

WHO Expert Committee on Biological Standardization

Report of the seventy-second and seventy-third meetings



World Health
Organization

Who Expert Committee On Biological Standardization Fiftysecond Report W

United States. Congress



Who Expert Committee On Biological Standardization Fiftysecond Report W:

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, 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 Consultation on Rabies World Health Organization,2005-12-31 More than 99% of all human rabies deaths occur in the developing world and although effective and economical control measures are available the disease has not been brought under control throughout most of the affected countries Given that a major factor in the low level of commitment to rabies control is a lack of accurate data on the true public health impact of the disease this report of a WHO Expert Consultation begins by providing new data on the estimated burden of the disease and its distribution in the world It also reviews recent progress in the classification of rabies viruses rabies pathogenesis and diagnosis rabies pre and post exposure prophylaxis the management of rabies patients and canine as well as wildlife rabies prevention and control

Vaccine Analysis: Strategies, Principles, and Control Brian K. Nunnally,Vincent E. Turula,Robert D. Sitrin,2014-11-27 This book is an indispensable tool for anyone involved in the research development or manufacture of new or existing vaccines It describes a wide array of analytical and quality control technologies for the diverse vaccine modalities Topics covered include the application of both classical and modern bio analytical tools procedures to assure safety and control of cross contamination consistent biological transition of vaccines from the research laboratory to manufacturing scale whole infectious attenuated organisms such as live attenuated and inactivated whole cell bacterial vaccines and antiviral vaccines using attenuated or inactivated viruses principles of viral inactivation and the application of these principles to vaccine development recombinant DNA approaches to produce modern prophylactic vaccines bacterial subunit polysaccharide and glycoconjugate vaccines combination vaccines that contain multiple antigens as well as regulatory requirements and the hurdles of licensure **Technical Report Series** ,2011 WHO Expert Committee on Biological Standardization WHO Expert Committee on Biological Standardization. Meeting,2004 *Toxicity and Drug Testing* Bill Acree,2012-02-10 Modern drug design and testing involves experimental in vivo and in vitro measurement of the drug

candidate s ADMET adsorption distribution metabolism elimination and toxicity properties in the early stages of drug discovery Only a small percentage of the proposed drug candidates receive government approval and reach the market place Unfavorable pharmacokinetic properties poor bioavailability and efficacy low solubility adverse side effects and toxicity concerns account for many of the drug failures encountered in the pharmaceutical industry Authors from several countries have contributed chapters detailing regulatory policies pharmaceutical concerns and clinical practices in their respective countries with the expectation that the open exchange of scientific results and ideas presented in this book will lead to improved pharmaceutical products

DNA Vaccines Mark W. Saltzman,Hong Shen,Janet L. Brandsma,2008-02-02 In the early 1990s almost 200 yr after Edward Jenner demonstrated the effectiveness of the smallpox vaccine a new paradigm for vaccination emerged The conventional method of vaccination required delivery of whole pathogens or structural subunits but in this new approach DNA or genetic information was administered to elicit an immunological response Once it was observed that plasmid DNA delivered in vivo led to production of an encoded transgene 1 two ground breaking studies demonstrated that immunological responses could be generated against antigenic transgenes via plasmid DNA delivered by DNA vaccination as this approach is called 2 3 The appearance of this new vaccination strategy coincided with advances in molecular biology which provided new tools to study and manipulate the basic elements of an organism s genome and also could also be applied to the design and production of DNA vaccines DNA Vaccines is a major updated and enhancement of the first edition It reviews state of the art methods in DNA vaccine technology with chapters describing DNA vaccine design delivery systems adjuvants current applications methods of production and quality control Consistent with the approach of the Methods in Molecular Medicine series these chapters contain detailed practical procedures on the latest DNA vaccine technology The enthusiasm for DNA vaccine technology is made clear by the number of research studies published on this topic since the mid 1990s

International Health; a Report of the Committee on Interstate and Foreign Commerce, House of Representatives United States. Congress. House. Committee on Interstate and Foreign Commerce,1957

Reports and Documents United States. Congress,1957 *Quality assurance of pharmaceuticals: a compendium of guidelines and related materials. Volume 2. Good manufacturing practices and inspection* World Health

Organization,2024-01-31 The GMP Compendium for Medical Products is a valuable resource for manufacturers regulators and other stakeholders involved in producing and distributing medical products It covers various topics from quality management systems to personnel hygiene equipment validation and complaint handling The guidance provided is based on the latest scientific and technical knowledge and considers the evolving regulatory landscape and the challenges faced by the industry

WHO Expert Committee on Biological Standardization World Health Organization. Expert Committee on Biological Standardization,1950 **Official Records of the World Health Organization** World Health Organization,1976

WHO Technical Report Series ,1964 **Rabies in Man and Animals** Sudhi Ranjan Garg,2013-10-23 Rabies is the

deadliest zoonotic disease that threatens humans and animals on all continents except Antarctica Asia and Africa are worst affected as more than 95 per cent of rabies associated human deaths occur in these regions India alone bears about 36 per cent of the global human rabies burden Dogs are the main transmitters of rabies that potentially threaten over 3 billion people in Asia and Africa Many developed nations have been able to successfully control dog rabies but continue to face the risk from wildlife including bats Bat rabies is responsible for most human rabies deaths in the United States of America and Canada but has emerged as a public health threat in Australia Latin America and Western Europe as well Despite being vaccine preventable rabies continues to haunt the mankind Poor resources is a major constraint but the factors like low priority attributed to rabies misconceptions in the community about the disease and unsystematic approach for its prevention and control are also responsible for the grim situation Targets have been set for elimination of human and dog rabies in all Latin American countries by 2015 and of human rabies transmitted by dogs in South East Asia by 2020 However the myths prevailing among the people together with inadequate knowledge of the health professionals veterinarians and the civic body staff about the rabies prevention and control strategies might make the task very difficult This book comprising eight chapters elaborates the causation of rabies in man and animals its global epidemiology risk analysis and effective strategies for the management of exposures Proven methods of rabies prevention and control have been discussed in length along with the challenges and ways to overcome the constraints through intersectoral coordination The inclusion of 200 frequently asked questions is a unique feature of the book which may help not only the common people and pet lovers in clearing their doubts about rabies in man and animals also be equally instrumental in updating the knowledge and skills of the public health personnel veterinarians and other professionals Apt illustrations and simple language make the contents of the book easily comprehensible and a reading pleasure

Medical Methods for Termination of Pregnancy World Health Organization, 1997 A state of the art report on the use of pharmaceutical agents and other non invasive methods for the medical termination of pregnancy Addressed to service managers the report draws together a wealth of recent findings useful in evaluating the safety efficacy cost effectiveness and acceptability of medical methods whether currently in use or undergoing clinical trials Information on established surgical procedures for abortion is also provided to facilitate comparisons and balanced decisions While noting that the prevention of unwanted pregnancies remains the first public health priority the report aims to help health care personnel providing legal abortion services to determine whether these newer medical methods can improve the management of abortion in specific patient groups and in different resource settings Over 250 references to the literature are included The report has eight sections The first on the demography of abortion explores the many factors that contribute to unwanted pregnancies and influence abortion rates Section two on mechanisms for medical abortion explains how pharmaceutical agents act to interrupt the pregnancy process and cause the pregnancy to end Of particular value is a review of some 18 agents categorized as prostaglandins antiprogestogens including mifepristone

epostane oxytocin hypertonic agents ethacridine lactate hydrophilic cervical dilators and cervical ripening devices Each is profiled in terms of its mechanisms of action efficacy side effects and safety mode of administration and advantages and disadvantages when compared with other medical and surgical methods Against this background the main part of the report provides detailed information on the current or potential place of medical methods for abortion at up to 9 weeks of gestation at 9 14 weeks of gestation and after 14 weeks of gestation In each section conclusions and recommendations identify methods of choice and their most acceptable alternatives summarize procedures that can enhance safety and point out factors that should be considered when selecting a method for routine use Needs for further research are also identified Subsequent sections discuss the complications of abortion and measures for their prevention and review findings from several recent studies of the acceptability to both women and service providers of medical abortion The final section provides a guide to the introduction of medical abortion as a routine clinical service **Joint FAO/WHO Expert Committee on**

Brucellosis Joint FAO/WHO Expert Committee on Brucellosis,1964 *Medical Books and Serials in Print* ,1983

Handbook of Resolutions and Decisions of the World Health Assembly and the Executive Board ,1983 International Books in Print ,1990

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