WHO prequalifies diagnostic test to support safer administration of P. vivax malaria treatments

18 January 2025 - the World Health Organization (WHO) prequalified the first diagnostic test for glucose-6-phosphate dehydrogenase (G6PD) deficiency which can help to safely deliver WHO-recommended treatments to prevent relapse of Plasmodium vivax (P. vivax) infection.

The prequalification of this G6PD diagnostic test marks a significant milestone in facilitating safe and effective P. vivax malaria treatment, reaffirming WHO's dedication to ensuring equitable access to life-saving health solutions globally. Some 500 000 people die each year from malaria, most of them children.

The prequalification of this test immediately followed the prequalification, in early December, of two new tafenoquine products for anti-relapse treatment of P. vivax malaria, and these therapeutics were recommended in updated WHO malaria guidelines released a few days earlier, in late November.

This package of actions by WHO reflects the organization's recent adoption of synchronized and parallel processes for two key functions: developing recommendations for essential health products and overseeing their prequalification.

While these processes remain entirely independent, their alignment aims to significantly reduce the time required to bring vital health products to low- and lower-middle-income countries. This streamlined approach underscores WHO's commitment to improving global health equity by expediting access to life-saving products.

P. vivax malaria is endemic in all WHO Regions except the European Region, with an estimated 9.2 million clinical cases occurring in 2023. P. vivax is the dominant malaria parasite in most countries outside of sub-Saharan Africa.

G6PD deficiency, a genetic condition, affects more than 500 million people. While most people are unaware of their G6PD deficiency and go through life without suffering ill effects, certain drugs administered to prevent malaria relapse caused by P. vivax can result in acute haemolysis (destruction of red blood cells). Without accessible and reliable G6PD testing, it has been challenging to safely provide anti-relapse treatments, limiting the widespread use of this effective therapy.

"The prequalification of this G6PD enzyme test for patients with P. vivax malaria can help countries in enhancing access to much-needed quality-assured tests, enabling safe and effective treatment and prevention of this type of relapsing malaria," said Dr Yukiko Nakatani, WHO Assistant Director-General for Access to Medicines and Health Products. "Currently, no other prequalification applications are received for this type of tests. We encourage the submission of additional products to expand the range of effective diagnostic tools available to countries in need."

"Wider availability of the test can help strengthen the global malaria response by reducing the number of P. vivax infections due to relapse and in turn reduce onward transmission," said Dr Daniel Ngamije Madandi, Director of WHO's Global Malaria Programme.

Testing devices that can accurately distinguish patients with G6PD activity levels above and below the normal levels provide critical information to clinicians to decide which of P. vivax anti-relapse treatment regimens is most appropriate, including low- and high-dose primaquine and single-dose tafenoquine.

The STANDARD G6PD System diagnostic tool manufactured by SD Biosensor, Inc., is a semi-quantitative, near-patient solution designed for the measurement of G6PD enzyme activity in capillary or venous whole blood.

The device is intended for use in both laboratory and non-laboratory settings and operates with the STANDARD G6PD Analyzer, a hand-held device, delivering results in a few minutes.

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