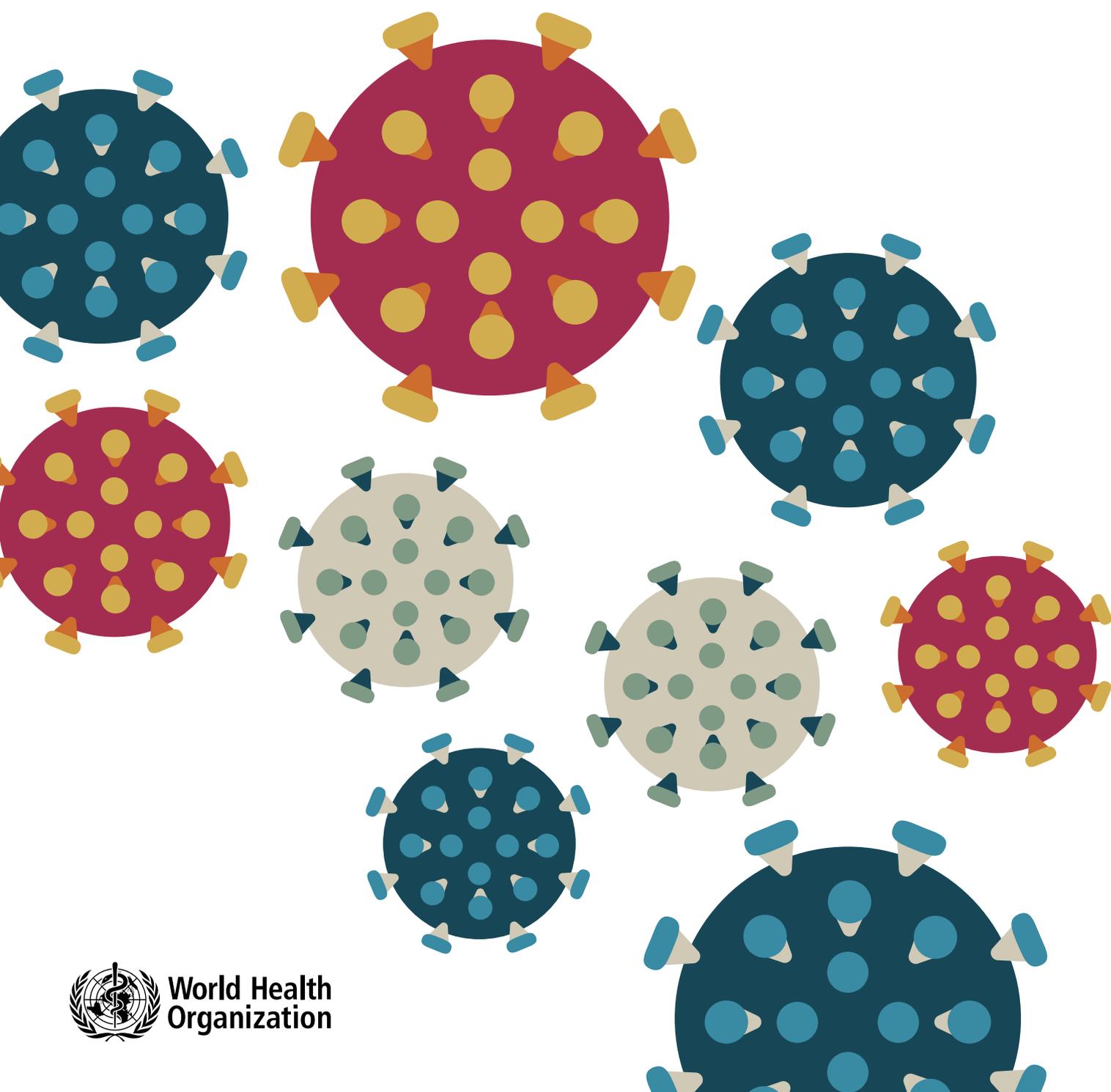


WHO preferred product characteristics for herpes simplex virus vaccines



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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.



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