ROADMAP FOR ACCELERATING ACCESS TO RADICAL CURE FOR VIVAX MALARIA IN THAILAND
Thailand has made tremendous progress towards malaria elimination. The number of indigenous cases reported annually has fallen from 32,480 in 2010 to 6,750 in 2018. Migrant/mobile men who spend time in the forest are particularly at risk: 62% of the confirmed cases in 2018 were identified among adult men in 34 provinces.

The country is on target to achieve a further 40% reduction in annual cases by 2020. Accelerating access to radical cure for vivax is critical because currently, vivax accounts for 83% of all malaria cases in Thailand. Its ability to relapse from dormant liver stage complicates treatment and generates extended hardship on those infected, their families, communities and the health system.

Current vivax treatment methods are having limited impact. Appropriate radical cure for vivax using Tafenoquine (TQ) and quantitative G6PD screening—a new, easy to read test that provides a result in two minutes—simplifies treatment to a single dose and therefore has great potential to improve adherence and prevent relapse.

Other regimens—including seven-day primaquine (PQ7) together with quantitative G6PD screening—maybe used at lower-levels of the health system where capacity to provide TQ may be more challenging.

Thailand is expected to be the first country in Asia to approve TQ. To launch and scale radical cure for vivax in time to support the country’s goal of elimination by 2024, the following milestones are key:

- Timely implementation of feasibility study to pilot TQ & quantitative G6PD and collect evidence relevant to ensuring safety and pharmacovigilance standards are met as access is scaled.
- Health system readiness and financial planning for access beyond the province included in the feasibility study.
- Funding and technical assistance to ensure universal access to appropriate radical cure in time to support the country’s elimination target. Domestic financing will be critical, as will external support.
Without timely and safe roll-out of radical cure for vivax, Thailand's goal to eliminate malaria by 2024 may not be feasible. Experience from other countries suggests that the number of years after P. falciparum is eliminated that vivax is also eliminated can be up to 20 years. Access and adherence to the current vivax treatment options are limited due to a number of factors including the 14-day treatment regimen, which is particularly challenging for those most-at-risk including mobile forest-workers.

Tafenoquine (TQ), one new radical cure tool, was fast-tracked by multiple global health stakeholders including United States Food and Drug Administration (US FDA) and Australia's Therapeutic Goods Administration (TGA) based on recognition of TQ's potential to contribute to malaria elimination efforts in Asia Pacific. In addition, TQ is being used as a case study for a new abbreviated prequalification process by the World Health Organization (WHO). A variety of qualitative and quantitative tests are being developed to screen for G6PD deficiency, validation studies are underway for the quantitative G6PD test—required prior to using TQ—which will be submitted for FDA approval and WHO prequalification in 2020. In the interim, the quantitative SD Biosensor test has secured temporary WHO Expert Review Panel approval meaning it can be procured with Global Fund or Unitaid support into 2020.
Thailand has made very good progress implementing the National Malaria Elimination Program. The Department of Disease Control, Ministry of Public Health, coordinates with international and local partners to strengthen malaria case detection and treatment for all strains, including vivax. We are determined to achieve the goal of elimination by 2024 and recognize that accelerating access to radical cure for vivax is critical to this goal.

-Honorable Dr. Suwannachai Wattanayingcharoenchai, Director General Department of Disease Control, Ministry of Health, Thailand
The Thai malaria treatment guidelines were updated in October 2019 to include a special section covering G6PD screening together with TQ for radical cure. The status of approvals relevant to the roll-out of appropriate radical cure is as follows:

- Following approval of TQ by the US FDA and TGA in 2018, the dossier was submitted to Thai FDA in March 2019 with approval expected by January 2020. An abridged, 150-day review was used with support from TGA assessment reports and technical assistance. The path from dossier-submission to launch can require up to 2 years given the need to meet local and global safety planning requirements.

- SD Biosensor STANDARD G6PD test received WHO Expert Review Panel approval in July 2019 and was approved for import by the Thai FDA in September 2017. Further risk assessment and review will be conducted to align with the ASEAN regional harmonization tools.

- Global assessment of TQ under the abbreviated WHO pre-qualification (PQ) process and policy recommendations from WHO, both estimated to be issued by Q2 of 2021, will provide key technical guidance.
III. AVAILABILITY

In addition to securing approvals and testing feasibility of adhering to radical cure treatment guidelines at various levels of the health system in endemic areas, the following steps are key to preparing availability of all products needed to support universal access to radical cure:

1. Quantifying product supplies needed to support scaled access, including G6PD, TQ and other products depending on model/s selected for scale. Understanding and planning to address procurement needs for all products required to ensure universal access to radical cure.

2. Identifying importation responsibility and ensuring access to the ‘public health’ pricing (for locally produced products) and minimizing import fees (where applicable.)

3. Planning a supply chain for radical cure products to efficiently integrate distribution of these elimination tools into existing delivery channels and prevent stock outs.

4. Ensuring safety and pharmacovigilance criteria will be met at every level of the health system, through joint-planning with input from both the DVBD and the FDA.
Moving from feasibility to scaled access to radical cure will require detailed planning to:

- Identify appropriate service delivery model/s all levels of national health system, to ensure safer access for all including breastfeeding/pregnant women and children younger than 16 years of age, considering current contraindications for TQ as well as health system capacity.
- Train and organize quality assurance activities to build capacity of health workers to comply with national treatment guidelines and to complete the manufacturer’s required ‘postmarketing’ safety checks including the periodic safety update report (PSUR) and risk management plan. PSUR & RMPs will need to meet local as well as global requirements. AEs will be reported from malaria clinics=>DVBD=>HPVC and GSK, as well as from other hospitals directly to HPVC.
- Develop a pharmacovigilance plan with the Health Products Vigilance Center (HPVC) unit within the Thai FDA as well as the DVBD to monitor, report and address adverse events.
- Distribute and create demand to ensure radical cure commodities—including Quantitative G6PD tests—are consistently available, and to promote correct and complete treatment for vivax among confirmed cases.
- Monitor and evaluate outcomes and lessons using updated surveillance forms as well as studies.
- Cost budget requirements for appropriate radical cure at scale. Advocacy for domestic and external financing to sustain universal access and eliminate all species of malaria.
The Thailand Vivax Access Roadmap was developed by APLMA/APMEN in collaboration with the Thailand Ministry of Public Health and other partners (see below) to advocate for accelerated introduction and scaling of vivax radical cure in Thailand and other countries in Asia Pacific. Vivax Access Roadmaps for Thailand and other prioritized countries in Asia Pacific are accompanied by "Vivax Access Tracker" tools which highlight key milestones on the path to achieving universal access to vivax radical cure and elimination. The roadmap & tracker access tools are part of APLMA's advocacy efforts and are designed to complement the work of APMEN's Vivax Working Group.

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