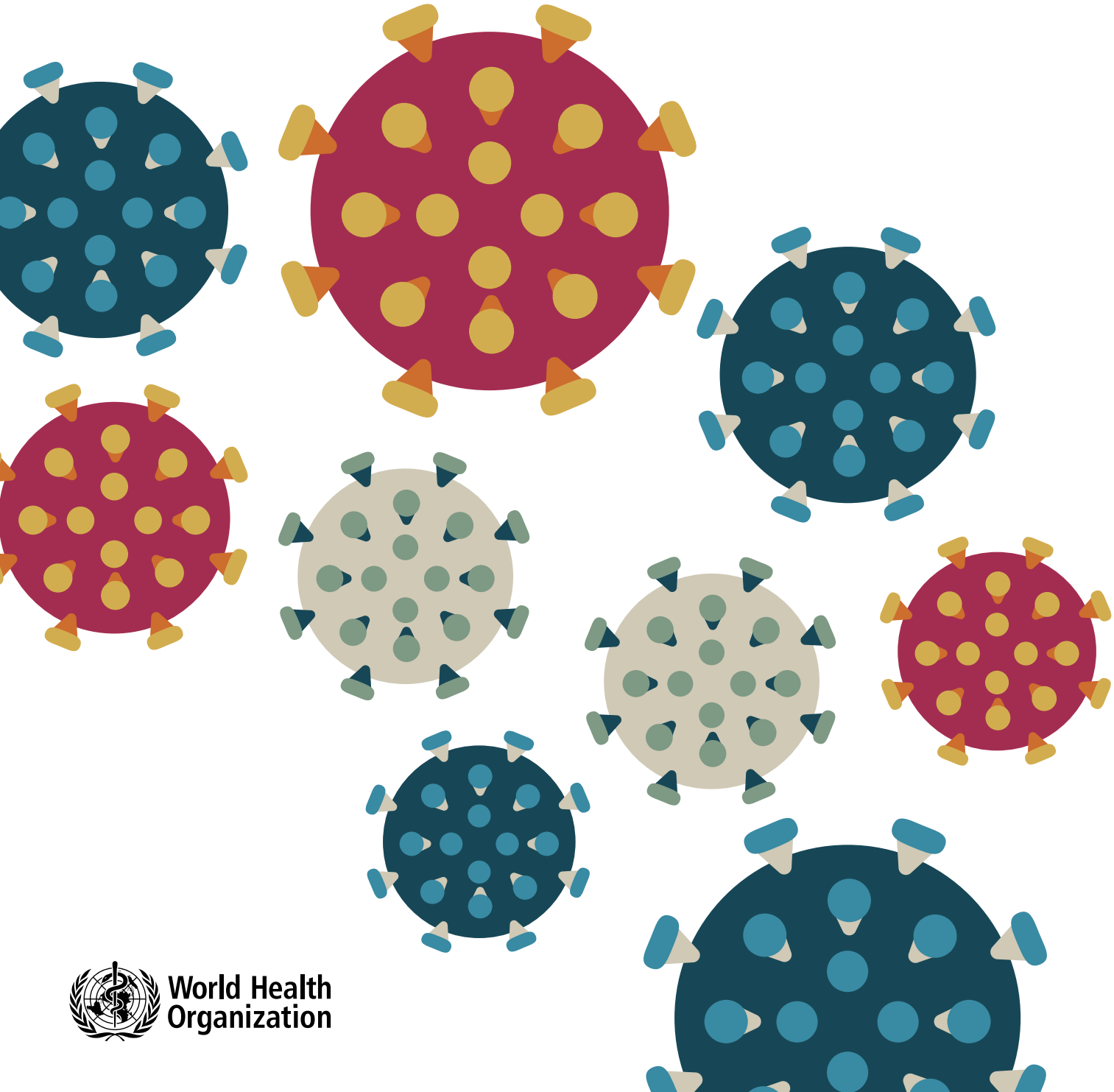
WHO preferred product characteristics for herpes simplex virus vaccines



World Health Organization

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ISBN 978-92-4-151558-0

Suggested citation. WHO preferred product characteristics for herpes simplex virus vaccines. Geneva: World Health Organization; 2019. Licence: CC BY-NC-SA 3.0 IGO.

Cataloguing-in-Publication (CIP) data. CIP data are available at http://apps.who.int/iris.

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Design and layout by Lushomo.

Printed in Switzerland.

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Acknowledgements

The Department of Reproductive Health and Research and the Department of Immunizations, Vaccines and Biologicals at the World Health Organization (WHO) would like to thank the many individuals who contributed to the development of this document. The consultation process for developing herpes simplex virus (HSV) vaccine preferred product characteristics (PPCs) and preparation of this publication were coordinated by Sami Gottlieb, Department of Reproductive Health and Research, and Birgitte Giersing, Department of Immunizations, Vaccines and Biologicals.

We thank the members of the HSV Vaccine PPC writing and working groups for their assistance with drafting and revising this document: Jeff Cohen, National Institute of Allergy and Infectious Diseases (NIAID), Bethesda, MD, United States of America (USA); Carolyn Deal, NIAID, Bethesda, MD, USA; Sinead Delany-Moretlwe, University of Witwatersrand, Johannesburg, South Africa; Birgitte Giersing, WHO, Geneva, Switzerland; Sami Gottlieb, WHO, Geneva, Switzerland; Julian Hickling, WHO consultant, Cambridge, UK; Christine Johnston, University of Washington, Seattle, WA, USA; Rebecca Jones, WHO consultant, Cambridge, UK; David Kaslow, PATH, Seattle, WA, USA; David Koelle, University of Washington, Seattle, WA, USA; Nelly Mugo, Kenya Medical Research Institute (KEMRI), Nairobi, Kenya; Francis Ndowa, Skin and GU Medicine Clinic, Harare, Zimbabwe; Julia Schillinger, US Centers for Disease Control and Prevention (CDC) and New York City Department of Health and Mental Hygiene, New York, NY, USA; Deborah Watson-Jones, London School of Hygiene and Tropical Medicine, London, United Kingdom (UK) and National Institute for Medical Research, Dar es Salaam, United Republic of Tanzania.

We gratefully acknowledge the contributions of the expert participants at the initial consultation on HSV vaccine PPCs in March 2017: Ian Askew, WHO, Geneva, Switzerland; Marie-Claude Boily, Imperial College, London, UK; Martha Brady, PATH, Washington, DC, USA; Nathalie Broutet, WHO, Geneva, Switzerland; Z. Mike Chirenje, University of Zimbabwe, Harare, Zimbabwe; Carolyn Deal (Co-Chair), NIAID, Bethesda, MD, USA; Sinead Delany-Moretlwe, University of Witwatersrand, Johannesburg, South Africa; Birgitte Giersing, WHO, Geneva, Switzerland; Sami Gottlieb, WHO, Geneva, Switzerland; Raymond Hutubessy, WHO, Geneva, Switzerland; Christine Johnston, University of Washington, Seattle, WA, USA; David Kaslow (Co-Chair), PATH, Seattle, WA, USA; David Koelle, University of Washington, Seattle, WA, USA; Peter Leone, University of North Carolina, Chapel Hill, NC, USA; Odile Leroy, European Vaccine Initiative, Universitäts Klinikum, Heidelberg, Germany; Katharine Looker, University of Bristol, Bristol, UK; Nicola Low, University of Bern, Bern, Switzerland; Purnima Madhivanan, Florida International University, Miami, FL, USA; Nelly Mugo, KEMRI, Nairobi, Kenya; Nicolas Nagot, University of Montpellier, Montpellier, France; Julia Schillinger, US CDC and New York City Department of Health and Mental Hygiene, New York, NY, USA; James Southern, Medicines Control Council, Pretoria, South Africa; João Paulo Toledo, Ministry of Health, Brasília, Brazil; Anna Wald, University of Washington, Seattle, WA, USA; Pingyu Zhou, Shanghai Skin Disease and STD Hospital, Shanghai, People's Republic of China.

We are grateful to the members of the WHO Product Development for Vaccines Advisory Committee for their review of the document: Klaus Cichutek, Paul Ehrlich Institut, Langen, Germany; Sinead Delany-Moretlwe, University of Witwatersrand, Johannesburg, South Africa; Bernard Fritzell, BFL Conseils, Jau-Dignac-et-Loirac, France; Barney Graham, NIAID, Bethesda, MD, USA; Gagandeep Kang, Translational Health Science and Technology Institute, Faridabad, India; Ruth Karron, Johns Hopkins School of Public Health, Baltimore, MD, USA; Jerome Kim, International Vaccine Institute, Seoul, Republic of Korea; David Kaslow, PATH, Seattle, WA, USA; Claudio Lanata, US Naval Medical Research Unit No 6, Lima, Peru; Shabir Mahdi, University of Witwatersrand, Johannesburg, South Africa; Mark Papania, US CDC, Atlanta, GA, USA; Yiming Shao, Chinese Center for Disease Control and Prevention, Beijing, People's Republic of China; Peter Smith, London School of Hygiene and Tropical Medicine, London, UK; Marian Wentworth, Management Sciences for Health, Medford, MA, USA.

Finally, we thank the members of the public and HSV community who commented on the document through the online public consultation process.

Funding

This work was supported by the National Institute of Allergy and Infectious Diseases of the National Institutes of Health (Grant U01 AI108543) and by the UNDP-UNFPA-UNICEF-WHO-World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP).

Abbreviations

GUD ..... genital ulcer disease (genital ulcers, blisters, or other painful lesions)

HIC ..... high-income country

HIV ..... human immunodeficiency virus

HPV ..... human papillomavirus

HSV-1 ..... herpes simplex virus type 1

HSV-2 ..... herpes simplex virus type 2

Ig ..... immunoglobulin

LMIC ..... low- or middle-income country

PBMC ..... peripheral blood mononuclear cell

PPCs ..... preferred product characteristics

SAGE ..... WHO Strategic Advisory Group of Experts on Immunization

SRH ..... sexual and reproductive health

STI ..... sexually transmitted infection

WHO ..... World Health Organization

Executive summary

The development of one or more herpes simplex virus (HSV) vaccines is an important goal for sexual and reproductive health (SRH) worldwide. Sexually transmitted genital HSV infections are estimated to affect more than 500 million people worldwide. Most of these infections are caused by HSV type 2 (HSV-2) but can also be caused by HSV type 1 (HSV-1). Genital infection with either type is lifelong and can lead to genital ulcer disease (GUD) and neonatal herpes. GUD caused by HSV-2 can recur frequently, and HSV-2 infection is also linked to increased risk of acquiring and transmitting HIV infection.

Although several candidate HSV vaccines have been tested in humans, currently there are no licensed vaccines against either HSV type. In addition to potential direct effects on HSV-associated morbidity and mortality, HSV vaccines might also have indirect effects on HIV acquisition and transmission, especially in settings with a substantial burden of HIV infection.

World Health Organization (WHO) preferred product characteristics (PPCs) provide guidance on the Organization's preferences for new vaccines in priority disease areas, specifically from the perspective of low- and middle-income countries (LMICs). Articulation of product attributes that meet LMIC needs, in addition to those that address high-income country (HIC) concerns, can help advance the development of vaccines that are suitable for global use. As a first step to define HSV vaccine PPCs, WHO convened a global stakeholder consultation in March 2017, which proposed two overarching global public health goals, of equal priority, for HSV vaccines:

- to reduce the burden of HSV-associated disease, including mortality and morbidity due to neonatal herpes and other impacts on SRH;
- to reduce the acquisition of HSV-2-associated HIV infection, particularly in settings or populations with high HIV prevalence.

This document describes two sets of PPCs for HSV vaccines:

- **PPCs for prophylactic HSV vaccines** to be used primarily before exposure to HSV-2 to prevent infection. Prevention of HSV-2 infection would prevent associated GUD and HSV transmission, including to neonates as neonatal herpes, as well as HSV-2-associated HIV acquisition.
- **PPCs for therapeutic HSV vaccines** that reduce symptomatic HSV-2 GUD in individuals who are already infected with HSV-2. For broader public-health impact, disease will need to be modified in a way that reduces HSV transmission and/or HSV-2-associated HIV acquisition.

Prophylactic vaccines are preferred for LMIC use, but therapeutic vaccines are more advanced in development and might also have public health benefits if they can be delivered effectively within existing health systems. HSV-2 is a higher priority vaccine target than HSV-1, based on its larger burden of SRH outcomes in LMICs; however, vaccines that also prevent HSV-1 infection or disease would have added benefits.