Australian Government
Department of Veterans' Affairs

Department of Veterans Affairs submission:

Therapeutic Goods Administration Public Consultation on Medicinal Cannabis Regulatory Reform

The Department of Veterans' Affairs (DVA) spends approximately $4.3 billion annually on health and wellbeing services. This funding supports more than 280,000 eligible DVA clients and covers a wide range of treatment, including primary care, medical specialist, allied health, dental, pharmaceutical, medical aids and appliances, social health, community nursing and aged care services.

DVA arrangements are designed to facilitate funding of health care services through a nationally consistent framework to meet the needs of Veteran Card holders across the country. Entitlement to DVA-funded health services is based on the Veteran Card arrangements, with Gold, White and Orange Veteran Cards representing a DVA client's entitlement to health care services as follows:

- Veteran Gold Card – the Gold Card covers individuals for clinically required health care services in Australia for all medical conditions
- Veteran White Card – the White Card covers individuals for clinically required health care services in Australia for accepted medical conditions for which DVA has agreed to fund treatment, and
- Veteran Orange Card – the Orange Card entitles certain Commonwealth and allied veterans to access pharmaceuticals at the concessional rate at pharmacies in Australia.

DVA funds access to a range pharmaceuticals through the Repatriation Pharmaceutical Benefits Scheme (RPBS) at a concessional rate. The RPBS ensures DVA clients have access to an appropriate range of safe and effective pharmaceuticals. This includes items listed under the Department of Health, Disability and Ageing's Pharmaceutical Benefits Scheme (PBS), the Repatriation Schedule of Pharmaceutical Benefits (the Schedule), or unlisted items via prior approval, where there is a clinical justification. Both the listed and unlisted arrangements fund access to a broader range of pharmaceuticals that are not funded or subsidised for the general community.

Medicinal cannabis is funded as an unlisted product under the RPBS.

Since DVA commenced funding medicinal cannabis in 2018, there has been an increase in expenditure each financial year. However, since 2022 DVA has seen a significant growth in expenditure on medicinal cannabis. Rapid increases in expenditure are often associated with increases in risks and behaviours which are outside accepted practices. This has been the case with medicinal cannabis where DVA has become aware of concerning behaviours from some providers, particularly those within the vertically integrated business model involving prescribers and providers, which may adversely affect the well-being of veterans.

DVA has a keen interest in the TGA consultation on medicinal cannabis regulatory reform and will align with any changes that TGA makes to the management of medicinal cannabis.

Background

Funding decisions for the approval of medicinal cannabis are made on a case-by-case basis and in line with the DVA Medicinal Cannabis Framework (the Framework) which is published on the DVA website. DVA's approval process focusses on procedural matters and does not involve clinical assessment or judgement, relying instead on the prescribing doctor.

By tightening the current regulatory framework for medicinal cannabis to exclude products that are not proven to be safe or effective, the Therapeutic Goods Administration (TGA) can provide an external standard that supports DVA to only fund products that are as safe and effective as possible.

DVA commenced funding medicinal cannabis in 2018 with an initially low uptake of veterans accessing products. In 2022, DVA undertook a review of the Framework and changes were implemented to streamline the process for prescribers. Since this time DVA has seen a significant increase in the uptake of medicinal cannabis. DVA acknowledge that this growth is in line with uptake in the broader community and is reflected in TGA's Special Access Scheme (SAS) data (TGA 2024a). This increase in uptake also aligns with the rise of vertically integrated business models where one business controls all aspects from prescription to supply/dispense and distribution of product.

The number of veteran card holders accessing medicinal cannabis through the RPBS has grown by 50% from 8,000 in 2023-2024 financial year to 12,000 veterans in the 2024-2025 financial year. DVA has also seen a large increase in the number of products being prescribed for individual veterans, and the level of concentration of active ingredients, with many prescribed four or more different medicinal cannabis products concurrently raising concerns about prescribing behaviours.

DVA notes new evidence about the safety and efficacy of medicinal cannabis, particularly with higher concentrations and dosages of active ingredients. This is of particular concern to those users of medicinal cannabis who have a mental health condition (Hoch et al 2024).

DVA is considering changes to the Framework to address risks to patient safety including the prescription of large numbers and high dosage products. DVA will continue to work with the TGA in this regard.

Behaviours of concern

DVA shares the concerns of TGA as outlined in the consultation paper.

TGA has identified three key issues:

- the appropriateness and effectiveness of the unapproved goods pathway for medicinal cannabis access
- the safety and quality concerns about medicinal cannabis, and
- the impact in the growth of direct-to-consumer and telehealth models of care.

As the TGA is focusing on issues 1 and 2, DVA has also largely focused this submission on these two areas. However, much of the concerning behaviour identified by DVA is also associated with vertically integrated/single medicine online businesses that, in some cases, target veterans.

DVA is aware of medicinal cannabis companies, particularly those with telehealth-based business, adopting strategies to unduly influence veteran choice. These strategies include directly targeting veterans by using misleading social media campaigns and are often accompanied by a lack of transparency regarding commercial or other relationships between the commercial entities involved.

DVA believes that greater rigour in the TGA's unapproved goods pathway will limit the poor prescribing practice that appears to be flourishing in these business models.

DVA has identified providers engaging in a range of concerning practices including:

- targeted marketing, especially on social media platforms
- using phrases such as 'DVA funded' or 'fully covered by DVA' that do not comply with DVA legislative requirements and/or legislation such as the *Health Practitioner Regulation National Law*
- persistent sales techniques, such as encouraging veterans to sign up for subscription-like services for medicinal cannabis products, and
- rebranding existing medicinal cannabis products to deliberately restrict veteran choice whilst increasing product cost (to DVA).

DVA has been working with Australian Health Practitioner Regulation Agency's (Ahpra) Rapid Regulatory Response Unit on concerning prescribing behaviours relating to medicinal cannabis. These include:

- unexpectedly large volumes of patients being seen by some prescribers
- prescribers outlining a clinical need for multiple (up to 7) different products per day, all with the same THC concentration
- rapid increases in doses and THC levels, particularly with dried herb, as high as 4g per day
- potential lack of individualised therapy where prescribers are acutely changing all their patients to different brands or formulations month to month or identical treatment regiments (products, doses, etc) for all patients seen by a prescriber
- prescribers choosing products belonging to brands they are affiliated with, or that have connections to the clinics in which they work without proper disclosure of any pecuniary interests
- reports from veterans that their care has been taken over by new companies or prescribers without their awareness
- reports from veterans who are receiving unwanted medicinal cannabis products (including increases in THC content) even when they have expressed a desire to cease treatment
- veterans with known mental health conditions being prescribed high doses of THC without acknowledgement of their mental health conditions by the prescriber
- reports from veterans that they have minimal consultation with their prescribing doctors, with all follow-ups occurring with nursing staff, and
- reports from patients that they do not have the option or ability to speak directly to their prescribing doctor when engaging with a medicinal cannabis clinic.

DVA responses to TGA consultation questions

Quality and safety requirements for medicinal cannabis products

1. ***Do you consider the current quality and safety requirements to be appropriate and sufficient for medicinal cannabis products?***

   DVA has confidence in the quality, efficacy and safety of products that are listed on the Australian Register of Therapeutic Goods (ARTG). This is because these products are extensively evaluated by the TGA, including demonstrating safety and efficacy, having appropriate therapeutic names and packing, having appropriate standards for manufacture and labelling, and having undergone post-market surveillance. For example, the quality and safety of approved medicinal cannabis products such as Sativex (nabiximols) or Epidyolex (cannabidiol) for their respective approved indications.

   It would be beneficial to regulate medicinal cannabis in a way that would support a similar confidence.

   The Special Access Scheme (SAS) and Authorised Prescriber Scheme (AP) pathways are usually for drugs that are supported by robust clinical trial data or real-world evidence and are often approved for use in other countries with strong regulatory systems (e.g. United States with FDA approval or European Union with EMA approval). For this reason, medications obtained through the SAS or AP schemes have usually been carefully evaluated, demonstrated safety and efficacy, have met high standards for quality manufacturing, labelling and packaging, and have undergone adequate post-market surveillance, even though the TGA has not been involved. This system provides medical practitioners with confidence in prescribing treatments for patients otherwise unavailable in Australia as they have already been found safe following rigorous evaluation processes.

   However, this is not true for unapproved medicinal cannabis products. Their availability through SAS and AP give prescribers and the general public the impression that the TGA has provided tacit "sign-off" to all medicinal cannabis products, leading to false reassurance about their safety and efficacy. The fact that they are then prescribed by a doctor and dispensed by a pharmacist supports the belief that these products are subject to the same rules and scrutiny as other prescription medications obtained in Australia. This accords with anecdotal reports that patients are being reassured by their prescriber that the medicinal cannabis is being provided through a legal pathway, but patients are unaware that the products are unapproved. The current system also supports use of medicinal cannabis for a wide range of medical conditions, without the need for clinical evidence. This can lead to confusion from patients who are unaware that there is no clinical evidence for the treatment being prescribed. For example, many veterans are unaware that medicinal cannabis can exacerbate mental health conditions and are confused by the fact that it is being prescribed for mental health conditions but is not eligible for DVA funding.

   DVA is concerned about the absence of product information for providers and medicines information for consumers. The naming of many medicinal cannabis products is not consistent with therapeutic products, are suggestive of recreational drugs and can be misleading in terms of potential side effects. The marketing of medicinal cannabis products leans heavily on safety of 'natural' or 'plant based' products and can provide a false sense of safety. There is concern that a range of additional cannabinoid variables are listed as active or not, with them being included in some products and marketed as being more effective.

2. ***Are there any changes you would recommend to the current quality requirements for medicinal cannabis products? If yes, please describe what changes are required and why.***

DVA suggests there is an urgent need for improved national regulation of medicinal cannabis products that imposes strict quality assurance and testing requirements along with evidence of safety and efficacy for specific identified medical conditions. If medicinal cannabis products are to be available via SAS and AP, only products that have been approved and listed for therapeutic use in other countries with strong regulatory systems should be considered. These products must have appropriate therapeutic names, high manufacturing packaging and labelling standards, and have undergone adequate post-market surveillance in keeping with that of products that are ARTG-listed. Alternatively, medicinal cannabis products should be transitioned to the ARTG along with the cessation of widespread access via SAS and AP pathways.

By creating a pathway for ARTG registration, the responsibility would be placed on the sponsors, instead of practitioners. This includes evidence of safety and efficacy, Good Manufacturing Practice (GMP) certification, quality standards, specific labelling requirements, and obligations for post-market safety monitoring and reporting.

The rapid growth of the medicinal cannabis industry in Australia and the widespread use of unapproved medicinal cannabis products have seen these products become "mainstream". As such, they should be subject to the same checks and balances as other "mainstream" therapeutic products.

3. ***Noting the current labelling requirements outlined in TGO 93, do you consider these to be adequate to allow prescribers and consumers sufficient information to properly identify the goods and know how to use and store them safely? If not, please describe which changes are required.***

DVA does not consider the current labelling requirements to be adequate to allow prescribers and consumers sufficient information on the product being prescribed. Currently, sponsors are only required to list active ingredients on medicinal cannabis products. There are concerns that novel cannabinoids other than THC and cannabidiol (CBD) that must be biologically active are not always listed/labelled, and possibly their biological activity occurs at low concentrations. Given the lack of public data available on all cannabinoids, but particularly non-CBD/THC cannabinoids, consideration should be given to requiring the inclusion of all cannabinoid ingredients on labelling for medicinal cannabis products. DVA do not fund any medicinal cannabis products that have novel cannabinoids labelled as active ingredients. There is also evidence that labelling of cannabis products can be highly variable with inaccurate representation of drug content and/or concentration.

DVA supports sponsors being required to include consumer medicine information (CMI) leaflets with all medicinal cannabis products. The CMI leaflets should include the following:

- active and inactive ingredients
- warnings/precautions
- interactions
- safe use instructions

- side effects
- actions to take in case of an overdose
- storage instructions, and
- conditions for which it is 'listed'.

In-depth CMI leaflets provide patients with essential safety information, helps combat the incorrect belief that 'plant-based' or 'natural' products are benign and reinforces that medicinal cannabis is a form of medication and should be treated as such.

4. ***What information would you like to see on medicinal cannabis product labels to help better understand what is in them and to ensure their safe use?***

The labelling of medicinal cannabis products should follow Therapeutic Goods Order (TGO) No. 91 – Standard for labels of prescription and related medicines. This would include information on maximum dosage, contraindications and warnings and would be in addition to what is stipulated in TGO 93 (Vida et al 2023).

Emerging safety concerns for medicinal cannabis products

5. ***In general, what are the safety risks you have identified or are concerned about with unapproved medicinal cannabis products? If possible, please provide data or other forms of evidence to support these views.***

DVA is concerned about the safety of large doses and high concentrations of THC, especially for those who have been prescribed these products over long periods, given the paucity of evidence for their safety and/or ongoing clinical benefit. There is also a concern about the emerging evidence of harms, particularly harms related to mental health conditions. While many products consumed in sufficient quantity can result in excessive THC doses, DVA have concerns about those products with very high THC concentrations. An example is a product described as 'extracts for inhalation' that cite THC concentrations of above 80%. DVA does not fund applications for these product types due to concerns about both the high THC concentration and product formulation.

There are also concerns about the product names being used by many medicinal cannabis companies. The proprietary names of many medicinal cannabis products are inappropriate and do not align with therapeutic use. In most cases, the names correspond to ideas of recreational use, such as Blueberry Frost, Rainbow Lava, Monkey Bus, Chapel of Love, Colour of Space, Afghan Layer Cake.

Dosage forms and routes of administration

6. ***The following dosage forms are being prescribed for unapproved medicinal cannabis medicines for the following routes of administration – detailed descriptions of each dosage can be viewed on the TGA's Code Table:***

Dosage form	Associated route of administration
Capsule	Oral
Extract – concentrated	Inhalation
Granules	Oromucosal
Herb, dried (for vaporisation)	Vaporisation
Herb, dried (oral)	Oral
Inhalation	Inhalation
Inhalation, pressurised	Inhalation
Lozenge	Oral
Oral liquid	Oral
Pastille	Oral
Patch, dermal	Topical
Pessary	Vaginal
Powder	Oral
Spray, solution	Oral
Suppository	Rectal
Tablet	Oral
Tablet, chewable	Oral
Topical	Topical
Wafer	Sublingual

a. ***Do you consider there to be safety risks associated with certain dosage forms of medicinal cannabis products that may require mitigation measures? If yes, please provide evidence to support your response. Please also provide any potential mitigation measures that could be considered.***

DVA has concerns about the safety risks of formulations that most appeal to children and animals, such as gummies and pastilles, as these may be unintentionally ingested. Some products are inappropriately designed to replicate well known lolly brands, further increasing the risk of unintentional consumption. There are other formulations that are available for those who prefer to prescribe medicinal cannabis via an oral route which are less appealing to children and animals (e.g. tablets, capsules or oral liquids).

The risk of harm to children from accidentally ingesting edible medicinal cannabis products ranges from minor symptoms, such as sedation, abnormal heart rates or arrhythmias, and breathing difficulties, to more severe cases of poisoning which can cause seizures or coma. Due to the smaller size and differing physiology of children, consumption of cannabis products can cause more pronounced effects than in adults. In adults, edible products have a delayed onset of effect increasing the risk of overdosing and prolonging the period of impairment.

An analysis of New South Wales Poisons Information Centre (PIC) data from 2014-2024 has shown large increases in calls relating to cannabis, with a particular rise in those relating to edible cannabis products in gummy or lolly form (Cairns et al 2025). This data indicates that unintentional poisoning has increased rapidly. This is compounded by a lack of regulatory oversight in relation to

child safe packaging. DVA would support strengthened requirements for child safe packaging across all products.

DVA also holds concerns for the formulations that use routes of administration that do not have adequate safety or efficacy data, such as liquids for inhalation, topical preparations (including patches), concentrated extracts, granules, suppositories and pessaries. There are also concerns about variability in the potency of individual edible products, even when labelled.

b. Are there any dosage forms of medicinal cannabis products that should not be permitted due to safety risks? If yes, please provide evidence to support your response.

DVA has concerns that there is no long-term safety data on the health impacts of liquids for vaporisation, concentrated extracts, or granules for sprinkling on dried herb. The pharmacokinetics of these novel formulations is not well understood, has not been evaluated by the TGA and accurate dosing options for consumers is unclear. For these reasons, DVA does not fund medicinal cannabis in these forms. DVA is also concerned about solid cannabis concentrates (e.g. shatter) or vape liquids, which often contain the highest concentration levels of THC, making them particularly dangerous.

As an example, medicinal cannabis vape liquids contain thinning agents and flavouring which become ultrafine droplets that are inhaled. The risks associated with their inhalation are unknown. The lack of manufacturing and quality standards further compound the danger, due to the risk of contamination with microorganisms, pesticides, or chemicals used in the extraction process, including vitamin E which has been associated with EVALI. Imposing strict testing and quality assurance standards would ensure products do not contain contaminants or toxins at levels unsafe for human exposure.

DVA supports TGA implementing measures to further improve the safety of medicinal cannabis products by removing access via SAS and AP to dosage forms that have evidence of harm or a lack of safety data, especially for those containing high concentrations of THC, such as liquids for vaporisation or granules. There is no clinical justifiable indication for those dosage forms when alternative forms are available with a more established safety profile.

c. Do you consider there to be safety risks with certain dosage forms being prescribed for specific routes of administration? If yes, please provide evidence to support your response.

There are concerns about medicinal cannabis products, such as edibles packaged as lollies, that can easily be unintentionally ingested by children and pets. These products have not been carefully evaluated and it is very difficult, if not impossible to know the precise dose of CBD or THC that is being delivered. This is especially concerning if these products are taken by people to whom it was not prescribed, let alone children and animals.

Inhaled medicinal cannabis products have not been properly assessed for long term safety. This is concerning given the growing popularity of vaping. As an example, medicinal cannabis vape liquids contain thinning agents and flavouring which become ultrafine droplets that are inhaled. The risks associated with their inhalation are unknown. The lack of manufacturing and quality standards further compound the danger, due to the risk of contamination with microorganisms, pesticides, or chemicals used in the extraction process, including vitamin E which has been associated with EVALI.

Other routes of administration such as topical preparations (including patches), concentrated extracts, granules, suppositories and pessaries are also a concern due to the lack of adequate safety and efficacy data, particularly for long-term usage.

Concentration of medicinal cannabis components

7. ***CBD is currently considered to be well tolerated and generally safe for most clinical situations. Is there any evidence to suggest that CBD at specific concentrations poses a safety risk for patients generally or for specific population groups?***

Although CBD is considered to be well tolerated and generally safer than THC, it is not without risks. Human studies have reported drug-drug interactions, liver enzyme abnormalities, gastrointestinal upset, fatigue and somnolence (Huestis et al 2019). The only area for which there is robust evidence for the use of CBD is the control of refractory seizures as part of certain childhood epilepsy syndromes.

There is evidence of potential interactions between CBD and several common medications (Balachandran et al 2021). Among medicinal cannabis prescribers, there does not appear to be an adequate understanding of the potential interactions, resulting in limited checking of co-prescribed medications and a lack of collaboration with other treating doctors to support modifications to treatment to avoid potential interactions between medications. A systematic review of serious adverse effects of CBD found that they are rare but can be serious, with concerns largely related to the levels of drugs that CBD can interact with, most commonly anti-epileptic drugs. CBD use in patients with epilepsy who are concomitantly taking AEDs should be monitored carefully (Dos Santos et al 2020).

Much of the adverse effect data has come from trials of CBD use in childhood epilepsy syndromes. These are the same trials that resulted in Sativex (nabiximols) and Epidyolex (cannabidiol) being ARTG-listed. Additional safety data from clinical trials outside of childhood epilepsy syndromes and from studies of over-the-counter CBD products are needed to assess whether the conclusions drawn from clinical trials can be applied more broadly (Chesney et al 2020). There is evidence that CBD can be harmful in adolescents and young adults, as well as those with psychotic disorders (Hill et al 2021). As previously discussed, the risk is also higher with children.

An improved understanding and oversight of the safety profile of unlisted products would be supported by requiring ARTG listing of medicinal cannabis products.

8. ***Concerns have been raised over safety risks associated with high THC-containing products, particularly when inhaled or vaped. Do you have information on safety risks or harm associated with inhaling or vaping high-THC containing products? If yes, please provide evidence to support your response.***

DVA is aware of evidence that high dose THC is associated with adverse outcomes, particularly in those with a mental health condition. Its use can exacerbate existing mental health conditions and trigger anxiety or psychotic events. The use of higher potency cannabis has been correlated with an increased risk of cannabis use disorder and psychosis (Petrilli et al 2022). Studies in countries which have expanded access to products with higher levels of THC have found a potential correlation with an increase seen in the prevalence of cannabis use disorder (Connor et al 2021). A European study demonstrated a near doubling of cannabis-related diagnoses in outpatients over a 12-year period. The increase in cannabis-related diagnoses was strongly correlated with increases in THC concentration (Manthey et al 2024).

The addictive and reinforcing properties of THC creates concern for the development of cannabis use disorders, particularly with the consumption of higher doses of THC. This risk is higher in those with existing mental health conditions. There is particular concern that individuals suffering from chronic pain are at an increased risk of developing a cannabis use disorder (Sideli et al 2021), which is the medical indication for the majority of medicinal cannabis funded by DVA. A large systematic review and meta-analysis found that THC significantly increased the severity of positive and negative psychotic symptoms relative to the placebo with a large effect size. A similar effect size was found for all general psychiatric symptoms of concern (Hindley et al 2020).

The DVA Medicinal Cannabis Framework requires medical practitioners to undertake mental health assessments prior to considering funding medicinal cannabis prescriptions. They are also required to confirm ongoing mental health assessments during treatment, including monitoring for signs of cannabis use disorder. Anecdotally, some prescribers do not appear to counsel their patients about the significant mental health risk related to the use of medicinal cannabis, therefore it is unclear if these assessments are effective.

DVA supports TGA addressing the risks imposed by high THC concentration products through the introduction of limits on THC content and total dose of medicinal cannabis products.

Further evidence to support this response comes from the Drug and Alcohol Clinical Advisory Service (2025), and Dawson (2024) et al (2025).

9. ***Do you consider there to be a 'safe' upper limit of THC use? If yes, what is this limit. Please provide evidence to support your response.***

DVA is considering amending the Medicinal Cannabis Framework to restrict funding of dried herb products to those with a THC concentration of 25% or less. This would align with THC caps currently in place in Canada, Germany, Uruguay and the Netherlands, as well as the concentrations being prescribed across Australia as outlined in the TGA's Rapid Evidence Review – Efficacy and Safety of Higher THC Potency Category 5 Medicinal Cannabis Products.

It should be noted that this does not represent a safe upper limit. Placing a cap on the concentration of THC that is within the biological limits of the cannabis plant is an attempt to avoid the harms associated with high doses of THC. The risk of adverse effects, such as psychosis and cannabis use disorder, appear to be dose dependent. DVA believes that changes to THC limits from TGA would carry more weight with providers and patients, than DVA-led restrictions alone.

10. ***Do you consider there to be safety concerns with other cannabinoids? If yes, please provide evidence to support your response.***

DVA does not fund any medicinal cannabis products that list novel cannabinoids as active ingredients due to the lack of safety information and evidence of efficacy for non-CBD/THC cannabinoid products. Without TGA pre-market assessments, laboratory testing, and post-market monitoring, there is no reliable data available on the impact of non-CBD/THC cannabinoids as active ingredients in medicinal cannabis products. These additives may also have unexpected impacts on the effects of CBD and/or THC.

11. ***Do you consider there to be certain dosage forms when combined with certain routes of administration that present unacceptable safety risks. If yes, which combinations and please provide evidence to support your response.***

    There are concerns about the risk of children accidentally ingesting medicinal cannabis products, in particular gummies and pastilles as they may be more appealing. These products are easily ingested and are not well understood in terms of exact dosage. This is an unacceptable safety risk, due to the known increased harms of cannabis in children.

Population Groups

12. ***Due to the concern over its impact on developing brains, access to medicinal cannabis products for paediatric patients (under 18 years of age) accessed via the SAS and AP scheme requires a letter of support from a paediatrician or relevant medical specialist. Do you consider this current restriction to paediatric patients appropriate and sufficient? If not, please provide an explanation to support your response.***

    Heavy cannabis use is associated with memory impairment in young adults, with a greater effect seen in those with recent cannabis use (Gowin et al 2025). Given the increased risks in paediatric populations and already existing ARTG listed products for paediatric patients with epilepsy, medicinal cannabis should only be considered as treatment where safety and efficacy are well understood and demonstrated, and where there are no other feasible alternatives. As should be the case with all medicinal cannabis products going forward, appropriate post-market monitoring should occur for any products used in the paediatric population.

    DVA supports the consideration of additional limits to the conditions for which medicinal cannabis can be prescribed to children.

13. ***Are there any additional risk mitigation elements you consider should be applied to support medicinal cannabis use in paediatric patients? If yes, please provide an explanation to support your response.***

    DVA does not support the use of medicinal cannabis in paediatric patients without clear evidence of therapeutic benefit. This is due to evidence of an age-dependent association between cannabis use and the risk of psychotic disorders (McDonald et al 2024). Young adult populations (under 25) also appear to be at greater risk, which may not be broadly known amongst prescribers and patients. To increase education, DVA supports the introduction of warnings on packaging, as well as an increased use of Consumer Medical Information (CMI).

    For paediatric patients, the only area for which there is evidence supporting CBD use is in the control of refractory seizures for certain childhood epilepsy syndromes. As medicinal cannabis products are listed on the ARTG for this condition, the use of unapproved products is not necessary. DVA supports the consideration of restrictions to the conditions for which unapproved medicinal cannabis can be prescribed for the younger population.

14. ***Do you have concerns with specific types of medicinal cannabis products being prescribed to paediatric patients, including different dosage forms, concentration of certain components or any other pharmaceutical aspects? If yes, please provide an explanation to support your response.***

    Please see above responses. DVA also holds specific concerns about edible medicinal cannabis products, such as gummies and pastilles, which are designed to replicate common lollies and are

at a high risk of accidental ingestion by children and pets. There are also concerns about the dosages, concentration, additional additives and formulations.

15. ***Given the unknown safety impact of medicinal cannabis products on foetal development, do you consider there to be a need to restrict access or should risk mitigation elements be applied for pregnant or breastfeeding women? If yes, please provide an explanation to support your response.***

    Along with the other suggested regulatory reforms, medicinal cannabis products should be managed like other medications for pregnant and breastfeeding women. This includes utilising the Prescribing Medicines in Pregnancy database and the Australian categorisation system for prescribing medicines in pregnancy. Pregnant women should be receiving adequate counselling prior to being prescribed medicinal cannabis, as they would for other medications. Prescribers are already familiar with these systems where responsibility lies with prescribers and dispensing pharmacists.

16. ***Should restrictions or risk mitigation steps be applied to other vulnerable population groups, such as those with a history of mental health conditions, addiction etc? If yes, please provide an explanation to support your response.***

    At present, there is insufficient evidence to support the use of medicinal cannabis for many of the medical conditions for which it is prescribed according to TGA data and includes conditions where there is evidence of increased risk of harm (e.g. PTSD) (Myran et al 2025). This is consistent with the original guidance provided on the TGA Medicinal Cannabis Hub, and the perspective of the Veteran Affair's National Centre for PTSD (NCPTSD) and the Royal Australian and New Zealand College of Psychiatrists (RANZCP).

    TGA has previously advised that medicinal cannabis is not appropriate for people with a previous history of psychosis, or concurrent active mood or anxiety disorder (TGA 2024). This does not appear to be followed in practice. Further, the NCPTSD states that the current research does not support medicinal cannabis as a treatment for PTSD and are strongly against its use for mental health conditions, recommending against it in their treatment guidelines (Hill et al 2025). In addition, the RANZCP have stated that the clinical use of medicinal cannabis, particularly for psychiatric disorders, should be confined to clinical trials and case studies in order to assess safety and efficacy. They have called for medicinal cannabis products to be tested in randomised controlled trials and subject to the same regulatory approval processes as other prescription medicines (RANZCP 2024).

    DVA does not fund medicinal cannabis to treat mental health conditions, however there are many veterans who have a mental health comorbidity (e.g. PTSD) alongside a condition for which medicinal cannabis can be funded under the Framework (e.g. chronic pain). This is a significant concern for DVA.

    Concerns regarding cannabis use and mental health conditions are not new. Australian researchers demonstrated in 2002 that frequent cannabis use predicted depression and anxiety later in life, with daily use carrying the greatest risk (Patton et al 2002, Hayatbakhsh et al 2007). Since then, the link between cannabis use and poor mental health outcomes, such as cognitive impairment, psychosis and treatment resistance have become well established (Solmi et al 2023).

    As cannabis use has increased, the use of emergency healthcare services relating to the mental health side effects of cannabis use has also increased around the world, even in countries which

have not legalised cannabis (Crocker et al 2021). A cohort study of 438,700 individuals in Canada, found that rates of emergency department visits for anxiety disorders with cannabis involvement increased by 31.4% while visits for anxiety disorders with alcohol involvement decreased (McCarthy et al 2024).

Cannabis use has been shown to be associated with increased depressive and manic symptoms in the general population and an increased risk of developing, and a more unfavourable prognosis for, major depressive disorder and bipolar disorder (Sorkhou et al 2024). It has also been shown to worsen positive and negative psychotic symptoms, total psychiatric symptoms, and overall cognition. Other data shows that the risk of psychotic, depressive and manic symptoms in cannabis users is correlated with the frequency of cannabis use and the potency of THC (Polkosnik et al 2021).

There are concerns about high potency cannabis use which is associated with greater odds of depression, anxiety, and frequent or distressing psychotic experiences in adolescents (Hines et al 2020). This was supported by The Lancet Psychiatry (Petrilli et al 2022) who demonstrated that higher potency cannabis was associated with an increased risk of psychosis and cannabis use disorder. Further, a systematic review published in the Annals of Internal Medicine (Rittiphairoj et al 2025) found that high-concentration THC products were associated with adverse mental health outcomes, especially psychosis, schizophrenia and cannabis use disorder.

DVA's clients include veterans with complex service-related mental health conditions who require access to quality health care. Mitigation of potential harm to our more vulnerable client cohort is of key importance. DVA supports the restriction of medicinal cannabis to vulnerable population groups and the prescription of medicinal cannabis to medical conditions only where there is evidence of benefit without evidence of harm.

How do we address the current issues with medicinal cannabis products?

17. ***Do you have specific feedback on elements or principles that could be considered when developing regulatory options to address the current issues with medicinal cannabis products outlined in this paper? If yes, please provide an explanation to support your response.***

DVA is investigating changes to its Medicinal Cannabis Framework. Areas of concern are:

- the safety and efficacy of medicinal cannabis usage, especially at high doses
- the increase in opportunistic business models targeting veterans that are focused on profits and not clinical outcomes, and
- the number of separate products, and products with high levels of THC that are being prescribed to veterans concurrently.

DVA will continue to work with TGA to ensure medication safety and practice standards for the in relation to medicinal cannabis.

18. ***Would you support restricting or preventing access to most or all unapproved medicinal cannabis products via the SAS and AP scheme? If yes, please provide an explanation to support your response.***

DVA supports restricting or preventing access to all unapproved medicinal cannabis products via the Specialised Access Scheme (SAS) and Authorised Prescriber (AP) scheme, provided an alternative arrangement, with appropriate regulatory rigour is put in place. The SAS allows health

practitioners to prescribe medicines, medical devices or biologicals that are not included in the ARTG to a single patient in some circumstances. This does not fit the current scale of medicinal cannabis prescribing in Australia.

DVA supports removing medicinal cannabis from SAS and requiring products to apply for ARTG listing. It is expected that this would require a period of transition with additional restrictions as outlined below for the AP system. It should be noted that DVA does not report on any statistics of SAS or AP usage.

The AP system is currently supporting large scale prescribing of medicinal cannabis with very limited oversight or restrictions. If the AP system is to continue, DVA supports implementing additional restrictions:

- limiting which practitioners can become APs for medicinal cannabis, as is the case with MDMA and psilocybin for psychedelic-assisted psychotherapy
- imposing maximum THC concentrations to reduce the risks posed by high THC doses and/or maximum daily doses of CBD/THC (time-dependent dispending limits per patient)
- limiting access to last line treatment of medical conditions for which there is some evidence of clinical benefit without evidence of harm
- restricting access to non-CBD/THC cannabinoids for which there is adequate safety data
- restricting access to formulations for which there is evidence of harm and a lack of safety data (e.g. vape liquid, concentrated extracts, granules)
- requiring product names that are in keeping with therapeutic products
- implementing strict labelling standards and requiring the inclusion of Consumer Medical Information (CMI) leaflets, and
- restricting access to formulations that appeal to children and pets.

Consideration also needs to be given to strengthening care provisions in relation to appropriate prescribing practices, such as appropriate assessment of need, presence of comorbidities and other factors, along with proper collaboration with other members of the treating team.

19. ***Would you support a time-limited regulatory mechanism that could allow sponsors of unapproved medicinal cannabis products time to gather evidence of efficacy or conformity assessment certification to transition to the ARTG? If yes, please provide an explanation to support your response.***

DVA would support a transition period for medicinal cannabis products to transition to the ARTG. Unlike unapproved therapeutic goods, ARTG listed items have been evaluated by the TGA for quality, safety, efficacy and performance. However, there should not be any loosening of restrictions for medicinal cannabis products in the transition to the ARTG.

Funding medicinal cannabis products that are ARTG listed would mean DVA are supporting treatments that have been demonstrated to be safe and effective.

20. ***What do you consider to be an appropriate length of time to allow sponsors to gather sufficient clinical evidence to support their medicinal cannabis product?***

DVA supports a grandfathering period to allow sponsors time to gather sufficient clinical evidence and to support health practitioners to work with patients to deprescribe to transition to ARTG listed medications.

Given the prolonged period for which medicinal cannabis products have been available and during which manufacturers could have gathered evidence, expedient regulatory reforms are needed to address safety concerns. If interim measures are implemented (e.g. restrictions on prescribers, conditions for which medicinal cannabis can be accessed, improved labelling, etc) a more prolonged transition could be used to allow sponsors to design, implement, and analyse good quality clinical trials.

21. ***What are some potential amendments that could be made via scheduling for cannabis and its cannabinoids that could address safety concerns? Please provide detail.***

The current scheduling of medicinal cannabis is based on composition, with products that are at least 98% CBD being Schedule 4 (prescription-only), while all other medicinal cannabis products being Schedule 8 (controlled drugs). DVA supports a rescheduling of medicinal cannabis products to better reflect the lack of safety data and evidence for their clinical benefit, especially those with high THC content. In the absence of evidence for their use, high-THC containing products should be rescheduled to Schedule 9 (prohibited substance).

DVA supports a revision of the current TGA categories for medicinal cannabis products. The current categories are not well understood by providers and the public, in that they refer to the ratio between cannabinoids rather than absolute quantities. Category 5 products are not those that are >98% THC by weight, rather the cannabinoid content of the products of this category is >98% THC. New categories that would better describe the level of concern related to a product would be more useful. As an example, there is far greater risk from a prescription of 4g per day of dried herb with a THC concentration of 26% than there is from an oral liquid which is 26mg/mL THC even though both are category 5 products.

22. ***Please provide your feedback on certain labelling requirements that could be implemented to assist prescribers and patients understanding of what is contained in a product, and what would provide greater transparency on a product's regulatory status?***

DVA does not consider the current labelling requirements to be adequate to allow prescribers and consumers sufficient information on the product being prescribed. Currently, sponsors are only required to list active ingredients on medicinal cannabis products. There are concerns that novel cannabinoids other than THC and cannabidiol (CBD) that may be biologically active are not always listed/labelled. Given the lack of public data available on all cannabinoids, but particularly non-CBD/THC cannabinoids, consideration should be given to requiring the inclusion of all cannabinoid ingredients on labelling for medicinal cannabis products. DVA do not fund any medicinal cannabis products that have novel cannabinoids labelled as active ingredients. There is also evidence that labelling of cannabis products can be highly variable with inaccurate representation of drug content and/or concentration.

Reference List

Balachandran, P., Elsohly, M., & Hill, K.P. 2021, 'Cannabidiol interactions with medications, illicit substances and alcohol: a comprehensive review', *Journal of General Internal Medicine*, vol 36, pp 2074-2084

Cairns, R., Allaf, S., & Buckley, N.A. 2025, 'Cannabis poisonings in Australia following the legalisation of medicinal cannabis, 2014-2024: analysis of NSW Poisons Information Centre data', *The Medical Journal of Australia*, 222(3), pp 155-157

Chesney, E., Oliver, D., Green, A., Sovi, S., Wilson, J., Englund, A., Freeman, T.P., & McGuire, P. 2020, 'Adverse effects of cannabidiol: a systematic review and meta-analysis of randomised clinical trial', *Neuropsychopharmacology*, vol 45, pp 1799-1806

Connor, J.P., Stjepanovic, D., Le Foll, B., Hoch, E., Budney, A.J., & Hall, W.D. 2021, 'Cannabis use and cannabis use disorder', *Nature Reviews Disease Primers*, 7(16)

Crocker, C.E., Carter, A.J.E., Emsley, J.G., Magee, K., Akson P., & Tibbo, P.G. 2021, 'When cannabis use goes wrong: mental health side effects of cannabis use that present to emergency services', *Frontiers in Psychiatry,* vol 12, 640222

Dos Santos, R.G., Guimaraes, F.S., Crippa, J.A.S., Hallak, J.E.C., Rossi, G.N., Rocha, J.M., & Zuardi, A.W. 2020, 'Serious adverse effects of cannabidiol (CBD): a review of randomised controlled trials', *Expert Opinion on Drug Metabolism & Toxicology*, 16(6), pp 517-526

Drug and Alcohol Clinical Advisory Service. 2025, 'Cannabis', accessed 22 September 2025, https://www.dacas.org.au/aod-info/cannabis

Dawson, D. 2024, 'Cannabis use disorders: an unappreciated risk of medical use for chronic conditions', *Drug and Alcohol Research Connections*, accessed 22 September 2025, https://www.connections.edu.au/opinion/cannabis-use-disorders-unappreciated-risk-medical-use-chronic-conditions

Dawson, D., Lorenzetti, V., & Hall, W. 2025, 'What is cannabis use disorder? And how do you know if you have a problem', *The Conversation*, accessed 22 September 2025, https://theconversation.com/what-is-cannabis-use-disorder-and-how-do-know-if-you-have-a-problem-256098

Gowen, J.L., Ellingson, J.M., Karoly, H.C., Manza, P., Ross, J.M., Sloan, M.E., Tanabe, J.L., & Volkow, N.D. 2025, 'Brain function outcomes of recent and lifetime cannabis use', *JAMA Network Open*, 8(1), e:2457069

Petrilli, K., Ofori, S., Hines, L., Taylor, G., Adams, S., & Freeman, T.P. 2022, '*Association of cannabis potency with mental ill health and addiction: a systematic review'*, The Lancet Psychiatry, 9(9), pp 736-750

Polkosnik, G.L., Sorkhou, M., & George, T.P. 2021, 'Effects of cannabis use on psychotic and mood symptoms: a systematic review', The Canadian Journal of Addiction, 12(3), pp 10-21

Hayatbakhsh, M.R., Najman, J.M., Jamrozik, K., Mamun, A.A., Alati, R., & Bor, W. 2020. 'Cannabis and Anxiety and Depression in Young Adults: A Large Prospective Study', *Journal of the American Academy of Child & Adolescent Psychiatry, 46(3), pp 408-417*.

Hill, K.P., Gold, M.S., Nemeroff, C.B., McDonald, W., Grzenda, A., Widge, A.S., Rodriguez, C., Kraguljac, N.V., Krystal, J.H., & Carpenter, L.L. 2021, 'Risks and benefits of cannabis and cannabinoids in psychiatry', *The American Journal of Psychiatry*, 179(2), pp 98-109

Hill, M., Loflin, M., Hicks, T., Browne, K., & Norman, S.D. 2025, 'Cannabis use and PTSD among veterans', United States Department of Veterans Affairs, PTSD: National Centre for PTSD, accessed 23 September 2025, https://www.ptsd.va.gov/professional/treat/cooccurring/marijuana_ptsd_vets.asp

Hindley, G., Beck, K., Borgan, F., Ginestet, C.E., McCutcheon, R., Kleinloog, D., Ganesh, S., Radhakrishnan, R., D'Souza, D.C., & Howes, O.D. 2020, 'Psychiatric symptoms caused by cannabis constituents: a systematic review and meta-analysis', *Lancet Psychiatry*, 7, pp 344-353

Hines, L.A., Freeman, T.P., & Gage, S.H. 2020, 'Association of high-potency cannabis use with mental health and substance use in adolescence', *JAMA Psychiatry*, 77(10), pp 1044-1051

Hoch, E., Volkow, N.D., Friemel, C.M., Lorenzetti, V., Freeman, T.P., & Hall, W. 2024, 'Cannabis, cannabinoids and health: a review of evidence on risks and medical benefits', *European Archives of Psychiatry and Clinical Neuroscience*, 275(2), pp 281-292

Huestis, M.A., Solimini, R., Pichini, S., Pacifici, R., Carlier, J., & Busardo, F.P. 2019, 'Cannabidiol adverse effects and toxicity', *Current neuropharmacology*, 17(10), pp 974-989

Manthey, J., Rosenkranz, M., Jonas, B., Schwarzkopf, L. 2024, 'Can the THC concentration predict the number of patients with cannabis-related diagnoses?', *Drug and Alcohol Review*, 43(7), pp 1764-1772

McCarthy, S.D.S., Xiao, J., Pugliese, M., Perrault-Sequeira, L., Myran, D.T. 2024, 'Changes in cannabis involvement in emergency department visits for anxiety disorders after cannabis legalisation: a repeated cross-sectional study', *The Lancet Regional Health – Americas*, 36, 100815

McDonald, A.J., Kurdyak, P., Rehm, J., Roerecke, M., & Bondy, S.J. 2024, 'Age-dependent association of cannabis use with risk of psychotic disorder', *Psychological Medicine*, 54(11), pp 2926-2936

Myran, D.T., Pugliese, M., Harrison, L.D., Solmi, M., Anderson, K.K., Fiedorowicz, J.G., Finkelstein, Y., Manuel, D., Taljaard, M., Webber, C., & Tanuseputro, P. 2025, 'Changes in incident schizophrenia diagnoses associated with cannabis use disorder after cannabis legalisation', *JAMA Network Open*, 8(2), e2457868

Patton, G.C., Coffey, C., Carlin, J.B., Degenhardt, L., Lynskey, M. & Hall, W. 2002. 'Cannabis use and mental health in young people: cohort study', *British Medical Journal*, 325, pp 1195-1198.

Petrilli, K., Ofori, S., Hines, L., Taylor, G., Adams, S., & Freeman, T.P. 2022, 'Association of cannabis potency with mental ill health and addiction: a systematic review', *The Lancet Psychiatry*, 9(9), pp 736-750

Rittiphairoj, T., Leslie, L., Oberste, J., Yim, T.W., Tung, G., Bero, L., Riggs, P., Hutchison, K., Samet, J., & Li, T. 2025, 'High-concentration delta-9-tetrahydrocannabinol cannabis products and mental health outcomes: a systematic review', *Annals of Internal Medicine*

Royal Australian and New Zealand College of Psychiatrists. 2024, 'Clinical memorandum: therapeutic use of medicinal cannabis products', RANZCP March 2024, accessed 23 September 2025, https://www.ranzcp.org/getmedia/233218fd-068d-875e-3bf319bb5d0a/CM-Therapeutic-use-of-medicinal-cannabis-products.pdf

Sideli, L., Trotta, G., Spinazzola, E., La Cascia, C., & Di Forti, M. 2021, Adverse effects of heavy cannabis use: even plants can harm the brain', *The Journal of the International Association for the Study of Pain*, 162, pp S92-S104

Solmi, M., De Toffol, M., Kim, J.Y., Choi, M.J., Stubbs, B., Thompson, T., Firth, J., Miola, A., Croatto, G., Baggio, F., Michelon, S., Ballan, L., Gerdle, B., Monaco, F., Simonato, P., Scocco, P., Ricca, V., Castellini, G., Fornaro, M., Murru, A., Vieta, E., Fusar-Poli, P., Barbui, C., Ioannidis, J.P.A., Carvalho, A., Radua, J., Correll, C.U., Cortese, S., Murray, R.M., Castle, D, Shin, J.I., & Dragioti, E. 2023, '*Balancing risks and benefits of cannabis use: umbrella review of meta-analyses of randomised controlled trials and observational studies'*, BMJ, 382, e072348

Sorkhou, M., Dent, E.L., & George, T.P. 2024, 'Cannabis use and mood disorders: a systematic review', *Frontiers in Public Health*, vol 12, 346207

Therapeutic Goods Administration. 2024, 'Guidance for the use of medicinal cannabis in Australia: patient information', version 1.1, accessed 23 September 2025, https://www.tga.gov.au/products/unapproved-therapeutic-goods/medicinal-cannabis-hub/medicinal-cannabis-guidance-documents/guidance-use-medicinal-cannabis-australia-patient-information

Therapeutic Goods Administration. 2024a, 'Medicinal cannabis Special Access Scheme data', accessed 29 September 2025, https://www.tga.gov.au/products/unapproved-therapeutic-goods/medicinal-cannabis-hub/medicinal-cannabis-access-pathways-and-usage-data/medicinal-cannabis-special-access-scheme-data

Vida, R.G., Strauss, L.V., Bajtel, A., Kiss, T., Csupor, D., & Fittler, A. 2023, 'Safety and risks of CBD oils purchased online: unveiling uncertain quality and vague health claims', *Frontiers in Pharmacology,* vol 14

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Australian Government

Department of Veterans' Affairs

DEPUTY SECRETARY
POLICY & PROGRAMS GROUP

Professor Anthony Lawler
Deputy Secretary
Health Products Regulation Group
Department of Health, Disability and Ageing
GPO Box 9848
CANBERRA ACT 2601
via email: anthony.lawler@health.gov.au

Dear Professor Lawler, Tony

As you are aware the Department of Veterans' Affairs (DVA) shares the growing concerns about the appropriateness of the current regulatory arrangements for medicinal cannabis in Australia. As an agency dedicated to supporting the health and wellbeing of veterans DVA funds a range of treatments and access to pharmaceuticals, including medicinal cannabis, and is well placed to observe trends in take up and the emerging and concerning behaviours by providers.

In our previous discussions about the Therapeutic Goods Administration's (TGA) consultation on *reviewing the safety and regulatory oversight of unapproved medicinal cannabis products,* I undertook to provide you with further advice on the growth of DVA's medicinal cannabis expenditure, and outline the Repatriation and Military Rehabilitation Compensation Commission (Commissions) decision on proposed changes to DVA's Medicinal Cannabis Framework (the Framework). I provide this information to support the internal consideration of these matters by the Department of Health, Disability and Ageing, noting these matters are currently before the Government.

Since those discussions, I also note that both the Australian Medical Association (AMA) and the Pharmacy Guild of Australia (the Guild) have provided submissions to the TGA and written a joint letter to the Minister for Health and Ageing, the Hon Mark Butler MP, outlining their concerns. These concerns are aligned with other peak bodies and regulators which have emerged in response to rapid growth in community demand and development of business models focussed on profits over patient care.

DVA has experienced a rapid growth in the number of veterans accessing medicinal cannabis and in corresponding expenditure. Since DVA commenced funding medicinal cannabis in 2018, there has been an increase in expenditure each financial year. In 2022-23 DVA spent around $18.5 million. This increased to around $36 million in 2023-24 and to $87.8 million in 2024-25. In this financial year (up to 20 October) DVA has spent $36 million which, if there were no changes in policy, would place annual expenditure around $110-$120 million. There are now over 12,000 veterans accessing medicinal cannabis under Veteran Card arrangements.

Prior to the TGA submission DVA engaged the Commissions on modifications to the Framework. The Framework is a policy document that sets out the conditions under which DVA will fund medicinal cannabis and is published on the DVA website.

The changes to the Framework discussed with the Commissions, which are now before the Government for consideration, are:

- General Practitioners (GPs) and other Specialists prescribers must be Fellows of an Australian Health Practitioner Regulation Agency (Ahpra) registered college (e.g. the Royal Australian College of General Practitioners (RACGP)) with an accredited medical specialty listed on their Ahpra registration.

- Access to medicinal cannabis will only be approved if there has been an initial in-person consultation between the veteran and the prescriber, including increases in prescription and when changing to a new prescriber.

- Introduction of a product THC concentration cap and a daily dosage cap on the amount of dried herb medicinal cannabis products that DVA will fund with a maximum of any three products per person.

- Cessation of funding oral medicinal cannabis in the form of pastilles and gummies to reduce the risk of harm from accidental ingestion by children and animals.

- No funding for other cannabinoids (other than THC or CBD) as an active ingredient. This expands on existing policy and will broaden DVA's approach to exclude other cannabinoids given the lack of evidence of their efficacy.

Further changes to the Framework also under consideration, which may be revisited in the context of any regulatory changes, or residual utilisation concerns include:

- TGA Category 5 or Category 5 (high THC to CBD ratio) products would not be funded for veterans who do not already have this level of product prescribed. Existing users will be grandfathered for 6 months to adjust to the new arrangements. This measure will be implemented as a second tranche change.

These measures will build on activities already in train in DVA to:

- Develop targeted clinical guidelines for the prescribing of medicinal cannabis to veterans for chronic pain with supporting client material.

- Strengthen DVA's relationship with Ahpra and National Boards.

The proposed changes to the Framework are an important first step to ensure DVA's funding aligns with best practice and emerging safety concerns.

Given the broad scope of this issue and its impact across the community, we consider regulatory changes made by Ahpra and the TGA are warranted. These regulatory changes, driven by the broader concerns about current prescribing and supply arrangements, would also strengthen DVA's arrangements and the effectiveness of the Framework.

Noting our shared interest and role in providing advice to government on these matters, I would be open to exploring opportunities to share DVA data on the trends and practices related to medicinal cannabis, as appropriate, on a more regular basis.

Should you team wish to discuss these matters further, the most appropriate contact in DVA would be Ms Cath Haffner, Assistant Secretary, Health & Wellbeing Policy Branch. Ms Haffner can be contacted on s 47F or via Cath.Haffner@dva.gov.au.

Yours sincerely,

Andrew Kefford PSM

31 October 2025