SUBMISSION TO PARLIAMENT’S JOINT STANDING COMMITTEE ON FOREIGN AFFAIRS, DEFENCE AND TRADE INQUIRY INTO THE USE OF MEFLOQUINE AND TEFENOQUINE IN THE ADF

“The League (RSL) did not believe that Agent Orange was the culprit that some Vietnam veterans felt it was. And, in particular, there had been a huge push among some Vietnam veterans for a Royal Commission into Agent Orange. Now the League was opposed to a Royal Commission. As a result, a lot of Vietnam vets felt very unsupported by the (government), RSL and the Vietnam veterans went off and formed their own organisations as a result”.

Jacqui Rees, Historian & co-author Lest We Forget

Background

This submission does not address the Terms of Reference per se. Rather, it seeks to comment on and highlight the damage done to individuals and to the credibility of the ADF and the various governments involved in ignoring the concerns of so many service men and women over many years.

The submission is made by the Defence Force Welfare Association (DFWA), founded in 1959 with the brief of, “fostering the best interests and wellbeing of all members of the Australian Defence Force and their families in any matter likely to affect them during or after their period of service”. This role has broadened in recent years as the role and composition of the ADF has evolved in the 21st century.

DFWA acknowledges that this Senate Inquiry was initiated by the Labor Party with the support of the Greens and for that we thank you. This Inquiry has resulted from the active lobbying campaign of a well-meaning group of individuals who have felt unheard and been aggrieved by the apparent lack of response to their concerns regarding their use of the Quinoline anti-malarial drugs, mefloquine and tafenoquine. These anti-malarial drugs were prescribed to those members of the ADF who were deployed as part of the nation’s contribution to the International Force East Timor (INTERFET).

The submission is presented by Mr Kel Ryan, National President of the DFWA, a retired Lieutenant Colonel, with 24 years’ service in the ADF. This service included two tours of Vietnam, service in PNG with the Pacific Island Regiment, the SASR, three battalions of the Royal Australian Regiment, and a tour as Commanding Officer of 51 Far North Queensland Regiment.
Furthermore, I am the National Spokesman for the Alliance of Defence Services Organisations (ADSO) comprising 18 national ESOs, and a Life Member of the RSL currently completing a PhD through James Cook University.

**Introduction**

The continuing difficulties with the use of the quinoline anti-malarial drugs mefloquine and tafenoquine by the ADF have not ceased. Mefloquine has been in use now since the early 1990s, while the experimental drug tafenoquine was used in a series of clinical trials during the period 1998-2001. Despite decades of increasing evidence linking quinoline drugs to acute as well as chronic neurological and psychiatric illnesses, including the risk of suicide in some affected ADF personnel the latter are struggling to receive appropriate and adequate health care.

Having carried out an investigation as notified, the Repatriation Medical Authority (RMA) declared that it does not propose to make a Statement of Principles concerning chemically-acquired brain injury caused by mefloquine or tafenoquine, for the purposes of subsection 196B (2) or (3) of the Veterans Entitlement Act 1986.

The RMA is of the view that there is insufficient sound medical-scientific evidence that exposure to mefloquine and tafenoquine causes chronic brain injury. Further, it also maintains that there is insufficient sound medical-scientific evidence of a characteristic and persisting pattern of signs and symptoms following exposure to mefloquine or tafenoquine that could be determined to be a particular kind of disease of, or injury to, the brain.

**RMA - Isolated**

However, this leaves the RMA isolated in their opinion from other Defence Authorities in the English-speaking world, principally Canada, UK and the USA. Although Defence and DVA have offered some assistance, there is a continuing lack of awareness of the adverse effects of these drugs within the ranks of health professionals.

The absence of effective diagnostic routines, referral protocols and dedicated rehabilitation programs is leading to very poor health care. Affected individuals are commonly wrongly diagnosed with post-traumatic stress disorder (PTSD) or other mental health disorders and subsequently subjected to treatments which fail to improve their condition and may inadvertently make it worse.

The patient's neurological and psychological difficulties arise not from a functional brain problem as current treatment follows but from a structural change problem, drug mediated, that will require a different treatment approach. Here in lies the reason for these individual patient’s failure to thrive. And for their on-going treatment.

The ADF, the government and DVA have studiously avoided acknowledging that these drugs have caused lasting or irreversible damage to members of the ADF and, by implication, their families suffer as well. Currently, DVA claims Mefloquine has already been included as a factor in the Statements of Principles for 14 conditions where there was at least a reasonable hypothesis that the relevant condition can occur, namely, acquired cataract, anxiety disorder, bipolar disorder, depressive disorder, epileptic seizure, heart block, myasthenia gravis, peripheral neuropathy, psoriasis, sensorineural hearing loss, schizophrenia, suicide and attempted suicide, tinnitus and trigeminal neuropathy.

Tafenoquine likewise has been included as a factor in the Statements of Principles for 6 conditions where there was at least a reasonable hypothesis that the relevant condition can occur: acquired cataract, epileptic seizure, methaemoglobinemia, psoriasis, sensorineural hearing loss and tinnitus.
The fact that these agents are being recognised as causal factors in each of these clinical entities mentioned above, where there was at least a reasonable hypothesis, is significant. Many of these are specific anatomical, neurological complaints (similar to a specific brain areas), yet, there are few scientific trials demonstrating this association with the drug in question.

Also, the U.S. Food and Drug Administration (FDA) is currently advising the public about strengthened and updated warnings regarding neurologic and psychiatric side effects associated with the antimalarial drug mefloquine hydrochloride. A boxed warning, the most serious kind of warning about these potential problems has been added to the drug label. FDA has revised the patient Medication Guide dispensed with each prescription and wallet card to include this information and the possibility that the neurologic side effects may persist or become permanent.

**RMA View**

Despite the above, the RMA earlier concluded as follows:

"Among the difficulties with attributing persistent symptoms to mefloquine is the lack of comparative studies and the non-specific nature of most of the reported symptoms. While there is often a plausible relationship between a patient’s initial symptoms and mefloquine exposure, the cause of progression of symptoms over the subsequent periods is difficult to ascertain.

Without a comparison group, it is not possible to be sure that symptoms can be attributed to neurotoxicity, especially when these symptoms are common in the general population and overlap with other disorders, including PTSD and depression in relation to military settings. The occurrence of acute neuropsychiatric reactions in a minority of mefloquine users suggests that individual susceptibility is likely, but no biomarkers or genotypes of susceptibility have yet been confirmed (Nevin and Ritchie 2016). There is no imaging modality which has been able to reliably diagnose damage in the human brain after taking mefloquine.”

The latter now is no longer the case.

**The Agent Orange Experience**

This is an issue that resonates with the Agent Orange controversy in the post-Vietnam period. While the number of ADF members affected using the anti-malarial drugs may not be comparable with those affected by Agent Orange, the numbers do constitute a significant defect in the Defence & DVA Health Care System in this country.

**Adverse Health Effects**

Research from the 1940s onwards has demonstrated that the quinoline class of anti-malarial drugs can cause lasting or permanent brain damage in some users. The U.S. Food and Drug Administration warns that neuropsychiatric side effects from mefloquine, "may persist or become permanent", including dizziness, hearing and balance problems, anxiety, depression, paranoia or hallucinations.

Mefloquine is also known to be a potential confounder of PTSD. The U.S. Army research institute which developed both drugs found that tafenoquine “is more neurotoxic than mefloquine”.

Very few affected ADF personnel have received the appropriate health care that they require, leading to unemployment, family breakdowns, self-harm and suicide in too many cases. An occupational health approach to treatment is required where upon patients can learn to live with and manage their symptoms and not expect a complete cure.
**DoD Submission**

The Department of Defence (DoD) Submission spells out clearly the need for anti-malarial protection for deployed forces. Further, it identifies the adverse impact on operations in East Timor where “64 ADF members became infected with malaria and over two hundred more developed malaria on return to Australia. From 1998 to 2007, 637 cases of malaria were recorded in ADF members; between 2012 and 2017, there were 30 cases recorded”. Cases of malaria continue to be recorded. DFWA does not seek to argue these figures or question the positive contribution of the ADF and the DVA in providing support for those impacted.

**Conclusion**

Current care and treatment of these individuals suffering neurological and psychological symptoms because of ingesting these anti-malarial prophylactic agents is wrongly directed and inadequate. This is a result of health providers treating a patient's symptoms in isolation as though they were functional and failing to acknowledge the cause is a structural one due to drug damage inflicted on that individual's brain tissue.

DFWA was initially of the view that a Judicial Inquiry be established immediately to resolve the difficulties outlined and bring this country’s Defence Community Health Care into line with other similar international groups.

**DFWA Concerns**

DFWA does, however, express profound concerns with:

a. The length of time for government, the ADF and DVA to recognise a problem exists. If we learnt anything from the ‘Agent Orange’ imbroglio in the post-Vietnam period it is that the expressed concerns of deployed forces must be addressed promptly. Hoping such will go away does not cut it any more. The RSL to its detriment learnt the hard lesson that it cannot deny the expressed concerns of veterans based on the approach of those from a previous generation;

b. The belated recognition by the ADF that it has a responsibility to monitor all members and former members who have claimed to have been affected by the use of the Quinoline anti-malarial drugs; and

c. The use of members of the ADF in human drug trials must cease. Yes, members of the ADF are a captive audience and by their very nature are keen to deploy yet the matter of coercion and bullying that has been identified in various submissions is concerning.

The DFWA does acknowledge that there is a developing suite of measures to identify and to provide support and care for members and former members of the ADF who were involved in the Quinoline anti-malarial drug ‘trial’, and who now consequently present with certain conditions.

Yours Sincerely

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**Kel Ryan**
National President
Defence Force Welfare Association