WHO/IVB/14.09

WHO Preferred Product Characteristics (PPC) for Malaria Vaccines

DEPARTMENT OF IMMUNIZATION, VACCINES AND BIOLOGICALS

Family, Women's and Children's Health (FWC)

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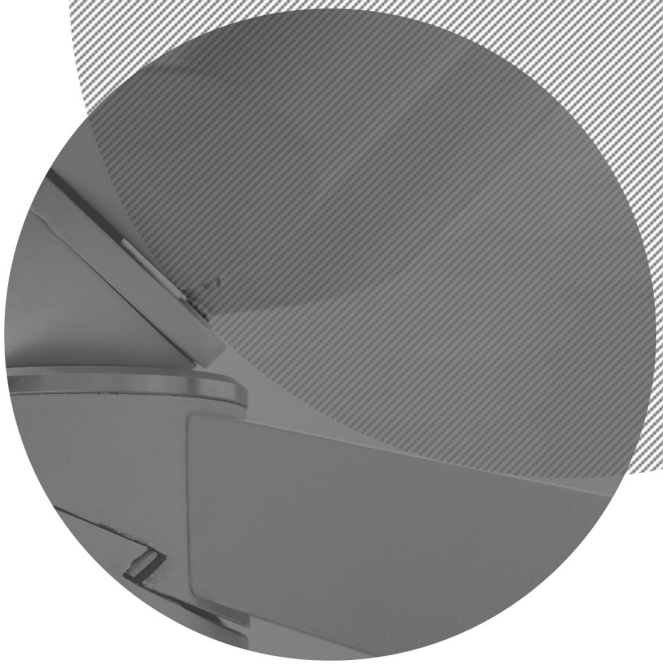

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World Health Organization
Department of Immunization, Vaccines and Biologicals
CH-1211 Geneva 27, Switzerland
• *Fax:* + 41 22 791 4227 • *Email:* vaccines@who.int •

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1. Background and purpose

Preferred product characteristics (PPCs) describe WHO preferences for parameters of vaccines, in particular its indications, target groups, possible immunization strategies, and features of clinical data desired related to safety and efficacy. These preferences are shaped by the unmet public health need in a priority disease area for which WHO encourages vaccine development. In keeping with its mandate, WHO preferences reflect its desire to promote the development of vaccines with high public health impact and suitable for use in low to middle-income countries.

PPCs are meant to provide early guidance for the development of new products or the improvement of existing ones. Each PPC addresses early stage vaccine R&D generally at least 5-10 years from vaccine availability, and will be reviewed and updated if necessary at least every 5 years. PPC are not static exit criteria, but are structured in such a way so as to drive innovation towards meeting public health needs.

Although the parameters in PPCs are commonly found in another product development tool often developed by industry known as target product profile (TPP), PPCs provide guidance tailored with the public health perspective. As the name suggests, PPCs focus on the preferred characteristics, while industry TPPs often specify minimally acceptable in addition to preferred criteria.

PPCs do not provide new guidance on other characteristics often described in TPPs such as vaccine presentation, packaging, thermostability, formulation and disposal, as this area is well-addressed by existing WHO processes such as the WHO Vaccine Presentation and Packaging Advisory Group (VPPAG) and the WHO Prequalification (PQ) process. The VPPAG interacts with manufacturers on questions related to presentation and packaging and has developed a preferred product profile on these aspects. (*http://www.who.int/immunization/policy/committees/vppag/en/index2.html*)

The WHO PQ process which assesses vaccine quality, safety, efficacy and suitability for use in low and middle-income countries has developed criteria called Programmatic Suitability for Prequalification (PSPQ) criteria to review vaccines submitted for prequalification. (*http://apps.who.int/iris/bitstream/10665/76537/1/WHO_IVB_12.10_eng.pdf*)

In addition to the documents related to PSPQ and VPPAG referred to above, malaria vaccine developers should be familiar with "Guidelines on the quality, safety and efficacy of recombinant malaria vaccines targeting the pre-erythrocytic and blood stages of *Plasmodium falciparum*"[1].

Thus WHO encourages developers to consult the above links, in addition to the PPCs for guidance covering many aspects of TPPs, particularly if they intend to seek WHO Policy Recommendation and Prequalification for their products.

1.1 Target audience for WHO PPCs

The primary target audience is any entity intending to eventually seek WHO policy recommendation and prequalification for their products. Knowledge of WHO preferences can be useful to all those involved in malaria vaccine development, including academic groups from pre-clinical development onwards.

The PPCs are intended to encourage innovation and the development of vaccines that perform in settings most relevant to the global unmet public health need. At the same time, changes in scientific and technological feasibility could affect the PPCs. Each PPC document will be reviewed and, where necessary, revised at least every 5 years. In addition, changes to the Malaria Vaccine Technology Roadmap Strategic Goals may prompt revision of WHO PPCs for malaria vaccines. It is important to note that if a vaccine does not meet the PPC criteria, it could still be assessed by WHO for possible policy recommendations in the standard way.

1.2 Malaria Vaccines, A Strategic Priority for WHO

Malaria vaccine PPCs are aligned to the strategic priorities of WHO and partners as articulated by the two updated Malaria Vaccine Technology Roadmap goals[2]. The geographical distribution and burden of disease of *Plasmodium falciparum and Plasmodium vivax* malaria make these two pathogens high priority targets for vaccine development. In 2013, WHO's principal advisory group on immunization, SAGE (Strategic Advisory Group of Experts) stated that "malaria vaccine development remains a global public health imperative". The changing epidemiology of malaria and the call for eradication of the malaria parasite as a public health goal in recent years has led the global malaria vaccine community, in 2013, to update the *Malaria Vaccine Technology Roadmap*, which provides a blueprint for developing malaria vaccines. The current update calls for the development of vaccines targeting *Plasmodium falciparum and Plasmodium vivax*, by 2030 that address two unmet priority public health goals:

- Roadmap strategic goal 1: Malaria vaccines with a protective efficacy of at least 75% against clinical malaria, suitable for administration to appropriate at-risk groups in malaria-endemic areas[3].

[1] http://who.int/entity/biologicals/vaccines/Malaria_Guidelines_TRS_980_Annex_3.pdf. This document is part of a class of documents known as WHO written standards used by National Regulatory Authorities to guide assessment of dossiers for licensure of vaccines. Written standards are also used by the WHO Prequalification team to guide PQ assessments of vaccines.

[2] http://www.who.int/immunization/topics/malaria/vaccine_roadmap/en/

[3] Duration of protection will be assessed over at least two years, with a booster dose required at most once during the two year period.

- Roadmap strategic goal 2: Malaria vaccines that reduce transmission of the parasite and thereby substantially reduce the incidence of human malaria infection. This will enable elimination in multiple settings. Vaccines to reduce transmission should be suitable for administration in mass campaigns.

This guidance presents PPCs that correspond to these goals.

Any malaria vaccine that becomes licensed and potentially available will undergo evidence-based assessment for policy recommendations by the Strategic Advisory Group of Experts (SAGE) on Immunisation and the Malaria Policy Advisory Committee (MPAC).

1.3 Context of available WHO recommended malaria interventions

Malaria vaccines will be tested and deployed in conjunction with other WHO recommended malaria control measures. These include effective artemisinin combination anti-malarial chemotherapy, use of quality-assured rapid diagnostic tests, long-lasting insecticide-treated bednets and other vector control measures, including indoor residual spraying with insecticide In addition drug-based prophylaxis is recommended by WHO in certain settings and target groups. In the future, the recommended malaria control measures may also include a first-generation malaria vaccine.

Even if a first-generation malaria vaccine becomes available, it seems likely that the efficacy and duration of protection will be modest and there will remain a pressing need to develop second generation vaccines with higher efficacy to further reduce malaria cases and deaths. Furthermore, control measures are increasingly threatened by the development of resistance to drugs and insecticides, and so authorities in most malaria-endemic countries will view a safe and highly effective second generation malaria vaccine as a high priority for possible introduction.