The Quinism Foundation Calls on the Department of Defense to Use Tafenoquine Only as a Drug of Last Resort for the Prevention of Malaria

"Use of Tafenoquine During Military Deployments Could Lead to Adverse Effects Including Insomnia, Nightmares, and Anxiety Being Misattributed to the Sleep-Disrupting Effects of Travel or to the Effects of Trauma and Other Stressors"

WHITE RIVER JUNCTION, Vt. (PRWEB) September 05, 2018 -- The Quinism Foundation has sent correspondence to Patrick M. Shanahan, Deputy Secretary of Defense, calling on the Department of Defense (DoD) to enact policy declaring the antimalarial drug tafenoquine a, “drug of last resort” for the prevention of malaria. Tafenoquine was recently approved by the U.S. Food and Drug Administration (FDA) for this indication, to be marketed by 60 Degrees Pharmaceuticals as Arakoda™.

“The foundation is asking that a comparable policy be implemented for use of tafenoquine as previously implemented for use of the related drug mefloquine, which both the U.S. military and 60 Degrees Pharmaceuticals note is neurotoxic [1],” said Remington Nevin, MD, MPH, DrPH, executive director of The Quinism Foundation. “In 2013, when this policy was first implemented, FDA required that the U.S. drug label for mefloquine carry a ‘black box’ warning, advising of the need to discontinue mefloquine at the onset of psychiatric symptoms, and cautioning that neuropsychiatric adverse effects, presumably from the drug’s neurotoxicity, could be permanent.”

“Scientists with the U.S. military have shown tafenoquine to be even more neurotoxic than mefloquine [2],” said Dr. Nevin. "It is the position of The Quinism Foundation that, as with mefloquine, any psychiatric symptoms that develop with use of tafenoquine for the prevention of malaria, including symptoms as seemingly mild as insomnia or nightmares, should be considered prodromal to more serious adverse effects [3].”

“In recognition of tafenoquine’s neuropsychiatric liability, the FDA has required comparable language in the approved U.S. drug label for Arakoda™, warning that those taking the drug should be promptly evaluated by a medical professional if psychiatric symptoms occur during use, such as changes in mood, anxiety, insomnia, and nightmares if they are moderate and last more than three days or are severe.”

“The Quinism Foundation is concerned that FDA’s guidance for the use of Arakoda™ will be prove exceptionally difficult, if not prohibitive, to implement in military settings,” said Dr. Nevin. “Particularly during deployments for combat missions, humanitarian emergencies, and disaster response, side effects from tafenoquine are likely to be underreported by service members and misattributed by medical professionals to other causes.”

“As with mefloquine, we ask that tafenoquine not be prescribed to service members with a history of psychiatric symptoms or disorders, or to service members with a history of symptomatic traumatic brain injury,” said Dr. Nevin. “Among these service members, use of medication to treat such conditions may mask tafenoquine side effects, and any prevalent symptoms from such conditions may confound recognition of side effects”.

"In those rare cases where tafenoquine is prescribed as a drug of last resort, we ask that military prescribers be limited to prescribing an initial six tablet (three day) loading dose prior to deployment,” said Dr. Nevin. “We also ask that service members be warned that the most common side effects of tafenoquine include insomnia,
depression, abnormal dreams and anxiety, and that they be reassessed 3 days after completion of the loading dose for the development of these and other side effects. Only after such side effects have been ruled out, should the remaining tablets for deployment be prescribed.”

“We ask that this be done in recognition that contacting a medical professional will be more difficult after deployment begins, and that correctly attributing side effects will be similarly more difficult during deployment," said Dr. Nevin. "For example, during deployment, the common use of hypnotics and other sleep-aids is likely to mask recognition of insomnia as a side effect of tafenoquine, and will limit the likelihood that service members will seek prompt evaluation should this symptom develop. Similarly, service members are known to underreport the development of psychiatric symptoms during deployment, limiting the likelihood that anxiety, changes in mood, nightmares, and other psychiatric symptoms will prompt their seeking evaluation should these develop as side effects of the drug."

"It is now understood that well over 10% of those prescribed mefloquine for the prevention of malaria will experience insomnia, nightmares, anxiety, or changes in mood, which require the drug's immediate discontinuation [4]," said Dr. Nevin. "Yet for nearly a quarter century, the U.S. military reported nowhere near this rate of suspected side effects with use of mefloquine during military deployments. This adds urgency to findings that tafenoquine appears to share a similar adverse effect profile to mefloquine. For example, a randomized blinded trial of tafenoquine in comparison to mefloquine for prevention of malaria found that deployed military users of tafenoquine reported a comparable rate of neuropsychiatric symptoms as users of mefloquine [5], but that these were significantly underreported in comparison to rates reported by military users in non-deployed settings [6]."

"Even if these side effects are reported during deployment, insomnia could be misattributed by medical professionals to the sleep-disrupting effects of travel across time zones, or to other common causes of insomnia in military settings. Similarly, anxiety, changes in mood, and nightmares, could be misattributed to the effects of trauma and other stressors commonly encountered during deployments," said Dr. Nevin. "This misattribution could further limit the reporting of these side effects to FDA, and as occurred with mefloquine, contribute to a vicious cycle where stigma or command pressure is created against the reporting of side effects, based on an erroneous belief that side effects are rare."

About The Quinism Foundation

The Quinism Foundation, founded in January 2018, in White River Junction, Vermont, promotes and supports education and research on quinism, the family of medical disorders caused by poisoning by quinoline drugs, including mefloquine and tafenoquine.

Executive director Dr. Nevin is a board-certified occupational medicine and preventive medicine physician and former U.S. Army medical officer and epidemiologist. He is author of more than 30 scientific publications on malaria and the quinoline antimalarials.


2. Agboruche RL. 529.3 In-Vitro Toxicity Assessment of Antimalarial Drug Toxicity on Cultured Embryonic


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