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WHO Expert Committee on Biological Standardization

Who Expert Committee Biological Standardization

World Health Organization. Expert Committee on Biological Standardization

Who Expert Committee Biological Standardization:

WHO Expert Committee on Biological Standardization World Health Organization,2019-08-13 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 biological substances 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 and adoption of new and revised WHO Recommendations Guidelines and guidance documents Following these discussions WHO Recommendations to assure the quality safety and efficacy of recombinant hepatitis E vaccines WHO Guidelines for the safe development and production of vaccines to human pandemic influenza viruses and influenza viruses with pandemic potential and WHO Guidelines for the safe production and quality control of poliomyelitis vaccines were adopted on the recommendation of the Committee In addition a WHO questions and answers guidance document on the evaluation of similar biotherapeutic product SBPs was also adopted with the Committee recommending that it be posted on the WHO website Subsequent sections of the report provide information on the current status proposed development and establishment of international reference materials in the areas of antibiotics blood products and related substances cellular and gene therapies in vitro diagnostics standards for use in public health emergencies and vaccines and related substances A series of annexes are then presented which include an updated list of all WHO Recommendations Guidelines and other documents on biological substances used in medicine Annex 1 The above three WHO documents adopted for publication on the advice of the Committee are then presented as part of this report Annexes 2 4 Finally all additions and discontinuations made during the 2018 meeting to the list of International Standards Reference Reagents and Reference Panels for biological substances maintained by WHO are summarized in Annex 5 The updated full catalogue of WHO International Reference Preparations is available at http www who int bloodproducts catalogue en *Who Expert Committee on Biological Standardization* WHO Expert Committee on Biological Standardization. Meeting,World Health Organization,World Health Organization. Expert Committee on Biological Standardization,2013 The WHO Expert Committee on Biological Standardization ECBS met in Geneva from 17 to 21 October 2011 Introduction *WHO Expert Committee on Biological Standardization* World Health Organization. Expert Committee on Biological Standardization,2015-06-30 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 biological substances 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 and adoption of new and revised WHO Recommendations Guidelines and guidance documents Following these discussions a WHO guidance document on the Scientific principles for regulatory risk evaluation on finding an adventitious agent in a marketed vaccine was adopted along with WHO Guidelines on procedures and data requirements for changes to approved vaccines and revised WHO Recommendations to assure the quality safety and efficacy of poliomyelitis vaccines inactivated Subsequent sections of the report 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 all WHO Recommendations Guidelines and other documents on biological substances used in medicine Annex 1 The above three WHO documents adopted on the advice of the Committee are then published as part of this report Annexes 2 4 Finally all additions and discontinuations made during the 2014 meeting to the list of International Standards Reference Reagents and Reference Panels for biological substances maintained by WHO are summarized in Annex 5 The updated full catalogue of WHO International Reference Preparations is available at http www who int bloodproducts catalogue en WHO Expert Committee on Biological Standardization World Health Organisation Staff,World Health Organization. Expert Committee on Biological Standardization,1991-10 WHO Expert Committee on Biological Standardization World Health Organization,2018-07-18 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 biological substances 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 and adoption of new and revised WHO Recommendations Guidelines and guidance documents Following these discussions WHO Guidelines on the quality safety and efficacy of Ebola vaccines and WHO Guidelines on procedures and data requirements for changes to approved biotherapeutic products were adopted on the recommendation of the Committee In addition the following two WHO guidance documents on the WHO prequalification of in vitro diagnostic medical devices were also adopted a Technical Specifications Series TSS for WHO Prequalification Diagnostic Assessment Human immunodeficiency virus HIV rapid diagnostic tests for professional use and or self testing and b Technical Guidance Series TGS for WHO Prequalification Diagnostic Assessment Establishing stability of in vitro diagnostic medical devices Subsequent sections of the report provide information on the current status proposed development and establishment of international reference materials in the areas of antibiotics biotherapeutics other than blood products blood products and related substances in vitro diagnostics and vaccines and related substances A series of annexes are then presented which include an updated list of all WHO Recommendations

Guidelines and other documents on biological substances used in medicine Annex 1 The above four WHO documents adopted on the advice of the Committee are then published as part of this report Annexes 2 5 Finally all additions and discontinuations made during the 2017 meeting to the list of International Standards Reference Reagents and Reference Panels for biological substances maintained by WHO are summarized in Annex 6 The updated full catalogue of WHO International Reference Preparations is available at http www who int bloodproducts catalogue en *WHO Expert Committee on Biological Standardization* WHO Expert Committee on Biological Standardization. Meeting,2013 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 endocrinological substances and in vitro diagnostic devices The second part of the report of particular relevance to manufacturers and national regulatory authorities contains revised WHO recommendations for production and control of live attenuated influenza vaccines and for production and control of pneumococcal conjugate vaccines New WHO guidelines on the regulatory evaluation of similar biotherapeutic medicines are also provided 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 ,2022-04-12 **WHO Expert Committee on Biological Standardization** WHO Expert Committee on Biological Standardization,World Health Organization,1984-01-01 *WHO Expert Committee on Biological Standardization* World Health Organization,2022-09-30 The 75th meeting of the WHO Expert Committee on Biological Standardization was held from 4 to 8 April 2022 by Zoom video conferencing The meeting was opened on behalf of the Director General of WHO by Dr Mari ngela Batista Galvao Sim o Assistant Director General Access to Medicines and Health Products The Expert Committee on Biological Standardization reviews developments in the field of biological substances used in human medicine which include vaccines biotherapeutics blood products and related substances and in vitro diagnostic reagents It coordinates activities leading to a the adoption of WHO guidelines and recommendations for assuring the quality safety and efficacy of such substances and b the establishment of WHO international standards and other reference materials The use of international reference materials for designating the activity of biological substances used in prophylaxis or therapy or for ensuring the reliability of quality control or diagnostic procedures allows for the comparison of data worldwide Target audience includes but is not limited to regulators manufacturers developers of vaccines and other biological products and academia *WHO Expert Committee on Biological Standardization* WHO Expert Committee on Biological Standardization. Meeting,World Health Organization,2004 This publication contains the recommendations of a

WHO Expert Committee which met in Geneva in February 2003 relating to quality and standardisation of biological products Aspects discussed include International recommendations guidelines and other matters related to the manufacture and quality control of biologicals international reference standards antibodies antigens and related substances blood products and related substances cytokines growth factors and endocrinological substances and diagnostic reagents WHO Expert Committee on Biological Standardization World Health Organization. Expert Committee on Biological Standardization,World Health Organization,2016 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 biological substances 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 and adoption of new and revised WHO Recommendations Guidelines and guidance documents Following these discussions a WHO guidance document on Regulatory assessment of approved rDNA derived biotherapeutics was adopted along with WHO Guidelines on the stability evaluation of vaccines for use under extended controlled temperature conditions and on WHO good manufacturing practices for biological products In addition revised WHO Recommendations to assure the quality safety and efficacy of recombinant human papillomavirus virus like particle vaccines were also adopted by the Committee Subsequent sections of the report 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 all WHO Recommendations Guidelines and other documents on biological substances used in medicine Annex 1 The above four WHO documents adopted on the advice of the Committee are then published as part of this report Annexes 2 5 Finally all additions and discontinuations made during the 2015 meeting to the list of International Standards Reference Reagents and Reference Panels for biological substances maintained by WHO are summarized in Annex 6 The updated full catalog of WHO International Reference Preparations is available at http www who int bloodproducts catalogue en WHO Expert Committee on Biological Standardization World Health Organization. Expert Committee on Biological Standardization,1969 *WHO Expert Committee on Biological Standardization* World Health Organization,2024-04-25 The seventy eighth meeting of the WHO Expert Committee on Biological Standardization was held from 16 to 19 October 2023 as a hybrid meeting with Committee members attending in person at WHO headquarters in Geneva and others participants attending virtually Dr Yukiko Nakatani Assistant DirectorGeneral Access to Medicines and Health Products welcomed all participants and thanked them for devoting their time and expertise to the work of the Committee Noting that the frequency of Committee meetings had increased to meet increasing demands for new and

replacement standards for biological products including products used during public health emergencies Dr Nakatani remarked that this 78th meeting of the Committee was taking place in the same year that WHO celebrated its 75th anniversary Dr Nakatani also highlighted the 57th meeting of the Expert Committee on Specifications for Pharmaceutical Preparations which had met in the previous week and the 77th consultation on International Nonproprietary Names which was taking place at the same time as the current meeting **WHO Expert Committee on Biological Standardization** ,2021-03-10 **WHO Expert Committee on Biological Standardization** ,2017 *WHO Expert Committee on Biological Standardization* WHO Expert Committee on Biological Standardization,1981-01-01 *WHO Expert Committee on Biological Standardization* ,1973 **WHO Expert Committee on Biological Standardization** WHO Expert Committee on Biological Standardization. Meeting,World Health Organization,2005-12-14 The WHO Expert Committee on Biological Standardization is commissioned by WHO to establish detailed recommendations and guidelines for the manufacturing licensing and control of blood products cell regulators vaccines and related in vitro diagnostic tests Members of the Expert Committee are scientists from national control agencies academia research institutes public health bodies and the pharmaceutical industry acting as individual experts and not as representatives of their respective organizations or employers The decisions and recommendations of the Committee are based entirely on scientific principles and considerations of public health The Expert Committee on Biological Standardization meets on an annual basis since 1947 and is reponsible for the establishment of the WHO International Biological Reference Preparations and for the adoption of the WHO Recommendations and Guidelines The Expert Committee directly reports to the Executive Board which is the executive arm of the World Health Assembly

Thirty-second Report World Health Organization. Expert Committee on Biological Standardization,1982 WHO Expert Committee on Biological Standardization WHO expert committee on biological standardization,1972

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