Malaria Policy Advisory Group Meeting

4–5 March 2024, Yaoundé, Cameroon
Background document for Session 6

World Health Organization

Update on development of guidelines recommendations on tafenoquine, primaquine and near-patient G6PD diagnostic test to support radical cure of *P. vivax*

The Global Malaria Programme has convened two Guidelines Development Group (GDG) meetings to develop guidelines recommendations on the use of 8-aminiquinolines and near-patient G6PD tests for radical cure of *P. vivax* and *P. ovale*. On 14–15 November 2023, the GDG on malaria chemotherapy reviewed the evidence and generated recommendations on tafenoquine and primaquine as anti-relapse therapy. For primaquine this included a review of the standard WHO recommendations of primaquine daily for 14 days as well as the recommendation on high dose primaquine for 7-days, and the safety of primaquine administration to infants aged < 6 months and women breastfeeding infants aged < 6 months. On 30 November–1 December 2023, the GDG on malaria diagnostics reviewed the evidence to recommendations on near-patient diagnostic tests for G6PD deficiency. Since then the systematic review of G6PD tests has been further refined and cost-effectiveness analysis completed and these have informed the second meeting of the GDG on G6PD tests, convened on 26 and 29 February 2024. The GDG on G6PD developed recommendations on the use of qualitative and semi-quantitative G6PD tests, comparing diagnostic accuracy with quantitative spectrophotometric G6PD assays as reference test, at the critical thresholds critical to inform administration of 8-aminoquinolines, i.e. < 30%, 30–70%, and > 70% G6PD activity.

The recommendations on single low-dose primaquine to reduce the transmissibility of *P. falciparum* were not reviewed by the GDG as the current WHO guidelines already provides recommendations for areas of low transmission to reduce the transmissibility of treated falciparum malaria infections as well as for areas with artemisinin-resistant falciparum malaria, that a single low dose of primaquine of 0.25 mg/kg should be given with an artemisinin-based combination therapy (ACT) to patients with *P. falciparum* malaria (WHO guidelines for malaria, pp 109 and 208, 2023 https://www.who.int/teams/global-malaria-programme/guidelines-for-malaria, accessed on 22 February 2024).

Following the elaboration of the new guidelines for malaria sections, the inputs from the external review group and the submission to the WHO Guidelines Review Committee, the plan is to finalise new recommendations on the use of tafenoquine, primaquine and near-patient G6PD tests by April 2024. In line with the "Master plan for developing recommendations on the use of tafenoquine and companion quantitative point-of-care G6PD in vitro diagnostics" (WHO internal document, 2019) these new recommendation will be released when near-patient G6PD tests will be included in the WHO prequalification lists for in-vitro diagnostics. The aim of the master plan is to coordinate "one WHO" to the generation of WHO guidelines recommendations on the use of tafenoquine and companion G6PD point-of-care tests *(3)*; the WHO prequalification lists of finished pharmaceutical products and in vitro diagnostics; and the Model Lists of Essential Medicines and Essential In Vitro Diagnostics.

Following the inclusion tafenoquine and near-patient G6PD tests in the WHO prequalification lists and the release of the new guidelines, GMP will convene a Technical Consultation to develop a field guide on the case management of *P. vivax*, providing practical guidance to support the implementation of the new WHO recommendations on 8 amino-quinolines and near-patients G6PD tests.