Executive Summary

This has been a complex and challenging inquiry for the committee. The committee wishes to thank the individuals who appeared before it to share their personal stories. During the course of the inquiry the committee read and heard many moving personal accounts of individuals suffering from debilitating symptoms. The committee is deeply concerned to hear their distress as well as the frustration and dismay experienced by these individuals when seeking help.

The committee recognises that for these individuals to appear before a parliamentary committee is not easy. It showed their determination to contribute in a positive way to ensure that they and their mates and families receive the support they need. The committee also thanks the family members who spoke with the committee about the challenges of getting their loved ones and themselves access to assistance and support.

The disagreement over the cause of symptoms

A common theme was presenting to a medical practitioner with various symptoms, being referred to multiple specialists and eventually being diagnosed with Posttraumatic stress disorder (PTSD). However, individuals and advocates claim it is their exposure, in most cases, over 18 years ago, to the antimalarial drugs mefloquine and/or tafenoquine, which has resulted in their current symptoms and some of them are being misdiagnosed with PTSD.

It is important to note that although individuals presenting evidence to the committee appeared to group them together, mefloquine and tafenoquine are different drugs that act differently in the body.

The first issue from the evidence is whether the symptoms being experienced now by individuals can be causally related to prior antimalarial drug use. The Australian Quinoline Veterans and Families Association claim there is a condition which they call 'mefloquine poisoning' or an acquired brain injury (ABI)[1]. The Quinism Foundation in the USA calls it 'chronic quinoline encephalopathy' or 'neuropsychiatric quinism'.

The committee needs to state that it is not comprised of medical professionals or health experts and so cannot make any findings or rulings in relation to the medical causes for health issues. However, it notes that the weight of prevailing medical evidence provided to the committee in response to these claims is that long term problems as a result of taking mefloquine are rare and there is no compelling evidence that tafenoquine causes long term effects. To be clear, there has always been recognition by Defence that mefloquine, like any drug, has side effects and this has been taken into consideration in the development of its health policy.

The committee takes confidence that Australia's independent medical bodies have looked at the claim of ABI from the use of mefloquine. The committee was informed that the claim that mefloquine and tafenoquine results in ABI is not backed by

1 An umbrella term covering any damage to the brain that occurs after birth.

definitive evidence. In August 2017, the Repatriation Medical Authority (RMA) found there was insufficient sound medical evidence to support this claim. This decision was reviewed by the Specialist Medication Review Council which in September 2018 supported the decision of the RMA.

The medical evidence provided to the committee shows that the incidence of long term or persistent neuropsychiatric adverse reactions to mefloquine is very rare. If the committee looks at the 40 million doses of mefloquine worldwide, the committee was provided with no evidence that the same symptoms are manifesting in the Australian population or across the world in the civilian population. To the committee this is a critical point. The committee heard there is no evidence of an emerging global public health issue. The medical evidence is presented in Chapter 2 (covering ToR a(ii), b and d).

The committee was reassured that, should any sound medical-scientific evidence pertinent to this inquiry arise in the future, it would be identified through existing channels and responded to by Defence and DVA.

The committee notes that tafenoquine, which was not an approved drug at the time of the Australian Defence Force (ADF) trials, was approved in 2018 by the US Food and Drug Administration (US FDA) and the Australian Therapeutic Goods Administration (TGA). Tafenoquine has undergone a rigorous safety evaluation by these regulatory bodies. TGA's Advisory Committee on Medicines and the US FDA's Antimicrobial Drug Advisory Committee (AMDAC) have all had input for both indications, prevention and radical cure, and the findings are consistent. The processes of the US FDA and TGA included an audit of the relevant Defence studies.

This issue appears to be manifested in military populations where it seems to the committee trying to assign a single cause to veterans' illnesses does not reflect the many potential contributors to their physical and mental health at the time and in the years since the medications were taken.

The symptoms are real

However, the committee does not doubt that the symptoms being experienced by individuals are real and regardless of the cause or causes, these veterans are unwell and should receive the assistance to which they are entitled. The committee notes that this is not a different view to that stressed by the Department of Defence (Defence) and the Department of Veterans' Affairs (DVA), i.e. that regardless of the cause of the symptoms, help is available. It will therefore be the committee's focus in Chapter 4 to review and improve processes to ensure that any current and past ADF members receive appropriate treatment and support they need.

Regarding treatment, the committee notes that an independent review of the published literature by Professor Sandy McFarlane concluded that there is no specific way to diagnose chronic mefloquine effects as many symptoms are shared with other conditions such as PTSD and there is no specific treatment except to cease the drug and treat the symptoms.

As there is no specific treatment and there is help available for symptoms being experienced, in Chapter 4, the committee will look at the barriers to people accessing appropriate treatment. Some individuals were calling for there to be more treatment

available for neurocognitive issues and the committee was pleased to hear that a neurocognitive program is being developed by DVA which the committee commends and supports.

The committee notes with concern that for some individuals having their symptoms recognised as resulting from mefloquine or tafenoquine appears to be of overriding importance which may keep some of them from seeking and receiving available treatment.

The committee's inquiry into veterans' suicide highlighted to the committee how challenging it can be to deal with DVA, which is exacerbated when someone is unwell. The committee made a number of recommendations the government agreed to which the committee trusts are leading to improvements in service delivery over time. The committee has been monitoring actions being taken by DVA to improve services through the estimates process. However, the individual stories indicate to the committee that there is still work to be done and that some individuals and their families are not in a position to wait until improvements flow through the system from reforms. The committee has made more targeted recommendations which it believes will improve processes for those needing assistance.

Conduct of the studies

The second area of contention is the conduct of the antimalarial drug trials undertaken in the late 1990s and early 2000s. Individuals who blame mefloquine or tafenoquine for their current symptoms believe that the trials should not have taken place, were unethical and used them as 'guinea pigs'. These allegations have been investigated in an independent investigation outside the military chain of command by the Inspector-General of the ADF (IGADF). The investigation of some of the trials undertaken by the Army Malaria Institute (AMI) from 2000 to 2002 in Timor-Leste involving mefloquine and tafenoquine found that they 'were conducted ethically and lawfully' and 'in accordance with the National Guidelines issued by the NHMRC [National Health and Medical Research Council] and the TGA'.[2] The IGADF also found trial participants voluntarily consented to participate in the trials, and were adequately informed of the potential side effects known at the time.[3] The committee acknowledges that these findings have not been accepted by some veterans, but it is not the role of the committee to repeat or reopen the IGADF investigation. The Australian Defence Human Research Ethics Committee, TGA and US FDA have also examined the conduct of some of the trials and found no indication that good clinical practice was not followed.

However, the committee shares the IGADF and witnesses' concerns about how to ensure ADF members are able to provide informed consent in the military environment. The Departments of Defence and Veterans' Affairs Human Research Ethics Committee (DDVA HREC) already reviews research protocols in accordance

2 IGADF, *Inquiry report into issues concerning anti-malarial trials of the drug mefloquine between 2000 and 2002 involving Australian Defence members deploying to East Timor*, 2016, pp. ii–iii.

3 IGADF, *Inquiry report*, 2016, pp. iv, vi–vii.

with the NHMRC National Statement on Ethical Conduct in Human Research (National Statement). This identifies defence force personnel as a potentially vulnerable group due to the unequal relationships within the military hierarchy. However, there are opportunities to improve the consent process, as outlined in the recent correspondence asking DDVA HREC to consider additional measures to ensure participants 'are fully informed of all aspects of the studies and that there is no belief created that Command is endorsing or actively encouraging the study'.[4] The committee also suggests that the appointment of independent participant advocates should be considered.

The committee does not believe that all medical research with members of the ADF should be prohibited, provided it does not disrupt the work of the ADF and has been approved in accordance with the National Statement. This is because research is essential for advancing medical care and force protection measures, and the ADF has a duty of care to protect and maintain the health of its personnel. For example, in relation to the trials, the committee is aware that during the INTERFET deployment, 64 ADF members became infected with malaria and over 200 more developed malaria on return to Australia. These cases of malaria were of concern to Defence as potentially indicating resistance to the preferred antimalarial medication doxycycline, or non-compliance in taking the medication, and were the catalyst for approved clinical studies to be undertaken to assess whether policy changes were necessary to ensure adequate protection against malaria in the ADF.

The committee commends the work of the ADF Malaria and Infectious Disease Institute (formerly AMI), and recognises the importance of its research in protecting ADF members and the international community more broadly. The conduct of the trials and the issue of informed consent is discussed in Chapter 3 (covering ToR a, a(i), a(ii) and b).

Moving forward

The committee recognises that for some individuals, the outcomes of this inquiry will be insufficient unless the committee supports their view of the medical evidence and the trials and supports calls for a Royal Commission. As the committee does not have the role or expertise to make any medical findings and the conduct of the trials has been reviewed by the IGADF and some of the trials audited by the US FDA and TGA, the committee believes the focus of the recommendations for this inquiry should be on the common ground of making sure that individuals are able to access the assistance and support they need and are entitled to receive.

While the committee recognises that both Defence and DVA have taken actions to respond to the concerns raised by veterans, reports from veterans indicated that they were either unaware of many of the current initiatives, believed that they were inappropriate or did not go far enough. It was of concern to the committee that, despite the efforts made to date, the message that assistance is available is not being received by many veterans. Veterans are reporting that they are still facing a number

4 Defence, *Letter from AVM Tracy Smart AM to Mr Ian Tindall, Chair DDVA HREC*, 4 October 2018, [p. 1] (tabled 11 October 2018).

of practical barriers when trying to access assistance including: ADF cultural issues, the provision of information and trying to access and navigate the DVA claims process.

This suggests that improvements can be made to ensure that veterans have access to support and assistance. The committee heard a number of suggestions from veterans about the assistance and support they would like. While there have been concerns raised about some of the suggestions put forward by veterans, the committee emphasises that there is unanimous agreement that their symptoms are real and the veterans and their families who participated in this inquiry need help.

With this in mind, the committee's focus has been to explore how best to address the health concerns identified by veterans and their families and how to connect them with the help available. It is positive that DVA is actively taking steps to address concerns and it is important that this is continued. In particular, DVA has acknowledged that individuals need tailored, wrap around assistance and that this needs to include support from a range of specialists to address their complex needs.

The committee heard how the role of GPs is central to ensuring veterans have access to a range of health services and ongoing support. Actions have been taken to make GPs aware of the issues raised with the committee and suggestions were made to ensure this flow of information is continued and enhanced.

Noting the need for research to be independent so veterans can have confidence in the outcomes, the committee was pleased to hear that Defence and DVA have jointly commissioned the University of Queensland to undertake a research study looking at the self-reported health of ADF personnel using antimalarials on deployment. This research is due to be completed in late 2018. The committee anticipates that the findings of this research may be used by DVA in the context of developing services and support that address the challenges reported by this cohort of the veteran community.

The committee commends the recent consultation forums being undertaken by DVA and notes that preliminary feedback from the first forum is that some veterans who attended found it beneficial. These forums provide an opportunity to enhance trust in the system by facilitating greater collaboration and fostering connections.

Another important initiative being developed by DVA is a Neurocognitive Health Program to assist veterans who may have symptoms of a neurocognitive disorder. Further details about initiatives to improve veterans' access to assistance and to enhance collaboration between DVA and the veteran community are outlined in Chapter 4 (covering ToR c). ToR e is covered in Chapter 1.