Information paper: mefloquine and tafenoquine

Concerns have been raised about links between the antimalarial medications, mefloquine and tafenoquine, and adverse health effects.

What is malaria?

- Malaria is a deadly disease which in 2016 killed over 400,000 people worldwide, and affected more than 200 million people.
- The Australian Defence Force (ADF) has a duty of care to ensure its people deploying to malaria prone areas are protected.

What is mefloquine?

- Mefloquine (also known by the trade name Lariam) is one of three anti-malarial medications approved by the Therapeutic Goods Administration for malaria prevention in our region. The ADF uses mefloquine as a third line agent and it is only used when members are unable to tolerate the alternatives.
- Mefloquine may not be suitable for individuals with particular medical conditions or those taking some other medications. In particular, mefloquine should not be taken for malaria prevention by people who have, or have had, a psychiatric condition, seizures, kidney disease or liver disease.
- For these reasons, Defence health policy requires ADF members be properly informed of the potential side-effects of mefloquine and the drug may only be prescribed by a qualified medical practitioner after the member has provided their informed consent.
- Mefloquine can cause psychiatric symptoms in some people, including disturbed sleep, anxiety, paranoia, depression, hallucinations and psychosis. Dizziness and loss of balance have also been reported as side effects from the use of mefloquine. For this reason, the medication is not used in ADF aircrew.
- Mefloquine is commonly used in the broader Australian community for the prevention of malaria in travellers. Mefloquine is also included on the World Health Organization List of Essential Medicines for both the prevention and treatment of malaria.

Further information about malaria and anti-malarial medications is available on the 'Malaria, mefloquine and the ADF' website (www.defence.gov.au/Health/Health/Portal/Malaria/).

How many people have been given mefloquine?

- The ADF's use of mefloquine is conservative compared to the use of the medication in other militaries around the world and in the civilian population.
- The vast majority of ADF members have never been prescribed mefloquine.
- Records show that between July 2000 and January 2018, less than 2,000 ADF personnel were prescribed mefloquine. Most of these prescriptions were as part of the ADF trials in East Timor from 2000-2002 (a total of 1,319 soldiers).

• It is far more commonly prescribed across the general community, with an estimated 11,457 civilian prescriptions for mefloquine in 2016 alone.

Statistics are available on the <u>'Malaria, mefloquine and the ADF' website</u> (www.defence.gov.au/Health/Health/Portal/Malaria/Anti-malarial_medications/Mefloquine/).

What is tafenoquine?

- Tafenoquine is a relatively new anti-malarial medication. Tafenoquine is not related to mefloquine and acts quite differently in the body.
- The main advantage of tafenoquine is that it is effective for both prevention and treatment of malaria.

Further information about malaria and anti-malarial medications is available on the 'Malaria, mefloquine and the ADF' website (www.defence.gov.au/Health/Health/Portal/Malaria/).

How many people have been given tafenoquine?

 To date, more than 4,000 people, both military and civilian, have taken tafenoquine in clinical studies around the world. Tafenoquine has successfully treated relapsing malaria (i.e. continued infections long after exposure) when combined with another medication called chloroquine.

What concerns have been raised?

- Concerns have been raised about the conduct of the ADF trials of mefloquine in East Timor. The Inspector General ADF (IGADF), an independent and impartial statutory authority, examined a number of allegations relating to this matter.
- The IGADF report found that the trials were conducted ethically and in compliance with National Health and Medical Research Council Guidelines for the conduct of human research. It also found that the trials were voluntary and participants were informed about possible side effects. This was consistent with relevant product and consumer medicine information available at the time.
- Concerns have also been raised that taking mefloquine causes chemically-acquired brain injury.

Further information on the ADF mefloquine trials is available on the 'Malaria, mefloquine and the ADF' website (www.defence.gov.au/Health/Health/Portal/Malaria/AMI_research/).

Statements of Principles

What are Statements of Principles (SoPs)?

- Serving and ex-serving ADF members can claim compensation at any time for medical conditions they believe are related to their service.
- For DVA to accept liability for compensation there has to be causal link determined between the person's service and their medical condition.
- Under the *Veterans' Entitlements Act 1986* and the *Military Rehabilitation and Compensation Act 2004*, the potential link between a medical condition and service is assessed using SoPs.
- Together, mefloquine and tafenoquine are included as a potential causal factor in SoPs for 16 conditions. Of these, mefloquine is covered by 15 SoPs and tafenoquine is covered by six SoPs.

What conditions are covered?

	Condition	Anti-malarial Medication
1.	Anxiety disorder	Mefloquine
2.	Bipolar disorder	Mefloquine
3.	Depressive disorder	Mefloquine
4.	Heart block	Mefloquine
5.	Myasthenia gravis	Mefloquine
6.	Peripheral neuropathy	Mefloquine
7.	Schizophrenia	Mefloquine
8.	Suicide and attempted suicide	Mefloquine
9.	Trigeminal neuropathy	Mefloquine
10.	Epileptic seizure	Mefloquine and Tafenoquine
11.	Acquired cataract	Mefloquine and Tafenoquine
12.	Sensorineural hearing loss	Mefloquine and Tafenoquine
13.	Tinnitus	Mefloquine and Tafenoquine
14.	Psoriasis	Mefloquine and Tafenoquine
15.	Methaemoglobinaemia	Tafenoquine
16.	Toxic Retinopathy	Mefloquine

What did the Repatriation Medical Authority (RMA) investigate?

- The RMA investigated whether SoPs may be determined in respect of 'chemically-acquired brain injury caused by mefloquine, tafenoquine or primaquine.'
- Mefloquine, tafenoquine and primaquine belong to the chemical class of drugs known as quinolines.
- The RMA decided that there is insufficient sound medical scientific evidence that exposure to these pharmaceuticals causes acquired brain injury.
- For these reasons, the RMA decided that it does not propose to make SoPs in relation to chemically-acquired brain injury caused by mefloquine, tafenoquine and primaquine.
- The report can be accessed from the <u>RMA website</u> (www.rma.gov.au/sops/condition/chemically-acquired-brain-injury-caused-by-mefloquine-tafenoquine-or-primaguine).
- The Specialist Medical Review Council (SMRC) completed its review of the RMA investigation and it confirmed the RMA's decision.
- Further information is available on the SMRC website (www.smrc.gov.au).

This decision means that DVA will not be able to accept claims for this specific condition, or the same condition described differently. However, it is important to note that DVA claims staff will still investigate to determine whether another diagnosis may be appropriate and whether it is possible to accept the claim in accordance with that diagnosis.

What is the Repatriation Medical Authority?

- The Repatriation Medical Authority (RMA) is an independent statutory authority which is entirely separate from the Department of Veterans' Affairs (DVA).
- The RMA is responsible for determining Statements of Principles (SoPs) for any disease, injury or death that could be related to military service, based on sound medical-scientific evidence.

Further information is available on the <u>RMA website</u> (www.rma.gov.au).

What is the Specialist Medical Review Council (SMRC)?

- The SMRC is an independent statutory body responsible to the Australian Government Minister responsible for veterans' affairs.
- On request from an eligible person or organisation, the SMRC can review decisions of the RMA.
- Further information is available on the SMRC website (www.smrc.gov.au).

Information on the SMRC's review process is available in the <u>'SMRC Members Handbook'</u> (www.smrc.gov.au/node/5).

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What has been, or is being, done?

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- Response to Senate Inquiry Recommendations The Government tabled its response to the Senate Inquiry into the use of quinolone anti-malarial drugs mefloquine and tafenoquine in the ADF on 15 March 2019. The Government has completed actions in response to eight of the fourteen recommendations, with actions ongoing for the other six recommendations.
- Mefloquine and Tafenoquine Consultation Forums In late 2018, DVA hosted seven
 mefloquine and tafenoquine consultation forums across Australia for veterans concerned about
 having taken mefloquine or tafenoquine. A <u>summary of the key themes</u> of the forums was
 published on the DVA Website.
- DVA's Improved Client Support Framework DVA is dedicated to providing our clients with the right support at the right time to help meet their health and wellbeing needs. Every day we work hard to help resolve issues for clients, and provide a single point-of-contact to help them navigate DVA and external support arrangements. Our improved Client Support Framework provides a coordinated case management and triage service to quickly assess a client's whole situation and create a streamlined pathway to individually tailored supports. This puts veterans at the centre of a coordinated case management approach, to ensure that they and their families are well-supported. DVA can also enact a client wellbeing and support program providing access to an exceptional needs team when additional specialist supports may be required.
- Health assessment from a GP Between January 2021 and June 2023 DVA offered an assessment service specifically for veterans who were concerned about having taken the anti-malarial medications (mefloquine or tafenoquine), to enable them to receive a health assessment from a GP. Veterans were able to discuss their health concerns with a clinician with an understanding of mefloquine or tafenoquine, the complex conditions with which some veterans may present, and the veteran experience. The Anti-Malarial Health Assessment program ended on 30 June 2023, in line with the initial funding period. Any veteran with ongoing concerns about having taken Mefloquine and Tafenoquine and their health can continue to access a range of other support services, including a general GP check-up using their Veteran Card, the Veterans' Health Check and support for mental health through Non-Liability-Health Care (futher information in the below table).
- 1800 MEFLOQUINE DVA has a designated phone line for veterans who are concerned about having taken mefloquine and tafenoquine – 1800 MEFLOQUINE (1800 633 567). This support

line can assist concerned veterans with enquires about the support available to them and the claims process.

• **Defence's dedicated email address** - Defence has established a <u>dedicated email address</u> (<u>adf.malaria@defence.gov.au</u>) and the <u>'Malaria, mefloquine and the ADF' information portal</u> (<u>www.defence.gov.au/Health/Health/Portal/Malaria/</u>).

What support is available?

Topic	Information	(icon)	Website, email address or phone number
1800 MEFLOQUINE	The dedicated support team can help people who were administered anti-malarial medications by the ADF and are concerned about possible side effects. Support may include accessing treatment under non-liability health care arrangements, or lodging a claim for any condition they think was caused by anti-malarial medications.	ر	1800 MEFLOQUINE (1800 633 567)
Veteran Card	Veterans can visit their GP for a general check-up free of charge using their Veteran Card. The Veteran Card is used to pay for approved health treatment. Veterans should check their entitlements before the appointment.	_	If a veteran does not have a Veteran Card, they can apply through their MyService account. Visit www.dva.gov.au/myservice
Veterans' Health Check	For a more comprehensive health assessment, the Veterans' Health Check can be conducted by a veterans' usual GP, to help them better understand their health and wellbeing. It is fully funded by DVA for eligible veterans.	Ţ	visit www.dva.gov.au/veteranhealthcheck
	• The Veterans' Health Check can help them manage and take charge of their own health, take action to stay well, address health concerns early and develop a relationship with their GP.		
	 Veterans who have served one day in the ADF and transitioned out of the ADF from 1 July 2019 are eligible for an annual Veterans' Health Check for up to five years after transition. 		
	Veterans who have served one day in the ADF and transitioned out of the ADF at anytime before 30 June 2019 are eligible for a one-off Veterans' Health Check.		
Non-Liability Health Care (mental	 For support for mental health, any veteran who has completed one day of full-time service in the ADF can access fully funded treatment of mental health conditions under Non-Liability Health Care (NLHC). 		DVA website: www.dva.gov.au/free-mental-health-care
health)	 Mental health treatment through NLHC is also available to reserve members who have rendered border protection or disaster relief service, or who were involved in a serious service related training accident. 		
	 Mental health conditions do not need to be related to military service, and a claim for compensation is not required to access this treatment. 		
	 This treatment can be accessed for as long as it is needed, at no cost to the veteran. 		

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Open Arms	Current and former members who have served at least one day can access free and confidential, nation-wide counselling and mental health support through Open Arms – Veterans & Families Counselling. Open Arms is also accessible to the families of ADF members.	Ç	1800 011 046 (VVCS – 24/7)
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All-hours Support Line	A confidential telephone service to help serving ADF members and their families access ADF or civilian mental health services.	Ç,	1800 628 036 (All-hours support line – 24/7)
1800 IMSICK	Serving personnel can ring 1800 IMSICK if they become ill or injured after hours or they are not in close proximity to an On-Base health facility. 1800 IMSICK is not an emergency number.	Ç.	1800 467425 (1800 IMSICK – 24/7)