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| Assisting medicinal cannabis patients to drive safely  Report of the Medicinal Cannabis and Safe Driving Working Group  February 2021 |



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# Introduction

#### The Working Group

The Medicinal Cannabis and Safe Driving Working Group (Working Group) was established to consider approaches on managing medicinal cannabis and safe driving in Victoria following the introduction of the Road Safety Amendment (Medicinal Cannabis) Bill 2019 (the Bill) by Ms Fiona Patten MP.

The Bill proposed legislative amendments that would see medicinal cannabis, when prescribed by a medical practitioner, treated in the same way as other prescription medication under the *Road Safety Act 1986.* In debating the Bill in the Legislative Council on 14 October 2020, the Victorian Government committed to working with Ms Patten to investigate this issue, while noting that road safety risk issues would form a key part of the discussion.

The Working Group was tasked with:

* reviewing the existing evidence on the road safety risks and impairment effect on driver behaviour associated with medicinal cannabis, specifically the main psychoactive form of cannabis, delta-9-tetrahydrocannabinol (THC), in Victoria,
* investigating potential options that may allow conditional access to driving for legitimate medicinal cannabis patients,
* ensuring that any new approach is not detrimental to road safety, and
* ensuring that the integrity of the Victorian drug driving program in tackling impaired driving related road trauma is preserved.

The Terms of Reference of the Working Group can be found in Appendix A.

#### Discussion framework and key findings

Each representative of the Working Group was chosen to bring a unique and expert perspective on various aspects of medicinal cannabis and safe driving to provide the government with the evidence base to develop effective policy in this area. As such, the Working Group members held a range of different views on how to assist medicinal cannabis patients to drive safely.

With the competing perspectives in mind, the Working Group considered two key intervention points that provide a potential pathway for medicinal cannabis patients to access safe driving, namely, options at the point-of-prescription of medicinal cannabis by a medical practitioner, and at the point-of-detection at the roadside by a police officer when driving.

#### Point-of-prescription

The Working Group considered two broad categories of approach with various levels of formalised advice for managing medicinal cannabis patients at the point-of-prescription:

1. A low level of intervention
2. A higher level of intervention

The Working Group were presented with a decision tree support tool to support medical practitioners to work through a clear and logical pathway to determine their patient’s fitness to drive.

Point-of-detection

The Working Group were presented with four potential approaches for managing a potential positive test at the roadside for a driver who has been prescribed medicinal cannabis:

1. Drug Impairment Assessment

*This approach involves physical impairment tests and a subsequent blood test with the aim of determining driver impairment.*

1. THC level in blood

*This approach involves determining a threshold of THC in blood levels that indicates impairment, analogous to the 0.05 blood alcohol content (BAC) process.*

1. Hybrid approach of existing approach and approach 2

*This approach involves the current roadside saliva test, but with medicinal cannabis patients being given the option of a follow-up blood test to determine driver impairment.*

1. Medical defence/exemption

*This approach allows drivers who can prove they are legitimate medicinal cannabis patients to be exempt from a drug driving offence. This could be designed to include conditional factors, such as a zero BAC.*

#### The Working Group sought to consider the potential impacts of each approach in terms of practicality and effects on medicinal cannabis patients and road safety, in particular the need to maintain the current mass screening testing program that underpins general deterrence against drug driving. Further consideration of these matters is described later in this report.

Consideration was given to the difficulties encountered by medicinal cannabis patients in terms of potential transport disadvantage through limited mobility options. These patients may be avoiding consuming medicinal cannabis when it is beneficial due to concerns about drug driving laws, or, in some cases, may risk breaking these laws by driving after consuming their dose, including to doctors’ appointments.

Consideration was also given to the road safety risk associated with both recreational and medicinal cannabis containing THC. In this discussion, the Working Group heard evidence that the research literature specifically on medicinal cannabis products containing THC and road safety risk is currently limited.

The Terms of Reference for the Working Group limited the focus to prescribed medicinal cannabis, as the consideration of the road safety risk of other prescription drugs would require a more lengthy and detailed investigation. The question of whether medicinal cannabis should be treated in the same manner as other impairing prescription drugs was raised by the Working Group. It was also noted that there is already a health-based regulatory system in place for managing road safety risks associated with all other potentially impairing prescription medications.

The Working Group was able to identify the critical scientific and operational issues that underpin a logical framework to enable the government to make informed decisions on medicinal cannabis and safe driving. This represents a significant contribution to public debate on this matter.

# Current prescription approach and current drug-detection processes in Victoria

### Current approach for medicinal cannabis patients, products, and prescribing approaches in Victoria

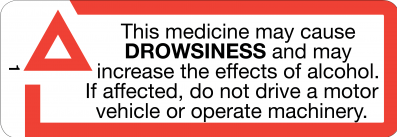
Medicinal cannabis products, like other medications, can be prescribed by any medical practitioner in Victoria to treat any patient if the medical practitioner believes it will provide clinical benefit. Most commonly, Schedule 8 medicinal cannabis products (containing >2 per cent THC) are commonly prescribed to treat chronic pain, symptoms related to cancer and cancer treatment, multiple sclerosis, and sleep disorders. The majority of patients are female and over 50 years of age.

As of 31 January 2021, the Therapeutic Good Administration (TGA) had issued over 91,000 approvals for Australian medicinal cannabis patients via the Special Access Scheme Category B (SAS-B), which is the main access pathway for medicinal cannabis products in Australia, with 20-25 per cent of these estimated to be Victorian. Approval under the SAS-B scheme does not necessarily mean the patient has accessed or continues to access treatment. Following approval, the actual supply of medicinal cannabis is a matter for the medical practitioner and their patient. Around 80 per cent of SAS-B approvals are for Schedule 8 products, with additional prescribing of Sativex (the only product containing THC registered on the Australian Register of Therapeutic Goods), and a small number of patients gaining access via the Authorised Prescriber pathway not included in these totals.

The issue of prescription medications causing impairment that may pose a risk to the safe operation of a motor vehicle is already well known and is managed through a product labelling and warning system.

This system, which applies to medicinal cannabis, requires identified medications to include a warning (Figure 1) about possible sedating effects/drowsiness, recommendations not to drive or operate machinery if experiencing such effects, and to avoid alcohol or be aware that the medication may increase its effects. Medical practitioners and dispensing pharmacists are also required to advise patients using medications with these warnings to monitor drug effects and refrain from driving if impaired.

*Figure 1.*



Patients taking prescriptions with this label are required to self-monitor and refrain from driving when appropriate. Other than for medicinal cannabis, patients taking these medications are not committing an offence driving with the presence of the medicine in their system, if not impaired. However, they would be committing an offence if driving while impaired by the medication.

Advice from medical practitioners is that they often inform patients they cannot drive while taking medicinal cannabis medications. This advice is typically premised on the illegality of driving with a THC presence, rather than a knowledge of driver impairment associated with THC.

Critical data on Victorian medicinal cannabis patients, in terms of assessing safe driving, is not currently available. Despite this lack of aggregate data, it is likely that medicinal cannabis patients are a different demographic to those drivers currently overrepresented in THC related crashes (typically younger males). Specifically, the following data is not readily available to road safety agencies (unless patients are referred for medical review because of their underlying long-term or chronic medical condition or disability):

* underlying condition and co-morbidities,
* matching of prescription types and dosages with underlying medical conditions (the reason for the prescription),
* combination prescription drug use (e.g. medicinal cannabis and other prescription drugs),
* other relevant behavioural factors such as alcohol and illicit drug use and driving patterns (how soon after consumption), and
* licence type (e.g. commercial, private vehicle, probationary, relevant to road safety risk).

### Application of fitness to drive guidelines in Victoria

Health professionals use the national medical standards for licensing, *Assessing fitness to drive for commercial and private vehicle drivers 2017*, when assessing a patient’s fitness to drive.

The guidelines detail medical standards for driver licensing purposes for use by health professionals and driver licensing authorities. They assist health professionals to:

* assess the fitness to drive of their patients in a consistent and appropriate manner based on current medical evidence,
* promote responsible behaviour of their patients, having regard to their medical fitness,
* conduct medical examinations for the licensing of drivers as required by state and territory driver licensing authorities, and
* recognise the extent and limits of their professional and legal obligations with respect to reporting fitness to drive.

For the range of medical conditions, disabilities and treatment impacts covered by the guidelines, a set of criteria identify when a driver is not eligible to hold an unconditional licence. These criteria serve as the initial trigger for a health professional to start thinking about the impact of the person’s medical condition, disabilities or use of treatments on their fitness to drive (e.g. the person has had a seizure, is diagnosed with a sleep disorder and begins a course of treatment etc.). Periods of abstinence from driving may be required. If the driver is not eligible for an unconditional licence as a result of their long term/permanent diagnosis or impairment, this is also a trigger for the health professional to advise the driver about their obligation to report their condition to VicRoads.

The VicRoads Medical Review process provides a mechanism for assessment and decision making about licensing, and for facilitating ongoing review if required. It aims to optimise driver capacity to drive in conditions that suit their abilities, providing they are safe to do so. As at February 2021, less than 20 medicinal cannabis patients have been assessed by the Medical Review process.

As medicinal cannabis is still a relatively new form of treatment for a range of medical conditions, the current 2017 Assessing Fitness to Drive Guidelines (AFTD) do not explicitly cover or reference medicinal cannabis. However, the guidelines do provide general guidance regarding other prescription drugs that have effects on the central nervous system, such as benzodiazepines, opioids, and antipsychotics; and where medication is relevant to the management of specific conditions, such as epilepsy, psychiatric conditions and diabetes.

In relation to prescription drugs, the AFTD states that health professionals should consider “the balance between potential impairment due to the drug and (effect on) the patients improvement in health on safe driving ability”, in addition to factors such as individual response, drug interactions, and history of substance abuse.

The National Transport Commission (NTC) is currently reviewing the guidelines and will be seeking stakeholder inputs including from licensing authorities, peak medical groups, disability advocacy groups and the public. The NTC has established a dedicated medicinal cannabis and driving working group to assist with developing relevant content and guidance information for both health professionals and licensing authorities. The Department of Transport (DoT) is directly contributing to this process. It is envisaged the updated AFTD Guidelines will be finalised in the second half of 2021. Further information on health professional obligations in regards Fitness to Drive is available at Appendix B.

*Limitations of current process*

The current process for prescribing medicinal cannabis products containing >2 per cent THC does not include comprehensive guidelines for medical practitioners to provide individually relevant advice to patients on whether they should drive. Without medical practitioners having access to consistent, evidence-based data around driving, it is difficult for them to provide their patients with comprehensive advice on consuming THC and the associated driving risks.

### Current process for drivers testing positive to THC at the roadside

There are two legislative provisions underpinning the drug driving testing program, the Road Safety (Amendment) Bill 2000 and the Road Safety (Drug Driving) Bill 2003.

The Road Safety (Amendment) Bill 2000 introduced police powers to undertake a “Standard Impairment Assessment” at the roadside, which, if indicative of impairment, authorises the taking of a blood sample by a medical officer, and the analysis of that sample. Depending on the drug/level detected, expert evidence is presented at court on the level of driver impairment.

The Road Safety (Drug Driving) Bill 2003 allows police to take a saliva sample at the roadside, which is analysed in a laboratory if positive. This was introduced as a response to evidence demonstrating the elevated road safety risk associated with the presence of THC when driving. This saliva-based process allows for mass random screening which is critical in achieving a level of general deterrence across the community which directly correlates to a reduction in drug-related road deaths and injuries.

A laboratory certificate stating the presence of a proscribed drug is the basis for a drug driving infringement or court summons. This process is sufficiently quick to allow mass roadside screening. This legislation is based on a presence approach, as THC levels in saliva does not indicate THC levels in blood, but is rather mouth residue from smoking or consumption, meaning impairment cannot be accurately determined from saliva samples alone. Rather, the quick metabolism of THC in saliva means that a saliva detection is indicative of recent consumption that is likely to be associated with a level of impairment. It is not possible to be more precise on the rate of THC metabolism over a period of time, as this is dependent on a number of individual circumstances, including dosage.

A more detailed discussion of drug-driving legislation and process can be found at Appendix C.

*Limitations of current process*

The current roadside drug testing program in Victoria, as outlined above, does not distinguish between medicinal cannabis patients who legally consume THC and recreational cannabis users as THC has the same chemical compound in both. As such, any driver who tests positive to THC at the roadside is further investigated for a presence offence.

As the current mass screening roadside drug testing program is based on presence, not impairment, a driver cannot roughly estimate safe driving in a manner that is comparable to alcohol use, and as such there are no guidelines to help drivers estimate how long THC will be detectable in their saliva. Alcohol impairment is easily measurable by BAC which can be determined at a roadside breath test. In addition to this, all alcohol sold in Australia contains information on standard drinks, allowing the consumer to roughly calculate their level of impairment and/or BAC level before making a decision to drive.

Prescribed medicinal cannabis products have varying levels of THC. For drivers consuming products containing high levels of THC, the likelihood of testing positive to a roadside drug test is greater than for patients taking products containing lower levels. For drivers consuming products containing high levels of THC, their likelihood of being impaired is also greater. The Working Group heard evidence that medicinal cannabis patients who delay their driving by a number of hours may limit their potential exposure to a positive roadside saliva test. However, if a patient drives immediately after taking their dose, takes an increased amount, or also consumes recreational cannabis, they may have accumulated sufficient THC in their saliva to trigger a positive roadside drug test.

These issues arise from the limitations of current roadside drug testing technology, coupled with no agreed THC threshold in blood relating to driving impairment and the road safety risk (akin to 0.05 BAC for alcohol being the legal limit for fully licenced non-commercial drivers in Victoria). Victoria’s road safety agencies maintain market awareness of technology in this field, however, at this stage there are no new candidate technologies that will overcome these inherent limitations. If THC levels could be measured in a similar way to BAC at the roadside, it would improve the ability to underpin a similar scheme to breath testing for alcohol where a prescribed maximum level of THC could be considered. Overseas jurisdictions that have set THC threshold impairment levels in blood have set these at different levels, often dependent on legal or technology issues. If Victoria were to set a level, overseas experience would be considered. However, the primary basis would be scientific evidence on impairment in blood.

### Post-collision hospital blood testing

In the circumstance where an injured driver is taken to hospital after a collision, a compulsory blood sample is taken. This sample is subsequently analysed at the Victorian Institute of Forensic Medicine (VIFM) for prescribed drugs, which includes THC.

Victoria Police, in the course of investigating the collision, will consider the totality of the collision circumstances. If Victoria Police, in using their discretion, do not pursue a drug driving prosecution, other road safety options are available, including referral to VicRoads licence review. Victoria Police may form the view that a driver’s legitimate use of medicinal cannabis was not a causal factor in a collision warranting prosecution. However, should Victoria Police form the view that THC-based impairment was a causal factor in the collision, Victoria Police do have the option of issuing an infringement or taking the matter to court.

The Department of Health (DH) presented evidence from a recent scientific paper on residual blood THC levels in frequent cannabis users, which found that frequent cannabis users, likely including medical users, can have THC levels exceeding 2ng/mL and possibly 5ng/mL after days of abstinence.[[1]](#footnote-2)

VIFM and the Monash University Accident Research Centre (MUARC) have provided contrary advice, specifically that there is no evidence that a typical medicinal cannabis user would show similar blood THC levels from prescribed dosages. VIFM noted that the DH referenced paper specifically stated that no medicinal cannabis users were included in the studies reviewed, which only covered recreational cannabis users. VIFM also noted that, should any driver have a detectable THC level in their blood arising from THC use either many hours or days prior, impairment may be inferred.

# Road safety risks associated with medicinal cannabis

### THC and driving

Evidence on THC and road safety risk shows that there is global consensus that THC impairs key driving skills for up to a few hours after consumption[[2]](#footnote-3). This is supported by a host of psychometric, behavioural and on-road studies. These studies show that THC causes risky driving behaviours such as lane weaving, inappropriate speed changes and following distances, reduced reaction time, reduced capacity to divide attention, and reduced vigilance. The Working Group also heard evidence of large scale odds ratio studies which have shown increased crash risk in relation to recreational THC use. A summary of these studies is in Appendix D.

However, there is limited research specifically on the driver impairment effect of THC in medicinal cannabis products. One recent study showed that in healthy cannabis volunteers, effects similar to those found for THC more broadly were found with medicinal cannabis in relation to lane weaving but not speed changes[[3]](#footnote-4).

The Working Group heard that medicinal cannabis patients are expected to have a lower road safety risk than recreational users of cannabis due to a variety of factors. A number of studies have investigated the use of medicinal cannabis by patients, including large registry studies in Europe of Sativex, a medication containing THC, and four large epidemiological studies in the United States examining the change in road traffic accidents following the introduction of different types of cannabis access pathways. These studies found either a nil impact or a reduction in fatal crashes in jurisdictions introducing medical-only access pathways. In contrast, in jurisdictions where cannabis was legalised or decriminalised, THC was associated with an increase in fatalities for some groups (see Appendix E for a summary of these studies).

However, the Working Group also heard that population level odds-ratio studies clearly show that crash risk increases in relation to recreational cannabis, that the epidemiological studies undertaken in the United States which found nil impact on fatal crashes did not assess driver impairment, and that a study of driver performance when medicinal cannabis products are consumed found evidence of driver impairment[[4]](#footnote-5).

This difference in research findings was not resolvable by the Working Group with current knowledge at this stage, and further research is required. Despite the limited research, the assumption that research into the impairing effects of recreational THC can be applied to inform options is appropriate, up until the point where there is sufficient research related to medicinal cannabis to consider.

In relation to how impairment may translate into crash risk, a recent study by the VIFM on 5,000 drivers in Victoria injured and taken to hospital show an odds ratio of 1.9 for drivers only positive to blood THC. Drivers with THC concentrations 5 ng/mL or higher showed an increased risk over all drivers positive to THC-alone (over 3), while drivers with blood THC 10 ng/mL or higher, had an odds ratio of 10 (see Appendix F for further information). The VIFM study noted that this distinction is often missed in reports and meta-analyses. Low level THC is unlikely to show detectable impairment and elevated crash risk, but drivers smoking an hour or two before, or during driving, are at highest risk.[[5]](#footnote-6)

Further, VIFM autopsy blood analysis of driver fatalities has shown that over the last decade, THC is detected in approximately 15 per cent of driver road deaths in Victoria. This figure may be conservative on the rate of THC in all Victorian road trauma as it does not include other road users (passengers, other drivers, pedestrians) who may have been killed in crashes involving drivers with THC detected. This figure does not exclude multi-substance cases, for example, alcohol and THC. In addition, an Australian Institute of Health and Welfare survey from 2020 indicates that in 2019, roughly 12 per cent of Victorians aged over 14 self-reported use of cannabis in the previous 12 months.[[6]](#footnote-7) This might be taken to indicate a proportional rate of THC in post-mortem autopsies. However, it remains the case that odds culpability studies referenced in the above paragraph show that there is an increased collision risk when THC is present.

In terms of impairing substances found in autopsy blood analysis, THC is second to methamphetamine, and roughly equal to alcohol.

Blood analysis is the standard method for estimating THC impairment, however, there are a number of confounding factors that may impact on assessments of impairment. These factors include naïve vs regular consumers of THC and individual sensitivity. While these individual differences are of interest to medical practitioners in terms of case management, it is not feasible to account for the range of individual reactions to specific substances in the context of a mass screening general deterrence drug driving program.

### CBD and driving

Several common medicinal cannabis products contain cannabidiol (CBD), which is a non-psychoactive form of cannabis. The current scientific evidence on CBD indicates that it is not impairing. However, high-dose CBD products may contain small amounts of THC. Further research needs to be undertaken on CBD.

CBD is not the focus of this report, nor is it a prescribed illicit drug under the 2003 legislative amendments to the *Road Safety Act 1986*.

# Key insights of the Working Group

### There were divergent views within the Working Group

A central question that the Working Group sought to address was the fairness of the application of existing drug driving laws to medicinal cannabis patients balanced against the potential road safety risk to all Victorian road users. A range of perspectives were raised throughout Working Group discussions. These were centred around the fundamental questions about the extent to which medicinal cannabis patients can drive in the context of the current Victoria Police roadside drug testing program, the available evidence on road safety risk associated with medicinal cannabis, and whether the drug testing program can be amended to better accommodate medicinal cannabis patients should they test positive at the roadside saliva test or in a post-collision blood sample analysis.

Some members considered that there is no road safety risk associated with medicinal cannabis products. As such, they believed that medicinal cannabis patients should not be subject to sanctions associated with testing positive to THC at the roadside.

Other members held the view that there is research evidence showing the road safety risks associated with medicinal cannabis products.

These conflicting views could not be reconciled within the context of the Working Group. As a result, the Working Group did not reach a consensus on an approach for managing medicinal cannabis patients at a roadside drug test, and therefore, does not make specific recommendations on point-of-detection processes. Further research into road safety risks associated with medicinal cannabis would clarify this issue.

The Working Group did reach agreement on the critical role of point-of-prescription processes in the form of a decision tree support tool. This would provide medicinal cannabis patients and their medical practitioners with better information around when they may be impaired, and when they may be likely to test positive at a roadside drug test.

The Working Group heard evidence that if a patient was to consume an approved medicinal cannabis product as prescribed, and had considered factors such as not driving immediately after consumption and not taking it alongside other substances, the likelihood of testing positive to a roadside drug test would be lower.

### Medicinal cannabis is a unique prescription drug

During the course of Working Group discussions, some members raised the issue of relativity with other prescription drugs. The Terms of Reference outlined that the Working Group is not tasked with investigating wider prescription drug driving issues, however, it did give consideration to any generic prescription related issues that arose.

Noting the limited scope outlined in the Terms of Reference, the Working Group heard that there are several reasons for treating medicinal cannabis as a unique prescription drug. These include that:

* + THC, which has been reported to be used recreationally by 12 percent of Victorians[[7]](#footnote-8), is detected in autopsies of road deaths to a greater extent than other prescription drugs;
  + THC is used recreationally by a larger number of Victorians in comparison to other recreational drugs and other prescription drugs used recreationally, which likely explains its higher rate of involvement in road crashes; and
  + it is not possible to distinguish between recreational and medicinal cannabis-based THC when analysing oral fluid samples at the laboratory.

### Management of medicinal cannabis patients and driving varies in other jurisdictions

The Working Group considered how medicinal cannabis is managed in other jurisdictions in order to assess whether those approaches could be applied in the Victorian context. To assist with this, MUARC provided a report on overseas experience in managing medicinal cannabis patients and driving (Appendix H). The DH paper (Appendix E) and ‘*Potential approaches to THC detection at the roadside*’ report prepared by a consultant (Appendix C) also provided context about processes in other jurisdictions to the Working Group.

The MUARC report assisted the Working Group in identifying the key issues to be considered by describing medicinal cannabis and driving laws adopted overseas. This included reviewing prescription processes, the type of medicinal cannabis products prescribed, the current Victorian drug driving testing process compared with those used overseas, and risk mitigation strategies.

The report identified that there is no universal approach to managing medicinal cannabis and driving. In some European jurisdictions such as Germany and Switzerland, the explicit aim is to mitigate road safety risk in their approach to managing drivers consuming medicinal cannabis. Other jurisdictions, including Canada and individual states in the United States of America, have different approaches that are based on their particular legislative framework and specific roadside testing technology and processes. This makes it difficult to compare these jurisdictions with Victoria.

The report prompted the Working Group to consider solutions and structures that minimise risk, such as case-managed medical assessment and fitness to drive processes.

Most Australian jurisdictions test for THC in mass screening, presence-based roadside drug driving programs similar to Victoria. Overseas jurisdictions have various technical approaches and testing levels. In general, overseas jurisdictions do not undertake mass screening programs similar to those in Australia.

The DH paper (Appendix E) looked at jurisdictions that had tightly controlled prescription-only access pathways for medicinal cannabis, which were comparable to the Australian medicinal cannabis access framework – the United Kingdom, New Zealand, Norway, Germany, and Ireland. In all of these jurisdictions a 'medical defence’ had been implemented to enable legitimate medicinal cannabis patients to drive by ensuring they would not be found guilty of a drug driving offence due to the presence of THC in their system, if they were not impaired and were using the drug as directed. The report also noted that a medical defence is already available for medicinal cannabis patients in Tasmania, and that a medical defence exists for other drugs that can be prescribed and are covered by presence offences (for illicit use) such as morphine in New South Wales and amphetamine in the Northern Territory.

Advice provided by MUARC showed that the different European jurisdictions mentioned above have a range of approaches to medical defence for medicinal cannabis patients. In these jurisdictions, all drivers require blood analysis to determine impairment (noting jurisdictions apply different THC impairment thresholds), and fitness to drive assessments before a medical defence can be considered. Blood analysis and fitness to drive assessments may be undertaken at the driver’s cost. In all jurisdictions, a medical defence is not available if the driver is impaired. Further information is provided in the table below.

*Table 1: Selection of European jurisdictions with a medical defence for medicinal cannabis drivers*

|  |  |  |
| --- | --- | --- |
| European jurisdictions with a medical defence | Medical conditions where medicinal cannabis is prescribed | Conditions for medical defence |
| Ireland | Narrow – 3 specific conditions only (epilepsy, nausea and vomiting caused by chemotherapy, and multiple sclerosis) | Must not be impaired.  Extensive impairment testing, including blood and fitness to drive testing. |
| United Kingdom | Narrow – primarily 3 conditions (epilepsy, nausea and vomiting caused by chemotherapy, and multiple sclerosis) | Must not be impaired.  Based on THC levels in blood and evidence of being a medicinal cannabis patient (“CanCard”). |
| Norway | Broad – determined by physician as required | Must not be impaired.  Impairment testing includes blood and fitness to drive testing. |
| Germany | Broad – any conditions where the patient has not responded to standard treatment and is ‘seriously ill’ | Must not be impaired.  Extensive impairment testing, including blood and fitness to drive testing. |

### Point-of-prescription processes can be improved

The Working Group concluded that focussing on the prescription process offers an opportunity to assist medicinal cannabis patients to drive safely. If a patient complies with better evidence-based advice from their medical practitioner, they will be able to make better informed decisions about driving safely while taking medicinal cannabis and will also be less likely to test positive for THC at the roadside.

The Working Group developed a detailed decision tree support tool for medical practitioner and patient use at the point-of-prescription and in follow-up reviews. The decision tree support tool can be found in section five.

The decision tree sets out a consistent and coherent framework that enables medical practitioners and patients to work through the key issues and considerations in a systematic manner to determine whether an individual patient can drive safely. The decision tree fills a current gap within the existing AFTD guidelines, as these guidelines do not explicitly cover or reference medicinal cannabis.

# Managing medicinal cannabis patients at the point-of-prescription

### Potential approaches to point-of-prescription

The Working Group heard anecdotal evidence that medical practitioners had difficulty accessing information on the impact of medicinal cannabis products, including their effect on safe driving and likelihood of the detection of medicinal cannabis products containing THC under the mass screening roadside drug testing program.

As medicinal cannabis is not covered under the current AFTD guidelines, the Working Group considered a range of approaches to support medical practitioners in providing consistent and evidence-based advice regarding the safe driving and fitness to drive requirements of patients using medicinal cannabis products.

The Working Group considered two broad categories of approach with various levels of formalised advice for managing medicinal cannabis patients at the point-of-prescription:

1. A low level of intervention
2. A higher level of intervention

Approach 1 – a low level of intervention

A low level of intervention would be centred around assisting prescribing medical practitioners to provide appropriate advice to medicinal cannabis patients regarding assessing fitness to drive. At this level of intervention, medical practitioners would be provided with generic advice, for example, in the form of fact sheets, regarding medicinal cannabis and safe driving that may not be widely known.

This approach would result in a greater level of awareness of this issue amongst prescribing practitioners and may provide some confidence when advising patients on safe driving. This advice could, for example, point to the need for practitioners to consider confounding factors that may increase road safety risk, such as the combination of alcohol and THC.

#### *Key considerations and risks*

This approach may not adequately address road safety risk as it does not account for a patient’s individual circumstances, including underlying medical conditions, dosages of medicinal cannabis products and other medications being prescribed. Further, advice on THC in this form may not be regularly updated with current information which may result in outdated information being provided to patients. As a result, this approach may not provide a high level of confidence to medicinal cannabis patients about whether they can safely drive after consuming their prescribed dose, particularly if patients change the timing and dosage of their prescription, which could impact on decisions around safe driving.

Approach 2 – a higher level of intervention

A higher level of intervention would be centred around providing comprehensive and up-to-date advice to medical practitioners in order to assess their patient’s fitness to drive. This would support a more detailed case-by-case approach which considers an individual patient’s underlying medical conditions, dosage and other medications being prescribed. This approach may provide a higher level of confidence to patients when considering their ability to drive safely.

The Working Group considered options with differing levels of intervention, including providing medical practitioners with a standardised format for assessing a patient’s fitness to drive, and a more detailed assessment framework, for example, an online form completion process.

An option that could be considered for early implementation is a tool that prescribing practitioners can use to systematically approach this issue. The Working Group discussed the key components and decision points of this option.

This option would have multiple benefits, including for:

* the medicinal cannabis patient

It would raise awareness regarding product use, including the impact of timing and dosage on driving (especially for patients who drive for work), reduce individual driving impairment risk, potentially reduce likelihood of roadside detection and provide clarity on individual driving parameters.

* the prescriber

It would provide easy to access evidence-based information, support consistency of information provision/practice and facilitate regular and ongoing fitness to drive review and management.

* the Victorian community

It would reduce road safety risk to the driver and other road users and provide overall confidence around use of medicinal cannabis within the context of driving.

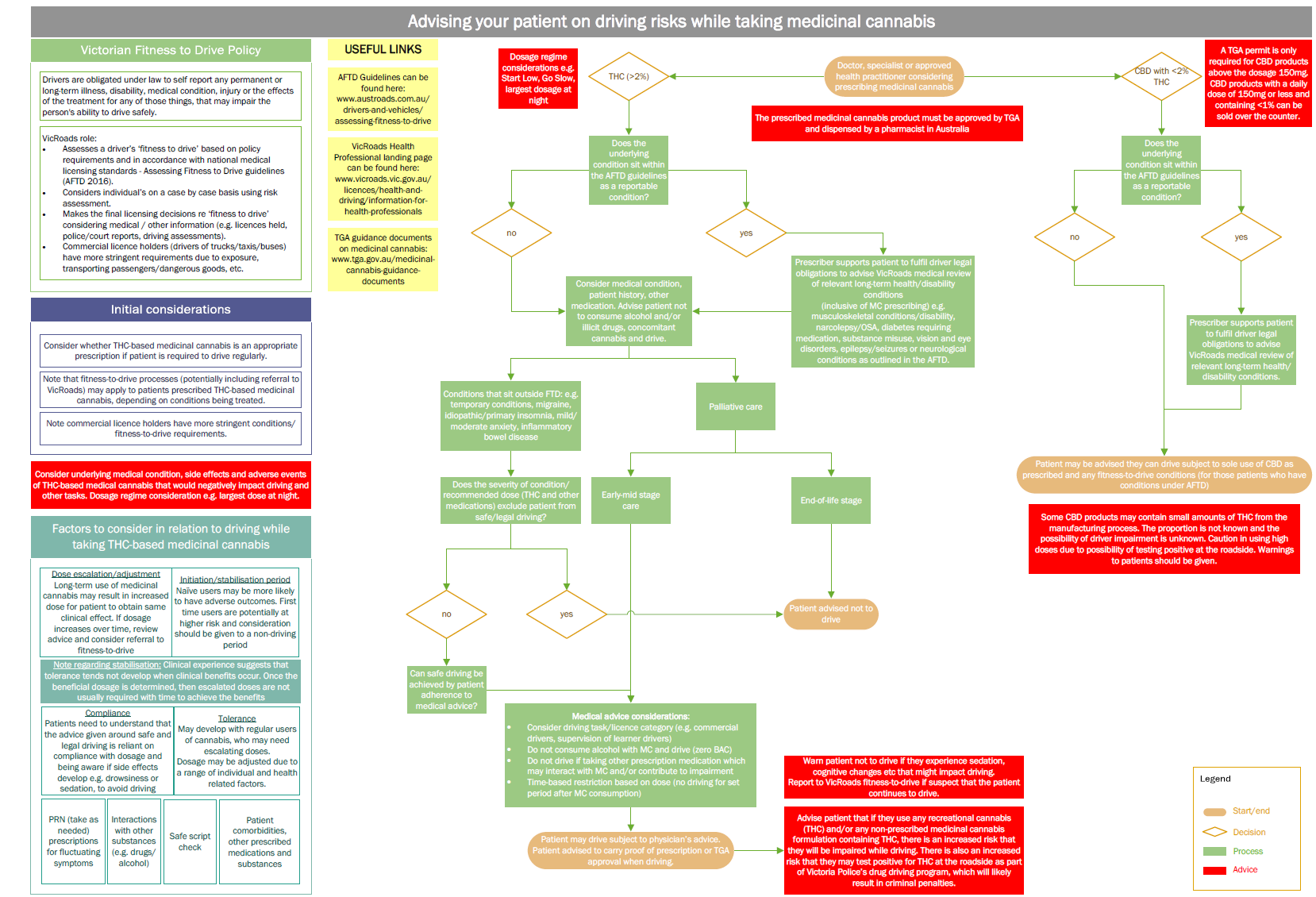
A decision tree support tool has been developed by the Working Group

The Working Group developed a decision tree support tool (Figure 2) for prescribing practitioners to work through a clear and logical pathway to determine their patient’s fitness to drive. This tool is similar to tools currently used by medical practitioners, such as the AFTD guidelines. The decision-tree support tool is not intended to replace any current process already followed by medical practitioners regarding TGA and non-TGA assessments. It is important to note that the decision tree support tool provided in Figure 2 is a draft and is subject to review and feedback from peak medical bodies.

#### *Key considerations and risks*

A key consideration is the extent to which prescribing practitioners would find this approach a practical and useful tool, as well as potential blockages to widespread use of the tool. The decision tree support tool would benefit from socialisation with relevant peak medical bodies, including the Australian Medical Association, the Royal Australian College of General Practitioners, the Australian College of Rural and Remote Medicine, the Pharmaceutical Society of Australia and peak nursing groups in order to seek further comment and to assist with communication and engagement. Implementation of this support tool would require a communications strategy to ensure uptake of the tool by prescribing practitioners. The Transport Accident Commission (TAC) can work with DoT to develop a strategy that targets prescribing practitioners, and ensure relevant information is provided.

Concerns were raised in the Working Group about the cost to a patient for a longer consultation, which may be required for medical practitioners to provide comprehensive advice on safe driving issues.



*Figure 2.*

# Managing medicinal cannabis patients at the point-of-detection

### Current process for point-of-detection

The current process provides for high volume roadside testing of drivers for the presence of THC, methamphetamines and methylenedioxymethamphetamine (MDMA) and is a three-stage process. Currently, Victoria Police annually undertakes 150,000 roadside drug tests.

*Table 2: Victoria Police roadside saliva testing process*

|  |  |  |
| --- | --- | --- |
| Stage | Process | Timeframe |
| One | A preliminary saliva test is conducted while the driver remains in the vehicle. Victoria Police data shows that the presence of a drug is detected in approximately 8-10 per cent of preliminary saliva tests. | Approximately 5 minutes |
| Two | Where the preliminary saliva test indicates the presence of a drug, a second saliva sample is obtained in a police alcohol and drug testing bus or police patrol vehicle at the same location. | Approximately 30 – 40 minutes |
| Three | Where the second sample indicates the presence of a drug, a portion of the second sample is delivered to a laboratory for confirmatory analysis, which ensures the exclusions of false positives (which occur in 3 – 4 per cent of tests) arising from technical limitations of the roadside device. When the laboratory analysis confirms a drug is present, the driver is prosecuted. When the offence is a first offence, the driver may be issued with an infringement notice. | 1 – 2 weeks |

This is a relatively non-invasive sampling process which can be easily carried out by police, and is completed at the roadside in approximately 30 minutes for a positive detection. In addition, there is no process or legislative change required. As this is an existing process, there are no new resource implications for the police, courts, or the forensic services provided by the VIFM. Victoria Police is currently investigating whether this process can be refined.

#### *Impact on medicinal cannabis patients*

If a patient is compliant with their medicinal cannabis prescription and advice provided by their prescribing medical practitioner, they should be at a low risk of testing positive to THC at the roadside. However, continuation of this process means these patients would still be subject to a drug-driving offence if they test positive to THC, which may result in patients being advised or choosing not to drive, noting that the Working Group heard evidence that most patients in Victoria take medicinal cannabis multiple times a day.

Where a medicinal cannabis patient does test positive to THC, authorities must consider the possibility that they have also consumed THC outside of their prescribed dose – either additional medicinal cannabis or recreational cannabis.

The unfairness of this approach for medicinal cannabis patients compared to drivers consuming other prescription medication was raised by members of the Working Group as a key concern.

#### *Impact on road safety*

Noting the limitations of current detection/screening technology, a mass saliva screening presence-based process is required to deliver the test numbers necessary to achieve a general deterrence drug driving program.

### Potential alternative approaches to point-of-detection

Approach 1 – Drug Impairment Assessment

This approach is a variation of the existing Drug Impairment Assessment (DIA) process. This process is a structured and systematic procedure to identify drug impairment and is used for other impairing drugs, including benzodiazepines and opioids.

An initial roadside assessment involves undertaking a saliva drug test and an alcohol breath test. If the driver tests negative to these two tests, physical impairment tests are undertaken. These tests must be undertaken by specially trained police at a police station and are video recorded. Where the physical impairment tests indicate a driver is impaired, a Forensic Medical Officer is required to attend the police station and obtain a blood sample from the driver for laboratory analysis.

Where the laboratory analysis identifies a known impairing drug, and behaviour analysis indicates that the driver is impaired by the identified drug, a *Driving While Impaired* offence is pursued at court. There is no option for an infringement notice to be issued within this process.

This approach could be made available exclusively to medicinal cannabis patients who test positive to THC at the roadside, as it directly addresses the question of impairment raised by the Working Group.

#### *Impact on medicinal cannabis patient*

The DIA process is a lengthy process that can take up to six hours. The process must be carried out by a specially trained and authorised police officer in a controlled environment, such as a police station, and in circumstances where a video recording can be made. As such, the process cannot be completed at the roadside. This means that the driver must be transported to a police station to carry out the DIA, and in some circumstances be transported to a second location, such as a hospital, to obtain a blood sample. The driver may be detained for up to three hours to complete the testing process and obtain a blood sample, during which time blood concentrations of THC will decline rapidly.

The physical impairment tests may be complicated by the existence of physical or neurological conditions, and it is important to note that that medicinal cannabis patients often have underlying medical conditions. Further, obtaining a blood sample involves an invasive procedure and must be carried out by a Forensic Medical Officer. The Working Group heard evidence that a blood sampling process would be stressful for medicinal cannabis patients.

#### *Impact on road safety*

The DIA process is resource intensive and is not designed for use in a high-volume testing regime. An additional three hours of police time is needed to complete the entire investigatory process. Further, as the DIA process can only be carried out by specially trained and authorised police officers, more than one police patrol unit may be involved in the investigatory process. Due to the complexities involved in carrying out this process, it is rarely used as a standard roadside drug test and is usually only undertaken as part of a post-crash investigation.

Victoria Police has advised the Working Group that a wider adoption of the DIA process would compromise the current high-volume general-deterrence drug driving program due to the significantly increased resource requirements.

Approach 2 – THC level in blood

The second approach would be a new process which endeavours to determine the impairment of a medicinal cannabis patient who tests positive to THC in a saliva test at the roadside. This approach differs from the existing blood test component of the DIA, as it would be based on a yet-to-be determined impairment level of THC in blood, rather than evidence being presented to court on the impairing effects of the measured level.

This new process could be made available to medicinal cannabis patients who test positive to THC in the preliminary and secondary saliva test at the roadside, and who provide evidence that they are a medicinal cannabis patient.

Once the driver is established as a medicinal cannabis patient, police would require a blood sample to be taken. The sample would then be delivered to a laboratory for analysis in line with approach one. Immediately after the blood sample is taken, the driver would not be allowed to drive for a set number of hours, despite the results not yet being confirmed. Where the laboratory analysis result confirms the presence of THC in the blood sample at a level above the prescribed impairment THC level (to be determined), an offence is pursued. If the result is below the prescribed impairment THC level, a presence offence would not be pursued.

Victoria Police would have a duty to confirm the legitimacy of a medicinal cannabis patient at the roadside before engaging this process.

#### *Impact on medicinal cannabis patient*

Similar to approach one, this process may not be able to be completed at the roadside as the driver may need to be transported to another location to obtain a blood sample. The driver may be detained for a considerable time to obtain the blood sample as the sampling must be carried out by a Forensic Medical Officer. Further, obtaining a blood sample involves an invasive procedure. The Working Group heard that a blood sampling process would be stressful for medicinal cannabis patients who already have significant underlying medical conditions.

Currently, there is no scientific consensus on what a THC impairment level in blood should be. While other jurisdictions such as Norway and the United Kingdom have designated blood levels that are assumed to correspond with impairment, these levels are not universally accepted in the scientific literature. In relation to the United Kingdom, judicial officers must consider whether a driver has taken medicinal cannabis in accordance with their prescription in determining whether an offence is committed. If this is established, a medical defence is available.

Further research is needed to determine what a threshold THC level should be. If a THC level in blood was established, there would be no definitive way for a medicinal cannabis patient to determine whether they might be below or above this impairment level. This may discourage medicinal cannabis patients from driving.

#### *Impacts on road safety*

A wide adoption of this approach would compromise the current high-volume general-deterrence drug driving program due to the significantly increased resource requirements.

This approach would require legislative change to support the process, including amendment to the *Road Safety Act 1986* to facilitate a requirement to obtain a blood sample from a medicinal cannabis patient after testing positive to THC at the roadside. A new offence would likely be legislated together with supporting evidential provisions, for example, ‘exceed prescribed level of THC in blood’.

Consideration would need to be given to designating this offence as an infringeable offence to avoid an increase in court workload. In addition, Victoria Police would require further resources to train police in the operation of a new process and supporting legislative framework.

A wide adoption of this approach would compromise the current high-volume general-deterrence drug driving program due to the significantly increased resource requirements.

Approach 3 – Hybrid approach of existing saliva-based approach and approach 2

The third approach is a hybrid of the existing saliva-based approach and approach two. In this approach, a medicinal cannabis patient would follow the current saliva-based roadside drug testing process. Where a driver tests positive to THC at the secondary roadside saliva test and provides authoritative evidence that they are a medicinal cannabis patient, they would be informed that they may request a blood test which would measure their THC level against a prescribed THC blood level, noting that this level would need to be set based on scientific evidence. Where the blood sample result exceeds the prescribed THC level, an offence is pursued.

This approach differs from approach two, as it provides patients with the option to undergo a blood test, as opposed to a compulsory blood test as outlined in approach two. Should the driver not wish to pursue the option of a blood test, they would be processed based on the positive roadside saliva test.

This approach does not require legislative amendment to cover a new process, however, it would require legislative amendment to create a new offence to support the process.

#### *Impact on medicinal cannabis patient*

The same issues around time, resources, lack of an agreed impairment level in blood and invasiveness of a blood test that are described in approach two would apply to this approach.

#### *Impact on road safety*

This approach may compromise the current high-volume general-deterrence drug driving program due to members being diverted from the roadside to facilitate the driver undergoing a blood sample test.

Victoria Police would require further resources to train police in the operation of a new offence and supporting legislative framework. Consideration would also need to be given to designate this offence as an infringeable offence to avoid an increase in court workload.

Approach 4 – Medical defence or exemption

A medical defence is an extension of an existing mechanism available for all drivers prosecuted under the DIA process outlined in approach one.

The medical defence mechanism would allow a driver detected with a prescribed drug to be exempt from a drug driving offence if they can prove that they have been compliant with their prescription at court.

This approach could be extended to be a medical exemption for medicinal cannabis patients who test positive to the presence of THC at a roadside saliva test and provides evidence at the roadside that they are a medicinal cannabis patient.

A medical defence or exemption approach may be structured to include other conditions, such as zero BAC.

A medical defence or exemption process exists in other jurisdictions, for example, the United Kingdom. Some jurisdictions have different approaches to this process, which may include a medical defence or exemption that are dependent on underpinning legislation and the detection method employed.

#### *Impact on medicinal cannabis patient*

This approach would provide confidence to medicinal cannabis patients that they can drive without risk of being charged with a positive THC detection.

#### *Impact on road safety*

The main concern around the use of a medical defence/exemption is that it would not address the road safety risk of THC if applied to roadside saliva presence-based testing.

In addition, the defence may be abused by drivers who are consuming more than their prescribed dose of medicinal cannabis, and also those who are ‘topping up’ with recreational cannabis. It is not possible to differentiate between medicinal and recreational THC at laboratory analysis as it is the same substance.

A medical exemption at the roadside may also create liability for Victoria Police in terms of allowing drivers that may be a road safety risk to themselves and other road users to remain on the road. Other causes of road safety risk apart from THC would still need to be managed at the roadside, for example, drink driving and other illicit drug use.

Comparison of potential approaches

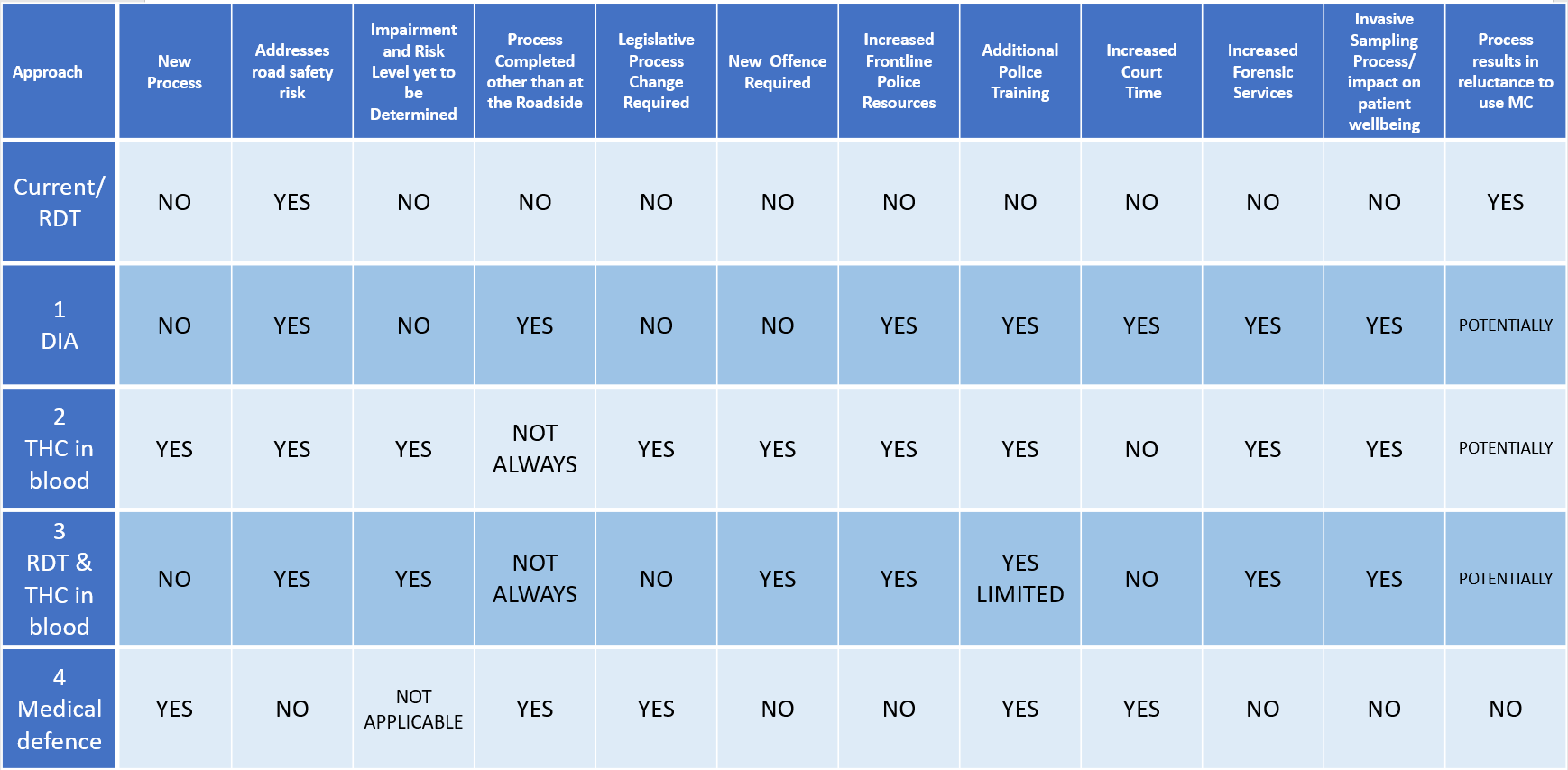
The factors relevant to the operation of the current process and the four new potential approaches are compared in the table below. It should be noted that all of the potential new approaches will require a systematic process for identifying medicinal cannabis drivers at the roadside.

Some Working Group members raised concerns that additional public health related issues should also be more explicitly considered, including significant patient harms associated with the current regulatory approach, such as:

* excluding seriously ill patients that have not responded to other medicines from accessing medicinal cannabis and associated therapeutic benefits,
* excluding seriously ill medicinal cannabis patients from car use and associated mobility, with impacts on access to basic services, healthcare, and social/vocational activities, and
* potential criminal charges being laid against medicinal cannabis patients who need to drive and are not impaired and using the drug as directed by their doctor.

Other Working Group members emphasised the road safety risks potentially associated with medicinal cannabis and driving, including:

* limited research specifically on medicinal cannabis and road safety risk,
* the known impairing risk of recreational THC,
* the potential for abuse of a special scheme to manage medicinal cannabis patients by recreational cannabis users due to the inability to differentiate between medicinal cannabis and recreational cannabis, and
* balancing the harms to the Victorian community by weakening the mass screening general deterrence drug driving regime with the harms accruing to individual medicinal cannabis patients who may have difficulty accessing driving.

*Table 3: Comparison of the potential approach factors*

# Options for further consideration

The Working Group did not reach consensus on a clear way forward due to divergent perspectives on policy priorities. However, it did identify a framework to guide decision-making on medicinal cannabis and safe driving. The framework is intended to mitigate medicinal cannabis patients driving unsafely by establishing a more effective point-of-prescription process. It also reduces the likelihood of a medicinal cannabis patient testing positive to THC at a roadside drug test.

This framework allows initial work to commence on point-of-prescription issues, specifically the development of a decision tree support tool, as for example set out in figure 2, that will allow medical practitioners to consider their patient’s fitness to drive in a logical and consistent way. Consideration could be given to the development of an interactive, online version of this tool that supports prescribing practitioners in the long-term.

Implementation of any of these approaches is likely to require government funding. A main funding consideration is further resourcing to increase the ability of Victoria Police to maintain testing levels if introducing a more time-consuming process, as well as potentially increased ancillary costs such as more callouts of forensic officers. These costs have not been quantified at this time but may be significant depending on the chosen approach.

Further work for point-of-prescription and point-of-detection processes may consider the following areas:

* research
* engagement with medical groups
* legislation
* communications.

### Research

While there were differing views amongst the Working Group about the ability of further research on medicinal cannabis to bring clarity on outstanding issues, some members expressed the view that further research is necessary to better inform policy in this area.

The Victorian Government is currently funding two research projects on medicinal cannabis and driving, which are outlined below.

1. MUARC has commenced a pharmaco-epidemiological study of medicinal cannabis use and driving among Victorian adults. The study includes:

* collating data on Victorian prescriptions from the DH to develop an understanding of the demographics of Victorian patients, and
* interviews with a cross-section of patients to investigate the range of issues that may impact safe driving.

MUARC has flagged a potential further stage of this study which would involve a driving simulator-based assessment of the driving performance of medicinal cannabis patients who have consumed their prescription.

1. DoT has contracted the Swinburne University of Technology to complete a study on the effectiveness of the current roadside screening devices in detecting medicinal cannabis products and to improve understanding of formulations and amounts.

A possible area for future research would be investigating an increase in the threshold for reporting levels of THC in saliva samples analysed at VIFM. The input of scientific experts in the drug impairment field could be sought to inform this research. Currently, VIFM does not report a positive THC finding in the saliva sample unless it is greater than 13ng/mL (13 billionths of a gram in a millilitre). This level was set based on the then Australian Standard for the laboratory reporting of THC in saliva of 10ng/mL, with an additional buffer. Increasing this threshold could result in low level THC detections, which may include low level medicinal cannabis readings being excluded from the formal drug detection certificate. This certificate, provided by VIFM, is the basis for a drug driving offence.

A potential risk of increasing the threshold would be that some impaired drivers with low detected levels of THC would also be excluded. This risk, along with other scientific unknowns, would need to be investigated before policy implications can be considered.

The Working Group heard that research in the following areas could assist the government to better understand implications of the approaches set out in this report:

* A research study following a number of medicinal cannabis patients, which could include tracking their driving habits and crash rates.
* A study to establish where a blood THC threshold should be set to underpin a new offence of exceeding a prescribed concentration of THC (analogous to 0.05 BAC).

### Engagement with medical groups

The Working Group heard evidence from the medical practitioner member of the importance of engaging more widely with peak medical bodies. This would ensure that point-of-prescription processes are well-designed to support prescribing practitioners and medicinal cannabis patients in making informed decisions about driving.

The Working Group heard that an engagement outreach to the Australian Medical Association, the Royal Australian College of General Practitioners and other medical specialist associations would offer an opportunity to add significant value to this policy approach.

Other key industries identified by the Working Group that could be consulted are the Insurance Council of Australia and the Medical Indemnity Industry Association of Australia, as there may be liability issues with medical practitioners advising patients they are safe to drive following the consumption of their medicinal cannabis dose containing THC.

### Legislation

This report presents key data, facts and evidence presented to the Working Group around the central issues on medicinal cannabis and safe driving. These can be considered in the context of further debate on the Bill introduced into the Legislative Council by Ms Patten.

Noting the pending Bill, the issues described in the point-of-detection section can inform further debate on legislative changes, including the operational structures, processes and risks inherent in any proposed new legislative approach.

### Communications

A communications strategy aimed at prescribing practitioners, developed in consultation with peak medical groups, may offer value in encouraging the use of a decision tree support tool at the point-of-prescription.

# Appendices

### Reports/papers provided by Working Group

The Working Group provided the following documents which are included as appendices below.

* Working Group Terms of Reference (Appendix A)
* DoT advice – Assisting health professionals at point-of-prescription and obligations for Fitness to drive (Appendix B)
* Consultant report – Potential approaches to THC detection at the roadside (Appendix C)
* MUARC paper – Evidence on the crash risk associated with THC (Cannabis) and implications for users of medicinal cannabis, including reference list of scientific literature (Appendix D)
* DH report – Medicinal Cannabis and Driving: Issues paper (Appendix E)
* VIFM report – Medicinal Cannabis and Driving (Appendix F)
* DJCS paper – background information for working group (Appendix G)
* MUARC report – International and Australian experience of medicinal cannabis programs with respect to driving and road safety (Appendix H)

# Document information

Document details

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Audience

The audience for this document is the Minister for Police and Emergency Services and the Minister for Roads and Road Safety to assist the government to consider approaches on managing medicinal cannabis and safe driving in Victoria.

1. Peng et al 2020, cited in Attachment E [↑](#footnote-ref-2)
2. VIFM Report, Medicinal Cannabis and Drug Driving, February 2021 (Appendix F) [↑](#footnote-ref-3)
3. See reference in Appendix D [↑](#footnote-ref-4)
4. See reference in Appendix D [↑](#footnote-ref-5)
5. VIFM Report, *Medicinal Cannabis and Drug Driving*, February 2021 (Appendix F) [↑](#footnote-ref-6)
6. Australian Institute of Health and Welfare, *Alcohol, tobacco & other drugs in Australia*, https://www.aihw.gov.au/reports/alcohol/alcohol-tobacco-other-drugs-australia/contents/interactive-data/illicit-drugs [↑](#footnote-ref-7)
7. Australian Institute of Health and Welfare, *Alcohol, tobacco & other drugs in Australia*, https://www.aihw.gov.au/reports/alcohol/alcohol-tobacco-other-drugs-australia/contents/interactive-data/illicit-drugs [↑](#footnote-ref-8)