Second WHO International Standard for high-molecular-weight urokinase	34
5.1.6	Third WHO International Standard for low molecular weight heparin	34
6.	International reference materials – in vitro diagnostic device reagents	35
6.1	WHO International Standards and Reference Reagents – in vitro diagnostic device reagents	35
6.1.1	Second WHO Subtype Reference Panel for HIV-1 NAT-based assays	35
7.	International reference materials – biotherapeutics other than blood products	36
7.1	WHO International Standards and Reference Reagents – biotherapeutics other than blood products	36
7.1.1	Third WHO International Standard for erythropoietin (recombinant) for bioassay	36
7.1.2	Fifth WHO International Standard for follicle-stimulating hormone and luteinizing hormone (human, urinary) for bioassay	36
7.1.3	Second WHO International Standard for interleukin-2 (human, rDNA-derived)	37
7.1.4	First WHO Reference Reagent for interleukin-29 (human, rDNA-derived)	38
8.	International reference materials – antibiotics	39
8.1	WHO International Standards and Reference Reagents – antibiotics	39
8.1.1	Second WHO International Standard for neomycin B	39
8.1.2	Third WHO International Standard for neomycin	39
9.	Proposed projects for endorsement	40

Annex 1

WHO Recommendations, Guidelines and other documents related to the manufacture and quality control of biological substances used in medicine	43
--	----

Annex 2

Recommendations to assure the quality, safety and efficacy of poliomyelitis vaccines (oral, live, attenuated)	
Replacement of Annex 1 of WHO Technical Report Series, No. 904, and Addendum to Annex 1 of WHO Technical Report Series, No. 910	49

Annex 3

Guidelines on the quality, safety and efficacy of recombinant malaria vaccines targeting the pre-erythrocytic and blood stages of <i>Plasmodium falciparum</i>	141
--	-----

Annex 4

Recommendations to assure the quality, safety and efficacy of diphtheria vaccines (adsorbed)	
Replacement of Annex 2 of WHO Technical Report Series, No. 800, and Annex 5 of WHO Technical Report Series, No. 927	211

Annex 5

Recommendations to assure the quality, safety and efficacy of tetanus vaccines (adsorbed)	
Replacement of Annex 2 of WHO Technical Report Series, No. 800, and Annex 5 of WHO Technical Report Series, No. 927	271

Annex 6

Recommendations to assure the quality, safety and efficacy of DT-based combined vaccines	
Replacement of Annex 2 of WHO Technical Report Series, No. 800	335

Annex 7

Recommendations to assure the quality, safety and efficacy of Japanese encephalitis vaccines (live, attenuated) for human use	
Replacement of Annex 3 of WHO Technical Report Series, 910	407

Annex 8

Biological substances: WHO International Standards and Reference Reagents	487
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WHO Expert Committee on Biological Standardization

15 to 19 October 2012

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