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Director Access & Policy

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Dear Foreign Affairs, Defence and Trade References Committee Members,

This message is in relation to the use of Tafenoquine as a quinoline anti-malarial drug and its crucial role as a malaria prophylaxis and as a radical cure for *P. vivax* malaria. The Asia Pacific Leaders Malaria Alliance (APLMA) believes Tafenoquine is of public health value to the Asia Pacific region in supporting malaria elimination efforts.

APLMA is an affiliation of Asian and Pacific heads of government formed to accelerate progress against malaria and to eliminate it in the region by 2030. APLMA was created in 2013 to mobilise political commitment, and broker technical, policy and financing solutions to expedite the elimination of malaria. We convene partnerships in support of better access to new and priority antimalarial commodities, from treatments to diagnostic tests and vector control solutions.

More specifically, APLMA would like to highlight the public health value of Tafenoquine for the Asia Pacific, a region that holds over 90% of the global burden of *P. vivax*. Recurrence in relapsing malaria is a major driver of transmission, and the more episodes of *P. vivax* there are, the greater the negative impact on morbidity and mortality rates in the region. *P. vivax* can have fatal outcomes if left untreated, associated with anaemia, respiratory distress and even renal dysfunction.

As expressed during the recent Malaria World Congress in Melbourne (1-5 July 2018) by world experts on *P. vivax*, the promise of Tafenoquine as a single dose radical cure is revolutionary. Not only will Tafenoquine improve patient adherence by reducing a current standard regimen from 14 days, but will also reduce the risks of resistance, because of its single-dose formulation as a radical cure. This is particularly relevant in settings where regular follow-up with patients is a challenge due to poor geographic accessibility to public health services.

In addition, Tafenoquine as a preventive treatment is crucial from a public health perspective to mitigate the risk of malaria spreading beyond borders, as well as to reduce the number of imported malaria cases, which could reverse efforts to eliminate malaria. What is more, Tafenoquine as a prophylaxis could support efforts to prevent transmission from asymptomatic carriers.

The malaria community is aware of the challenges it will contend with when introducing a new treatment. The roll-out of Tafenoquine will require strong pharmacovigilance systems to monitor adverse events in country. To address this, APLMA facilitates the Regional Regulatory Partnership for Malaria Elimination (RRPME) through which partners like the Australian Therapeutic Goods Administration (TGA) and the World Health Organization (WHO) work to strengthen regulatory systems in Low-Middle Income Countries of the Asia Pacific region, to expedite the registration of new drugs while strengthening pharmacovigilance systems.



The deployment of Tafenoquine will require concurrent strengthening of G6PD deficiency screening to mitigate the risk of haemolysis. New point-of-care handheld G6PD tests are currently in the last phase of development and will be deployed hand-in-hand with the deployment of Tafenoquine. Through the RRPME, APLMA and partners work closely with Product Development Partnerships developing these new tools to ensure an efficient and safe joint roll out plan.

Regulators of the Asia Pacific and members of the RRPME have expressed keen interest in this new promising compound and are eagerly awaiting the recommendation of both the USFDA and the Australian Therapeutic Goods Administration on its approval for use.

We encourage the Committee Members to strike a balance between the encouraging prospects of Tafenoquine as a radical cure and prophylaxis treatment, its benefits for public health, and the acknowledgement of potential risks of rolling it out in low and middle-income settings. In summary, APLMA supports the approval of Tafenoquine as a key tool for supporting the elimination of malaria in the Asia Pacific region by 2030 and as a crucial scientific advancement and weapon in the battle against malaria globally.

Sincerely,

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