Assisting medicinal cannabis patients to drive safely

Report of the Medicinal Cannabis and Safe Driving Working Group

February 2021

VICTORIA State Government | Justice and Community Safety

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1. 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.

2. 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.

3. 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.

4. 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.

2. Current prescription approach and current drug-detection processes in Victoria

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

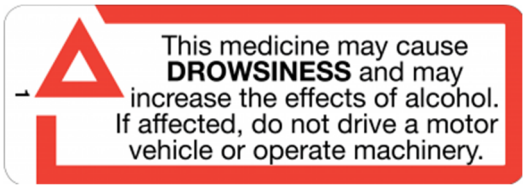
Medicinal cannabis products, like other medications, can be prescribed by any medical practitioner in Victoria to treat any patient if the medical practitioner believes it will provide clinical benefit. Most commonly, Schedule 8 medicinal cannabis products (containing >2 per cent THC) are commonly prescribed 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]

[1] Peng et al 2020, cited in Attachment E

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.

3. 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]. 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].

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].

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

[2] VIFM Report, Medicinal Cannabis and Drug Driving, February 2021 (Appendix F)

[3] See reference in Appendix D

[4] See reference in Appendix D

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]

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] 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*.

4. 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

[5] VIFM Report, *Medicinal Cannabis and Drug Driving*, February 2021 (Appendix F)

[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

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], 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*

[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

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	Must not be impaired.

	caused by chemotherapy, and multiple sclerosis)	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.

5. 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.

Advising your patient on driving risks while taking medicinal cannabis

Victorian Fitness to Drive Policy

Drivers are obligated under law to self report any permanent or long-term illness, disability, medical condition, injury or the effects of the treatment for any of those things, that may impair the person's ability to drive safely.

VicRoads role:

- Assesses a driver's 'fitness to drive' based on policy requirements and in accordance with national medical licensing standards - Assessing Fitness to Drive guidelines (AFTD 2016).
- Considers individual's on a case by case basis using risk assessment.
- Makes the final licensing decisions re 'fitness to drive' considering medical / other information (e.g. licences held, police/court reports, driving assessments).
- Commercial licence holders (drivers of trucks/taxis/buses) have more stringent requirements due to exposure, transporting passengers/dangerous goods, etc.

Initial considerations

Consider whether THC-based medicinal cannabis is an appropriate prescription if patient is required to drive regularly.

Note that fitness-to-drive processes (potentially including referral to VicRoads) may apply to patients prescribed THC-based medicinal cannabis, depending on conditions being treated.

Note commercial licence holders have more stringent conditions/ fitness-to-drive requirements.

Consider underlying medical condition, side effects and adverse events of THC-based medical cannabis that would negatively impact driving and other tasks. Dosage regime consideration e.g. largest dose at night.

Factors to consider in relation to driving while taking THC-based medicinal cannabis

<u>Dose escalation/adjustment</u> Long-term use of medicinal cannabis may result in increased dose for patient to obtain same clinical effect. If dosage increases over time, review advice and consider referral to fitness-to-drive	<u>Initiation/stabilisation period</u> Naïve users may be more likely to have adverse outcomes. First time users are potentially at higher risk and consideration should be given to a non-driving period

<u>Note regarding stabilisation:</u> Clinical experience suggests that tolerance tends not develop when clinical benefits occur. Once the beneficial dosage is determined, then escalated doses are not usually required with time to achieve the benefits

<u>Compliance</u> Patients need to understand that the advice given around safe and legal driving is reliant on compliance with dosage and being aware if side effects develop e.g. drowsiness or sedation, to avoid driving	<u>Tolerance</u> May develop with regular users of cannabis, who may need escalating doses. Dosage may be adjusted due to a range of individual and health related factors.

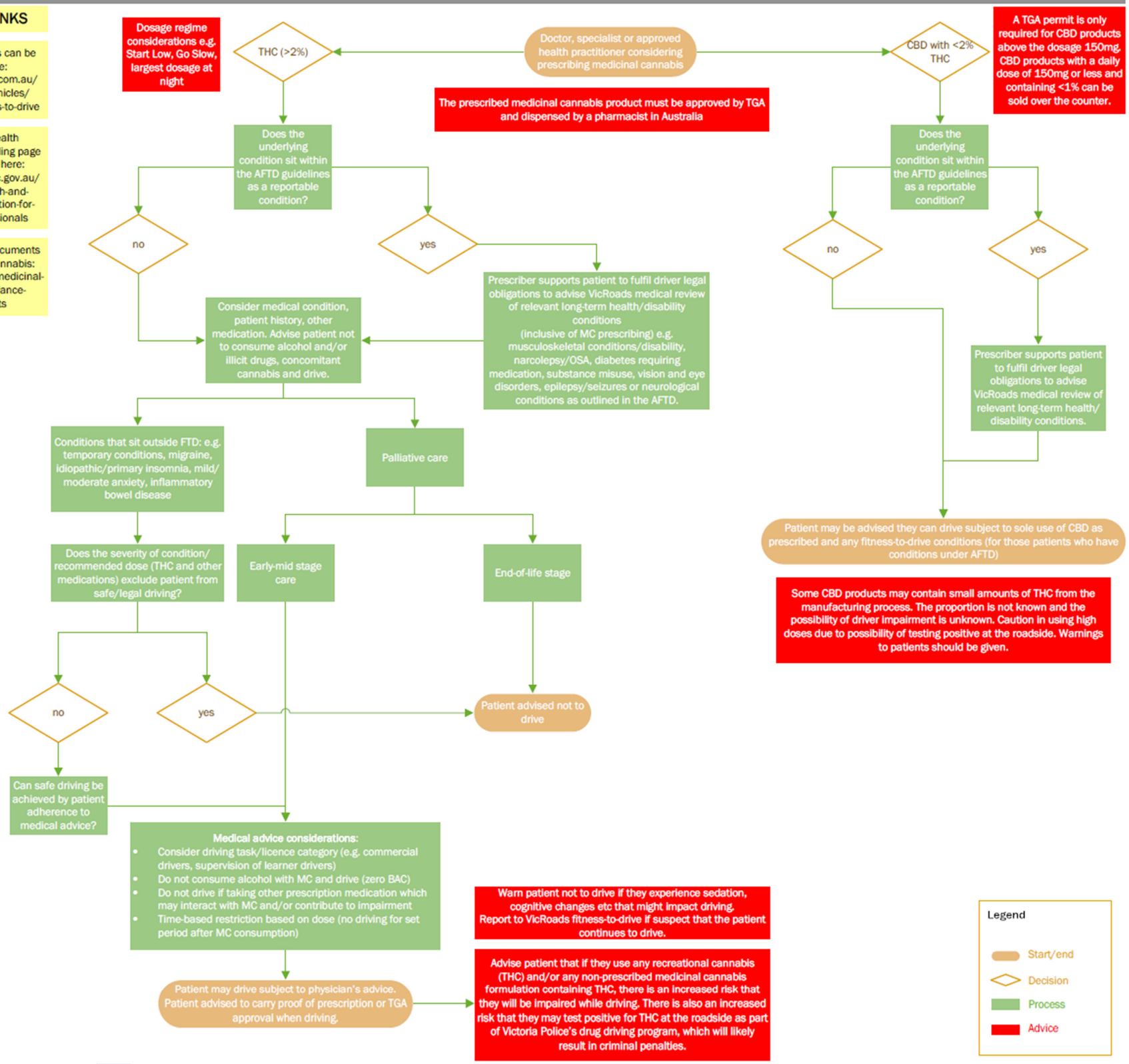
PRN (take as needed) prescriptions for fluctuating symptoms	Interactions with other substances (e.g. drugs/ alcohol)	Safe script check	Patient comorbidities, other prescribed medications and substances

USEFUL LINKS

AFTD Guidelines can be found here: www.austroads.com.au/drivers-and-vehicles/assessing-fitness-to-drive

VicRoads Health Professional landing page can be found here: www.vicroads.vic.gov.au/licences/health-and-driving/information-for-health-professionals

TGA guidance documents on medicinal cannabis: www.tga.gov.au/medicinal-cannabis-guidance-documents



VICTORIA State Government | Justice and Community Safety

6. 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

Approach	New Process	Addresses road safety risk	Impairment and Risk Level yet to be Determined	Process Completed other than at the Roadside	Legislative Process Change Required	New Offence Required	Increased Frontline Police Resources	Additional Police Training	Increased Court Time	Increased Forensic Services	Invasive Sampling Process/ impact on patient wellbeing	Process results in reluctance to use MC
Current/ RDT	NO	YES	NO	NO	NO	NO	NO	NO	NO	NO	NO	YES
1 DIA	NO	YES	NO	YES	NO	NO	YES	YES	YES	YES	YES	POTENTIALLY
2 THC in blood	YES	YES	YES	NOT ALWAYS	YES	YES	YES	YES	NO	YES	YES	POTENTIALLY
3 RDT & THC in blood	NO	YES	YES	NOT ALWAYS	NO	YES	YES	YES LIMITED	NO	YES	YES	POTENTIALLY
4 Medical defence	YES	NO	NOT APPLICABLE	YES	YES	NO	NO	YES	YES	NO	NO	NO

7. 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.
2. 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.

8. 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)

9. Document information

Document details

Criteria	Details
TRIM ID:	
Document title:	Assisting medicinal cannabis patients to drive safely
Document owner:	DJCS

Version control

Version	Date	Description	Author
1.0		Report of the Medicinal Cannabis and Safe Driving Working Group	DJCS

Document approval

This document requires the following approval:

Name	Title	Organisation

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.

Appendix A: Terms of Reference

Medicinal Cannabis and Safe Driving Working Group

Terms of Reference

VICTORIA State Government | Justice and Community Safety

Table of contents

1. Introduction

The Medicinal Cannabis and Safe Driving Working Group (MCSDWG) is tasked with reviewing the existing evidence on the road safety risks and impairment effect on driver behaviour associated with medicinal cannabis use in Victoria, and investigating potential options that may allow conditional access to driving for legitimate medicinal cannabis patients. The term patient is used to describe those with a valid prescription for medicinal cannabis as it is legally prescribed by doctors to treat a wide range of medical conditions.

The Working Group is tasked with ensuring that any new approach is not detrimental to road safety, and that the integrity of the Victorian drug driving program in tackling impaired driving related road trauma is preserved.

The Victorian Government is already undertaking research projects on the impairment effect of medicinal cannabis and road safety, including assessing the experience of overseas jurisdictions who have similar drug driving prohibitions and enforcement programs as well as medicinal cannabis programs. This research will inform the Working Group's considerations.

The Working Group will provide a final report that examines the feasibility and evidence base to enable drivers in Victoria who are legally prescribed medicinal cannabis to drive safely.

On 14 October 2020, Minister Leane restated the government's commitment to Ms Patten that it is very keen to work with her on this particular issue to ensure people are not disadvantaged by taking medicinal cannabis.

2. Scope

The Working Group will consider:

Evidence regarding road safety risks

1. the existing evidence of the effect or otherwise of medicinal cannabis on a person's ability to drive safely, including the scientific evidence around prescribed medicinal cannabis products, on driving impairment and crash risk
2. the existing evidence of impacts on patient access to a needed medication or loss of mobility

Means to assist medicinal cannabis patients to drive safely

1. designing a licensing system that does not unfairly disadvantage legitimate medicinal cannabis patients, including ways that conditional access to driving for legitimate medicinal cannabis patients can be implemented
2. examining the fitness for purpose of the current system for regulating medicinal cannabis and reducing road safety risk
3. the options available that can assist medical cannabis patients to drive safely, for example a more structured medical assessment approach
4. the issues that would inform the credibility of identified options, such as the impact on safe driving of underlying medical conditions, prescription substances, dosages and timings, and topping up prescriptions with higher dosages or recreational cannabis
5. reviewing processes to determine whether prescribed medicinal cannabis patients are medically fit to drive
6. the positioning of any new approaches within the current drug driving testing process and sanction regime, including any required legislative amendments

7. the implications of a new approach on maintaining the effectiveness of the Victorian drug driving testing program to counter impaired driving

Controls to reduce risk and improve roadside drug driving testing

1. the scope of a potential eligibility criteria for medicinal cannabis patients to access an alternative approach, such as driver offence history, polydrug use, or a zero BAC condition
2. the benefit of other requirements to support ease of roadside identification as a medicinal cannabis patient, such as a valid medical prescription and licence (including the feasibility of a new licensing condition)
3. consideration of the evidentiary standard required to prosecute driver impairment from medicinal cannabis
4. consideration of a bespoke impairment assessment protocol for identifying driver impairment from medicinal cannabis at roadside
5. options to ensure that recreational cannabis users are not able to abuse and/or undermine a medical-based approach to medicinal cannabis and safe driving
6. options to allow robust monitoring and evaluation of any alternative approach.

The Working Group is not tasked with investigating wider prescription drug driving issues, however will give consideration to any generic prescription related issues that arise.

3. Governance

The Working Group will be led by the Department of Justice and Community Safety.

The Working Group will be supported by a Project Team with representation across the road safety agencies, including team leads and research and secretariat staff. The Project Team will report to the Chair.

4. Roles and responsibilities

4.1 Senior Responsible Owner (Working Group Chair)

- Chairing the Working Group
- Providing effective oversight and guidance on the identification of risks and associated option development and ongoing risk management activities
- Ultimate accountability for the realisation of outcomes
- Ensuring the appropriate processes are in place to enable the project to proceed
- Proactively monitor, mentor, challenge and support the Project Team on the project's/program's progress: asking the right questions, offering alternatives and making timely decision
- Approving or endorsing project deliverables, products or certain documents for release

The Senior Responsible Owner also locates replacements for Working Group members who discontinue membership. Membership should be based on individuals' specialist knowledge, their ability to represent stakeholders' interests, and to help resolve issues the project may face.

4.2 Project Team

The Project Team is responsible for:

- Ensuring expertise from across the Road Safety Partnership are engaged so that policy, legislative and operational implications are fully considered

- Coordination of the research and other inputs into the report
- Providing a first draft of the report
- Secretariat support

4.3 Working Group members

Table 1 lists the Working Group members.

Table 1: MDSDIG Members

Organisation	Representative	Title	Role
Department of Justice and Community Safety	Corri McKenzie	Deputy Secretary Police, Fines and Community Safety	Chair/Sponsor
Victoria Police	Elizabeth Murphy	Assistant Commissioner Road Policing	Member
Road Safety Victoria	Robyn Seymour	CEO	Member
Transport Accident Commission	Joe Calafiore	CEO	Member
Department of Health and Human Services	Dr Daniel Perkins	Acting Director, Office of Medicinal Cannabis	Member
Legislative Council	Fiona Patten	MLC	Member
Legislative Council	Harriet Shing	MLC	Member
Victorian Institute of Forensic Medicine	Professor Noel Woodford	Director	Member
Burnet Institute of Health	Professor Paul Dietze	Program Director, Behaviours and Health Risks	Member
Prescribing Medical Practitioner	Vicki Kotsirilos	Doctor	Member
Department of Transport	Paul Salter	Director, Legislative and Regulatory Reform	Member
Department of Transport	Nicole Denton	Director, Road safety Strategy and Policy	Member

Organisation	Representative	Title	Role
Department of Justice and Community Safety	John Katsoulas	Executive Director, Police and Community Safety	Member
Department of Justice and Community Safety	Simon Grieve	Director, Road Safety	Member

Project Team members are:

DJCS: [redacted]
DoT: [redacted]
Victoria Police: [redacted]
TAC [redacted]
DHHS: [redacted]

The co-leads are the Project Team contacts.

5. Administrative arrangements

This section outlines the Working Group decision-making process, frequency of meetings, requirements for agendas, minutes and papers requiring decisions, and rules for proxies.

5.1 Quorum

All Working Group members or their proxies are required for decision-making purposes.

5.2 Decision-making process

The Working Group will make decisions by agreement. If the Working Group cannot come to an agreement, the Chair will seek further advice from the members and will make the decision on the Working Group's behalf.

Out-of-session decisions will be deemed acceptable by agreement. Where agreed, all out-of-session decisions will be recorded in the minutes of the next scheduled meeting.

5.3 Change Control

A change in a project's scope, quality, schedule or budget will trigger the following actions by the Working Group:

- a re-assessment of the project where, at minimum, this reassessment must be documented within meeting minutes
- a determination of what action to be taken

5.4 Proxies

Departmental or Institute members of the Working Group may can send proxies to meetings. Proxies are entitled to participate in discussion and are allowed a role in decision-making.

Working Group members will inform the Chair and the Project Team contacts as soon as possible if they intend to send a proxy to a meeting – no less than one business day before the scheduled meeting.

5.5 Meetings

5.5.1 Frequency

The Working Group will meet once per week (or more often or less, by exception, when key decisions or approvals are required). Unless otherwise agreed, meetings will be limited to one hour.

5.5.2 Agendas, minutes and reporting

A package will be sent delivered to members two business days before each Working Group meeting. This will include:

- the date, venue and agenda for the upcoming meeting
- the minutes of the previous meeting
- a progress report for the project
- papers requiring decisions
- any other documents/information to be considered at the meeting.

5.5.3 Reporting between meetings

If required and at the direction of the Chair, the Project Team will provide members with status updates and/or other documentation between meetings.

5.5.4 Reporting by the Working Group

The Working Group is required to present a preliminary written report to the Minister for Police and Emergency Services and the Minister for Roads and Road Safety, by 28 February 2021.

5.5.5 Secretariat

DJCS (via the Project Team) will provide secretariat services for Working Group meetings, including:

- ensuring meeting records and minutes are properly recorded and distributed in a timely manner
- circulating agendas and packages at least two business days before the meeting
- circulating draft minutes to members within three business days after a meeting
- scheduling meetings and arranging facilities
- performing other duties, as delegated by the members.

6. Document information

Document details

Criteria	Details
TRIM ID:	
Document title:	MCSDWG Terms of Reference
Document owner:	Director, Road Safety, DJCS

Version control

Version	Date	Description	Author
0.1	15/10/20	Initial Draft	RSCP, DJCS
0.2	4/01/21	Second draft	RSCP, DJCS
Final	25/01/21	Final	RSCP, DJCS

Document approval

This document requires the following approval:

Name	Title	Organisation
Corri McKenzie	Deputy, Secretary, Police Fines and Crime Prevention	DJCS
MCSDWG Members		

Audience

The audience for this document is MCSDWG Members to define the terms of reference

Reference material

Attached references	TRIM ID/Location
None	None

Acronyms	Description
DJCS	Department of Justice and Community Safety
MCSDWG	Medicinal Cannabis and Safe Driving Working Group

Terms	Description

Appendix B: DoT – Assisting health professionals at point-of-prescription and obligations for Fitness to Drive

The point of prescription of any drug with potential impairing effects that impact safe driving is an important interaction time with patients. It provides health professionals with:

(a) an opportunity to provide clear guidance to patients around the safe use of medication with respect to their driving needs, and

(b) to explain driver legal obligations to advise VicRoads of any long-term health or disability issues that may impact on their fitness to drive.

Prescription processes involving medicinal cannabis for drivers/riders are no different. Prescribers[1] appreciate the increasing heterogeneity of diagnoses for which medicinal cannabis may be considered a treatment option. Further, they know that patients will be anxious to understand side effects and any impacts on driving (especially if they drive for work) and will want to act responsibly and within the law in relation to usage of medicinal cannabis products.

Health Professional obligations with regards to Fitness to Drive

All drivers have a legal responsibility to notify VicRoads of significant long-term health conditions and disabilities that may affect their ability to drive safety.

Health professionals in Victoria do not have a legal obligation to report drivers with fitness to drive issues to the driver licensing authority. (Such provisions do exist in the Northern Territory and South Australia). However, all health professionals have a duty of care to advise patients about impacts of illness, disability, or treatments on driving capacity, as well as drivers' legal obligations to report to VicRoads. There is also an ethical obligation to support public safety.

Patients rely on health professionals for this advice and for strategies regarding management and monitoring. This is particularly important for patients who drive for work for whom fitness to drive restrictions are more stringent due to risk issues (e.g. driving exposure, transporting passengers and hazardous loads).

Health professionals can support the process of self-reporting or can report directly to VicRoads if they believe a patient lacks insight/judgement, and/or is not heeding advice to cease driving where considered appropriate. Such reports can be submitted anonymously by any member of the public: any individual who makes a report in good faith is protected from legal action, and details won't be shared without consent (unless it is required by law).

[1] The term 'prescriber' is used throughout this section to note any health professional who has the authority to medically prescribe medicinal cannabis.

Appendix C: Consultant report – Potential approaches to THC detection at the roadside

VICTORIA State Government | Justice and Community Safety

Medicinal Cannabis

Potential Approaches to THC Detection at the Roadside

February 2021

Martin C Boorman Consulting Pty Ltd

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Abbreviations

BAC	Blood Alcohol Concentration
DJCS	Department of Justice and Community Safety
DUI	Drive Under the Influence
DWI	Drive While Impaired
EBT	Evidential Breath Test
FMO	Forensic Medical Officer
MA	Methamphetamine
MDMA	3,4-methylenedioxymethamphetamine
PCA	Prescribed Concentration of Alcohol
PCD	Prescribed Concentration of Drug
PIT	Physical Impairment Tests
RMP	Registered Medical Practitioner
RSA	Road Safety Act
THC	Delta-9-tetrahydrocannabinol
VIFM	Victorian Institute of Forensic Medicine

1 Purpose

The purpose of this report is to provide advice to the Department of Justice and Community Safety (DJCS) on potential approaches to medicinal cannabis patients detected at the roadside with delta-9-tetrahydrocannabinol (THC) present.

2 Background and Context

Strong evidence exists that drug driving is a significant causal factor in road trauma. The contribution of drug driving to road trauma in Victoria has led to the introduction of a comprehensive legislative framework to combat the risk of drug driving to road safety.

The current legislative approach to drug driving in Victoria is a three tiered framework. The evidence gathering process and offence structure of the framework is set out in the Road Safety Act 1986 (RSA). The RSA drug driving framework is also linked to drug driving offences involving death and serious injury contained in Crimes Act 1958.

The first tier of the framework is the drive under the influence of a drug to such an extent as to be incapable of proper control of a motor vehicle offence that was introduced in 1949. This offence is known as the drive under the influence or DUI offence and applies gross levels of drug effect. The road trauma involvement risk for this offence is comparative to driving with a blood alcohol concentration (BAC) of 0.15 or above.[1] The DUI offence is largely based on expert opinion evidence of drug effect on the driving at the relevant time.

The second tier is the drive while impaired by a drug offence that was introduced in 2000. This offence is known as the drive while impaired or DWI offence and applies to a significant level of drug effect. The road trauma involvement risk for this offence is comparative to driving with a BAC of 0.10 or above.[2] This offence is based on the evidence of a driver's behaviour when a drug impairment assessment (DIA) is carried out.

The third tier of the framework is based on an increased risk of road trauma involvement as a result of the presence of a drug. The offence is framed as a drive while exceeding the prescribed concentration of drug (PCD) offence. This offence came into force in 2004 and is based on the presence of a prescribed illicit drug being present in an oral fluid or blood sample at a level above the prescribed limit. This offence applies to three prescribed illicit drugs, delta-9-tetrahydrocannabinol (THC, the active metabolite of cannabis) and methamphetamine (MA) and 3,4-methylenedioxymethamphetamine (MDMA). The level of drug has been prescribed as zero.

[1] For example, see Crimes (Dangerous Driving Offences) Act 1994 (NSW), Transport Operations (Road Use Management) Act 1995 (Qld) and Road Traffic Amendment (Dangerous Driving) Act 2004 (WA).
[2] Tharp V, Burns M, Moskowitz H. Development and Field Test of Psychophysical Tests for DWI Arrest, National Highway Traffic Safety Administration, Washington (DC) 1981, DOT HS-805 864.

In this report the focus is on the PCD offence involving the presence of THC. Whilst the presence of impairment is not an element of the THC PCD offence, a link may be drawn to a lower level of impairment associated with a road trauma involvement risk comparative to driving with a BAC of at least 0.05.[3] The PCD offence is structured in the same way as a exceed the prescribed concentration of alcohol (PCA) offence as an absolute liability offence.

Medicinal cannabis products prescribed to patients in Victoria may contain combinations of cannabinoids that include THC. Concerns have been raised that patients taking prescribed medicinal cannabis products containing THC are exposed to prosecution under the third tier of the Victorian drug driving enforcement framework if they drive after taking their prescribed dose of medicinal cannabis.

It is not within the scope of this report to discuss the scientific literature relating to THC and driving impairment. This report is confined to the presentation of four potential approaches for when THC is detected on a roadside drug test and the driver is a medicinal cannabis patient. The factors for consideration relevant to each of the four potential approaches are identified and discussed below.

3 Approach One – THC Presence in Oral Fluid

The first approach considered for when a medicinal cannabis patient is detected on a roadside drug with THC present is to retain the current roadside drug testing (RDT) approach. The current RDT framework was introduced in 2004 as a general deterrence process to combat the increasing involvement of drugs in road trauma. The RDT framework provides for high volume roadside testing of drivers for the presence THC, MA and MDMA. The RDT process is a three stage process. A preliminary oral fluid test is conducted while the driver remains in the vehicle. When a preliminary test indicates the presence of a drug is present, a second oral fluid sample is obtained. The second sample is obtained and tested in a police alcohol and drug testing bus or police patrol vehicle at the same location. When a second sample indicates the presence of a drug, a portion of the second sample is delivered to a laboratory for confirmatory analysis. When the laboratory analysis confirms a drug is present, the driver is prosecuted PCD offence. When the offence is a first offence the matter may dealt with by the issue of an infringement notice.

The retention of the THC in oral fluid approach has the benefit of being relatively non-invasive in terms of the sampling process, the sampling process can be carried out by police and the process is completed at the roadside in less than 30 minutes. In addition, there is no process or legislative change required. Given the RDT program is an existing process, there are no new resource implications for the police, courts or the forensic services provided by the Victorian Institute of Forensic Medicine (VIFM).

[3] For example, see Drummer O, Gerastamoulos J, Batziris H, Chu M, Caplehorn J, Robertson M, Swann P. (2004) The involvement of drugs in drivers of motor vehicles killed in Australian road traffic crashes. Accident Analysis and Prevention, 36, 239-248 and Drummer O and Yap S, (2016) The involvement of prescribed drugs in road trauma. Forensic Science International, 265, 17-21.

4 Approach Two – Drug Impairment Assessment

The second approach also utilises an existing framework. The DIA process was introduced in 2000 in response to recommendations of the Victorian Parliamentary Road Safety Committee.[4] The DIA process is a structured and systematic procedure to identify drug impairment. A DIA involves an initial roadside assessment, an evidential breath test (EBT) and physical impairment tests (PIT). The DIA process must be video recorded. The conduct of the PIT may be complicated by the existence of physical or neurological conditions. When a DIA indicates the driver is impaired a blood sample is obtained for laboratory analysis and an opinion on impairment is provided by a Forensic Medical Officer (FMO). A DWI offence is committed when a drug is found present in the blood sample, the behaviour of the driver on the assessment is consistent with the behaviour usually associated with a person who has used the drug found and, the behaviour usually associated with a person who has used that drug would result in the person being unable to drive properly. An infringement notice cannot be issued for a DWI offence, the matter must be heard and determined by a court.

The DIA process must be carried out by 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. The process cannot be completed at the roadside. The driver under investigation must be conveyed to a police station to carry out the DIA and in some circumstances be transported to a second location to obtain a blood sample. The obtaining of the blood sample is a relatively invasive procedure and must be carried out by a registered medical practitioner (RMP). The driver under investigation may be detained for up to three hours to complete the testing process and obtain a blood sample. An additional three hours of police time is needed to complete the entire investigatory process. Given that not all police are trained and authorised to conduct a DIA, more than one police patrol unit may be involved in the investigatory process.

The DIA process is resource intensive and is not designed for use as a high volume testing mechanism. A wide adoption of the DIA process will compromise the current high volume drug driving general deterrence program due to the significantly increased resource requirements of the DIA process.

5 Approach Three – THC Level in Blood

Approach three is a new approach structured around a medicinal cannabis patient detected at the roadside with THC present in a blood sample above a prescribed limit. In this approach, a medicinal cannabis patient intercepted at either an alcohol and drug bus testing station or by a police mobile patrol unit and a roadside preliminary oral fluid test is carried out. When the roadside oral fluid test indicates a drug is present, the driver must declare they are a medicinal cannabis patient and provide authoritative evidence that they are a medicinal cannabis patient. Once the driver is established as a medicinal cannabis patient, police require a blood sample to be provided. A blood

[4] Road Safety Committee, Parliament of Victoria, Inquiry into the Effects of Drugs (Other than Alcohol) on Road Safety in Victoria, Final Report, Melbourne, 1996.

sample is then obtained and delivered to a laboratory for analysis. When the laboratory analysis result confirms the presence of THC in the blood sample at a level above the prescribed THC level, an offence is committed. The threshold THC level in blood relative to driving impairment and the comparative risk of road trauma involvement is yet to be determined. The determination of a threshold THC level in blood relative to driving impairment must be based on the scientific advice. Currently there is no scientific consensus on what a THC impairment level in blood should be.

In 2012, Norway introduced prescribed impairment levels in blood for 20 drugs including THC. The prescribed impairment level set for THC was 1.3 ng/ml and said to be comparative impairment at a 0.02 BAC. Two more levels were also set being 3 ng/ml and 9 ng/ml that were said to comparative to a 0.05 and 0.12 BAC, respectively. It is important to note the context in which the scientific advice was provided to arrive at the THC impairment levels implemented in Norway. The objective of establishing impairment levels was to enable the implementation a of limit based system and to harmonise the graduated sanctions framework for alcohol and drug driving offences. The scientific advisors acknowledged the lack of scientific evidence on which to base drug impairment levels and adopted a pragmatic approach in arriving at the suggested levels. It was also acknowledged that the suggested levels were open to debate.[5]

The United Kingdom is another jurisdiction that has implemented drug driving legislative framework based on drug levels in blood. In 2013, the United Kingdom enacted legislation to make it an offence to drive with more than the prescribed level a specified drug present. Scientific advice on what the drug levels should be for a number of drugs including THC was provided. The advice for what the THC level should be was 5 ng/ml in blood. The scientific advisors noted in their report that, “Even though ‘risk thresholds’ have been determined in the scientific literature it is noted that they remain approximations.”[6] The levels for illicit drugs, including THC, recommended by the scientific advisors were not adopted. The adopted levels for illicit drugs were set on the basis of avoiding claims of accidental exposure. The level set for THC was 2 ng/ml in blood.

The DRUID (Driving under the Influence of Drugs, Alcohol and Medicines) project, a comprehensive impaired driving research project sponsored by the European Union, investigated the calculation of risk thresholds for prescription drugs and in its final report recommended that no thresholds should be defined for medicinal drugs. There is little evidence to support the establishment of risk thresholds for drugs generally and prescription drugs particularly.[7]

The current scientific knowledge relating to the threshold THC level in blood relative to driving impairment and the comparative risk of road trauma involvement threshold suggests that further research is needed to determine what a threshold THC impairment level should be.

[5] Vindenes, V., et al., (2012) Impairment based legislative limits for driving under the influence of non-alcohol drugs in Norway, Forensic Science International 219(1-3,)1-11.
[6] Wolff, K, et al., Driving Under the Influence of Drugs: Report from the Expert Panel on Drug Driving, Department of Transport, London, 2013.
[7] DRUID, Final Report: Work performed, main results and recommendations, 2012.

There are a number of factors associated with the operation of the THC present in a blood sample above a prescribed limit approach that require consideration. The process may not be able to be completed at the roadside. 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 an RMP. The need to obtain a blood sample will require additional frontline police time to complete the process. A wide adoption of this approach will compromise the current high volume drug driving general deterrence program due to the significantly increased resource requirements of the approach. In addition to the increased police resource requirement, there will be an increase in the forensic services required to obtain and analyse an increased number of blood samples. The impact of an increase in the forensic services requirement on blood sample and oral fluid sample result turnaround times is not known.

This approach is a completely new approach that will require legislative change to support the process. The RSA will require amendment to facilitate a requirement to obtain a blood sample from a medicinal cannabis patient after a roadside drug test indicates the presence of a drug. The new exceed the prescribed level of THC in blood offence will need to be legislated together with supporting evidential provisions. The offence will also need to be designated as an infringeable offence to avoid an increase in court workload. In addition, there will be a need to train police in the operation of the new process and supporting legislative framework.

6 Approach Four - Hybrid of Approach One and Three

The fourth approach is a hybrid of approach one and three. In this approach a medicinal cannabis patient follows the RDT process. When drug is detected on the roadside preliminary oral fluid test, a second sample of oral fluid is obtained and tested. If the second sample test indicates the presence of a drug and the driver provides authoritative evidence that they are a medicinal cannabis patient, the driver advised they may request that a blood sample be taken. The taking and analysis of a blood sample in these circumstances is authorised under the current RDT legislative framework. As described in approach three, a blood sample is then obtained and delivered to a laboratory for analysis. When the laboratory analysis result confirms the presence of THC in the blood sample at a level above the prescribed THC level, an offence is committed. The offence is a new offence and the threshold THC level in blood relative to driving impairment and the comparative risk of road trauma involvement is yet to be determined.

The factors to be considered in the hybrid approach are as follows. This approach may not be able to be completed at the roadside. 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 an RMP. The need to obtain a blood sample will require additional frontline police time to complete the testing process. A wide adoption of this approach will compromise the current high volume drug driving general deterrence program due to the significantly increased resource requirements of the approach. In addition to the increased police resource requirement, there will be an increase in the forensic services required to obtain and analyse an increased number of blood samples. The impact of an increase in the forensic services requirement on blood sample and oral fluid sample result turnaround times is not known.

The hybrid approach will require amendment of the RSA to include a new exceed the prescribed level of THC in blood offence and supporting evidential provisions. The offence will also need to be designated as an infringeable offence to avoid an increase in court workload. There will also be a need for police training on the operation of the new supporting legislative framework, however, the training requirement will be limited.

7 Potential Approach Comparison

The factors relevant to the operation of the four potential approaches outlined above are compared in table 1 below using a traffic light indication of impact. Green indicates negative impact. Amber indicates neutral impact. Red indicates positive impact.

Table 1: Comparison of the potential approach factors

Approach	New Process	Impairment and Risk Level yet to be Determined	Process Completed other than at the Roadside	Legislative Process Change Required	New Offence Required	Increased Frontline Police Resources	Additional Police Training	Increased Court Time	Increased Forensic Services	Invasive Sampling Process
1 RDT	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
2 DIA	NO	NO	YES	NO	NO	YES	YES	YES	YES	YES
3 THC in Blood	YES	YES	NOT ALWAYS	YES	YES	YES	YES	NO	YES	YES
4 RDT & THC in Blood	NO	YES	NOT ALWAYS	NO	YES	YES	YES LIMITED	NO	YES	YES

When the ten factors identified in the above comparison table for each approach are cumulatively rated on the bases a negative impact (green) or a positive impact (red) are given an impact value of ten and a neutral impact (amber) is split to give a negative and positive impact value of five, an overall impact rating as a percentage may be calculated. Approach one – THC present in oral fluid, the existing process, has the lowest impact of the four approaches at a zero percent impact rating. Approach two – drug impairment assessment and approach four – hybrid of approach one and three, have the same level of impact at a 60 percent impact rating. Approach three – THC level in blood, a completely new approach, has the highest impact of the four approaches at an 85 percent impact rating.

It should also be noted that in terms of the level of physical intrusiveness and in terms of the detention time relevant to the completion of the investigatory process for each of the four approaches, approach one – THC present in oral fluid, the existing process, is the least intrusive. Approach two – drug impairment assessment is most intrusive approach. Approach three – THC level in blood and approach four – hybrid of approach one and three, is slightly less intrusive than approach two.

Appendix D: MUARC paper – Evidence on the crash risk associated with THC (Cannabis) and implications for users of medicinal cannabis, including reference list of scientific literature

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ROAD SAFETY ASPECTS OF MEDICAL CANNABIS

RAPID REVIEW - EVIDENCE ON THE CRASH RISK ASSOCIATED WITH THC (CANNABIS) AND IMPLICATIONS FOR USERS OF MEDICINAL CANNABIS

ASSOCIATE PROFESSOR MICHAEL FITZHARRIS

26 FEBRUARY 2021

RAPID REVIEW - EVIDENCE ON THE CRASH RISK ASSOCIATED WITH THC (CANNABIS) AND IMPLICATIONS FOR USERS OF MEDICINAL CANNABIS

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Date: 26/2/2021

Funding support: MUARC Baseline Research Program.

Background

Over the past 5 years MUARC has undertaken a considerable volume of research into the effects of drugs and driving. This has examined the published scientific literature on crash rates, crash risk, motivations for driving after drug use and countermeasure effectiveness (Mulvihill et al., 2020). Research has also been undertaken that has reported the number of drivers involved in crashes admitted to hospital and the number of offenders by drug type. This research showed that between 2010 – 2018 of the 33,484 drivers tested for illicit drugs following treatment in hospital, 2,073 (6.2%) tested positive to THC. In the same period, 12,695 drivers and riders tested positive to THC at the roadside (12.9% of drug-driving offenders, n = 34,984) (Liu & Fitzharris, 2020).

The research highlights the risk associated with cannabis use and driving in Victoria. The research presented below seeks provides a basis for understanding the road safety risk associated with cannabis (THC) use and driving.

Research evidence on THC/cannabis and crash risk

At the outset, the research presented below is specific to THC and does not address CBD, which is a non-psychoactive compound found in cannabis.

There is an extensive body of research literature that describes the increased crash risk associated with THC (see Mulvihill, Liu, Fitzharris, 2020; Shinar, 2017). Other studies undertaken in driving simulators and on closed test tracks have also demonstrated impairments in the skills required for safe driving, such as impaired reaction time, the number and extent of lane deviations, and other cognitive processing errors (see Mulvihill et al., 2020 for review; Arkell et al., 2020; Raemkaekers et al., 2004). Based on the weight of evidence, there is global consensus that the use of THC results in a range of impairments specific to driving, with these impairments being associated with an increase in crash risk.

Meta-analysis studies are those that summarise the findings of multiple research papers. By taking advantage of the findings of multiple research studies, it is possible to create a 'pooled estimate' of the crash risk associated with THC use.

Over the past decade, three important meta-analysis papers have examined the crash risk associated with cannabis use. These key papers were by Asbridge and colleagues (2012), Elvik (2013) and more recently Rogeberg, Elvik and White (2018). For each of these studies the odds ratio (OR) is the outcome of interest. The odds ratio (OR) is a measure of the magnitude (and direction) of association with THC (cannabis) use. An OR of > 1.0 indicates an increase in crash risk, while < 1.0 indicates a lower crash risk.

The meta-analysis conducted by Asbridge et al (2012) reported the combined effect of THC on crash risk using nine independently published studies. This highly cited study (708 times) reported a near doubling of crash risk associated with recent cannabis consumption, with the

odds ratio being 1.92 (95%CI 1.35-2.73). The 95% confidence intervals state that this increase could be a low as a 35% increase in crash risk or up to 173% times higher (2.7 times higher), with the best estimate being a 92% increase in crash risk. Asbridge et al.(2012) rated the quality of each of the nine studies and showed that after restricting the meta-analysis to only high-quality studies the OR was 2.21 (95%CI: 1.25 – 3.90). The quality assessment of each study is an important part of the meta-analysis process as it ensures that the derived outcome is based on data with the strongest research design and data collection processes.

Elvik (2013) expanded on Asbridge's work by including a larger number of research studies (66) in his meta-analysis. Like Asbridge et al. (2012), Elvik reported an increased crash risk associated with cannabis (THC) but the increase in crash risk was not statistically significant for fatality crashes (OR: 1.26, 95%CI: 0.88 – 1.81) or injury crashes (OR: 1.10, 95%CI: 0.88 – 1.39), but was for property damage only crashes (OR: 1.26, 95%CI: 1.10-1.44).

The works by Asbridge et al. (2012) and Elvik (2013) have received considerable criticism. This criticism was based on the number and mix of studies, the way the quality of the studies was assessed, the use of duplicated data and failing to statistically control for the presence of alcohol and other relevant factors. These limitations were addressed initially in a paper by Rogeberg and Elvik (2016) with a further correction subsequently issued in 2018 (Rogeberg, Elvik, White, 2018). This latest meta-analysis included additional research conducted as part of the Driving under the influence of drugs (DRUID) program in Europe (https://www.emcdda.europa.eu/emcdda-home-page_en).

The meta-analysis using mixed effects regression conducted by Rogeberg et al (2018) reported a combined odds ratio of 1.32 (1.09-1.59), indicating that the odds of crash involvement associated with cannabis intoxication is estimated to be 32%; this increased risk could be as low at 9% higher to 59% higher (Table 1).

Like the other authors, Rogeburg et al (2018) conducted a quality assessment to the studies included in their meta-analysis. When using only the high-quality studies in the meta-analysis, the crash risk associated with THC was 1.53 (95%CI: 1.11 – 2.09) and this result was statistically significant; that is, the use of THC was associated with a 53% higher crash risk associated with THC. Importantly, the studies rated as medium nor low quality did not show a statistically significant increase in crash risk. Using studies of all quality, but limiting the analysis to case-control studies, the OR was 1.82 (95%CI:1.19 – 2.79).

TABLE 1 ESTIMATES OF ODDS RATIOS OF CRASH RISK AND CANNABIS (MIXED EFFECTS MODEL; ROGEBURG ET AL., 2018)

Drug	Number of Studies	OR	95% Confidence Intervals
All	26	1.32†	(1.09, 1.59)
Quality assessment of study			
High quality	8	1.53†	(1.11, 2.09)
Medium quality	14	1.26	(0.88, 1.81)
Low quality	4	1.20	(0.7, 2.06)

*Source: Rogeberg et al (2018), Table 1.; † $p < 0.05$

Based on the evidence presented above, there is a demonstrable association between THC use and crash risk. The increase in crash risk was demonstrated in all three key meta-analysis studies, with debate focused on the quality of the individual research studies used. That this impacts the size of the crash risk association is important and highlights the importance of using the most well-designed studies when documenting the association between crash risk and illicit drugs.

To conclude, what is not in doubt is that THC is associated with an increase in crash risk, but what has been contested is the magnitude of this increased risk. Here, the Rogeburg et al (2018) study arguably provides the most robust estimate of the magnitude of association between cannabis use and crash risk, and while the overall result indicates a 32% higher crash involvement risk associated with crash risk (OR: 1.32, 95%CI: 1.09 – 1.59), limiting the meta-analysis to high quality studies shows that the crash risk is estimated to be 53% higher, with this possibly being as low as 11% and as high as 109% (i.e., double) (OR: 1.53, 95%CI: 1.11 – 2.09, $p < 0.05$).

Available research on the effects of medical cannabis and driving

Despite the increased focus on the use of cannabis for medical purposes, there has been little research to date that has examined the impact of medical cannabis on driving.

There have however been a number of pre-post evaluation studies of crashes in jurisdictions in the United States that have introduced medical cannabis programs. In short, findings of these studies have been mixed, with some jurisdictions reporting no change in the number of crashes and others reporting increases (e.g., Masten & Guenzburger, 2014).

The research by Masten and Guenzburger (2014) used the US National Fatality Accident Reporting Sample (FARS) system to assess prevalence of cannabinoids in crash-involved drivers and killed drivers in 14 US States where medical cannabis was legalised. The authors reported increased driver cannabinoid prevalence following the implementation of medical marijuana laws was detected in California (crashes: +2.1%; killed drivers: +5.7%), Hawaii (crashes: +6.0%; killed drivers: +9.6%) and Washington (crashes: +3.4%; killed drivers: +4.6%). Other US States showed no change. It is important to note that these studies have used population-level data to examine the impacts of medical cannabis programs once implemented but did not examine the impact of medical cannabis at the individual patient level. This is important for a number of reasons, with the authors themselves pointing out the limitations of the data, specifically stating that “the cannabinoid prevalence estimates likely do not reflect prevalence among drivers in general” (Masten & Guenzburger, 2014, p.49). It is also the case the drug test (toxicology) data are also poorly captured in FARS and is not standardized across the US States. These are significant data limitations. In addition, the proportion of tested drivers for drug and/or alcohol is low. In assessing the relevance of these US-based evaluations, one must also consider that these jurisdictions do not have random roadside drug-testing programs for drivers. For this reason alone, the value and application of this research to the Victorian context is limited.

The most important study to date on the effect of medical cannabis on driving performance is that undertaken by Arkell and colleagues (2020). This research was published in the prestigious Journal of the American Medical Association (JAMA). In an excellent study design, 26 young healthy occasional users of cannabis with tasked with driving on an off-road test track where their driving performance was monitored. These drivers were each tested in four conditions: 1) THC-dominant, 2) CBD-dominant, 3) THC/CBD-equivalent, and 4) placebo cannabis; hence, each driver acts as their own control. THC and CBD doses were 13.75 mg as the target dose.

The level of THC dosing is important as the day 14 maximum (stable) use of Sativex is 12 spays, with each 100 microlitre spray containing 2.7 mg THC and 2.5 mg CBD; this is recommended to be administered as 5 spays (13.5 mg THC) in the morning and 7 at night (18.9 mg THC), noting this would differ across patients (MIMS, 2020). Hence, the 13.75 mg THC dose approximates a therapeutic dose of THC-based medical cannabis. The CBD alone dose was noted by the study authors to be low and not be clinically relevant; that is, of value to the patient at that dose level, a point also made by the accompanying Editorial (see below).

The Arkell et al. (2020) study used the mean lateral position (SDLP) as the primary study outcome. This is weaving in a lane. The findings indicated impaired driving performance as shown by an increase in the SDLP measure in the THC and THC/CBD experimental condition for between 40 minutes to 100 minutes, but not in the CBD condition relative to the control (placebo) group that had no THC or CBD. No decrement in driving performance was reported between minute 240 to 300, however the authors did not report driving data from minute 101 to minute 239, hence the duration of the impaired driving performance on this measure is unknown.

Drivers in the THC and THC/CBD condition rated their driving to be more impaired than in the placebo condition at minute 100 and minute 300, as well as the quality of their driving (only at 100 minutes). There were a number of differences in cognitive tasks performed outside the vehicle.

An important aspect is that 16 of the 188 test drives were terminated by the instructor for safety reasons. Nine were in the first driving test, and 5 were in a THC condition, and 6 of the 7 terminations in the second drive were in a THC condition; these terminations in the second driver were due to excessive fatigue. In addition, 3 drives were cancelled due to participants themselves feeling unsafe and all three were in a THC condition. This is important to note as their inclusion would likely have degraded the reported results further.

In the accompanying *Editorial* (Cole & Saitz, 2020), *JAMA Editors stated that:*

> While the findings from this trial do not support the conclusion that it is safe to drive after consuming CBD, it is clear that THC did impair driving performance and that the effects of THC were not limited to just 1 driving task. Consumption of THC and THC/CBD adversely affected performance on standardized tests of processing speed, divided attention, psychomotor function, working memory, decision making, and cognitive flexibility. Drivers who consumed THC were generally aware that their driving was impaired, although participants reported that consumption of THC/CBD was associated with less anxiety, reduced strength of drug effects, and greater confidence to drive than THC alone.
>
> Clinicians should caution their patients that cannabis products containing equal parts CBD and THC are no less impairing than products containing THC alone.

To conclude, the study by Arkell et al (2020) is important as it has an excellent study design, tests THC at a therapeutic dose, and involved actual driving in a closed track environment. The findings demonstrated clear impairment in safe driving as evidence by increased weaving; this is a well-regarded measure of safe driving used in experimental, simulation and normal on-road driving (i.e., naturalistic studies). That impairment was seen up to 100 minutes post administration of the THC dose highlights the potential road safety risk. Finally, while the study design is very good, the number of participants was relatively low, noting the intensive nature of these studies to be fair. As each driver participated in each of the four conditions (THC, THC/CBD, CBD, Placebo), the statistical power of the study was good as each driver acted as their own comparison.

One last aspect of the study is that these drivers were young, healthy individuals. The findings of the study provide an important insight into the level and time-course of impaired driving performance post a therapeutic THC dose. Having said this, what is unknown is whether this level of impairment is similar, better or worse in an older population of drivers with a known medical condition who are prescribed medical cannabis. What can be concluded from the Arkell et al (2020) study is that drivers in an experimental setting taking a dose commensurate with a therapeutic level THC dose demonstrated impaired driving performance for at least 100 minutes following administration. While this can be stated, there is a clear need for research

to be undertaken that involves the study of actual driving of people prescribed medical cannabis.

Considerations relating to crash risk, road safety, and the use of medical cannabis and driving

Based on the limited available evidence regarding the effects of medical cannabis on driving, and by making reference to medical cannabis product information, at the levels of daily use as prescribed by a medical practitioner – and based on the recommended maximum daily dose of Sativex (the only approved medical cannabis product currently listed on the TGA ARTG) – the view can be taken that medical cannabis patients ***should*** be safe to drive without being impaired but only after a minimum delay of between 90-120 minutes post use. However, due to a lack of quality evidence this exact time period is unknown at this point. This statement is wholly dependent on non-use of alcohol (0.00 BAC), and minimal, if any use, of concurrent prescribed use of opioids and/or benzodiazepines, and an understanding of the underlying medical condition being treated and its impact on safe driving. Whether the driver/rider would test positive for THC at the roadside is unknown, however given current drug-driving processes in Victoria this risk is likely to be low.

Based on the above, and given the well-established and robust evidence of the impairing effects of THC associated increased crash risk, adopting the precautionary principal with respect to driving is arguably the most pragmatic path for the management of driving for medical cannabis patients at present.

Any proposal to implement new processes at the point of detection would require: a) the ability enable the rapid identification of medical cannabis patients by Police so as to ease the burden on the patient in proving legitimate use of medical cannabis, and b) the ability to discriminate between impaired and non-impaired driving among medical cannabis patients. Such systems and procedures, supported by appropriate policies, will complement and reinforce the value of any point-of-prescription process between the patient and the medical practitioner. Taking these steps will ensure the integrity of the process in its entirety. Implementing these policies and procedures will also be important in maintaining the integrity of current Victorian illicit drug-driving laws were any form of medical exemption for prescribed users of medicinal cannabis, as is seen in select European jurisdictions (Fitzharris, Liu, St Louis, 2020) be enacted.

Establishing the evidence base

Following from above, further research to document the time period effects of medical cannabis is urgently needed. This ought to include an assessment of different formulations of medical cannabis and modes of use. It is recommended that this include an assessment of screening device sensitivity and accuracy, as well as rapid methods to assess impairment.

Given the limited evidence base, there is a need to assess the impacts (and the time-course) of medical cannabis on the skills needed for safe driving; this needs to include an assessment of the actual driving performance of medical cannabis patients using on-road (naturalistic) and simulator studies. Finally, there is a need to better understand the broader impacts of medical cannabis on the health and mobility of medical cannabis patients by conducting cohort studies.

The evidence gathered from these research studies would enable robust decisions to be made on how best to balance the mobility needs of medical cannabis patients and to ensure the safety of the community.

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Appendix E: DH – Medicinal Cannabis and Driving: Issues paper

VICTORIA State Government | Justice and Community Safety

Medicinal Cannabis and Driving: Issues paper

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Introduction

In November 2016, regulatory changes implemented by the Commonwealth government enabled Australian patients to legally access medicinal cannabis when prescribed by their doctor with any relevant approvals. This change brought an end to the blanket prohibition on cannabis, which had been classified as a schedule 9 substance in the Australian Poisons Standard and was considered to have no recognised medical value.

Unlike some other countries, the approach to medicinal cannabis in Australia is based on the provision of pharmaceutical grade medicines available only via prescription from a doctor after any required Commonwealth and state government approvals. There are now over 100 medicinal cannabis products available, which vary in composition of the two primary cannabinoids delta-9-tetrahydrocannabinol (THC; that produces a psychoactive effect), and cannabidiol (CBD; non-psychoactive), although most contain at least some level of THC (Freshleaf Analytics 2020). Products also vary in route of administration (oil, spray, capsule, lozenge, plant matter etc.) and many are described as 'full spectrum', containing a range of other chemical constituents present in the cannabis plant.

As of 31 December 2020, over 85,000 approvals for medicinal cannabis had been granted (TGA 2020). However, the transition from controlled illicit drug to legitimate prescription medicine has not been entirely smooth. There have been some reports of enduring negative attitudes among medical professionals and an unwillingness to consider prescribing while schools and workplaces have been challenged to update existing policies to recognise the right of patients to possess and use cannabis

on their premises when legally prescribed (Benson, Abelev et al. 2020, Commonwealth of Australia 2020).

Another area where the approach to medicinal cannabis continues to be contentious is driving, with most road safety agencies around Australia remaining committed to a regulatory framework that treats patients taking legally prescribed medicinal cannabis containing THC in the same manner as users of some illicit drugs, by criminalising the presence of the drug regardless of impairment. However, some advocacy groups and politicians have asserted the need for change due to perceived inequitable treatment of medicinal cannabis patients (Patton 2020), and potential exposure to serious criminal penalties when using the drug for medical purposes and being unimpaired while driving. These concerns were echoed by a recent Senate Inquiry that recommended a review of current drug driving laws (Commonwealth of Australia 2020). In one of the first legal tests in January 2020, a South Australian magistrate dismissed a drug driving charge against a medicinal cannabis patient citing a lack of evidence of impairment (Bartle 2020). At the core of this issue is the need to optimise the regulatory framework to minimise potential harms relating to road safety risk, impediments to access to a needed medication, and the exclusion of a vulnerable patient group from motor vehicle access.

Prescription drugs and driving

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 via a regulatory framework including the Commonwealth *Poisons Standard* and corresponding state-based legislation. The Poisons Standard uses a scheduling system reflecting the differing levels of potential harms and therapeutic benefit of various substances. Drugs with a recognised medicinal value are identified as Schedule 2, 3, 4 or 8 depending on the level of regulatory control restricting their availability, while those with no recognised medicinal value and the potential for harm, abuse/misuse are listed as Schedule 9 prohibited substances.

Recognised medicinal drugs (Schedules 2,3,4 and 8) may still have risks associated with their use, including causing impairment that can affect the ability of patients to drive. A significant number of medicines prescribed in Australia are known to have such effects, including anticonvulsants, antihistamines, antipsychotics, benzodiazepines, muscle relaxants, hypnotics, and antidepressants (Drummer 2008). Experimental studies have found these medicines to have negative effects on psychomotor, cognitive, and driving skills, with an increased crash risk reported in epidemiological studies (e.g. case control and culpability studies). Table 1 provides a summary of such effects reported in systematic and meta-analytic reviews.

Table 1: Impairing prescription drugs: effects on driving performance and crash-risk

Class of drug	**Reported impairing effects** (experimental studies)	**Crash risk ratio (systematic or meta-analytic reviews)**
Anti-depressants	Drowsiness, hypotension, dizziness, decreased seizure threshold. (Ramaekers 2003). Impaired in psychomotor functions (Brunnauer, Laux et al. 2006)	↑ 1.40 (Hill, Lauzon et al. 2017). ↑ 1.39 (Elvik 2013) ↑ NQ[1] (Gjerde, Strand et al. 2015)
Antihistamines	Primarily sedation that can cause impairment comparable to >0.05 BAC (Verster and Volkerts 2004). Impaired reaction time and psychomotor performance (variation by type) (Popescu 2008)	↑ 1.20 (Gibson, Hubbard et al. 2009) ↑ 1.12 (Elvik 2013) ↑ NQ (Rudisill, Zhu et al. 2016)
Benzodiazepines	Sedation, drowsiness, learning impairment, psychomotor slowing (Longo and Johnson 2000 2016). Almost every aspect of driver behaviour shown to be affected (Rudisill, Zhu et al. 2016)	↑ 1.65-2.30 (Elvik 2013) ↑ 1.6-1.8 (Dassanayake, Michie et al. 2011) ↑ (Rudisill, Zhu et al. 2016) ↑ NQ (Gjerde, Strand et al. 2015)
Z-hypnotics	Sedation, increase attention lapses, increased tracking errors, reduced alertness, reduced body stability (Leufkens, Lund et al. 2009, Verster, Bervoets et al. 2014)	↑ 1.4 (Elvik 2013) ↑ NQ (Rudisill, Zhu et al. 2016) ↑ NQ (Gjerde, Strand et al. 2015)
Opiates	Sedation; diminished reaction times, reflexes and coordination; reduced peripheral vision due to the persistent miotic effects and impaired concentration (Stout and Farrell 2003, Drummer 2008, Wilhelmi and Cohen 2012, Strand, Fjeld et al. 2013).	↑ 2.29 (Chihuri and Li 2017) ↑ 1.94 (Elvik 2013) ↑ NQ (Rudisill, Zhu et al. 2016) ↑ NQ (Gjerde, Strand et al. 2015)

[1] NQ – statistically significant increase reported but not quantified

However, it is important to note that there are methodological difficulties in achieving accurate estimates of impairment and crash risk. Experimental studies are almost always undertaken on healthy controls, for which it is impossible to incorporate potential health benefits of the medication that may lead to a net reduction in impairment and improved driving ability. For epidemiological studies, which are typically observational, it is very difficult to adequately control for all potential confounding variables such as simultaneous use of other drugs (including alcohol), polypharmacy, time delays between crashes and drug testing, plus un-observed confounding factors. In addition, risks associated with some medications appear to diminish after a tolerance to the impairing effects has developed (Rudisill, Zhu et al. 2016).

Reducing risks associated with prescription drugs

Warnings and labelling requirements

To reduce risks associated with the use of prescription drugs such as those in the table above, a product labelling and warning system has been established via the Poisons Standard, TGO 91 and 69 (Standard and General requirements for labels of prescription and related medicines), Medicines Advisory Statements Specification, and the Required Advisory Statements for Medicine Labels (No.5). This includes warnings 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. Prescribing doctors and dispensing pharmacists are also required to advise

patients using medications with these warnings to monitor drug effects and refrain from driving if impaired.

Driving under the influence/Driving while impaired

In addition to the labelling and warning system, most Australian jurisdictions also have offences relating to driving under the influence (DUI) of alcohol or other drugs (licit or illicit). These offences usually require a level of impairment in driving capacity caused by alcohol or other drug use, with this assessed based on evidence of a driver's behaviour witnessed by police or others. The common formula is driving under the influence of a drug so 'as to be incapable of having proper control of the motor vehicle' (Victoria, Tasmania, Western Australia, ACT and Northern Territory). In South Australia the test is 'as to be incapable of exercising effective control of the vehicle'. The DUI offences in NSW and Queensland do not define what 'under the influence' means in impairment terms. Western Australia and Victoria also have driving while impaired (DWI) offences, which resemble the DUI laws but relate only to drugs (licit or illicit) other than alcohol. DUI and DWI offences are usually identified when police stop a vehicle or speak to a driver after the fact, should they have reason to believe that the driver is drug-impaired (e.g. reckless driving, tip off, motor vehicle accident etc). If a police officer reasonably suspects that a person's driving ability has been impaired by a drug, a sample of blood or urine may be obtained. An assessment of physical factors (balance, coordination, reactions etc) may need to be conducted in some jurisdictions prior to blood or urine being taken, as is the case in Victoria (National Transport Commission 2018). If a medicinal drug is then found in a person's system, they could be charged with DUI offences in most states and territories and DWI offences in Victoria and Western Australia. However, the presence of a medicinal drug alone does not prove the charge, and must generally be supported by other evidence or a positive alcohol test (National Transport Commission 2018) Penalties for DUI and DWI offences include fines, licence cancellation periods and possible imprisonment for repeat offences.

Fitness to drive

Individuals with certain health conditions (e.g. epilepsy) may also be referred for fitness to drive assessments (these can be mandatory in SA and NT), which are undertaken following guidelines established by the National Transport Commission. In relation to prescription drugs these guidelines state that health professionals should consider "the balance between potential impairment due to the drug and (effect of) the patient's improvement in health on safe driving ability" in addition to factors such as individual response, drug interactions, and a history of substance abuse (National Transport Commission 2017).

Illicit drugs and driving

The regulation of road safety risks associated with the use of illicit drugs is enacted in Australian States and Territories through their drug driving legislation, which in turn is informed by the National Road Safety Strategy. In all States and Territories, road safety legislation specifies a group of substances for which it is an offence to drive with any amount in a person's bodily fluids, regardless of impairment. These offences are loosely referred to as 'presence offences' and as any detectable amount constitutes an offence, Australian jurisdictions have been described as having a 'zero tolerance' approach to drug driving (Quilter and McNamara 2017). Although simply the presence of these drugs is an offence, in practice minimum detection thresholds have been adopted to control for accidental exposure, which vary across jurisdictions. These 'presence offences' are additional to the DUI and DWI offences referred to above.

Enforcement of presence offences for illicit substances is most commonly conducted via roadside oral fluid drug-testing regime (noting that Tasmania uses blood sampling). Presence offences are also enforced through mandatory blood tests, which are administered to any driver admitted to a hospital following a road accident (regardless of fault). Typically, only three illicit drugs are tested for in oral fluid: THC; MDMA; and methamphetamine. New South Wales added cocaine to this list of drugs tested for in oral fluid in 2018. While presence offences apply overwhelmingly to illicit drugs, Tasmania and the Northern Territory include a much larger number of drugs - most illicit, but some of which could be medically prescribed (see Table 2 below). New South Wales also has a separate offence of driving with the presence of morphine in the driver's blood or urine. No Australian jurisdiction currently tests for the presence of prescription drugs (other than medicinal cannabis) in preliminary oral fluid tests conducted at the roadside, with the examples above being tested for in secondary testing.

Table 2: Presence offences in Australian states and territories (oral fluid, blood or urine)

Jurisdiction Legislation	Drugs covered in addition to THC, methamphetamine, and MDMA	Potential medical exemptions	Penalties[1]
Victoria *Road Safety Act 1986*	None	No	F, LS, DE
New South Wales *Road Transport Act 2013*	Cocaine, morphine	Morphine	F, LS
Queensland *Transport Operations (Road Use Management) Act 1995*	None	No	F, LS[2], IM
South Australia *Road Traffic Act 1961*	None	No	F, LS, DP
Western Australia *Road Traffic Act 1974*	None	No	F, LS[2], DP
Tasmania *Road Safety (Alcohol and Drugs) Act 1970*	MDA, MDEA, amphetamine, cocaine, heroin, GBH, ketamine, LSD, Quaalude, morphine, DET, DMT, PMA, PCP, psilocybin	Yes - all	F, LS, IM
Northern Territory *Traffic Act 1987*	MDA, heroin, cocaine, morphine, methadone, amphetamine	Morphine, methadone and amphetamine	F, LS[2], IM
Australian Capital Territory *Road Transport (Alcohol and Drugs) Act 1977*	None	No	F, LS, IM[2]

[1] F=Fine; LC=licence suspension; DE=driver education; IM=imprisonment; DP=demerit points

[2] Repeat offences

Notably, in some Australian jurisdictions there exists a medical defence for having the presence of certain drugs with potential therapeutic application in blood or oral fluid, if they have been prescribed by a doctor and taken in accordance with a prescription. In NSW this medical defence covers morphine (Road Transport Act 2013 s 111(5)) and, in the Northern Territory, morphine, methadone and amphetamine (Traffic Act 1987 ss 29(1) and (2); Traffic Regulations 1999 reg 55A, Schedule 1A – Part B). In Tasmania, the medical defence covers any drug referenced in the legislation if it was

obtained and administered in accordance with the Poisons Act 1971 (Tas), including medicinal cannabis (Road Safety (Alcohol and Drugs) Act 1970 s 6A(2); Road Safety (Alcohol and Drugs) Regulations 2018 s 15). To be clear, these medical defences provide an exemption to presence offences, but not the DUI or DWI offences that exist in Australian states and territories.

Other than Tasmania, there is no medical defence for patients prescribed medicinal cannabis (containing THC) taking it as directed and who are not impaired. This creates an unusual situation where these patients are treated more harshly than people who use other illicit drugs not included in the relevant presence offences. In Victoria or Queensland for example, people who use LSD, cocaine, and heroin can drive with the presence of these drugs in their system and would not be guilty of an offence if not impaired, while patients prescribed medicinal cannabis to treat a medical condition face potential criminal charges in the same situation.

In states other than Tasmania (a review is also currently underway in Victoria), road safety agencies remain opposed to any change in the treatment of medicinal cannabis, due to concerns about the potentially impairing effects of THC. When an unsuccessful bill to change this situation in South Australia was introduced to parliament in 2017, the Police Minister labelled it ‘crazy’ and ‘inconsistent’ with road safety objectives (ABC 2017). The National Drug Driving Working Group recommended no change to current legislative arrangements in 2018, with reference to the 0.00 BAC alcohol requirement for some groups of drivers (Commonwealth of Australia 2018). However, such a comparison between a recreational drug (alcohol) and a prescription medicine indicates a lack of recognition of medicinal cannabis as a legitimate prescribed medication. This view also fails to recognise the potential health related harms associated with lack of access to a needed medicine, and the impacts of excluding vulnerable patients from driving based on a prescribed treatment. The key areas of concern for road safety agencies include possible impairment and elevated crash-risk associated with legal medicinal cannabis products, and the potential for misuse and supplementation by patients. We discuss these issues in turn below as well as the patient impacts of the current regulatory framework.

Areas of concern

Evidence of safety (road safety risks associated with medicinal cannabis)

As with compounds used in various other prescription medications discussed above in Table 1, experimental studies have found that THC can have negative impacts on driving via impeded coordination, visual function and attention (Strand, Gjerde et al. 2016, Ogourtsova, Kalaba et al. 2018). However, on road and driving simulation studies have also identified evidence of changes in driver behaviours that mitigate potential crash risk associated with these impairing effects (Strand, Gjerde et al. 2016). These changes include an increased likelihood of overestimating impairment, leading to more cautious driving through the use of compensatory behaviours such as driving more slowly, maintaining an increased ‘following distance’ to the cars ahead, and having fewer attempts to overtake (Smiley 1999, Lenné, Dietze et al. 2010, Hartman, Brown et al. 2016). This contrasts with driving under the influence of alcohol, where drivers tend to underestimate their level of impairment and display more risky driving behaviours (Sewell, Poling et al. 2009).

Findings of epidemiological studies have been less consistent in identifying an increased road safety risk associated with cannabis use (US Congress 2019, Wood and Dupont 2020). A recent review of meta-analyses by Rogeberg and Elvik (2016) found that cannabis-impaired driving was associated

with a “low-to-moderate increase in crash risk” with an odds ratios of 1.22-1.36, and below 1.2 when alcohol was controlled for. Similar estimates of increased crash risk and culpability risk odds of between 1.1 and 1.4 are confirmed by a number of other recent meta-analyses (Elvik 2013, Gjerde, Strand et al. 2015, Rogeberg 2019). Some older meta-analyses have identified higher and lower odds ratios, but these typically failed to control for confounders such as age, gender, alcohol intoxication, and polydrug use (Rogeberg and Elvik 2016). The impairing effects of cannabis are known to increase when combined with alcohol (Ramaekers, Theunissen et al. 2011), contributing to a higher estimated crash risk for individuals using both substances concurrently (Drummer, Gerostamoulos et al. 2004).

However, such studies are only of partial relevance to medicinal cannabis as none have differentiated between medical and recreational use, and there are several reasons that a lower risk among medical patients would be expected. Patients accessing legal medicinal cannabis in Australia are doing so under the supervision of a doctor and the goal of this treatment is to achieve a clinical benefit while avoiding psychoactive side effects. This contrasts to most recreational use, which specifically relates to obtaining psychoactive effects. Driving under the influence of cannabis is also associated with being a young, male adult, a subpopulation holding ‘high risk’ attitudes towards driving and an elevated crash risk irrespective of cannabis use (Richer and Bergeron 2009, Bergeron, Langlois et al. 2014, Bergeron and Paquette 2014, Rogeberg and Elvik 2016). The demographic profile of the average Australian medicinal cannabis patient is notably different, with available data provided by the TGA indicating the majority of patients are female and over 50 years of age (TGA 2019). Older drivers with physical ailments are also known to reduce their driving exposure, generally only driving during the day and in locales they know well, leading to a lower crash risk than younger age groups (Stutts 1998, Alvarez and Fierro 2008).

A further potential risk reduction factor relates to the harm-benefit assumptions that underlie the usual prescribing of potentially impairing medications, and potential offsetting of increased road safety risks (National Transport Commission 2017). In medicinal cannabis patients, substitution away from drugs with documented impairing effects, including benzodiazepines and opioids, has been documented, with one study reporting that 45% of medicinal cannabis patients taking benzodiazepines at baseline had ceased use of these drugs at six months, while another found large reductions in opioid use among chronic pain patients (Boehnke, Litinas et al. 2016, Purcell, Davis et al. 2019). Similarly, improvements in symptoms may contribute to enhanced driving ability, either directly or indirectly. Such effects have been reported for the one medicinal cannabis medicine containing THC listed on the Australian Register of Therapeutic Goods, Sativex. Both driving simulation and large patient registry studies of Sativex have identified no evidence of increased accident risk, with many patients reporting an improvement in driving ability (Freidel, Tiel-Wilck et al. 2015, Etges, Karolia et al. 2016, Celius and Vila 2018).

Other evidence of reduced crash risk associated with medicinal, but not recreational cannabis, is provided by a number of US epidemiological studies investigating changes in road traffic accidents after the introduction of different types of cannabis legalisation. Using fatal crash data from 2010–2017 in US states Cook et al. (2020) found that the move from prohibition to ‘medical cannabis only’ frameworks was associated with fewer fatal crashes for both males and females, with the greatest effect evident for 15- to 24-year-old drivers. By contrast decriminalisation was associated with an increase in fatal crashes for you male drivers. Similarly, another recent study reported no increase in fatal crashes for states moving to ‘medical cannabis only’ access models, whereas an increase was observed in states implementing decriminalisation, legalisation, and combined medicinal and

recreational approaches (Lee, Abdel-Aty et al. 2018). Other research has also reported a reduction in road traffic fatalities in states introducing medical cannabis legalisation (without decriminalisation/legalisation), as well as reduced opioid positivity rates among fatally injured drivers aged 21 to 40, suggesting a potential substitution effect (Kim, Santaella-Tenorio et al. 2016, Santaella-Tenorio, Mauro et al. 2017). It is worth noting that these findings have been reported in US states with much more permissive medicinal cannabis schemes than Australia's prescription-only access model.

Misuse and supplementation

The potential misuse of prescribed medicinal cannabis is relevant to consider given the issues in this area that currently exist for other prescription medications such as opioids and benzodiazepines (AIHW 2020). In addition, supplementation with a chemically indistinguishable illicit version of the substance (i.e. prescribed cannabis being supplemented with illicit cannabis), or black-market prescription cannabis products, would also be possible. This risk also exists for other prescription medications such as morphine, which could be supplemented by heroin or black-market prescribed opioids. While both misuse and supplementation of medicinal cannabis are possible, there are several factors that may mitigate this risk.

In contrast to other medicines with a risk of misuse, no medicinal cannabis products are currently subsidised via the Pharmaceutical Benefits Scheme, meaning that patients need to pay the full cost of the product themselves, which is higher than the street price of illicit cannabis (Freshleaf Analytics 2020). As a result, there is little financial incentive for the diversion or overuse of prescribed medicinal cannabis products. In addition, almost all prescribing of medicinal cannabis products available in Australia (with one exception, Sativex) is via the Special Access Scheme Category B, under which approval for access involves an assessment of clinical appropriateness on a case-by-case basis by the Therapeutic Goods Administration. Further state level approval, in the form of a Schedule 8 treatment permit, is also required for any products containing THC in most jurisdictions if the patient is a known drug dependent person.

However, conversely, the high cost of medicinal cannabis products may provide an incentive for patients to either supplement their prescription with illicit cannabis or substitute their prescribed medication with an illicit cannabis product. In 2019, the National Drug Strategy Household Survey found that of people who had used cannabis in the previous 12 months 6.8% always used it for medical purposes and 16.3% used it for both medical and non-medical reasons. People who used cannabis for medical purposes differed from those who used it only for non-medical reasons in being significantly older, more likely to be experiencing chronic pain and very high psychological distress, and less likely to have recently used another illicit substance. Only 1.8% of respondents who had recently used cannabis for medical purposes had obtained this via a prescription, but no analysis of recreational use among this group was possible due to the low numbers (AIHW 2020). It is therefore difficult to draw firm conclusions about supplementation risk among patients prescribed medicinal cannabis, and this would be difficult to accurately ascertain in any future research as patients are likely to be reluctant to admit illegally supplementing their prescribed medicinal cannabis.

It is also noteworthy that patients with a valid prescription approved by the TGA and state authorities have explicitly chosen to use a legal, pharmaceutical grade medicine and do not fit the demographic profile of people who use cannabis recreationally, who are typically younger males (AIHW 2020). Supplementing or substituting with an illicit medicinal cannabis product of unknown composition,

strength, and with potential contamination would be at odds with the effort and expense of obtaining a legal pharmaceutical grade product, although as with some other medications this possibility cannot be entirely excluded. The widespread availability of illicit/recreational cannabis creates a somewhat different risk profile compared with opioids or benzodiazepines for example, where risk is more likely to be associated with misuse or overuse of prescription products.

Access and patient impacts

A particular difficulty for regulating driving for cannabis patients relates to the nature of THC, which is a highly lipophilic substance that accumulates in body fat and soft tissue of people who regularly use the drug, from where it is slowly released enabling detection in blood over a prolonged period (Wood and Dupont 2020). A recent systematic review found that among people who frequently use cannabis, detectable blood levels of THC could remain elevated at above 2ng/ml (or even 5ng/ml in some individuals) for 6 days (Peng, Desapriya et al. 2020). This group have been found to have a higher baseline THC blood level, and display no direct correlation between driving impairment and blood THC level (Wood and Dupont 2020). Oral fluid THC readings have been reported for a shorter but also extended period of up to 78 hours after last consumption, with concentrations not correlated to either degree of impairment or blood THC level (Odell, Frei et al. 2015, Busardo, Pichini et al. 2018, Jin, Williams et al. 2018). This is important to note, given that an estimated 60% of medicinal cannabis products available in Australia are oil products administered orally, meaning the THC is metabolised at a significantly slower rate (Vandrey, Herrmann et al. 2017, Freshleaf Analytics 2020). A recent US Congress research report on cannabis and road safety reported a 'lack of correlation between both marijuana consumption and the level of THC in a person's system, and THC levels and driver impairment', concluding that simple driver guidelines such as that provided with alcohol, are not possible (US Congress 2019). As such, it is near impossible for medical practitioners or law enforcement agencies to provide accurate information about THC clearance to medicinal cannabis patients, with current advice that patients should not drive at all if they wish to avoid the risk of being charged with a presence offence.

The scope of presence offences in most Australian jurisdictions creates a major impediment to accessing medicinal cannabis for those who wish or need to continue driving lawfully, and a severe limitation on personal mobility for those who do access medicinal cannabis and then refrain from driving (Commonwealth of Australia 2020). A typical example of such an impact is provided by this 62-year-old female patient who has had ovarian cancer for 10 years:

> *"After exhausting all conventional treatments, I received medicinal cannabis as part of a clinical trial and found the results to be favourable. I wanted to continue via a prescription from my GP, however, the police informed me that even though it was medically prescribed, I would be fined and have to go to court should I ever take a roadside drug test. I decided not to continue as I didn't want to give up driving, which is crucial for me to be able to live an independent life. Because of this I am continuing to use MS Contin [opioid] and Lyrica, which I don't like, and would much rather be taking medicinal cannabis to deal with the discomfort."*

Patients accessing medicinal cannabis in Australia are typically facing serious health conditions, most commonly chronic pain and cancer, for which this treatment provides a final therapeutic option. This group would be classified as "vulnerable/impaired" based on a framework of transport disadvantage

developed by Currie et al. (2010). They are particularly reliant on car travel and face high travel difficulties related to getting on and off buses, trains or trams, being able to get around alone, feeling safe when travelling, and an overall heightened risk of social exclusion due to transport disadvantage (Currie, Richardson et al. 2010). Documented effects of lack of car transport include exclusion from accessing basic goods and services, social/recreational opportunities, and employment and education, with greater impacts identified in rural and remote areas (Rose, Witten et al. 2009, Kamruzzaman and Hine 2011). Lack of car access has also been identified as an important barrier to healthcare access, contributing to poorer chronic illness management and health outcomes. Identified effects include an increase in missed appointments, delayed care, and poorer medication adherence, with one study quantifying an 88% increase in odds of ED presentation among individuals citing 'lack of transport' as a barrier to primary care use (Rust, Ye et al. 2008, Rose, Witten et al. 2009, Syed, Gerber et al. 2013).

For medicinal cannabis patients who do drive, when not impaired, they face the possibility of conviction under the presence offences and associated serious penalties including fines, licence suspensions or even imprisonment, a situation noted as problematic in the recent Senate inquiry (Commonwealth of Australia 2020). However, they may also incur further substantial financial penalties if claiming compensation following a traffic related accident and THC is detected in their blood or oral fluids. For example, in Victoria, patients who have THC detected in blood or oral fluids within 3 hours of driving following an accident, even if not at fault, can have their income compensation reduced by a third (Transport Accident Commission, 2020).

Driving restrictions have also been reported to be the major impediment to recruiting patients to medicinal cannabis clinical trials in Australia. Prohibiting driving for the length of a clinical trial, which can run for several weeks or months, is an onerous requirement that deters participants and results in reduced access to novel medicinal cannabis treatments.

International approaches

Although many countries around the world have introduced medicinal cannabis access schemes over the last decade, some of these, such as Canada and most states within the United States, are far more permissive than Australia's medical access model. Several of these overseas jurisdictions have also decriminalised or legalised the recreational use of cannabis and are therefore not comparable to Australia when considering road safety risks. However, a few international jurisdictions have introduced similar medical-only access models, with pharmaceutical grade products available only via prescription from a doctor. These jurisdictions include Norway, Ireland, the United Kingdom, Germany, and New Zealand. All of these countries other than New Zealand have drug driving presence offences relating to THC, similar to those that exist in Australia, but in all cases have adopted some form of medical defence enabling patients to drive when using a prescribed product as directed and not impaired (see Table 3). In all countries listed, other than New Zealand, it remains an offence to drive if impaired.

Table 3: International drug-driving (THC) enforcement approaches

Country	THC presence offence?	THC detection method	Situation for medicinal cannabis patients	Additional information
United Kingdom	Yes	Oral fluid taken at roadside. Blood at police station or hospital and sent to laboratory.	Medical defence - if not impaired, and using a prescribed product as directed	Prescription medicines also tested for, but 'Zero tolerance' towards the presence of illicit substances. (UK Department of Transport 2013)
Norway	Yes	Oral fluid taken at roadside. Blood at police station or hospital and sent to laboratory.	Medical defence - if not impaired, and using a prescribed product as directed	20 drugs both licit and illicit are tested for against per se limits correlating with impairment. (Norweigen Government 2020)
Germany	Yes	Oral fluid taken at roadside. Blood at police station or hospital and sent to laboratory.	Medical defence - if not impaired, and using a prescribed product as directed	'Zero tolerance' towards the presence of illicit substances, some licit substances also tested for (Bundesregierung 2020).
Ireland	Yes	Oral fluid taken at roadside. Blood at police station or hospital and sent to laboratory.	Statutory medical exemption certificate – does not apply if the person is found to be impaired (Road Safety Authority 2020).	'Zero tolerance' towards the presence of illicit substances. (Irish Government 2017)
New Zealand*	No	Field impairment assessment at roadside. Blood at police station or hospital and sent to laboratory.	Medical defence - if using a prescribed product as directed.	Presence of a licit or illicit drug (in blood) alone is not an offence, there must be additional evidence of impairment. (Transport 2019)

*A bill was introduced into the NZ Parliament in July 2020 which, if passed, will introduce a presence offence for THC detected in oral fluid. A medical defence will be available to patients prescribed medicinal cannabis (Ministry of Transport 2020). Note, a recent report of the New Zealand Attorney General has concluded that provisions of the proposed Bill are inconsistent with the New Zealand Bill of Rights and recommends changing the focus from general deterrence to impaired driving (Attorney General 2020).

In many of these countries the medical defence applies to various prescription medicines that can be tested for and that have per se limits attached (UK, Norway, New Zealand). However, In Ireland, where only illicit substances are tested for, a medical defence specific to medicinal cannabis was introduced and utilises a statutory medical exemption certificate. Other than medicinal cannabis, the only international example of a medical drug being included in zero-tolerance offences is benzodiazepines in Sweden, but patients there are not guilty of this offence if using the drug as directed by a doctor (Morgland 2020).

Discussion

As the number of patients accessing medicinal cannabis in Australia continues to increase, achieving the appropriate balance between road safety and patient access objectives is likely to gain further attention. Extensive experimental and epidemiological research indicates that the recreational use of cannabis is associated with a low to moderate increase in crash risk (OR 1.1-1.4), which is of a similar or lower magnitude than several other potentially impairing prescription medications available in Australia. However, the crash risk for prescribed medicinal cannabis is likely to be substantially lower due to a range of factors, with this outcome supported by available international data suggesting a nil road safety impact of 'medical only' access models, even when implemented in jurisdictions with much more permissive medicinal cannabis access frameworks than Australia.

Given this risk profile, the appropriateness of the current regulatory approach criminalising the presence of THC for medicinal cannabis patients irrespective of impairment is questionable. Only in Tasmania does a medical defence cover medicinal cannabis patients. In all other jurisdictions, patients risk criminal conviction for the presence of THC, even when not impaired and using the medicine as directed by their doctor. This approach has serious negative impacts on patient access, health, and mobility. It also fails to adhere to established principles that mobility should not be limited on the basis of a specific treatment, and that the potentially impairing effects of a medication should be balanced against a patient's improvement in health and safe driving ability (Austroads 2003, Commonwealth of Australia 2017). These principles are incorporated into the risk minimisation framework used for other impairing prescription medications, coordinated via the TGA and state health and transport agencies.

The discrepancy in the treatment of medicinal cannabis patients compared with patients using other impairing medications is particularly marked when considering that medical defences are currently in place for all other potentially impairing prescription medications that are included in drug driving presence offences in Australian jurisdictions (morphine, methadone and amphetamine). This creates a strange situation where medicinal cannabis patients are more restricted than users of some illicit drugs (such as heroin, LSD or psilocybin, in Victoria, NSW and Queensland) who are able to drive with the drug in their system if not impaired. Similarly, even recreational users of alcohol with a BAC 0.01 to 0.05, who have crash-risk odds of 1.2-1.8, face no restrictions on driving in normal circumstances (Taylor, Irving et al. 2010, Bernhoft, Hels et al. 2012, Chihuri, Li et al. 2017).

The question then arises whether there may be other specific issues relating to medicinal cannabis that necessitate a harsher approach for these patients. Some potential concerns include possible misuse or supplementation of medicinal cannabis with black market products, and the difficulty in communicating why medicinal cannabis patients can drive (if not impaired), but not recreational users. Both issues are common to, and currently managed for, other potentially impairing prescription medications, with the public now well accustomed to different legal frameworks being in place for medical and illicit cannabis. The need for further research prior to any change has also been suggested, but considering the large number of observational and epidemiological studies that have already been undertaken in relation to THC, which provide an evidence base far exceeding numerous other known impairing medications, as well as agreement of recent meta-analyses of a relatively low risk profile, the value or justification for such an apparent higher evidence bar for medicinal cannabis is unclear.

It is also noteworthy that other countries with medicinal cannabis schemes similar to Australia's tightly controlled, medical only access model, have implemented some form of exemption from usual drug driving offences for patients. In the UK, Norway, Germany, New Zealand and Ireland, patients with a valid prescription for medicinal cannabis who have taken the drug in accordance with instructions from a health practitioner are permitted to drive, as long as they are not impaired.

Although not implemented elsewhere, further policy options that may be considered alongside a medical defence or exemption for THC presence offences, include: requiring a zero blood alcohol limit for medicinal cannabis patients (due to alcohol-THC cross impairment increasing road safety risk (Downey, King et al. 2013)), prohibition from driving during the first weeks of treatment to allow for dose finding and tolerance development, specifying a maximum daily prescribed THC limit, above which the medical exemption would not apply, and simply improving patient education or advice. Due to the nature of THC metabolism and elimination, lack of correlation between oral fluid or blood levels and impairment in high frequency users, and the inability to provide accurate advice to patients regarding THC clearance, the use of oral fluid or blood threshold levels is near unworkable. Even in Norway, for example, where an upper blood threshold of 9ng/ml has been adopted for the general population, a medical exemption from this limit is in place for legal medicinal cannabis patients. Ongoing improvement in roadside impairment detection, including the potential applications of new technologies such as apps and artificial intelligence, is also important and relevant for all potentially impairing medications.

The current regulatory approach to medicinal cannabis and driving in most Australian jurisdictions, which criminalises the presence of THC in bodily fluids while driving irrespective of impairment, appears to derive from the historical status of cannabis as a Schedule 9 substance with no recognised medical value. There is little evidence to justify this differential treatment of medicinal cannabis patients, compared with those taking other potentially impairing medications. The relatively low risk profile of medicinal cannabis, harms associated with the current regulatory approach, and successful implementation of alternative policies in comparable countries suggest that a review of the regulatory framework for prescribed medicinal cannabis and driving is warranted.

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Appendix F: VIFM – Medicinal Cannabis and Driving report

VICTORIA State Government | Justice and Community Safety

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MONASH University

Medicinal Cannabis and Driving

Olaf H. Drummer, Dimitri Gerostamoulos and Noel Woodford
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Medicinal Cannabis formulations

Medicinal cannabis products are increasingly prescribed around the world to treat various conditions such as nausea and vomiting due to chemotherapy, to stimulate appetite in HIV/AIDS, neuropathic pain, spasticity due to multiple sclerosis or paraplegia, and others such as overactive bladder, epilepsy in children and may even be useful in treating some cancers [1]. Most of the pharmacological properties of cannabis is believed to derive from delta-9-tetrahydrocannabinol (THC) and the related cannabidiol (CBD), although another cannabinoid, the propyl analogue of CBD, cannabidivarin (CBDV) may also contribute [2]. However, CBD appears to have the most potential as a medicinal agent compared to THC itself [3].

The only approved product in Australia is Sativex® which contains a mixture of 1:1 THC and CBD and is available under the special access scheme for moderate to severe spasticity due to multiple sclerosis (MS). This is an oromucosal spray with each dose containing 2.7 mg THC and 2.5 mg CBD. All other medicinal cannabis products are unregistered medicines that contain various ratios of CBD and THC or only CBD [4]. The formulations of CBD:THC are typically prescribed in much lower doses (5-20mg) than CBD only medications (50-1500mg).

While medicinal cannabis products are generally well tolerated at low to medium doses, higher doses can lead to somnolence and sedation effects which are dose-related [5, 6]. These effects can impair driving and those effects can be exacerbated if other drugs are also consumed (e.g. benzodiazepines, alcohol) [5].

Pharmacological considerations of cannabis

THC produces a sense of relaxation and euphoria caused by centrally mediated sympathetic stimulation and is associated with impaired cognition and reduced psychomotor activity along with increases in heart rate and cardiac output. CBD, aside from its medicinal properties, possesses anti-anxiety actions, anti-psychotic effects, and even modulates metabolism of THC and other co-administered drugs. The effect on metabolism occurs by inhibition of many of the CYP450 isozymes, particularly 1A1, 3A4 and 2C19. While not all of these pharmacokinetic interactions may be clinically relevant it is likely that the raised concentration of the active clobazam metabolite, norclobazam, by inhibition of CYP2C19 increases antiepileptic activity in children receiving both CDB and clobazam, and may even affect the concentration of other anti-epileptic drugs [7, 8]. Other potential interactions of cannabis products and prescribed medications are still being explored.

The bioavailability and pharmacokinetics of THC and other cannabinoids are complex. Illicit cannabis is mostly smoked either as a cigarette (joint) or through a water-pipe (bong), however, use of electronic vaporisers is also practised. When inhaled cannabinoids are rapidly absorbed in the lungs leading to rapid uptake into the circulating blood and tissues and a consequent rapid onset of actions. Oral consumption of cannabis in the form of baked

products is relatively uncommon but both THC and CBD show highly variable but largely low bioavailability due to extensive first pass metabolism. Oromucosal administration to volunteers gives a much higher bioavailability than ingestion due to sublingual absorption [9], however some drug sprayed into the mouth will be absorbed in other parts of the oral mucosa and even swallowed that will reduce the net amount available for activity. For example, oral absorption gives oral fluid concentrations of THC and CBD less than 1% of that obtained following sublingual dosing. Despite their very similar structures THC is not produced from CBD in humans.

Smoking joints, for example, leads to blood THC concentrations well over 100 ng/mL within minutes, followed by a rapid decline in blood concentrations as uptake into tissue compartments occur. Oral fluid (saliva) concentrations of THC are very high initially if cannabis is smoked due to local deposition of the combustion products in the membranes/tissues of the oral cavity (mouth). Even after a few hours there are still higher levels in the oral fluid compared to blood, often about 5-20 times higher. The relatively large amounts of cannabinoids in oral fluid enables easier detection of them using drug testing devices designed to detect these substances in saliva.

In controlled clinical studies oromucosal administration to patients with multiple sclerosis has shown highly variable peak plasma concentrations that are much lower than obtained using illicit smoked cannabis. The application of two sprays 15 minutes apart gave plasma CBD concentrations of 0.55 to 12 ng/mL (median 1.6) while for THC the range was 0.6 to 13 ng/mL (median 1.8) [10]. The detection of THC after both low (5.4 mg) and high (21.6 mg) doses of Sativex taken oromucosally showed the rapidly detectable presence of both THC and CBD in oral fluid with similar peak concentrations of both substances. In some patients the peak concentrations were well over 10,000 ng/mL shortly after administration. At 2 hours post-dose concentrations were still easily detectable and well over the usually applied analytical cut-off concentrations. At 10 hours post-dose oral fluid concentrations were still measurable with medians following low and high doses of Sativex of 17 and 34 ng/mL for THC, and 23 and 35 ng/mL for CBD [9].

Detection of cannabis at the roadside

In Australia it is currently an offence for a person to drive with any amount of THC in their body, including any amount of THC from medicinal cannabis. Penalties for drug driving include a mandatory driver license suspension and monetary fines. This law is mostly enforced by random roadside testing of drivers using collected oral fluid through the use of especially designed collection devices. A zero-limit applies with this law, which means that a person will be penalised with any amount of THC detected in oral fluid (above a zero concentration). This law is designed to deter use of cannabis (and other prescribed drugs) just before and during driving when an individual may be impaired and likely to be a higher crash risk to other road users. However, this law does not require a person to be impaired.

In practice, drivers are first tested by a swipe of their tongue or the inside of the cheek whilst in their vehicle using a first-stage roadside detection device, such as the DrugWipe. In essence if the device records a presumptive positive result, a sample of oral fluid is collected from the driver using an especially designed kit and a small aliquot tested on another device (this second stage varies somewhat around the country). If this test is also showing a positive response, the remaining specimen, or another specimen collected contemporaneously, is sent to an approved forensic laboratory for confirmatory testing. It is only after the confirmatory test determined to be positive that a driver will be penalised. This latter test is conducted using the highly specific mass spectrometry. The initial screening tests are based on lateral-flow immunoassays that recognise THC and some other cannabinoids but appears to have little or no cross-reactivity to CBD, although this needs to be confirmed with suppliers, or validated independently, as batches and products change.

As with any preliminary drug testing device the ability to detect a relevant concentration with a reliable degree of accuracy and specificity (ability to detect the right substance) is essential. For this reason, test devices have a cut-off concentration or a detection limit. This means that

the device is unlikely to detect the relevant drug below this concentration, but there is confidence in detecting the drug at concentrations higher than this cut-off.

The current roadside detection process in oral fluid and the parameters of the roadside screening device should mean that only users of illicit cannabis will be detected for about a few to several hours after last use; a time when they most likely to be impaired. However, it is known that low concentrations of THC may persist in oral fluid for at least 12 hours, and even longer in some situations, particularly regular high-dose users of illicit cannabis [11]. While drug testing devices such as the DrugWipe are unlikely to detect these lower concentrations there is still be a low probability the device will record a positive for longer than several hours in a small number of heavy users after their last use of cannabis.

Standards Australia AS/NZS 4760 provides guidance on the testing of drugs of abuse in oral fluid and has recently in a 2019 update lowered the confirmation cut-off in the laboratory to 5 ng/mL (from 10 ng/mL). This Standard was designed primarily for workplace testing rather than use for roadside detection of prescribed drugs, although many laboratories apply the cut-offs listed in this standard when reporting confirmed results. If laboratories reduce their reporting thresholds to 5 ng/mL this should only marginally increase the number of positive cases since the screening cut-off using DrugWipe has not changed, however these cases are more likely to be drivers who have had past use of cannabis (beyond several hours) and may not be significantly impaired and may detect some users of medicinal cannabis.

Controlled studies on subjects taking medicinal cannabis using the current first stage screening device have not been tested beyond 6-8 hours, however, a recent Australian study assessed the performance of DrugWipe in volunteers (users of cannabis up to 2 times weekly) who had smoked a 11% THC preparation using a vaporiser. In these 14 volunteers only 2 returned a DrugWipe positive at 60 min post-dose, and none in the next hour [12]. An earlier study published in 2014 from Belgium in 10 chronic users (at least 2 joints per week) who smoked 300 ug/kg (~20 mg) found DrugWipe detection at 80 minutes post dose was only 50% [13].

These studies show that THC might be detected in oral fluid in persons taking oromucosal THC/CBD formulations, but not if they consumed formulations designed for oral use or had swallowed the bulk of the sprayed formulation. Oromucosal use will be preferred since this route of administration will have far more efficacy as a treatment than oral use. Alternatively, if cannabis is smoked or vaporised then oral fluid concentrations will also be detectable for some hours post administration.

The detection of CBD in addition to THC in oral fluid (or blood) specimens is possible, and will produce similar concentrations to THC when patients use a 1:1 THC/CBD mixture, however there is CBD in illicit cannabis (and even can be sourced by users) but with considerable variability from one batch to another. At this point in time, it is not possible to use comparative CBD and THC levels to distinguish prescribed use of Sativex from other preparations.

Does Medicinal Cannabis affect driving?

There is no doubt that the use of cannabis (primarily THC) impairs key driving skills for a few hours post use. This is supported by a host of psychometric, behavioural and on-road studies, however the degree to which illicit cannabis affects crash risk has led to much debate, several epidemiolocal studies and publication of a few meta-analyses. While the increase is modest, on average, and less than for alcohol-positive drivers there is still an increased risk even when possible confounders have been examined. A large study conducted by us recently in Victoria on 5000 drivers injured and taken to hospital show an odds ratio of 1.9 for drivers only positive to blood THC. Importantly, as has been shown before, those drivers with THC concentrations 5 ng/mL or higher show an increased risk over all drivers positive to THC-alone (over 3), while drivers with blood THC 10 ng/mL or higher, had a odds ratio of 10 [14]. This distinction is often missed in reports and meta-analyses. Low level THC, like alcohol under 0.05%, 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.

Unfortunately, the ability to detect impairment in drivers is most difficult, even if a trained police officer or forensic medical physician were at the roadside. Most of the signs of impairment are subtle; including reduced concentration (inattention etc), reduced visual acuity and poorer divided attention tasks, and by the time a formal assessment is conducted an hour or two later any signs will have dissipated. Most of the drivers that fail a standardised sobriety assessment in the current (Victorian) Driving Whilst Impairment offence have two or more impairing drugs present that increase further detectable signs of impairment. As such, we do not recommend that only drivers on medicinal cannabis that are impaired be fined, since it is neither practicable nor feasible to perform such a test.

There are currently few published papers that specifically examine driving following the use of medicinal cannabis [12, 15, 16].

In a recent study the presence of CBD in medicinal cannabis formulations (CBD:THC, 1:1) was compared with administration of THC (11% formulation) and was shown to be no less impairing to THC on its own [16] when administered to healthy, infrequent users of cannabis. Individuals demonstrated impairment to THC on a number of different tasks including divided attention, cognitive function and lane weaving irrespective of the formulation of cannabis administered. Another more recent study demonstrated that neither CBD nor CBD dominant cannabis acutely impaired cognitive functioning [17].

In the most recent publication assessing the effect of CBD and THC/CBD on driving performance it was found that some impairment was observed in relation to maintaining a steady lateral position on a highway at 95 km/h for those given CBD and or CBD with THC. The impairment was significant up to 100 mins but not at 240-300 mins after administration. The administration (vaporised) of CBD dominant cannabis was found to have the same effects on driving as placebo however the doses of CBD administered may not be representative of common usage [12].

Summary

- Medicinal cannabis formulations vary in composition and strength of CBD and /or THC.
- Therapeutic doses of medicinal cannabis (CBD/THC) range from 5-20mg and up to 1500mg for CBD only preparations.
- Roadside screening devices are unlikely to detect drivers consuming CBD only preparations of medicinal cannabis.
- Drivers who take medicinal cannabis (CBD with THC) oromucosally are unlikely to test positive at the roadside using the current screening device and confirmatory cut-offs.
- Drivers that smoke cannabis (with or without CBD) are likely to be detected at the roadside for up to a few hours post-dose.
- Drivers that are heavy users of illicit cannabis (with or without CBD) are likely to be detected at the roadside for longer than a few hours post-dose.
- CBD/THC formulations of medicinal cannabis can impair driving. The impairment effects are significant within 2 hours of consumption and are similar to those effects observed in drivers consuming just THC.
- At low doses, CBD only medications do not impair driving, however it has not been established whether high dose preparations of CBD affect driving.

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Appendix G: DJCS – Background Information for Working Group

Medicinal Cannabis and Safe Driving WG

Background information

The following documents are provided as additional background for the Medicinal Cannabis and Safe Driving Working Group:

A. Drug related road trauma in Victoria

B. Victoria's drug driving program

C. Medicinal cannabis patients, products, and prescribing approaches in Victoria

A. Drug related road trauma in Victoria

Fatalities

- There were approximately 250 road deaths each year across the five-year average between 2015 and 2019. Drivers/riders (those in charge of the vehicle) accounted for approximately 160 of those deaths (64 per cent). Autopsy blood analysis found that THC was present in approximately 10.3 to 18.1 per cent of those deaths. Over the last decade, the rate of road deaths involving THC has been stable at roughly 15 per cent.
- Methamphetamine in crash autopsies has increased significantly over the last decade with stimulants (primarily methamphetamine) recorded in over 22 per cent in 2019.
- The main prescription drug found in crash autopsies are benzodiazepines, which ranged from 5.2 to 8.7 per cent in the five years between 2015-2019. This is likely to represent a mixture of legitimate prescription use and illicit abuse, however it is difficult to disaggregate this data.
- Alcohol above 0.05 BAC in crash autopsies has declined over the last decade from low-mid 20 percentages to mid-high teen percentages.
- Ecstasy, opioids and cocaine are found at lower rates (less than five per cent each).
- The above figures are conservative on the rate of these drugs in total Victorian road trauma as they do not include other road users (passengers, other drivers, pedestrians) who may have been killed in crashes caused by substance-impaired drivers. In total, drug driving is the current preeminent challenge in road safety in Victoria.

Serious injuries

- A Victorian Institute of Forensic Medicine (VIFM) program that analyses blood samples from 1000 serious injury road crash cases taken to Victorian hospitals have found similar patterns of impairing substances, namely the prevalence of methamphetamine, alcohol, cannabis and benzodiazepines. These serious injury findings support the inclusion of cannabis and methamphetamine as proscribed substances under Victorian drug driving laws.

B. Victoria's drug driving program

Roadside testing

- There are two legislative provisions underpinning the drug driving testing program.
    - 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. This is a time consuming and resource intensive process and is rarely used (about 300 per year), most typically after a crash. Penalties that can be imposed by the courts under this legislation are fines of up to 12 penalty units ($1,982) and 12 months licence cancellation for a first offence, with higher penalties for repeat offences.
    - The *Road Safety (Drug Driving) Bill 2003* allows police to take a saliva sample at the roadside, which if positive will be analysed in a laboratory. 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 – currently 150,000 test per year. This legislation/process only reports the presence of a drug, not an impairment level. The current penalty for a first offence infringement is three penalty units ($496) and six months licence suspension. Higher penalties apply for repeat offences.
- The 2003 legislation is based on a presence approach as THC in saliva is not consistent with blood levels as THC does not pass from blood to saliva but is rather mouth residue from smoking or consumption. That is, no per-se impairment level can be determined from saliva. The quick metabolism of THC (tens of minutes to a few hours) in saliva to non-impairing and non-prosecutable forms of THC, means that a saliva detection is indicative of recent consumption that is likely to be associated with a level of impairment.

Hospital testing

- Provision exists for the analysis of blood samples taken from injured drivers admitted to Victorian hospitals, and uninjured drivers involved in crashes. Positive findings may result in prosecutions under the 2000 legislation.

Laboratory processes

- All drug driving related fluid samples, whether saliva or blood, are analysed by VIFM to the applicable Australian Standard. VIFM toxicologists provide expert evidence to courts in prosecuted cases and provide expert scientific advice on drug driving issues.

C. Medicinal cannabis patients, products, and prescribing approaches in Victoria

- As with other medications, medicinal cannabis products can be prescribed by any doctor to treat any patient, if the doctor 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, MS and sleep disorders. The majority of patients are female and over 50 years of age.
- As of 30 November 2020, the TGA had issued over 80,000 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. Around 80 per cent of SAS-B approvals are for Schedule 8 products, with additional prescribing of Sativex (the one 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.
- Due to COVID-19, from 27 March 2020 to 27 March 2021, Victorian doctors have been permitted to prescribe all schedule 8 medicines (including medicinal cannabis) without the need for a Victorian permit. It is not known how many of these patients have filled their prescription. Palliative care patients are exempt from requiring a schedule 8 treatment permit at all times.
- Between January and November 2020, SAS-B approvals for medicinal cannabis prescriptions nationally increased from 3148 to 6356 per month, and are expected to reach around 14,000 per month by the end of 2021 (2,800-3,500 per month in Victoria)
- Any medicinal cannabis products containing THC must include the following warning statement “This medication may cause drowsiness. If affected do not drive or operate machinery”. Advice from prescribers is that they often inform patients they cannot drive while taking these 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 in aggregated format. Specifically, the following data is not readily available to road safety agencies (unless they are referred for medical review as a result of their underlying medical condition):
    - Underlying condition and co-morbidities
    - Matching of prescription types and dosages with underlying medical conditions (the reason for the prescription)
    - Other relevant behavioural factors such as alcohol use and driving patterns (how soon after consumption).
    - Licence type (e.g. commercial, private vehicle, probationary, relevant to road safety risk).

Appendix H: MUARC Report – International and Australian experience of medicinal cannabis programs with respect to driving and road safety

VICTORIA State Government | Justice and Community Safety

MONASH University

ACCIDENT RESEARCH CENTRE

REPORT TO MUARC BASELINE COMMITTEE ON MEDICINAL CANNABIS AND DRIVING

INTERNATIONAL AND AUSTRALIAN EXPERIENCE OF MEDICINAL CANNABIS PROGRAMS WITH RESPECT TO DRIVING AND ROAD SAFETY

ASSOCIATE PROFESSOR MICHAEL FITZHARRIS
RENEE ST. LOUIS
DR SARA LIU

16 OCTOBER 2020

FOREWORD

This report, titled I*nternational and Australian Experience Of Medicinal Cannabis Programs with Respect To Driving and Road Safety*, was commissioned by the Department of Justice and Community Safety (DJCS), the Transport Accident Commission, Victoria Police, the Victorian Department of Transport, and the Victorian Department of Health and Human Services, and funded under the Monash University Accident Research Centre Baseline Program.

This research was undertaken to document international and local practices concerning driving / riding for users of medicinal cannabis. This research was conducted as one input to understand the considerations surrounding the driving requirements of users of medicinal cannabis and associated road safety laws in Victoria.

MONASH University

CONTENTS

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ACKNOWLEDGMENTS

The authors express their sincere appreciation to the MUARC Baseline Sponsors for supporting this research. The sponsors and their representatives were:

Department of Justice and Community Safety: William Gibbons.

Department of Transport: Sharon Wishart, Christopher Poulter, Catherine MacDonald.

Transport Accident Commission: Michael Nieuwesteeg.

Victoria Police: Superintendent Glenn Owen

Department of Health and Human Services: Katharine Gibson.

EXECUTIVE SUMMARY

CONTEXT

While the use of cannabis for medicinal purposes has a long history outside of traditional medicine, the therapeutic applications of cannabis are increasingly recognised. Indeed, the use of medicinal cannabis is now permitted in a large number of countries–including Australia–following regulatory agencies placing medicinal cannabis on the register of therapeutic goods. This has led to greater access to medicinal cannabis products for people where conventional medicines have failed and its use is considered *clinically appropriate* by a medical practitioner.

As a consequence, a question has emerged as to whether drivers and motorcycle riders who are prescribed medical cannabis ought to be permitted to drive / ride. This question and issues can be stated as:

> Given the well-documented negative impacts on the skills required for safe driving associated with THC (i.e., the main psychoactive ingredient of cannabis)–and the well-documented increased crash risk–ought governments permit prescribed users of medicinal cannabis to drive a vehicle or ride a motorcycle? If so, what steps need to be taken, if any, to ensure this is safe to do so?

Notwithstanding differences in formulation and dose, the pertinent point is that THC is the primary psychoactive ingredient of cannabis, whether it is used for recreational purposes or as a medicine. Here, it is noted pure Cannabidiol (CBD) products are not considered in the same way as THC-based products as CBD does not have psychoactive effects.

A related point is whether the treatment benefits of medicinal cannabis are sufficient to provide symptom relief and overcome any difficulties with safe driving due to long-standing treatment resistant medical conditions. Here it is important to note that medicinal cannabis is used for a large range of medical conditions in many jurisdictions including Victoria; in contrast, in other countries the indications for use is significantly narrower and more closely linked to efficacy studies. This is important to consider as the number of permitted indications relates to access; in turn, this directly impacts the number of potential drivers and riders who are prescribed medicinal cannabis and who may present as a road safety risk.

Advocates of medicinal cannabis argue that when used as a medicine cannabis ought to be treated like any other medicine with respect to driving. It is also argued that consideration needs to be given to the important role of the vehicle in ensuring mobility and social engagement as well as rights-based arguments relating to the ability to use a legitimate medicine. Other arguments that driving is permitted following alcohol consumption and other prescription medications are also put forward as a basis for permitting users of medicinal cannabis to drive or ride a motorcycle.

The principal challenge for governments is this: given that cannabis can now be used as a medicine for the treatment of medical conditions and knowing the negative impacts of cannabis use on driving skills and the associated increased crash involvement, how can this cohort of drivers and riders be managed most appropriately in the context of enforcement programs designed to reduce the significant negative impacts of drug-driving on community safety?

AIM OF THE CURRENT RESEARCH

The medicinal cannabis access program commenced in Victoria in 2017 following the passage of the *Access to Medicinal Cannabis Bill* in 2016 passed. As at 2019, all Australian States and Territories have passed laws permitting the use of medicinal cannabis. Similarly, the Australian Government implemented a raft of regulatory changes to facilitate the use of medicinal cannabis in Australia. This follows the lead of many other jurisdictions around the world.

With the proliferation of medicinal cannabis programs globally, there is an opportunity for Victoria to examine how the question of driving is managed for users of medicinal cannabis. This is particularly important as medicinal cannabis is a new area of therapeutics and consequently our understanding of the impacts of medicinal cannabis on safe driving is limited

The overall aim of this research was to provide a detailed understanding of selected international medicinal cannabis programs as they relate to driving. This extends to whether prescribed users of medicinal cannabis are permitted to drive, and if so, under what conditions if any. Of particular interest is how other jurisdictions manage the question of roadside drug-driving detection protocols. By examining this process-based data and documenting impacts on road safety of medicinal cannabis programs, a contrast can be drawn with Victoria. Doing so will bring key insights into the challenging issue of medicinal cannabis and driving can be addressed.

METHOD

Extensive information was collected pertaining to medicinal cannabis programs and associated drug and drink-driving laws in selected international jurisdictions as well as all Australian States and Territories. The primary focus was on documenting laws and regulations concerning the rights of prescribed users of medicinal cannabis to drive. Associated processes concerning driver impairment, fitness-to-drive and other licensing provisions were collected. Attention was paid to whether programs had been subject to evaluation for their impacts on road safety outcomes.

A comprehensive data extraction template was created and applied to all selected jurisdictions to ensure uniformity. Documents were translated from German (Switzerland, Germany) and French (Switzerland, Quebec, Canada) to English.

Selection criteria for jurisdictions included whether recreational cannabis was legal or decriminalised, the nature of drug and alcohol enforcement procedures, and a desire to obtain a wide geographic and cultural mix.

FINDINGS

The characteristics of medicinal cannabis and drug-driving laws in selected jurisdictions in the Europe Union (Ireland, Germany), Switzerland, Canada (British Columbia, Quebec), the United States (Texas, Oregon) and Australia were examined. Each jurisdiction was examined individually with extensive information relating to medicinal cannabis program characteristics, legislation, and processes associated with drug-driving regimes being presented.

To facilitate a comparison with Victoria to be made, Table E.1 highlights selected features and points of difference across each jurisdictions with respect to drug-driving procedures and the exemption status for prescribed users of medicinal cannabis. A summary of commonalities and differences not noted in Table E.1 are described below.

Commonalities (base state) among all jurisdictions

- All jurisdictions examined have medicinal cannabis provisions under government approved process with medical doctor permitted to prescribe medicinal cannabis.
- All have extensive drug-driving penalties for THC (as well as other illicit drugs).
- All have extensive drink-drive provisions, with roadside breath testing.
- None of the jurisdictions examined have evaluated the impact of prescribed medicinal cannabis use and access programs on the driving behaviour and crash-involvement rates of prescribed users.

Differences

- For medicinal cannabis, qualifying conditions (indications) vary from very strict with limited medical conditions (Ireland) to any medical condition being eligible for medicinal cannabis use. This is important as it has an impact on the number of people who may be driving while prescribed and using medical cannabis.
- Differences are evident in available THC and CBD products, including pharmaceutical raw flower–used via vaporiser–through to oils, oral-mucosal sprays, extracts, tablets and gels.
- Exemptions from THC drug-driving offences apply in Ireland, Germany and Switzerland on the proviso the driver is not impaired nor shows any detrimental impact of the drug on driving performance. No such exemption applies to any jurisdiction in Australia.
- No jurisdiction permits an exemption for the use of medical cannabis for a driving-under-the-influence (DUI) or driving-while-impaired offence.
- Jurisdictions that have medical exemptions for cannabis to drive have extensive provisions and procedures for the assessment of driver impairment and fitness-to-drive, supported by toxicological results. Driver Impairment Assessments using a pre-determined test battery are well-defined and conducted. These however take extensive time, resource commitment and training.
- A number of jurisdictions test for a range of prescription and illicit substances not currently tested for routinely in Victoria.
- While a number of international jurisdictions use oral fluid tests, blood (or urine) is also used for evidential purposes.

- Penalty / offences differ in their quantum, and procedures to re-license post-licence or prove fitness-to-drive are extensive (e.g., Germany).
- While recreational cannabis is illegal in all Australian jurisdictions, noting recent decriminalisation in the ACT, the legal status of recreational cannabis was seen to differ.

TABLE E.1 COMPARISON OF SELECTED DRUG-DRIVING PROGRAM CHARACTERISTICS IN SELECTED JURISDICTIONS COMPARED TO VICTORIA

Jurisdiction	Roadside Oral Fluid Test (OFT) (Evidential, EV:)	Per se law (presence)	DUI / DWI offence	Formal Driver Impairment assessment	Medical cannabis exemption on per se offence	Recreational cannabis use permitted
Australia						
Victoria	OFT	Yes	DUI + DWI	For DWI (DIA)	No	No
NSW	OFT	Yes	DUI	No	No	No
ACT	OFT	Yes	DUI	No	No	De-criminalised
QLD	OFT	Yes	DUI	No	No	No
NT	OFT Ev:blood	Yes	DUI	No	No	No (small amounts de-criminalised)
WA	OFT	Yes	DUI + DWI	For DWI	No	No
SA	OFT	Yes	DUI	No	No	No (small amounts de-criminalised)
TAS	OFT	Yes	DUI	No	No	No
European Union (EU)						
Republic of Ireland	OFT Ev: blood / urine	Yes	DWI	Formal, fit-to-drive	**Yes**	No
Germany	OFT Ev: blood	Yes	DWI	Impairment procedures plus Fit-to-drive assessment	**Yes**	No (small amounts de-criminalised)
Europe						
Switzerland	OFT Ev: blood	Yes	DWI	Formal, incapacitation, Fit-to-drive	**Yes**	No (small amounts de-criminalised
Canada						
British Columbia	OFT Ev: blood	Yes	DWI	SFST† DRE‡	No	Yes
Quebec	OFT Ev: blood	Yes	DWI	SFST† DRE‡	No	Yes
United States						
Texas	**No OFT** Ev: blood/urine	Yes	DWI	Impairment battery, includes DRE tests	No	No (if THC >0.3%)
Oregon	**No OFT** Ev: blood/urine	Yes	DWI	Impairment battery, includes DRE tests‡	No	Yes

Note: †SFST – Standard Field Sobriety Test; ‡DRE: Drug Recognition Expert process (12 step process); Ev: Evidential.

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DISCUSSION POINTS, KEY LEARNINGS AND FUTURE QUESTIONS

This report highlights important differences in the way drivers in Victoria (and all other Australian jurisdictions) and international jurisdictions are managed with respect to medicinal cannabis use.

Exemptions for users of prescribed medical cannabis is permitted at roadside drug tests

A number of international jurisdictions (Switzerland, Germany, Ireland) apply an exemption for drivers who are prescribed medicinal cannabis and who return a positive drug-driving test. This exemption status is limited to drivers and riders who are prescribed medical cannabis by their medical practitioner and who are not impaired with respect to driving (see below). In the event of a positive roadside drug test, proof of this treatment relationship and care is required; indeed, this may include the direct involvement of the prescribing doctor. Drivers must present a prescription or a more formal medical cannabis certificate for this exemption to apply.

In practical terms, a driver stopped at a random roadside check-point who tests positive to THC but does not demonstrate any impairment or inability to drive safely is not subject to a drug-driving offence upon providing a prescription for medical cannabis or a medical cannabis certificate to the police officer.

The remaining jurisdictions (North America, Australia) examined do not permit any exemption from their drug-driving laws based on prescribed medicinal cannabis use

Prescribed use is no defence to impaired driving: Impairment assessment and fitness-to-drive protocols are robust

However**,** the exemption to permit users of medicinal cannabis to drive **only applies** where a driver is **not impaired** in any way nor demonstrates any safety risk to themselves of other drivers.

To enable this exemption, the relevant jurisdictions have implemented detailed regulations and processes concerning the assessment of driver impairment. This assessment can range from observation of a driver error or violation through to extensive driver impairment assessment protocols. Any demonstration of impairment or a driver / rider presenting as a safety risk results in the driver / rider being subjected to the drug-driving offence process. In short, a prescription of medical cannabis is not a defence to observed risky or impaired driving. In the event impairment is shown, a full fitness-to-drive assessment along with a full physical and mental health examination may be also required either immediately or upon re-licensing.

Following from above, it is notable that the jurisdictions where a medical exemption to cannabis is applicable also test for a range of prescription medications and illicit substances. In these jurisdictions, it is considered imperative to have provisions that permit users of prescription medications to drive whilst ensuring that the safety of all road users is adequately balanced against any impaired driving from any driver / rider that may result from use of any prescribed medications. The regulations and associated processes aim to achieve this balance have evolved over many years.

It remains important to point out that overseas jurisdictions take drug-driving extremely seriously. This is reflected by their extensive penalty regimes and in the well-established impairment assessment, fitness-to-drive, and associated licensing and post-offence protocols. The use of an impairment-based process permits a full range of substances (prescription/illicit) to be tested. It appears that these processes are well accepted by the communities that they are designed to protect.

Take outs for Victoria and future research questions

This report has highlighted a range of approaches in managing the safe driving of prescribed medicinal cannabis users. With the State of Victoria having recently introduced a prescription medical cannabis program, the insights gained from these jurisdictions may inform Victoria's response to the question of driving (riding) by individuals prescribed medicinal cannabis in relation to current drug-driving laws.

Given the recency of medicinal cannabis programs and the international experience on managing driving, there are a number of questions that remain outstanding. These relate to the pharmacokinetics of medicinal cannabis and detection of THC at the roadside, as well as measures of impairment and fitness-to-drive assessment procedures specific to this group. Further research to identify the most appropriate model for Victoria with respect to managing safe driving of prescribed medicinal cannabis users is recommended. An important input to this would be an assessment of the driving behaviour and crash-involvement rates of medicinal cannabis users now and in the future.

1 INTRODUCTION

1.1 BACKGROUND

1.1.1 MEDICINAL CANNABIS USE IN VICTORIA

Medicinal cannabis has been permitted for use in Victoria since 2016 following the passage of enabling legislation[1,2] with the program commencing in July 2017. This followed recommendations of the Victorian Law Reform Commission (VLRC) per their *Medicinal Cannabis* report (2015).[3] The move to permit medicinal cannabis has followed global trends. Globally, the decriminalisation or legalisation of cannabis for personal use has generally followed the implementation of medicinal cannabis programs.

The medicinal cannabis program–managed in Victoria by the Office of Medicinal Cannabis within the Department of Health and Human Services (DHHS)–can be considered expansive by international standards. In Victoria, medicinal cannabis is permitted for a large range of medical conditions noting that permitted use for individuals under 18 years is limited for those experiencing intractable epilepsy.

Since its commencement there has been strong interest in and uptake of prescribed medicinal cannabis. This is despite its high financial cost relative to other prescribed medications that are subsidised by the Australian Pharmaceutical Benefits Scheme (PBS). By the end of 2019, 4282 approvals under the Schedule 8 scheme were given to Victorians for conditions ranging from chronic pain, cancer, multiple sclerosis, and epilepsy, as well as for mental health and other unspecified medical conditions.[4] At present in Australia, only pharmaceutical, non-smokable, medicinal-grade products can be supplied (i.e., Dronabinol, synthetic THC; Nabilone, synthetic THC; Nabiximols (THC and CBD in 50:50 ratio).

One of the major challenges with medicinal cannabis regimes is whether prescribed users are 'safe' to drive, given the known impairing nature of THC which is an active constituent of a number of prescription cannabis preparations. A distinction needs to be made on whether the driver is safe to drive given the presence of the medical condition (see Austroads Fitness to Drive guidelines[5]) vs. the effects of medicinal cannabis. This latter point is important and is complicated by the purported symptom relief offered by medicinal cannabis vs. the known impairing effects of THC[6], both of which are dose-dependent. At this point there is little knowledge of the impacts of medicinal cannabis on driving and impacts on road safety, including whether the impairing effects on driving are consistent with that from recreational cannabis.

1.1.2 IMPLICATIONS OF MEDICINAL CANNABIS USE IN VICTORIA ON DRIVING

Concerns regarding the impact of medicinal cannabis use and safe driving were raised by the Victorian Law Reform Commission (VLRC) in their *Medicinal Cannabis* report (2015).[7] In making it recommendations, the VLRC noted under Consequential changes (section 3.219, pp 92-93):

> The impact of medicinal cannabis on driving would need to be considered. It is an offence to be in control of a vehicle while under the influence of a drug of dependence or with any concentration of THC in blood or saliva. The evidence strongly suggests that THC impairs a person's ability to drive. While some jurisdictions overseas have set the prescribed concentration of THC above zero the Commission does not recommend that this occur in Victoria. Accordingly, there would be a need to warn patients upon receipt of medicinal cannabis that their use of any THC-containing products could make them unable to drive.

On labelling products, specific mention was made with regards to warnings in relation to driving (see VLRC report, S. 7.64, p.187). Further to this, the Sativex (Nabiximols) *Consumer Information Leaflet* specifically states: "*The medicine can affect your ability to drive as it may make you sleepy or dizzy, and issues different warnings depending on the jurisdictions regarding the legality of driving and use of the medication*". On the Australian Sativex product, it states: "*You must not drive or use machinery when you are taking Sativex.*

1 Access to Medicinal Cannabis Act 2016 (Vic)
2 Access to Medicinal Cannabis Regulations 2016 (Vic)
3 Victorian Law Reform Commission (VLRC). Medicinal Cannabis, VLRC Report 32. https://www.lawreform.vic.gov.au/all-projects/medicinal-cannabis
4 https://www2.health.vic.gov.au/public-health/drugs-and-poisons/medicinal-cannabis/data-resources
5 Austroads and National Transport Council. Assessing Fitness to Drive 2016 as amended up to August 2017. Sydney: Austroads.
6 Mulvihill C., Liu S., Fitzharris M. MUARC Baseline Program to Assess the Impact of Drug Use on Road Safety: Report 1: Review of International Literature on Drug-Driving and Countermeasure Opportunities; 2020: Clayton: Monash University Accident Research Centre.
7 Victorian Law Reform Commission (VLRC). Medicinal Cannabis, VLRC Report 32. https://www.lawreform.vic.gov.au/all-projects/medicinal-cannabis

Sativex may cause you to feel sleepy or dizzy, which may impair your judgment and performance of skilled tasks".

Other medicinal cannabis preparations have similar warnings regarding driving. Due to differences in drug-driving laws, differences in the text of warning labels exist even for the same product. For instance, the U.K. Patient Information Leaflet for Sativex (as an example), the warning label states that driving is not advised upon commencement and until such a time the therapeutic dose is achieved and is stable. This highlights an important difference that primarily reflects differences in drug-driving legislation and enforcement practices.

In Victoria the situation regarding the use of medicinal cannabis is challenging for prescribed users because at present in Victoria any driver detected with cannabis (THC) in their body at the roadside is committing an offence, irrespective of whether the cannabis was associated with medicinal use or recreational use; that is, no distinction is made under the *Road Safety Act 1986 (*Vic). For completeness, the detection of medicinal cannabis by Oral Fluid Tests is poorly understood. Proponents for the use of medicinal cannabis have argued that this is unreasonable and the inability to drive represents a barrier to the legitimate use of medication; in effect denying symptom relief for those affected. This topic is important to address as it is acknowledged that there is a need to support the medical needs of participants of medicinal cannabis programs whilst maintaining the safety of all road users whilst at the same time ensuring the integrity of Victoria's drug-driving enforcement program.

A question then arises, how can the Victorian government approach the issue of medicinal cannabis use and driving, and what lessons can be learnt from Australian and overseas jurisdictions?

1.1.3 THE INTERNATIONAL EXPERIENCE

The number of countries and jurisdictions that have implemented medicinal cannabis programs has grown rapidly since 2010. This has followed concerned efforts by advocates of medicinal cannabis, including patients, and the cannabis industry itself.[8]

This growth is despite the evidence for the efficacy of medicinal cannabis is considered to be limited and of low-to-moderate quality.[9,10] It is worth noting however there is now evidence for use in the control of nausea and vomiting related to chemotherapy, relief of intractable epilepsy (i.e., Dravet Syndrome), stimulating appetite in HIV populations, and the alleviation of chronic neuropathic pain and muscle spasticity in multiple sclerosis, but mixed evidence of benefit for pain relief.[11],[12],[13] Generally speaking, medicinal cannabis is viewed as a last resort option and recommended for use where other first line treatments have failed. A commonly held view is that the evidence-base for use is limited and further substantive research is required to understand the therapeutic aspects of medicinal cannabis.[14]

While the above statements regarding medicinal cannabis appear tangential to the current report as it relates to the practices of jurisdictions with respect to driving, the range of medical conditions that medicinal cannabis is used for and the therapeutic dose of THC will have implications for the size of the affected driving population. In addition, whether driving is permissible for users of medical cannabis may differ according to the medical condition.

Internationally, medicinal cannabis schemes exist in 58 countries.[15] These countries include (by WHO region):

- African Region (Ghana; Malawi; South Africa; Zambia; Zimbabwe).

  Region of the Americas (Canada, since 2001); USA (33 States, 4 Territories); Mexico; Argentina; Brazil; Chile; Columbia; Ecuador; Peru; Uruguay; Jamaica; Saint Vincent and the Grenadines; Barbados; Bermuda; Saint Vincent and the Grenadines).

- South-East Asia Region (Thailand; Sri Lanka).

8 https://www.nap.edu/catalog/24625/the-health-effects-of-cannabis-and-cannabinoids-the-current-state
9 https://www.racgp.org.au/advocacy/position-statements/view-all-position-statements/clinical-and-practice-management/medical-cannabis
10 https://www.tga.gov.au/sites/default/files/medicinal-cannabis-evidence-for-efficacy-clinical-guidance-development.pdf
11 https://jamanetwork.com/journals/jama/fullarticle/2338251
12 https://www.thelancet.com/journals/lanpub/article/PIIS2468-2667(18)30110-5/fulltext
13 https://www.ncbi.nlm.nih.gov/pubmed/28934780
14 https://pediatrics.aappublications.org/content/early/2017/10/19/peds.2017-1818
15 Cannabis use is either decriminalised or permitted in 35 of 58 of these countries (or parts thereof).

- European Region (Austria; Belgium; Croatia; Czech Republic; Germany; Italy; Ireland; Luxemburg; Netherlands; Poland; Portugal; Spain; San Marino; Finland; Denmark; Norway; Switzerland; UK; Cyprus; Greece; Malta; Turkey; Lithuania; Estonia; Georgia; North Macedonia; Romania, Slovenia, Israel).
- Eastern Mediterranean Region (Lebanon).
- Western Pacific Region (Australia, New Zealand; South Korea; Philippines; Samoa; Vanuatu).

Across each jurisdiction, differences in the medicinal cannabis program exist in the following areas:

- Medical conditions covered.
- Modes of access (prescription, cannabis-clubs).
- Type of cannabis allowed (i.e., cannabis-derived products, synthetic, natural leaf, oil).
- THC concentration limits for medicinal cannabis.

It is also known that permissions to drive also differ across jurisdictions, as do enforcement practices for drug-driving, particularly with respect to per se limits vs. impairment-based THC limits.

For information purposes only, cannabis use is either decriminalised or permitted in 35 of 58 these countries (or parts thereof); equating to 60% of jurisdictions with a medicinal cannabis program, with NZ moving toward this in 2020 (subject to a non-binding referendum on 17/9/2020).

1.2 RESEARCH RATIONALE

With the recent proliferation of medicinal cannabis programs globally it valuable to document the key characteristics of medicinal cannabis programs in selected jurisdictions as a basis for comparing current practices in Victoria as they relate to driving. This is particularly important as medicinal cannabis is a new area of therapeutics and consequently our understanding of the impacts of medicinal cannabis on safe driving is limited

Documenting other Australian and international programs will provide an understanding as to how other jurisdictions mange drivers permitted to use medicinal cannabis. This can serve as one input in determining whether affected Victorian licence holders are able to drive, acknowledging the delicate balance between the rights of this (as yet small) cohort of drivers and the safety of the community given the known risks associated with recreational THC use and driving.

Key questions for this research are:

- What jurisdictions have implemented medicinal cannabis programs?
- For selected jurisdictions, what medical conditions are covered, what are the modes of access, what types of cannabis products allowed and THC concentration limits for use?
- For these selected jurisdictions where medicinal cannabis programs have been implemented, is recreational cannabis legal?
- For these selected jurisdictions, how do international jurisdictions manage drug-driving more generally? (i.e., laws, testing, per se vs. impairment; test regime, including blood, oral fluid)
- For these selected jurisdictions, what driving conditions / restrictions are imposed on users of medicinal cannabis? And following this, do these differ according to prescribed medical condition)

1.3 AIM OF THIS REPORT

The overall aim of this research is to provide a detailed understanding of selected international medicinal cannabis programs as they relate to driving, the objective of which is to enable best-practice decisions to be made on whether prescribed users of medicinal are able to drive / ride. This extends to how current practices in relation to drug-driving differ from the current approach in Victoria. Of particular interest is the impact of medicinal cannabis programs on road safety.

2 METHOD

2.1 ETHICS APPROVAL

Ethics approval was not required for the conduct of this research.

2.2 PROCEDURE

The methods used in this project were as follows:

1. Environment scan and document review of existing medicinal cannabis programs and related drug-driving laws and enforcement programs. Data reported will include medical conditions for which medicinal cannabis is permitted, inclusion age, program structure in terms of prescribing requirements, and restrictions on driving (if any).
2. Inclusion of insights gained by the research team from the ICADTS conference held in Canada in 2019 and Lisbon Addictions, also held in 2019.
3. Review of documents from the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) and Position Statements of professional scientific societies such as ICADTS, AAAM, the National Academy of Sciences and like bodies on medicinal cannabis and driving.
4. Inclusion of current cut-off limits for THC in selected countries, screening and test procedures.
5. Literature search for any description and/or evaluation of current medicinal cannabis programs, and specifically, as they relate to driving.

A 'data' extraction form was developed to ensure uniform collection of information. The data extraction form was developed and applied in the first instance to one jurisdiction, this being the *Republic of Ireland,* as well as Victoria. This was provided to the project sponsors for comment and discussion. This step was included to ensure that the target information was collected in sufficient depth to fulfil the objectives of the research undertaking. All project sponsors were given the opportunity to comment and all endorsed the supplied template.

Initially, the following jurisdictions were identified as being of interest for purposes of comparison based on road safety performance as well as attitudes to societal drug use more generally.

These jurisdictions, in addition to Victoria and Australian States and Territories include:

1. **Canada** – British Columbia, Alberta, Quebec, Ontario.
2. **United States** – Colorado, California, Texas, Arizona, Michigan, Oregon, Georgia, Connecticut, Virginia, Florida, New Hampshire.
3. **Europe** – Belgium, Germany, Luxemburg, Israel, Finland; Denmark; Norway; Switzerland; UK; Republic of Ireland; Portugal; Spain.
4. **Western Pacific** – New Zealand. Note: Australia is also in the WHO Western Pacific Region.

As the number of jurisdictions was considered substantial in the context of the project resources, additional work was performed to narrow this list to a manageable number. Factors considered were: the legal status of recreational cannabis, whether home cultivation is permitted, prescribing requirements, road safety performance and the recency of medicinal cannabis programs.

The jurisdictions selected for inclusion in this report are shown in Table 2.1.

TABLE 2.1 JURISDICTIONS WITH MEDICINAL CANNABIS PROGRAMS, THE LEGAL STATUS RECREATIONAL USE OF CANNABIS AND THE BASIS FOR INCLUSION IN THE PRESENT STUDY ON HOW DRIVING IS MANAGED

JURISDICTION	RECREATIONAL LEGAL	BASIS FOR INCLUSION INTO PRESENT STUDY TO DOCUMENT DRIVING RESTRICTIONS, IF ANY ON PARTICIPANTS OF MEDICAL CANNABIS PROGRAMS
CANADA		
British Columbia	Yes	Recent recreational legalisation; home growing allowed; 1000 grams
Quebec	Yes	Home growing not allowed, restrictive sale; 150 g store
UNITED STATES		
Texas	No	Medical only, specific rules for CBD/THC concentration; cultivation is illegal
Oregon	Yes	Cannabis decriminalised in 1973 (1st US State), laws reformed in 2015 including sale tax. Cultivation of 4 plants if 21+ years.
EUROPE		
Germany (EU)	No (tolerated, small amounts)	Loss of licence is used as a penalty; medical use permitted for seriously ill patients with no alternative treatment
Switzerland	Decriminalised. Note: legal< 1% THC	Possession <=10 g == fine; very highly developed economy and health service; strong road safety performer
Republic of Ireland (EU)	No	Medical: recent, 5-year pilot program (2016); highly developed program; introduced drug OFT recently (2018)
AUSTRALIA		
Australian States and Territories	ACT for personal use; Decriminalised in SA and NT Illegal QLD, WA, Tas, Vic, NSW	Natural comparisons to Victoria

2.3 REVIEW OF POLICY AND PRACTICE

The primary information source on medical cannabis programs and driving requirements were government websites within each target jurisdiction.

Information was also obtained from presentations at key conferences, including Lisbon Addictions and ICADTS.

For information on the evaluation of medical cannabis programs on road safety, a systematic search was conducted using four scientific databases relevant to the discipline of road safety. These databases comprised OVID Medline; OVID Transport; EMBASE and PsycINFO. Further a grey literature search was also conducted to identify relevant technical reports and research not published in academic journals.

3 EXAMINATION OF INTERNATIONAL MEDICINAL CANNABIS PROGRAMS WITH RESPECT TO DRIVING PERMISSIONS AND ASPECTS RELATING TO ROAD SAFETY

This section presents the key characteristics of medicinal cannabis programs across a number of jurisdictions in North America (Canada, United States) and Europe including the European Union (Ireland, Germany) and non-EU (Switzerland).

Common to all sections, a series of Tables with core information is presented. A summary table of key factors compared to Victoria is presented in the *Discussion*. The information in the Tables is designed to stand-alone and be self-explanatory.

3.1 MEDICINAL CANNABIS PROGRAM CHARACTERISTICS AND DRIVING REQUIREMENTS IN IRELAND (EU)

This section provides details concerning aspects of drug-driving in Ireland. The Medical Cannabis Access Programme (MCAP) is newly established (2019) and has been set up as a pilot program with a comprehensive 5-year evaluation planned.

Users of medicinal cannabis are permitted to drive and are exempted from per-se drug driving THC offence **unless** driver impairment is evident. Roadside testing is performed using oral fluid tests.

The following Tables provide a detailed outline of aspects relating to the medicinal cannabis program in Ireland and drug-driving considerations. Eligibility is limited to patients with specific medical conditions and is tightly regulated.

TABLE 3.1 FEATURES OF THE MEDICINAL CANNABIS PROGRAM IN IRELAND

PROGRAM CHARACTERISTIC	DETAIL
ADMINISTRATIVE	
Name of Scheme	Medical Cannabis Access Programme (MCAP)[16]
Legislation approved	26 June 2019
Date of commencement	2019
Government Department responsible for medical cannabis oversight	Health Services Executive (HSE)
Pilot program	Yes, 5-years, 'or as scientific evidence emerges to support the use of cannabis for the effective and safe treatment of other medical conditions.' (p.3)[FAQ)
Evaluation planned	Yes
STATUS OF THC AND CBD	
THC	Any product that contains THC is illegal, and covered under the *Misuse of Drugs Act;* exceptions for use only granted use for medical purposes as per below
CBD	No legal impediment. Any CBD only product can be sold without restriction
MEDICAL CONDITIONS FOR WHICH MEDICAL CANNABIS IS PERMITTED	
Three specific conditions only:	
1. Spasticity associated with multiple sclerosis	
2. Intractable nausea and vomiting associated with chemotherapy	
3. Severe, refractory (treatment-resistant) epilepsy	
All conditions: non-responsive to standard treatment	

[16] https://www.gov.ie/en/publication/90ece9-medical-cannabis-access-programme/

ENROLMENT STATISTICS	
Number of applicants approved	Unknown
By medical condition	Unknown
REQUIREMENTS FOR USE - PRESCRIBING	
Prescribing authority	Medical practitioner, patient under care of. Required to be working in medical speciality directly related to specified medical condition (with specialist medical training), stipulated in *Regulations.*[17] Applications made by consultant doctor via HSE Portal; once approved a prescription can be used.
REQUIREMENTS FOR USE - DISPENSING	
Pharmacy medication only	Dispensed at pharmacies
Cost	Subsidy / reimbursement is not automatic. Available on a named patient basis, contingent upon eligibility under drug (prescription medication) payment schemes (i.e., Medical Card, Long-term Illness and Drugs Payment Schemes). Irish-pharmacy supplied medication only. Cost of medication under these schemes is subsidised, and treated as per other medications.

[17] Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) Regulations 2019

TABLE 3.2 PERMITTED MEDICINAL CANNABIS PRODUCTS AND LEGISLATIVE FRAMEWORK

TYPE OF CANNABIS PERMITTED (TREATMENT) AND DISPENSING (INCLUDING LIMITS)	
Certification of cannabis products required	Yes, through the Medical Cannabis Access Programme. Required to assess the safety, efficacy and quality of available products. MCAP approved products are not licenced medical products
Registry of approved products under MCAP	Yes, through the MCAP, under the HSE. Re-classified as Schedule 2 drugs (not S.1).
• Aurora High CBD Oil Drops	Oral solution THC less than 3% w/v (weight/volume), (<30 mg/ml THC) CBD: 60% w/v (600 mg/ml)
• CannEpil *[Treatment: refractory epilepsy]*	Oral solution THC 0.5% w/v (weight/volume), (5 mg/ml THC) CBD: 10% w/v (100 mg/ml)
• Tilray Oral Solution	Oral solution THC 1% w/v (weight/volume) (10 mg/ml THC) CBD: 1% w/v (10 mg/ml)
Other approved THC-substance (outside of MCAP)	Sativex is approved for use for the treatment of spasticity in Multiple Sclerosis. Not yet reimbursed. Nabilone (for nausea, vomiting in chemotherapy) is an S.2 controlled drug.
PROGRESS TOWARDS MEDICAL CANNABIS PROGRAM	
Private Members Bill, December 2016	Focus on serious medical conditions: fibromyalgia, and multiple sclerosis. Rationale: evidence that patients prefer 'non-toxic' alternatives; 'war-on-drugs' failed. Rejected for host of reasons, including medical cannabis is a pathway to broader legalisation of cannabis, safety and quality of available products, and limited evidence for efficacy of medical use.
Early approvals	Approval for medical cannabis given to parents of 2-year-old boy from United States for treatment of Dravet's Syndrome (December 2016). Done through parallel (initial) route of Ministerial Licence (to be consumed within MCAP).
	Nabiximols approved for use in specialist clinic in 2004 in two cities
LEGISLATION	
Legislative instruments	The Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) (Amendment) Regulations 2019, update to Schedule 1. (Lists approved medical cannabis substances as medications) The Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) Regulations 2019 set out the legal provisions for the operation of the Medical Cannabis Access Programme and the legal obligations for healthcare professionals and commercial operators. The Misuse of Drugs (Designation) (Amendment) Order 2019 amends S.I. No. 533 of 2017, Misuse of Drugs (Designation) Order 2017 by removing from the scope of the Order certain cannabis-based products that will be permitted for use under the Medical Cannabis Access Programme. The Misuse of Drugs (Amendment) Regulations 2019 amends S.I. No. 173 of 2017 – Misuse of Drugs Regulations 2017 to reschedule certain acceptable cannabis-based products for medical use under the Medical Cannabis Access Programme from Schedule 1 to Schedule 2.

TABLE 3.3 DRIVING AND MEDICINAL CANNABIS

DRIVING WHILST PRESCRIBED MEDICINAL CANNABIS	
Driving permitted by prescription cannabis users	Yes, exemption for holders of Medical Cannabis Certificate. Per se offence does not apply, given Caveats
Caveats on driving	Impairment provisions remain. If impaired, drug-driving offence applies irrespective of *Certificate*
	Must carry Medical Cannabis Certificate when driving

TABLE 3.4 PROVISIONS RELATING TO DRUG-DRIVING, DRINK-DRIVING AND TESTING

LEGISLATION	
Legislative instruments	Road Traffic Act, 2016 (s.10) (http://www.irishstatutebook.ie/eli/2016/act/21/enacted/en/html)
	Road Traffic Act 1961. Person must not be impaired (alcohol and/or drugs) in charge of vehicle. This includes prescribed drugs / medications
DRIVING LAWS CONCERNING CANNABIS	
Detection of drugs	Roadside oral fluid test (Mandatory Intoxicant Testing Checkpoint), with laboratory confirmation THC oral fluid threshold: 10 ng/ml
Impairment	Impaired driving provisions, *including for drivers positive for medicinal cannabis* If OFT is negative, and Police believe impaired, can require blood/urine sample for laboratory testing Impairment tests required by legislation (2016, see above) are: pupil dilation test; modified Romberg balance test; walk and turn test; one-leg stand, finger-to-nose test.
Drugs tested for at roadside	Cannabis, Cocaine (per se limits, arrest) Opioids, Benzodiazepines (prescribed / pharmacy: must also be impaired when driving in opinion of Police, if not, no offence; if impaired, arrested) Fitness-to-Drive Guidelines exist (Medical Doctor)
Roadside oral fluid test introduced	13 April 2017
Test device	Draeger Drug Test 5000
Laboratory test / confirmation	In evidentiary blood or urine sample Tested for cannabis (THC: 1ng/ml limit; THC-COOH: 5 ng/ml limit), benzodiazepines, opiates, heroin (6-Acetylmorphine) methadone, amphetamines (including methamphetamine, MDA and MDMA), cocaine, cocaine (benzoylecgonine)
Penalties	Arrest A minimum 1-year driving disqualify cation if you are found to be above the legal threshold for cocaine, cannabis or heroin (since April 2017). Not < 2 years for second and subsequent offences. Minimum of 4 years driving disqualification if you are found to have drugs in your body and are impaired to such an extent that you do not have proper control of a vehicle; 6 years for second and subsequent offences. Up to €5,000 fine (per drink-driving) Up to 6 months imprisonment, on a summary conviction (per drink-driving) Criminal record Refusal to provide OR test carries similar penalties.

TABLE 3.5 PROVISIONS RELATING TO DRINK-DRIVING, GOVERNMENT AGENCIES AND FITNESS-TO-DRIVE

DRIVING LAWS CONCERNING ALCOHOL (BAC LIMITS) AND DRIVING	
Fully licenced	0.05 BAC
Learner permit	0.00 BAC
Professional	0.00 BAC
ENFORCEMENT (TRAFFIC, ROAD)	
Police service	An Garda Síochána
Forensic services (for drug testing)	Medical Bureau for Road Safety (University College Dublin); research, forensic testing. The MBRS is independent forensic body responsible for chemical testing of intoxicants under the Road Traffic Acts and also for the approval, supply and testing of apparatus for determining the presence or concentration of such intoxicants
LICENSING AUTHORITY	
Licensing authority	National Driver Licence Service (NDLS) (https://www.ndls.ie/index.php)
OTHER ROAD RELEVANT GOVERNMENT ROAD SAFETY AGENCIES	
Government	Road Safety Authority (RSA) (https://www.rsa.ie/en/)
Government	Roads and Accident Investigation Unit, of the Department of Transport, Tourism and Sport
MEDICAL FITNESS TO DRIVE (MFtD)	
Guidelines for Alcohol and Drugs Misuse and Dependence	Medical Fitness To Drive 7th Edition May 2018 National Programme Office For Traffic Medicine, RCPI/RSA

TABLE 3.6 IMPACTS ON ROAD SAFETY OF MEDICINAL CANNABIS PROGRAM

IMPACTS OF DRUG-DRIVING ON ROAD CRASHES IN IRELAND	
Prevalence in crashes	29% drivers drug positive
Positive rate, OFT	Approximately 10-15% positive rate (2018, monthly); cannabis most common (68%); cocaine (37%), opiates (7.9%), benzodiazepines (5.2%) Age: ~75% under 34 years/age Period: April 2017-July 2019; Source: Cusack, 2019
ROAD SAFETY IMPACTS OF MEDICINAL CANNABIS	
Crashes involving Medicinal Cannabis Certificate	Subject to Evaluation Study (5-year programs end in 2024)
Number detected at roadside	Subject to Evaluation Study (5-year programs end in 2024)

3.2 MEDICINAL CANNABIS PROGRAM CHARACTERISTICS AND DRIVING REQUIREMENTS IN GERMANY (EU)

This section provides details concerning aspects of drug-driving in Germany, with emphasis on the medicinal cannabis program. The detailed data shows that Germany has a complex program with many years of experience. Driving is permitted for holders of a medical cannabis prescription however driver impairment provisions apply. There is an extensive assessment process for drivers. Germany is considered as leader and a model for the EU with respect to drug-driving and medicinal cannabis program.

The following Tables provide a detailed outline of aspects relating to the medicinal cannabis program in Germany and associated drug-driving considerations.

TABLE 3.7 FEATURES OF THE MEDICINAL CANNABIS PROGRAM IN GERMANY

PROGRAM CHARACTERISTIC	DETAIL
ADMINISTRATIVE	
Name of Scheme	Cannabis as medicine
Legislation approved	2017 (10th March): Act Amending Narcotics and Other Provisions (Gesetz zur Änderung betäubungsmittelrechtlicher und anderer Vorschriften) (In: German Law Gazette, 6th March). Amended the German Narcotic Drugs Act (Betäubungsmittelgesetz, BtMG) of 1981 amended, changed status of cannabis enabling use as a medicine, Prior arrangements permitted use of prescribed medical cannabis but had low uptake to due regulatory complexity; involved special approval by the BfArM across 50 conditions.
Date of commencement	2017 (10th March)
Government Department responsible for medical cannabis oversight	The Cannabis Agency (Cannabisagentur), a sub-division in the area of the "Special Therapy Directions" of the Federal Institute for Drugs and Medical Devices (BfArM). Federal Opium Agency (part of BfArM) is a key controller of any substance listed under the Narcotics Act, which cannabis is one URL: https://www.bfarm.de/DE/Home/home_node.html Complex set of regulatory requirements, both on cultivation, harvesting, processing, quality assurance, storage, packaging and distribution to wholesalers and pharmacists or manufacturers. The Cannabis Agency is responsible for supply to manufacturers, wholesalers and pharmacies. Cost recovery only with BfArM setting price.
Pilot program	No
Evaluation planned	Federal Opium Agency (part of BfArM) conducting work to examine effects of cannabis as a medicine (to March 31 2022). Insured users only. Interim report (May 2019)[18] **No questions in survey regarding driving**.
STATUS OF THC AND CBD	
THC	**Medicinal only.** Recreational cannabis remains illegal under the *Narcotics Control Act,* **however** German Federal Constitutional Court (March 1994) issued laws ('cannabis decision' re: 'small amounts' effectively **decriminalised** for personal possession permitted unless used in public or in front of minors; 'small amount' differs across the 16 Bundesländer (States) of Germany. Personal cultivation not permitted. Note: under s.31a of the BtMG (refraining from prosecution), prosecution can be waived under certain circumstances (personal use, small amount, guilt deemed minor; no public interest in prosecution). This was effective from 1992 to relieve

[18] Interim evaluation: https://www.bfarm.de/SharedDocs/Downloads/DE/Bundesopiumstelle/Cannabis/Vortrag_Cannabis_Begleiterhebung.pdf?__blob=publicationFile&v=3, see also: Schmidt-Wolf G, Cremer-Schaeffer P. Begleiterhebung zur Anwendung von Cannabisarzneimitteln in Deutschland – Zwischenauswertung. Bundesgesundheitsblatt - Gesundheitsforschung - Gesundheitsschutz. 2019;62(7):845-54.

	judicial system and law enforcement of high volume activity; applicable to all listed in Narcotic Act but effectively only for cannabis.
CBD	No status for medicinal use. Significant legal requirements re: production and advertising. Legal under 0.2% THC (EU law)
MEDICAL CONDITIONS FOR WHICH MEDICAL CANNABIS IS PERMITTED	
Any medical condition, non-responsive to standard treatment and where a patient is 'seriously ill', would benefit clinically from use and without any other therapeutic alternative. Recommended: not prescribe to adolescents; pt. with addictions, personality disorders and psychoses. Common use[19]: chronic (neuropathic) pain; spasticity related to MS; loss appetite, nausea and vomiting (antiemetic) in chemotherapy). Other indications, including ADHD, PTSD, sleep disorders, movement disorders, and glaucoma among others where evidence is more limited.	
ENROLMENT STATISTICS	
Number of applicants approved	Available data: in year following program commencement, approximately 140,000 prescriptions issued. Other estimates: 50,000 to 60,000 patients covered by *Health Insurance* (Deutscher Hanfverband, DHV) *Previous scheme where special permit required from BfArM was ~1000 persons with on average 1g/day.
By medical condition	All medical conditions covered. No breakdown of prescribing available.
REQUIREMENTS FOR USE - PRESCRIBING	
Prescribing authority	Medical practitioner (any), patient under care of. Prescribed under a Narcotics prescription. Prescription must be done in accordance with the Narcotics Prescription Ordinance (BtMVV), including strain and dose (g, or ml). Limits on amount (except Nabilone); 100 g for cannabis flower (dried). Excluded: Dentists, Veterinarians. 30-day supply permitted. Under Sozialgesetzbuchs (SGB V) distribution is regulated as: insured persons entitled to a supply of cannabis in form of dried flowers or extracts in standardized quality, and to supply of prescription medications if: an alternative recognised medication is a) not available, or b) prescription is justified on opinion of Dr. considering expected side effects and level of illness of the patient, and some positive effect could be expected.
REQUIREMENTS FOR USE - DISPENSING	
Pharmacy medication only	Dispensed at pharmacies (Pharmaceutical Association: Bundesverband Der Pharmazeutischen Industrie (BPI)
Cost	Cost of medication is covered under *Health Insurance,* as per other medications, however subject to approval by Insurer. Under law, Insurers must cover with denial in only exceptional cases. Insurance arrangements also complex with Doctors subject to a prescribing budget and can be subject to a penalty payment if exceeded (recourse). This, combined with high cost (€23 per gram; 3x higher than Netherlands), reportedly leads to unwillingness to prescribe by some Doctors. Statistics indicate approx. 60%-70% are covered (BARMER, barmber.de)

19 Hoch E, Friemel C, Schneider M, et al. Wirksamkeit und Sicherheit von Cannabisarzneimitteln: Ergebnisse der CaPRis-Studie [Efficacy and safety of medicinal cannabis: results of the CaPRis study]. Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz. 2019;62(7):825-829. doi:10.1007/s00103-019-02965-3

TABLE 3.8 PERMITTED MEDICINAL CANNABIS PRODUCTS AND LEGISLATIVE FRAMEWORK

TYPE OF CANNABIS PERMITTED (TREATMENT) AND DISPENSING (INCLUDING LIMITS)	
Certification of cannabis products required	Yes, via BfArM (German Federal Institute for Drugs and Medical Devices) Manufacturers must be based in countries that are compliant with the 1961 UN Single Convention on Narcotic Drugs. In addition, licensed medical products receive the EU Good manufacturing practice (GMP) certification, a set of standards that all drug manufacturers must comply with co-ordinated by the European Medicines Agency (EMA), as well as Good Distribution Practices (GDP)
Registry of approved products	Yes, via BfArM Companies include: Aurora; Bedrocan; Cannaflos; Panaxia; Tilray, Materia Ventures, Tweed among others
Products	Cannabis flower (blossoms) (recommended: vaporisers; tea/baked less effective, and joint not recommended) Cannabis extract (from flower, pharmaceutical grade, delivered as capsule or drip solution). Content of THC:CBD depends on plant variety. Import, with Germany expect cultivation capacity in 2020 (tendered for 10,400kg in 2018; awarded to Aurora GmBH, Aphria GmBH, DEMECAN GmBH).
Other approved THC-substance (referred to as *finished products)*	Dronabinol (Marinol) *Approved for off-label use:* Nabilone (Canemes) / Cesamet (synthetic cannabinoid), indication: nausea and vomiting associated with chemotherapy (antiemetic; also: neuropathic pain) Sativex
Personal cultivation	Not permitted
PROGRESS TOWARDS MEDICAL CANNABIS PROGRAM	
Previous program	Approx. 1994 - Dronabinol rescheduled in Narcotic Drugs and Other Regulations (BtMG) Annex 1 to Annex II, meaning greater permitted use (**key step**); since moved to Annex III (1998). Pre-2017: Special permit scheme applied Moves from 2016 at National Cabinet (May 4th)
LEGISLATION	
Legislative instruments	Extensive provisions, given German law (https://www.gesetze-im-internet.de/) plus EU Regulations: German Narcotic Drugs Act (Betäubungsmittelgesetz, BtMG) (https://www.gesetze-im-internet.de/btmg_1981/BtMG.pdf); regulates sanctions, no level of danger ascribed to drugs. Courts decide based on harms. Annex define where drugs sit: Annex I: not eligible for trade & non-prescribable (e.g., heroin, LSD, MDMA, cannabis) Annex II: eligible for trade / marketable but non-prescribable (e.g., methamphetamine; Δ9-THC, cannabis, DHMP – synthetic, July 2018) **Annex III:** eligible for trade / marketable and prescription (e.g., cannabis for medical purpose per 1961 Single Convention on Narcotic Drugs **and approved** as finished medicinal products, i.e., Nabilone, Dronabinol); also cannabis plant. SGB, Sozialgesetzbuch: insurance provisions for treatment of drug/drug-related illness. AMG: Act on the Marketing of Medicinal Products (https://www.gesetze-im-internet.de/amg_1976/AMG.pdf) 1961 UN Single Convention on Narcotic Drugs (see A. 23 & 28(1)). Case law: https://justiz.de/bundlaender/bund/index.php

TABLE 3.9 DRIVING AND MEDICINAL CANNABIS

DRIVING WHILST PRESCRIBED MEDICINAL CANNABIS	
Driving permitted by prescription cannabis users	**Yes**. Under StVG the per se regulatory offence (1ng) does not apply conditional to (subject to) no impairment evident at the time of driving. Immediate impairment testing provisions apply and drivers must satisfy additional fitness-to-drive protocols if requested by the police under StVG(12) or licensing authority (see Table 3.11 for requirements). Under s.24(2): "An administrative offence shall be committed by any person who, under the effect of an intoxicating agent in road traffic. Such an effect exists if a substance mentioned in this Annex is detected in the blood. Sentence 1 shall not apply if the substance from the intended use of a drug prescribed for a specific case of illness" (**note: exemption, aka: 'drug privilege')** German: (2) Ordnungswidrig handelt, wer unter der Wirkung eines in der Anlage zu dieser Vorschrift genannten berauschenden Mittels im Straßenverkehr ein Kraftfahrzeug führt. Eine solche Wirkung liegt vor, wenn eine in dieser Anlage genannte Substanz im Blut nachgewiesen wird. Satz 1 gilt nicht, wenn die Substanz aus derbestimmungsgemäßen Einnahme eines für einen konkreten Krankheitsfall verschriebenen Arzneimittels herrührt. Note: this use exception applies to prescribed (medically used) morphine and amphetamine (e.g., Ritalin), and also benzodiazepines (see also s.14 of the 14 of the Driving License Ordinance, FeV) Note: argument of improper use (not as prescribed) has been put forward as requiring proof, but non-impairment and fitness-to-drive provisions apply.
Caveats on driving	Impairment provisions / negative impact of drug: if impaired, drug-driving offence applies irrespective of Prescription. Explicit reference is made to ensuring road safety in the *Act*. Hence, if impairment / negative impacts on driving, s.316 of the StGB (Criminal Code) applies. Fitness-to-drive assessment protocols also apply. See also DGVP and DGVM Position paper on assessment of driving fitness for users of medical cannabis and driving. [20] Note: driving is not recommended at commencement of therapy and until dose is stable. Specialist medical reports **and/or** MPU reports (see below) routinely requested by Police to determine fitness-to-drive, and hence level of penalty (if any as exemption applies) – further proof.
Driver responsibilities	Drivers are required to avoid driving if not safe to do so, either through effects of the medical condition or the medication, or is impaired for any reason. Considerations to be given to limiting journey length and time of driving as effects of medical condition plus cannabis medication present difficulty for drivers in these scenarios. (Fahreignungsbegutachtung bei Cannabismedikation, DGVP, DGVM).

[20]Fahreignungsbegutachtung bei Cannabismedikation –Handlungsempfehlung der Ständigen Arbeitsgruppe Beurteilungskriterien – StAB (Driving aptitude assessment for cannabis medication - Recommendation for action of the Standing Working Group on Assessment Criteria - StAB) (August 2018); https://www.dgvp-verkehrspsychologie.de/wp-content/uploads/2018/08/Handlungsempfehlung-_Cannabismedikation_v2_Stand-15.08.2018.pdf [in German]

TABLE 3.10 PROVISIONS RELATING TO DRUG DRIVING AND TESTING

LEGISLATION	
Legislative instruments	German Road Traffic Act (Straßenverkehrsgesetz, StVG): s.24a and Annex to s.24a lists intoxicating agents and substances (since 1998) Regulatory offence after consuming 'intoxicant' and drives while under its effects. Penalty: up to €3000, and driving ban (s.25(1) regulated under German Driving Licence Ordinance (Fahrerlaubnis-Verordnung, FeV) https://www.gesetze-im-internet.de/stvg/
	German Criminal Code (Strafgesetzbuch – StGB): s.315c, s.316; **unable to safely drive due to alcohol or any other intoxicating substance is a criminal offence**. Punishment: Prison up to 12-months or fine. Impairment, or unfit to drive evident if any incapability to drive due to presence of any physical or mental defects or be based on influence of drugs. If in this state endangered other persons or property, prison of up to 5-years is possible (s.315). English: https://www.gesetze-im-internet.de/englisch_stgb/ This supersedes the medical cannabis prescription
DRIVING LAWS CONCERNING MEDICINAL CANNABIS AND CANNABIS	
Detection of drugs	Roadside oral fluid test, with laboratory confirmation (blood, hospital). THC oral fluid threshold: unknown **Per se limit in blood: 1 ng/ml THC** (recommended to be 3 ng/ml for impairment level for (un)fitness-to-drive by the Commission on Legal Limits (Grenzwertkommission) who advise the German Federal Ministry of Transport (Bundesverkehrsministerium); case law follows the 1 ng/ml. *Note:* under the Act there are no specified statutory limits, hence, presence is sufficient however due to various Court rulings limits are in effect; the German Federal Constitutional Court ruled in 2004 a 'zero-value limit' to be unconstitutional, hence 1 ng/ml is used for THC. **If OFT is negative, blood can be taken if impairment is suspected.**
Impairment	Impaired driving provisions (error, failure when driving), *including for drivers positive for medicinal cannabis but proof of improper use.* Offence impairment level: detected (StVG); impaired (StGB, criminal code) If OFT is negative, and Police believe impaired, can require blood/urine sample for laboratory testing.
Drugs tested for at roadside	*Per Road Traffic Act, s.24a and Annex,* from 31 December 1992 *Checkpoints: Intoxicating substance (substance) under Annex, StVG:* Cannabis (THC); Heroin (morphine); Morphine (morphine); Cocaine (Benzoylecgonin); Cocaine (cocaine) Amphetamine and related substances (ATS): Amphetamine (AM), Methamphetamine (MA); Methylendioxyamfetamin (MDA); Methylendioxyethylamfetamin (MDE); Methylendioxymetamfetamin (MDMA) Note: under StGB, any substance/drug detected (not expressly stated)
Roadside oral fluid test introduced	Date not confirmed
Test device	Draeger Drug Test 5000; DrugWipe 6 S Speicheltest; RapidSTAT®; Mavand Solutions; SoToxa (Alere DDS2)
Laboratory test / confirmation	In evidentiary blood (serum) Tested for cannabis (THC: 1ng/ml limit; THC-COOH: 5 ng/ml limit), benzodiazepines, morphine [10 ng/ml]: opiates, heroin (6-Acetylmorphine) methadone, amphetamines [25 ng/ml](including methamphetamine, MDA and MDMA), cocaine [10 ng/ml), cocaine (benzoylecgonine)[75 ng/ml]

TABLE 3.11 MEDICAL FITNESS TO DRIVE PROTOCOLS – REQUIRED FOR DRUG-DRIVING

MEDICAL FITNESS TO DRIVE (MFtD)	
Assessment	Assessment of fitness to drive (*M 115: Assessment guidelines for suitability to drive, from 31/12/2019*[21]). A fitness-to-drive assessment is required to be performed under STVG (Road Traffic Act) and can include temporary impairment considerations (drugs, alcohol, careless driving, error, exceed demerit points, possession of illegal drugs; traffic offence or offence demonstrating aggression) but also suitability in terms of ability to drive (physical and mental, StVG, s2(4)). A MFtD assessment is also required upon re-licensing for offences committed. The licence authority uses the MPU as a basis for its own assessment. Processes under VwVfG, Licence Law and Administrative procedure. Stipulates role of police and licence authority and it is a responsibility of police to supply licence authority with evidence. The MPU is the primary assessment procedure in relation to fitness-to-drive and is used as the basis for licence revocation of licence conditions / restrictions. The MPU is a core part of the drug-driving offence process (including failing a drug-test) and must be completed after removal of licence. Failing to undertake the test, in addition to not being approved as fit-to-drive results in licence revocations. Conditions can also be placed on the driver to undertake further assessment and/or participation in rehabilitation programs for drug and/or traffic offences. **In relation to cannabis:** MFtD assessment explicitly distinguishes between three groups: 1. Patients prescribed cannabis by Doctor – assessment process focus on patient information and treatment compliance, as well as driving performance. 2. Patients with history of self-medication using illegal cannabis switching to prescription. Added focus on BtMG (Narcotics Act) violations). 3. Users with history of abuse who seek prescription to legalise abuse; believed likely to continue to use illegally and prescription. In these instances, fitness-to-drive assessment takes into consideration this behaviour and relevant German case law that justifies license authority to decide against fitness-to-drive. A driver can supply medical advice / input to justify use. Permitted use of cannabis flower and extracts complicates matters because dosing is individual and dependent on judgement of Doctor (i.e., medically justified). In the Assessment, consideration is given to whether the driver can adequately judge their own performance, medication compliance and risk compensation (i.e., self-regulate their driving). Subject to MPU examination. In the MPU, consideration must also be given to whether the underlying medical condition is relevant to driving. Extensive process, and driver can be subject to hair testing (EtG, alcohol), blood and urine testing for long-term and other drug use. Other factors associated with driving impairment are considered. **MPU processes (uniform procedures and drug-driving specific details)** A MFtD assessment can either be a medical examination or a full medical-psychological examination, referred to as an MPU. Police notify the licencing authority of a request for a MFtD if for any reason there is doubt or concern regarding capacity to drive; the licence authority then issues the order to the driver for this to be undertaken. The licence authority sends information to the assessment agency, having been informed by the driver of their choice. The MPU entails assessment by a medical doctor and a psychologist (for up to 60 minutes on driving, risk-taking, health and decision-making). The MPU also requires a computer-based hazard perception test and collection of past medical history and driving. Blood and urine tests are included.

[21] https://www.bast.de/BASt_2017/DE/Verkehrssicherheit/Fachthemen/U1-BLL/BLL-Download.html?nn=1816516

	The MPU is conducted by any number of specialist groups (not the road agency itself). These groups can be part of the German Association of Technical Inspection Agencies (VdTÜV e.V) and centres must be certified by the licence authority. The total cost for MPU can be €,2000+ For drug-driving (including medical cannabis), assessment is an important part of the process and can consider any additional risk factors and conditions that could be associated with driving impairment and in assessment of being safe to drive. This can extend to non-use (i.e., abstinence) of drug and alcohol appropriate testing and assessment. Under the fitness-to—drive guidelines, factors such as ability to separate drug-use from driving, level of use, addiction, and the presence of any psychological disturbance are all considered the assessment protocol. **Fitness-to-drive rests on three key factors:** 1. Any permanent limitation of performance; 2. Responsible use; 3. Use in accord with Dr. prescription. *Process is complex, expensive and can be contested*

TABLE 3.12 PENALTIES RELATING TO DRUG DRIVING

Penalties	**Penalties Under StVG (s24a)**: Administrative offence, with substantial fines (same for alcohol); basis is recent consumption. 1st offence: fine of from €500, 2 demerits in fitness-to-drive register, 1-month driving ban. 2nd offence: €1000, 2-points, 3-month driving ban Multiple: €1500, 2-points, 3-month driving ban Allowed fines: up to €3000, further bans *Applies to licence holder of an EU Member State* Fitness-to-drive Assessment / MPU required following licence ban (administrative or by Court) **Penalties also under StGB, Criminal Code** where driving impairment/error/failures in driving evident. Basis: crash, driving error, check-point Impairment is the primary determent (police do Drug Recognition program – specific checklist used to document behaviour, including pupil response and other behavioural and physical signs) High level of evidence required 1. Vehicle parked, blood sample, police retain drivers licence 2. Positive blood test: criminal actions commence If no adverse consequence to person or property: prison up to 1-year or fine (at least 1-month salary (s.316). If endanger person/property: prison up to 5-years or fine (s.315c) **Where criminal offence:** withdraw licence at least 10-months; 2-3 demerit points. In any case: require MPU to regain licence; this requires proof of drug-free status (hair//urine) for 12-months. **Combined costs of penalties and processes:** €5000-€7000 Crash-involvement may result in no insurance cover plus further civil and insurance payments, and future denial of cover *Additional sources: ADAC*

TABLE 3.13 LAWS RELATING TO DRINK-DRIVING AND RELEVANT ADMINISTRATIVE AGENCIES

DRIVING LAWS CONCERNING ALCOHOL (BAC LIMITS) AND DRIVING	
Fully licenced	0.05 BAC, per *Road Traffic Act, s.24a* *Either an administrative and criminal offence depending on BAC level* *(Note: substantial stepped penalties for exceed BAC; e.g., >0.16 == 3 demerit points, prison/fine, licence revocation for 6-m to 5 years, or lifetime driving ban.*
Learner / probationary permit	0.00 BAC, per *Road Traffic Act, s.24c (*applicable for probationary period under s.2a **or** before the age of 21.
Professional	0.00
ENFORCEMENT (TRAFFIC, ROAD)	
Police service	Federal Police (Bundespolizei, BPOL) under Federal Ministry of the Interior (BMI) State Police Force in all 16 States.
Forensic services (for drug testing)	Relevant to each German State
LICENSING AUTHORITY	
Licensing authority	Driver License Authority / Motor Vehicle Registration Authority / Kraftfahrzeug-Zulassungsbehörde Covered under State Authorities, example: Berlin - State Agency for Civil and Regulatory Affairs
OTHER ROAD RELEVANT GOVERNMENT ROAD SAFETY AGENCIES	
Government	BASt, Transport research / statistics; sits within the Federal Ministry of Transport, https://www.bast.de/BASt_2017/DE/Home/home_node.html

TABLE 3.14 IMPACTS ON ROAD SAFETY OF MEDICINAL CANNABIS PROGRAM

IMPACTS OF DRUG-DRIVING ON ROAD CRASHES	
Prevalence in crashes	Unknown (medical users); not reported in Federal Statistical Office (Destatis)
Positive rate, OFT	Unknown (medical users)
ROAD SAFETY IMPACTS OF MEDICINAL CANNABIS	
Crashes involving Medicinal Cannabis Prescription	Unknown / not reported
Number detected at roadside	State dependent
USE OF CANNABIS[22]	
Lifetime use	27.2% (population 18-64 years, 2015) 9.7% (population 12-17 years, 2015)
12-month	6.1% (population 18-64 years, 2015) 7.3% (population 12-17 years, 2015)

[22] Stöver H, Michels II, Werse B, Pfeiffer-Gerschel T. Cannabis Regulation in Europe: Country Report Germany. Amsterdam: The Transnational Institute (TNI); 2019.

3.3 MEDICINAL CANNABIS PROGRAM CHARACTERISTICS AND DRIVING REQUIREMENTS IN SWITZERLAND

This section provides details concerning aspects of drug-driving and medicinal cannabis in Switzerland. Switzerland has a complex program. Driving is permitted for holders of a medical cannabis prescription however driver impairment provisions apply. Roadside oral fluid tests are used.

The following Tables provide a detailed outline of aspects relating to the medicinal cannabis program in Switzerland and associated drug-driving considerations.

TABLE 3.15 FEATURES OF THE MEDICINAL CANNABIS PROGRAM IN SWITZERLAND

PROGRAM CHARACTERISTIC	DETAIL
ADMINISTRATIVE	
Name of Scheme	Cannabis medical exemption program
Legislation approved	Since 2011 (Amendment to *Narcotics Act (see below)* Moves to permit prescription without special permit with proposal to Federal Council in June 2019, which was revised and re-submitted June 24 2020
Date of commencement	2011 (special permit scheme)
Government Department responsible for medical cannabis oversight	Federal Office of Public Health (BAG)
Pilot program	No, exemption program applies
Evaluation planned	Yes, on effectiveness of cannabis as a medicine, by the Federal Health Office
STATUS OF THC AND CBD	
THC	Illegal since 1951 for medical and recreational use (classified as narcotic) Any product with THC <1% permitted (including plant) **Medical exemption**. Recreational use decriminalised if over 18 years age (<=10 g; not a criminal offence but confiscation and CHF 100 fine; since October 2013, moves from 2011). While possession is decriminalised, consumption remains illegal. Possession for purposes of trade remains illegal (subject of fine, 1-3 years prison), and repeat offending attracts higher penalties. Recreational: < 18, juvenile criminal code Cannabis Social Clubs exist
CBD	Access, use permitted (THC <1%); since 2011 (also, subject to tax)
MEDICAL CONDITIONS FOR WHICH MEDICAL CANNABIS IS PERMITTED	
Any approved condition, with spasticity associated with multiple sclerosis; intractable nausea and vomiting associated with chemotherapy, severe, refractory (treatment-resistant) epilepsy (neurological diseases), and pain most common.[23]	
ENROLMENT STATISTICS	
Number of applicants approved	In 2019, approximately 3000 under the exemption scheme
By medical condition	A number of papers published: MS most common, soft tissue (pain), spinal cord related complications.
REQUIREMENTS FOR USE - PRESCRIBING	
Prescribing authority	Medical Doctor (approval permit for up to 6-months, extension dependent on approval.

[23] Kilcher G, Zwahlen M, Ritter C, Fenner L, Egger M. Medical use of cannabis in Switzerland: analysis of approved exceptional licences. *Swiss Med Wkly*. 2017;147:w14463. Published 2017 Jul 10. doi:10.4414/smw.2017.14463

REQUIREMENTS FOR USE - DISPENSING	
Pharmacy medication only	Yes
Cost	Health insurance usually not covered; as at 2019, example: ~€400-500 /month) Prescription amendment does not address the reimbursement of cannabis-based treatments by the compulsory health insurance system; desire for efficacy and cost-effectiveness studies to assess clinical benefits.

TABLE 3.16 PERMITTED MEDICINAL CANNABIS PRODUCTS AND LEGISLATIVE FRAMEWORK

TYPE OF CANNABIS PERMITTED (TREATMENT) AND DISPENSING (INCLUDING LIMITS)	
Certification of cannabis products required	Yes, Federal Law on Narcotics and Psychotropic Substances
Registry of approved products	Yes, under Swissmedic (under proposals, will be responsible for cultivation (authorisation, supervision), manufacture, marketing
Approved THC-substance (under exemption permits)	Cannabis flower Sativex Dronabinol Epidiolex (CBD formulation) Other CBD preparations.
PROGRESS TOWARDS MEDICAL CANNABIS PROGRAM	
Medical exemption program	From 2011, under Federal Office of Public Health (FPOH/BAG): https://www.bag.admin.ch/bag/en/home.html Approx. 3000 authorisations in 2019 under the special permit scheme. Moves to approve recreational cannabis currently before Federal Council (passed lower house in June 2020); requires approval by Cantons (26) – 5-year study/ registered participant basis. **Note:** proposal to suspend driver licence for duration of registered use in the study was **not** approved.
LEGISLATION	
Legislative instruments	Federal Act on Narcotics and Psychotropic Substances (Narcotics Act) For fines, by substance/year (not traffic): https://www.bfs.admin.ch/bfs/de/home/statistiken/kriminalitaet-strafrecht/polizei/betaebungsmittelsubstanzen.html By drug type (not driving related): https://www.bfs.admin.ch/bfs/de/home/statistiken/kriminalitaet-strafrecht/polizei/betaebungsmittelsubstanzen.html
	Single Convention on Narcotic Drugs of 1961 https://www.unodc.org/unodc/en/commissions/CND/conventions.html
	Convention on Psychotropic Substances, 1971
	UN Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988

TABLE 3.17 DRIVING AND MEDICINAL CANNABIS

DRIVING WHILST PRESCRIBED MEDICINAL CANNABIS	
Driving permitted by prescription cannabis users	Yes – refer to VRV, Article 2 – incapacity to drive is not established by presence of substance in blood. Requires evidence of impairment / unfit to drive.
Caveats on driving	Requirements on being fit-to-drive apply. Article 16c cites a 'serious offence' as, a persons is c. is unable to drive due to the effects of anaesthesia or drugs or for other reasons and drives a motor vehicle in this condition. Article 55, *Determination of incapacity to drive* If the person concerned shows signs of inability to drive and these are not or not solely due to the influence of alcohol, they can be subjected to further preliminary examinations, in particular urine and saliva samples. Further, a blood sample must be ordered. The Federal Council: a. can stipulate for other substances that impair driving ability at which concentrations in the blood regardless of further evidence and individual tolerance driving inability within the meaning of this Act is assumed; b. issues regulations on preliminary examinations (para. 2), the procedure for the breath alcohol and blood sample, the evaluation of these samples and the additional medical examination of the person suspected of being unable to drive; c. may stipulate that samples obtained in accordance with this article, namely blood, hair and nail samples, are evaluated in order to determine an addiction that reduces a person's ability to drive.
	Must carry Medical Cannabis Certificate when driving

TABLE 3.18 PROVISIONS RELATING TO DRUG DRIVING AND TESTING

LEGISLATION	
Legislative instruments	Road Traffic Act – SVG, 1958 https://www.admin.ch/opc/de/classified-compilation/19580266/index.html
	VRV: Traffic Regulations Ordinance of November 13, 1962; https://www.admin.ch/opc/de/classified-compilation/19620246/index.html
	Ordinance on the control of road traffic, at 2007; https://www.admin.ch/opc/de/classified-compilation/20063193/index.html Article 2: 1) Anyone who is unable to drive because of fatigue, the effects of alcohol, drugs or narcotics or for any other reason may not drive a vehicle. 2) Inability to drive is considered proven if the following can be demonstrated in the **driver's blood**: a. Tetrahydrocannabinol (cannabis); b. free morphine (heroin / morphine); c. Cocaine; d. Amphetamine (amphetamine); e. Methamphetamine; f. MDEA (methylenedioxyethylamphetamine); or G MDMA (methylenedioxymethamphetamine). 2bis The Federal Roads Office (FEDRO) issues instructions on the detection of the substances in accordance with Paragraph 2. after consultation with technical experts **2ter For persons who can prove that they are taking one or more of the substances listed in paragraph 2 in accordance with a doctor's prescription, incapacity to drive is not deemed to have been proven when evidence of a substance in accordance with paragraph 2 is given.** (Inserted by no. I of the Ordinance of April 28, 2004, in force since Jan. 1, 2005 (AS 2004 2851)

DRIVING LAWS CONCERNING MEDICINAL CANNABIS AND CANNABIS	
Detection of drugs	Yes (zero tolerance)
Impairment	Fitness-to-drive and driving skills protocols in place, under s.14, SVG. Requires physical and psychological performance to drive safely; per: b. has the necessary physical and mental capacity to safely drive motor vehicles; c. is free from an addiction that interferes with the safe driving of motor vehicles; and d. according to his previous behaviour guarantees that as a motor vehicle driver he will observe the regulations and show consideration for fellow human beings. According to case law, looking pale or watery eyes is sufficient. Note: the Federal Office of Roads (FOR) considers suspicion of dependence if person uses twice/week. Arrest for offences outside traffic relevant. See below on Fitness-to-drive See: http://www.astra2.admin.ch/media/pdfpub/2000-08-03_235_d.pdf Ordinance on control of road traffic, Art.15 (Road Traffic Control Ordinance, SKV): If a blood sample has been ordered, the doctor commissioned to do so must examine the person concerned for medically detectable signs of inability to drive due to the consumption of alcohol, anaesthesia or medication. FEDRO defines the minimum requirements for the form and content of the relevant protocol. Per Art.17: Other determination of incapacity to drive Drunkenness or the influence of a substance other than alcohol that reduces driving ability can also be determined on the basis of the suspected person's condition and behaviour or by determining consumption, in particular if the breath alcohol test, the narcotics or drug pre-test or the blood sample could not be carried out. Note: FEDRO regulates the further requirements for the procedure for determining the inability to drive on the road as a result of the influence of alcohol, narcotics or drugs. (Article 18, SKV, Procedure)
Drugs tested for at roadside	THC, cocaine, heroin / morphine, amphetamines & related (ATS) Note: medically prescribed heroin program for registered users.
Roadside oral fluid test introduced	Police can use salvia or urine (not roadside) as preliminary test
Test device	DrugWipe, RapidSTAT®; Mavand Solutions
Laboratory test / confirmation	Blood test (hospital). Blood is evidentiary. Approved Forensic Toxicologist from the Swiss Society of Forensic Medicine (or foreign equivalent)
Penalties	Extensive
MEDICAL FITNESS TO DRIVE (MFtD)	
Fitness to drive processes.	Yes, under *Traffic medical examination* Under Article 15, SVG, Assessment of fitness to drive or driving skills: If there are any doubts about a person's fitness to drive, they will be subjected to a fitness test, in particular for: a. Driving while intoxicated with a blood alcohol concentration of 1.6 weight per mille or more or with a breath alcohol concentration of 0.8 mg alcohol or more per liter of breath; **b. Driving under the influence of narcotics or when carrying narcotics that severely impair driving ability or have a high potential for dependence;** c.Traffic rule violations that suggest recklessness Also, if 75+, every 2-years. Doctors to provide information under law. Drivers can be subject to a control drive, a theory test, a practical driver's test or other suitable measure such as training or further training See: Guideline of the expert group for road safety: "Reasons for suspicion of a lack of fitness to drive - Measures - Restoration of fitness to drive" FEDRO 03.08.2000. http://www.astra2.admin.ch/media/pdfpub/2000-08-03_235_d.pdf [german]

TABLE 3.19 PROVISIONS RELATING TO DRINK-DRIVING AND ROAD SAFETY AUTHORITIES

DRIVING LAWS CONCERNING ALCOHOL (BAC LIMITS) AND DRIVING	
Fully licenced	0.05 (Penalty: 0.05-0.079: final, prison; > 0.08, plus loss licence 3-months. If passenger of drunk-driver has a licence, they are equally responsibly
Learner permit	0.01
Probationary permit	0.01
Professional	0.01
ENFORCEMENT (TRAFFIC, ROAD)	
Police service	Federal Office of Police (https://www.fedpol.admin.ch/fedpol/en/home.html) Cantonal Police (see: https://polizei.ch/en)
Forensic services (for drug testing)	Institute for Forensic Medicine
LICENSING AUTHORITY	
Licensing authority	Canton specific - Road Traffic Office (Strassenverkehrsamt/Office Cantonal des Automobiles et de la Navigation – OCAN Note: requires medical certificate from optician or medical doctor. For detail: https://www.ch.ch/en/driving-licence/ https://asa.ch/strassenverkehrsaemter/adressen/
OTHER ROAD RELEVANT GOVERNMENT ROAD SAFETY AGENCIES	
Government	FOT: Federal Office of Transport, https://www.bav.admin.ch/bav/en/home.html
Government	FEDRO: Federal Roads Office, https://www.astra.admin.ch/astra/de/home.html

TABLE 3.20 IMPACTS ON ROAD SAFETY OF MEDICINAL CANNABIS PROGRAM

IMPACTS OF DRUG-DRIVING ON ROAD CRASHES	
Prevalence in crashes	Fatal: where suspected to be under influence, 60% were positive; half for BAC and other half drugs with THC most common (73%; 38% cocaine; 10% morphine; 4% amphetamines; 5% MDMA, 8% methadone). Estimated to be 5% for drugs and medicines in serious injury crashes 233 deaths, total (2018); 33873 seriously injured (Source: FEDRO) See: www.unfalldaten.ch;
Positive rate, OFT	Unknown.
OFFENCES[24]	
Licence loss due to drug addiction	3.1% (of 79,900)
Licence loss due to alcohol addiction	1.8% (of 79,900)
Traffic-related: Drunk-drive	16.4% (24%, 30-39; 23% 20-29)
SURVEY – SELF REPORT OF DRIVING AFTER USE	
Self-report of driving after use	~ 7% / 12-m. Source: Frequency of driving while under the influence of a substance that may impair the ability to drive [https://www.bfs.admin.ch/bfs/de/home/statistiken/kriminalitaet-strafrecht/polizei/strassenverkehrsdelinquenz.assetdetail.823652.html]
ROAD SAFETY IMPACTS OF MEDICINAL CANNABIS	
Crashes involving Medicinal Cannabis Certificate	Unknown
Number detected at roadside	Unknown

24 The number of ID withdrawals will remain stable in 2019 (March 2020). Source: https://www.astra.admin.ch/astra/de/home/dokumentation/medienmitteilungen/anzeige-meldungen.html

3.4 MEDICINAL CANNABIS PROGRAM CHARACTERISTICS AND DRIVING REQUIREMENTS IN BRITISH COLUMBIA, CANADA

This section provides details concerning aspects of drug-driving in British Columbia (BC), Canada. BC was an early adopter of medicinal cannabis and has recently legalised recreational cannabis. The medical cannabis program evolved from 2001 to its present form following changes in 2018.

The following Tables provide a detailed outline of aspects relating to the medicinal cannabis program and associated drug-driving considerations.

TABLE 3.21 FEATURES OF THE MEDICINAL CANNABIS PROGRAM IN BRITISH COLUMBIA

PROGRAM CHARACTERISTIC	DETAIL
ADMINISTRATIVE	
Name of Scheme	Marihuana Medical Access Regulations (MMAR, original)[25] Cannabis Act (2018-present)[26]
Legislation approved	14 June 2001
Date of commencement	30 July 2001
Government Department responsible for medical cannabis oversight	Health Canada
Pilot program	No
Evaluation planned	No
STATUS OF THC AND CBD	
THC	**Medical** and **recreational** cannabis use, cultivation, and possession by people aged 19 and older is legal with limits on quantities. No age limit for medical.
CBD	CBD products are strictly regulated and are only legal when sold in compliance with the Cannabis Act and its regulations.
MEDICAL CONDITIONS FOR WHICH MEDICAL CANNABIS IS PERMITTED	
There is no exhaustive list of conditions. An authorised health care practitioner and patient discuss their medical condition and conclude that cannabis for medical purposes is an appropriate option for her/him. Example conditions are: ADD/ADHD, Alzheimer's disease, anxiety, arthritis, cancer, nausea and vomiting due to chemotherapy chronic pain, depression, eating disorders, epilepsy, fibromyalgia, Hepatitis C, HIV/AIDS, kidney failure (including dialysis patients), migraines, multiple sclerosis, muscle spasms, muscular dystrophy, Parkinson's disease, Post-traumatic stress disorder (PTSD), sexual dysfunction, sleep disorders.	
Health care practitioners should: write in the medical record that conventional therapies were attempted but unsuccessful; assess a patient's risk of addiction using a validated addiction risk tool and retain a copy of that assessment in the medical record; and review the patient's PharmaNet information prior to issuing an authorisation for cannabis for medical purposes and in any reassessment of patients receiving cannabis for medical purposes.[27]	
ENROLMENT STATISTICS	
Number of applicants approved	17,053 active client registrations with a federal licence holder (March 2020)[28]; no limitation on age; ordinarily resides in Canada
By medical condition	Unknown

[25] https://laws-lois.justice.gc.ca/eng/regulations/sor-2001-227/page-1.html
[26] https://laws-lois.justice.gc.ca/eng/Regulations/SOR-2018-144/index.html
[27] College of Physicians and Surgeons of British Columbia's Practice Standard for Cannabis for Medical Purposes: https://www.cpsbc.ca/files/pdf/PSG-Cannabis-for-Medical-Purposes.pdf
[28] https://www.canada.ca/en/health-canada/services/drugs-medication/cannabis/research-data/medical-purpose.html

REQUIREMENTS FOR USE – PRESCRIBING	
Prescribing authority	An authorised health care practitioner is either a physician or nurse practitioner. In order to be eligible to provide a medical document, the health care practitioner must be eligible under the Cannabis Regulations, have the applicant for whom the medical document is provided under their professional treatment, and support that cannabis is required for the condition for which their patient is receiving treatment.
REQUIREMENTS FOR USE - DISPENSING	
Licensed dispensaries	Patients can access cannabis by: • Buying directly from a federally licensed seller (which is a company that has been granted a licence by Health Canada under the Cannabis Act to grow, package and sell cannabis to medical patients). • Registering with Health Canada to produce a limited amount for their own medical purposes (home grown). • Designating someone to produce it for them. • If aged 19 years or older, patients can also purchase cannabis at authorised retail outlets or through authorised online sales platforms. Companies who apply to become federal licence holders undergo a strict screening process that includes full background checks of owners and corporate board members, financial audits, a filed business plan, and multiple inspections of their growing operations.[29]
Cost	A limited number of insurance companies (e.g., Veterans Affairs Canada, Sun Life Financial) offer reimbursement of medical cannabis for specific conditions. Most federal licence holders now have compassionate pricing programs in place and offer discounts to patients meeting certain criteria. Patients can submit invoices for cannabis for reimbursement as a medical expense at tax time.

[29] https://www.canada.ca/en/health-canada/services/drugs-medication/cannabis/industry-licensees-applicants/licensing-summary/guide.html

TABLE 3.22 PERMITTED MEDICINAL CANNABIS PRODUCTS AND LEGISLATIVE FRAMEWORK

TYPE OF CANNABIS PERMITTED (TREATMENT) AND DISPENSING (INCLUDING LIMITS)	
Certification of cannabis products required	Cannabis products from licensed producers are strictly regulated to ensure they are fit for human consumption including mandatory testing for the presence of solvent residues and contaminants such as pesticides, mould, bacteria, and heavy metals.30
Registry of approved products	Products differ by federal licence holder. Cannabis is available as fresh, a dried plant or oil extracts from federal licence holders, for example, smoked, inhaled as a vapour, sprayed under the tongue, infused as a tea, or eaten in foods.
Limits	There are no personal storage limits for patients at home. Public possession limits for registered patients who are the lesser of 150 grams or a 30-day supply of dried cannabis (or the equivalent in cannabis product) in addition to the 30 grams allowed for non-medical purposes. Patients must be prepared to show they are legally allowed to possess more than 30 grams (or equivalent) in public, if requested by law enforcement. Where patients register to produce cannabis for their own medical purposes or to have it produced for them by a designated person, Health Canada will determine the maximum number of cannabis plants the patient is allowed to have for each production period. To make that determination, Health Canada will use a formula based on the daily quantity of dried cannabis indicated in the medical document and the average yield of a plant under certain growing conditions, such as indoor or outdoor growing.
Other approved THC-substance	Sativex is approved for use for the treatment of spasticity in Multiple Sclerosis. Covered by insurance. Nabilone (for nausea, vomiting in chemotherapy) is a synthetically produced THC. Covered by insurance.
PROGRESS TOWARDS MEDICAL CANNABIS PROGRAM	
Early approvals	Legal access to dried marijuana for medical purposes was first provided in 1999 using unique section 56 exemptions under the Controlled Drugs and Substances Act (CDSA). The Supreme Court of Canada decision in R. v. Parker in 2000 held that individuals with a medical need had the right to possess marijuana for medical purposes.
LEGISLATION	
Legislative instruments	The Cannabis Act and its regulations were enacted in 2018. This Act legalized recreational cannabis, and upheld the former medical cannabis regulations with some modifications. The Act created a strict framework for controlling the production, distribution, sale, and possession of cannabis throughout Canada, and also allows each province to control how and where cannabis is sold for non-medical adult use. History of Medical Cannabis Regulation 2001: Marihuana Medical Access Regulations (MMAR) legalized cannabis for medical use. 2013: Replaced MMAR with the Marihuana for Medical Purposes Regulations (MMPR) and set up the guidelines for the licensed producer system. 2015: The Supreme Court of Canada found that restricting legal access to only dried cannabis was unconstitutional. 2016: Replaced MMPR with the Access to Cannabis for Medical Purposes Regulations (ACMPR). This clarified some of the licensed producers'

[30] https://www.canada.ca/en/health-canada/services/cannabis-regulations-licensed-producers/good-production-practices-guide/guidance-document.html#appd

	responsibilities and roles, including being able to provide other cannabis products. 2018: Replaced ACMPR with the Cannabis Act and its Regulations, however, the previous regulations set out the framework for today's licensed producer system with modifications.

TABLE 3.23 DRIVING AND MEDICINAL CANNABIS, AND PROVISIONS RELATING TO DRUG-DRIVING

DRIVING WHILST PRESCRIBED MEDICINAL CANNABIS	
Driving permitted by prescription cannabis users	No exemption; per se limits apply to all drivers, including those with a medical authorisation for cannabis.
LEGISLATION	
Legislative instruments	Motor Vehicle Act (Provincial law). Amended to provide police with more tools to address and deter drug-affected driving. (https://www.bclaws.ca/civix/document/id/complete/statreg/96318_00)
	The Criminal Code of Canada (Federal law, s. 320.14, 320.19) prohibits driving while impaired to any degree by drugs, alcohol, or a combination of both.
DRIVING LAWS CONCERNING MEDICINAL CANNABIS AND CANNABIS	
Detection of drugs	Oral fluid test to detect the presence of THC. Before the police can demand an oral fluid sample on a drug screener, they must reasonably suspect there is a drug in the driver's body. Reasonable suspicion is based on objectively discernable facts, such as red eyes, muscle tremors, agitation, or speech patterns. Standard field sobriety tests Drug Recognition Expert (DRE) Evaluation
Impairment	Impaired driving provisions, *including for drivers suspected positive for medicinal cannabis* It is expected that the observed signs of impairment at the roadside, combined with a positive sample on the drug screener, would be sufficient for an investigation to move forward. If Police believe impaired, can require blood sample for laboratory testing.
Roadside oral fluid test introduced	22 August 2018
Drugs tested for at roadside	Cannabis (THC), Cocaine
Test device	Draeger Drug Test 5000 Abbot SoToxa
Laboratory test / confirmation	Blood sample Tested for Cannabis, Cocaine, LSD, 6-MAM (a metabolite of heroin), Ketamine, Phencyclidine (PCP), Psilocybin, Psilocin (magic mushrooms), and Methamphetamine, Gamma hydroxybutyrate (GHB)
Penalties	Immediate licence suspension ranges from 12 hours to 90 days with respect to the conditions of the situation.[31] A 90-day Administrative Driving Prohibition will be assessed to a driver whom officers reasonably believe operated under the influence of drugs and/or alcohol based on blood or fluid analysis or evaluation by a DRE. Having over 2ng but less than 5ng of THC per ml of blood within 2 hours of driving: Maximum $1,000 fine

[31] https://www2.gov.bc.ca/gov/content/transportation/driving-and-cycling/driving-prohibitions-suspensions/prohibitions-and-suspensions/alcohol-and-drug-related-suspensions#24hour

	Having 5ng or more of THC per ml of blood within 2 hours of driving OR Having a BAC of 50mg per 100ml of blood + 2.5ng or more of THC per 1ml of blood within 2 hours of driving: First offence: Mandatory minimum $1,000 fine; Maximum 10 years imprisonment; 1-3 years driving prohibition Second offence: Mandatory minimum 30 days imprisonment; Maximum 10 years imprisonment; 2-5 years driving prohibition Third offence Mandatory minimum 120 days imprisonment; Maximum 10 years imprisonment; a minimum 3 year to-lifetime driving prohibition Refusal to comply with demand for sample or perform physical coordination test: First offence: Mandatory minimum $2,000 fine Second offence: Mandatory minimum 30 days imprisonment; Maximum 10 years imprisonment Third offence Mandatory minimum 120 days imprisonment; Maximum 10 years imprisonment

TABLE 3.24 DRINK-DRIVING AND ADMINISTRATIVE AGENCIES AND FITNESS-TO-DRIVE PROTOCOLS

DRIVING LAWS CONCERNING ALCOHOL (BAC LIMITS) AND DRIVING	
Fully licensed	0.05 BAC
Learner permit	0.00 BAC
Professional (commercial driver)	0.00 BAC
ENFORCEMENT (TRAFFIC, ROAD)	
Police service	The Royal Canadian Mounted Police E Division is the largest police body, providing federal, provincial, and municipal policing
Forensic services (for drug testing)	National Forensic Laboratory Services (NFLS). Provides forensic services in biology, firearms, toxicology and trace evidence for police from across Canada. The toxicology service receives bodily fluid samples (e.g., blood and urine) and screens for a broad range of drugs and poisons, including alcohol and cannabinoids.
LICENSING AUTHORITY	
Licensing authority	Insurance Corporation of British Columbia (ICBC, https://www.icbc.com/Pages/default.aspx)
OTHER ROAD RELEVANT GOVERNMENT ROAD SAFETY AGENCIES	
Government	Ministry of Transportation and Infrastructure (https://www2.gov.bc.ca/gov/content/governments/organizational-structure/ministries-organizations/ministries/transportation-and-infrastructure)
Government	RoadSafetyBC (https://www2.gov.bc.ca/gov/content/transportation)
Government	Transport Canada (https://tc.canada.ca/en/road-transportation/road-safety-canada)
Government	Canadian Council of Motor Transport Administrators (https://ccmta.ca/en/)
MEDICAL FITNESS TO DRIVE (MFtD)	
CCMTA Medical Standards for Drivers with B.C. Specific Guidelines	The decision guiding tool used by RoadSafetyBC in determining driver licence status and is a reference for medical practitioners when assessing driver fitness. Developed to better assess the effects that a medical condition has on the driver's cognitive, sensory and motor functions necessary for driving. https://www2.gov.bc.ca/gov/content/transportation/driving-and-cycling/driver-medical/driver-medical-fitness/driver-medical-fitness-information-for-medical-professionals/ccmta-medical-standards-bc-specific-guidelines-quick-access

Canadian Medical Association Guide to Drive	The Driver's Guide: Determining Medical Fitness to Operate Motor Vehicles, latest edition released October 2019

TABLE 3.25 IMPACTS ON ROAD SAFETY OF MEDICINAL CANNABIS PROGRAM

IMPACTS OF DRUG-DRIVING ON ROAD CRASHES IN BRITISH COLUMBIA	
Prevalence in crashes	In a study of 3,005 non-fatally injured drivers, 8.3% tested positive for THC, 8.9% other recreational drugs, 19.8% sedating medications, and 14.4% alcohol. No increased risk of crash responsibility in drivers with THC < 2ng/ml or 2 ng/ml ≤ THC <5 ng/ml alcohol. Statistically non-significant increased risk of crash responsibility in drivers with ≥ 5ng/ml (Brubacher et al., 2019).[32]
Positive rate	Alcohol and Drug Use 2018 Roadside Survey[33] found 13.7% of drivers were positive for alcohol, drugs or both. Among drug-positive drivers, 70.5% tested positive for cannabis. Males accounted for 81.8% of drug-positive drivers; most common in 19-25 years and 55+ years
ROAD SAFETY IMPACTS OF MEDICINAL CANNABIS	
Crashes involving Medicinal Cannabis Certificate	N/A
Number detected at roadside	N/A

[32] Brubacher, J. R., Chan, H., Erdelyi, S., Macdonald, S., Asbridge, M., Mann, R. E., Eppler, J., Lund, A., MacPherson, A., Martz, W., Schreiber, W. E., Brant, R., & Purssell, R. A. (2019). Cannabis use as a risk factor for causing motor vehicle crashes: a prospective study. Addiction (Abingdon, England), 114(9), 1616–1626. https://doi.org/10.1111/add.14663
[33] https://www2.gov.bc.ca/assets/gov/driving-and-transportation/driving/publications/2018-roadside-survey-report.pdf

3.5 MEDICINAL CANNABIS PROGRAM CHARACTERISTICS AND DRIVING REQUIREMENTS IN QUEBEC, CANADA

This section provides details concerning aspects of drug-driving in Quebec, Canada.

The following Tables provide a detailed outline of aspects relating to the medicinal cannabis program and associated drug-driving considerations.

TABLE 3.26 FEATURES OF THE MEDICINAL CANNABIS PROGRAM IN QUEBEC

PROGRAM CHARACTERISTIC	DETAIL
ADMINISTRATIVE	
Name of Scheme	Marihuana Medical Access Regulations (MMAR, original)[34] Cannabis Act (2018-present)[35]
Legislation approved	14 June 2001
Date of commencement	30 July 2001
Government Department responsible for medical cannabis oversight	Health Canada
Pilot program	No
Evaluation planned	No
STATUS OF THC AND CBD	
THC	**Medical** and **recreational** cannabis use and possession by people aged 21 and older is legal with limits on quantities. No age limit for medical.
CBD	CBD products are strictly regulated and are only legal when sold in compliance with the Cannabis Act and its regulations.
MEDICAL CONDITIONS FOR WHICH MEDICAL CANNABIS IS PERMITTED	
There is no exhaustive list of conditions. An authorised health care practitioner and patient discuss their medical condition and conclude that cannabis for medical purposes is an appropriate option for her/him. Example conditions are: ADD/ADHD, Alzheimer's disease, anxiety, arthritis, cancer, nausea and vomiting due to chemotherapy chronic pain, depression, eating disorders, epilepsy, fibromyalgia, Hepatitis C, HIV/AIDS, kidney failure (including dialysis patients), migraines, multiple sclerosis, muscle spasms, muscular dystrophy, Parkinson's disease, Post-traumatic stress disorder (PTSD), sexual dysfunction, sleep disorders.	
Physicians must: exhaust other possible treatments before authorising cannabis, document the treatments that were attempted but failed, and keep a registry of all patients for whom they have provided a medical document for cannabis.[36]	
ENROLMENT STATISTICS	
Number of applicants approved	16,904 active client registrations with a federal licence holder (March 2020)[37]; no limitation on age
By medical condition	Unknown
REQUIREMENTS FOR USE - PRESCRIBING	
Prescribing authority	An authorised health care practitioner is either a physician or nurse practitioner. In order to be eligible to provide a medical document, the health care practitioner must be eligible under the Cannabis Regulations, have the applicant for whom the medical document is provided under their professional treatment, and support that cannabis is required for the condition for which their patient is receiving treatment.

[34] https://laws-lois.justice.gc.ca/eng/regulations/sor-2001-227/page-1.html
[35] https://laws-lois.justice.gc.ca/eng/Regulations/SOR-2018-144/index.html
[36] https://www.cmpa-acpm.ca/en/advice-publications/browse-articles/2014/medical-marijuana-new-regulations-new-college-guidance-for-canadian-doctors
[37] https://www.canada.ca/en/health-canada/services/drugs-medication/cannabis/research-data/medical-purpose.html

REQUIREMENTS FOR USE - DISPENSING	
Licensed dispensaries	Patients can access cannabis by: buying directly from a federally licensed seller (which is a company that has been granted a licence by Health Canada under the Cannabis Act to grow, package and sell cannabis to medical patients); registering with Health Canada to produce a limited amount for their own medical purposes (home grown); designating someone to produce it for them; or if aged 21 years or older, patients can also purchase cannabis at authorised retail outlets or through authorised online sales platforms. Companies who apply to become federal licence holders undergo a strict screening process that includes full background checks of owners and corporate board members, financial audits, a filed business plan, and multiple inspections of their growing operations.[38]
Cost	A limited number of insurance companies (e.g., Veterans Affairs Canada, Sun Life Financial) offer reimbursement of medical cannabis for specific conditions. Most federal licence holders now have compassionate pricing programs in place and offer discounts to patients meeting certain criteria. Patients can submit invoices for cannabis for reimbursement as a medical expense at tax time.

[38] https://www.canada.ca/en/health-canada/services/drugs-medication/cannabis/industry-licensees-applicants/licensing-summary/guide.html

TABLE 3.27 PERMITTED MEDICINAL CANNABIS PRODUCTS AND LEGISLATIVE FRAMEWORK

TYPE OF CANNABIS PERMITTED (TREATMENT) AND DISPENSING (INCLUDING LIMITS)	
Certification of cannabis products required	Cannabis products from licensed producers are strictly regulated to ensure they are fit for human consumption including mandatory testing for the presence of solvent residues and contaminants such as pesticides, mould, bacteria, and heavy metals.[39]
Registry of approved products	Products differ by federal licence holder. Cannabis is available as fresh, a dried plant or oil extracts from federal licence holders. It can be used in a variety of ways including, for example, smoked, inhaled as a vapour, sprayed under the tongue, infused as a tea, or eaten in foods.
Limits	There are no personal storage limits for patients at home. Public possession limits for registered patients who are the lesser of 150 grams or a 30-day supply of dried cannabis (or the equivalent in cannabis product) in addition to the 30 grams allowed for non-medical purposes. Patients must be prepared to show they are legally allowed to possess more than 30 grams (or equivalent) in public, if requested by law enforcement. Where patients register to produce cannabis for their own medical purposes or to have it produced for them by a designated person, Health Canada will determine the maximum number of cannabis plants the patient is allowed to have for each production period. To make that determination, Health Canada will use a formula based on the daily quantity of dried cannabis indicated in the medical document and the average yield of a plant under certain growing conditions, such as indoor or outdoor growing.
Other approved THC-substance	Sativex is approved for use for the treatment of spasticity in Multiple Sclerosis. Covered by insurance. Nabilone (for nausea, vomiting in chemotherapy) is a synthetically produced THC. Covered by insurance.
PROGRESS TOWARDS MEDICAL CANNABIS PROGRAM	
Early approvals	Legal access to dried marijuana for medical purposes was first provided in 1999 using unique section 56 exemptions under the Controlled Drugs and Substances Act (CDSA). The Supreme Court of Canada decision in R. v. Parker in 2000 held that individuals with a medical need had the right to possess marijuana for medical purposes.
LEGISLATION	
Legislative instruments	The Cannabis Act and its Regulations were enacted in 2018. This Act legalized recreational cannabis, and upheld the former medical cannabis regulations with some modifications. The Act created a strict framework for controlling the production, distribution, sale, and possession of cannabis throughout Canada, and also allows each province to control how and where cannabis is sold for non-medical adult use. The Quebec Cannabis Regulation Act tightened restrictions on the use of cannabis in public places, including for medical use. It is prohibited to smoke or vape cannabis in any indoor or outdoor public space.[40] History of Medical Cannabis Regulation 2001: Marihuana Medical Access Regulations (MMAR) legalized cannabis for medical use. 2013: Replaced MMAR with the Marihuana for Medical Purposes Regulations (MMPR) and set up the guidelines for the licensed producer system.

[39] https://www.canada.ca/en/health-canada/services/cannabis-regulations-licensed-producers/good-production-practices-guide/guidance-document.html#appd
[40] Cannabis Regulation Law: http://www.legisquebec.gouv.qc.ca/fr/ShowDoc/cs/C-5.3

	2015: The Supreme Court of Canada found that restricting legal access to only dried cannabis was unconstitutional. 2016: Replaced MMPR with the Access to Cannabis for Medical Purposes Regulations (ACMPR). This clarified some of the licensed producers' responsibilities and roles, including being able to provide other cannabis products. 2018: Replaced ACMPR with the Cannabis Act and its Regulations, however, the previous regulations set out the framework for today's licensed producer system with modifications.

TABLE 3.28 DRIVING AND MEDICINAL CANNABIS AND PROVISIONS RELATING TO DRUG-DRIVING

DRIVING WHILST PRESCRIBED MEDICINAL CANNABIS	
Driving permitted by prescription cannabis users	No. Current federal per se limits apply to all drivers, including those with a medical authorisation for cannabis. The introduction of a zero drug tolerance law prohibiting any person from driving if there is a detectable presence of cannabis or another drug in the person's saliva will come into force when detection equipment is approved for use in Québec by police (peace) officers.[41]
LEGISLATION	
Legislative instruments	Highway Safety Code (HSC, provincial law, http://legisquebec.gouv.qc.ca/en/ShowDoc/cs/C-24.2)
	The Criminal Code of Canada (federal law, s. 320.14, 320.19) prohibits driving while impaired to any degree by drugs, alcohol, or a combination of both.
DRIVING LAWS CONCERNING MEDICINAL CANNABIS AND CANNABIS	
Detection of drugs	Oral fluid test to detect the presence of THC. Standard field sobriety tests (horizontal gaze nystagmus test, walk and turn test, one-leg stand test); Drug Recognition Expert (DRE) Evaluation;
Impairment	Impaired driving provisions, *including for drivers suspected positive for medicinal cannabis* If Police believe impaired, can require urine/saliva/blood sample for laboratory testing. If the test is positive, it will be submitted as evidence.
Roadside oral fluid test introduced	22 August 2018
Drugs tested for at roadside	Cannabis (THC), Cocaine
Test device	Draeger Drug Test 5000 Abbott SoToxa
Laboratory test / confirmation	Blood/urine/saliva sample
Penalties	Immediate 90-day licence suspension for a driver whom an evaluating police officer believes is impaired by cannabis or any other drug or by a combination of cannabis or any other drug and alcohol. Immediate vehicle seizure and impoundment: 30 days (depending on the situation). Having over 2ng but less than 5ng of THC per ml of blood within 2 hours of driving: Maximum $1,000 fine

[41] Amendment of HSC. https://encadrementcannabis.gouv.qc.ca/loi/modification-du-code-de-la-securite-routiere/

	Having 5ng or more of THC per ml of blood within 2 hours of driving OR Having a BAC of 50mg per 100ml of blood + 2.5ng or more of THC per 1ml of blood within 2 hours of driving: First offence: Mandatory minimum $1,000 fine; Maximum 10 years imprisonment; 1-3 years driving prohibition Second offence: Mandatory minimum 30 days imprisonment; Maximum 10 years imprisonment; 2-5 years driving prohibition Third offence Mandatory minimum 120 days imprisonment; Maximum 10 years imprisonment; a minimum 3 year to-lifetime driving prohibition Refusal to comply with demand for sample or perform physical coordination test results in immediate seizure and impoundment of the vehicle for 30 days (90 days, in the case of a repeat offence)

TABLE 3.29 DRINK-DRIVING, GOVERNMENT AGENCIES AND FITNESS-TO-DRIVE

DRIVING LAWS CONCERNING ALCOHOL (BAC LIMITS) AND DRIVING	
Fully licenced, 22 years and older	0.08 BAC
Fully licenced, 21 years and younger	0.00 BAC
Learner permit	0.00 BAC
Professional (bus, minibus, taxi drivers)	0.00 BAC
Heavy vehicle drivers	0.05 BAC
ENFORCEMENT (TRAFFIC, ROAD)	
Police service	Sûreté du Québec
Forensic services (for drug testing)	Laboratory of Forensic Sciences and Forensic Medicine. The Laboratory is an autonomous service unit. Toxicology and alcohol specialists look for the presence of drugs, medications, poisons, certain biochemical parameters, alcohols and other volatile substances in the blood or other biological matrices. They do so mainly in cases of sexual assault, murder, suspicious death, driving a vehicle impaired by alcohol or drugs.
LICENSING AUTHORITY	
Licensing authority	Société de l'assurance automobile du Québec (SAAQ, https://saaq.gouv.qc.ca/en/)
OTHER ROAD RELEVANT GOVERNMENT ROAD SAFETY AGENCIES	
Government	Transports Québec (https://www.transports.gouv.qc.ca/en/securite/securite/Pages/securite.aspx)
Government	Canadian Council of Motor Transport Administrators (CCMTA, https://ccmta.ca/en/)
Government	Transport Canada (https://tc.canada.ca/en/road-transportation/road-safety-canada)
MEDICAL FITNESS TO DRIVE (MFtD)	
CCMTA Determining Driver Fitness in Canada	https://ccmta.ca/images/pdf-documents-english/dv/NSC_6/National-Safety-Code-Standard-6---Determining-Fitness-to-Drive-in-Canada---January-2020.pdf
Canadian Medical Association Guide to Drive	The Driver's Guide: Determining Medical Fitness to Operate Motor Vehicles, latest edition released October 2019

TABLE 3.30 IMPACTS ON ROAD SAFETY OF MEDICINAL CANNABIS PROGRAM

IMPACTS OF DRUG-DRIVING ON ROAD CRASHES IN QUEBEC	
Prevalence in crashes	53 of 152 (34.9%) of drivers fatally injured tested positive for drugs.[42] (2014 data)
Positive rate	The most common drug found within drivers testing positive was cannabis (56.6%). Other drugs drivers tested positive for were CNS depressants, narcotic analgesics, and CNS stimulants (39.6% each), as well as dissociative anaesthetics (1.9%). Multiple drugs found in blood samples of some drivers.
ROAD SAFETY IMPACTS OF MEDICINAL CANNABIS	
Crashes involving Medicinal Cannabis Certificate	Unknown
Number detected at roadside	N/A

[42] https://ccmta.ca/images/publications/pdf//2014_Alcohol_and_Drug_Crash_Problem_Report.pdf

3.6 MEDICINAL CANNABIS PROGRAM CHARACTERISTICS AND DRIVING REQUIREMENTS IN TEXAS, USA

This section provides details concerning aspects of drug-driving in Texas, United States of America (USA). The following Tables provide a detailed outline of aspects relating to the medicinal cannabis program and associated drug-driving considerations.

TABLE 3.31 FEATURES OF THE MEDICINAL CANNABIS PROGRAM IN TEXAS

PROGRAM CHARACTERISTIC	DETAIL
ADMINISTRATIVE	
Name of Scheme	Compassionate Use Act[43]
Legislation approved	1 June 2015; expanded in 2019 to include more medical conditions (listed below)
Date of commencement	1 June 2015
Government Department responsible for medical cannabis oversight	Texas Department of Public Safety (DPS)
Pilot program	No
Evaluation planned	No
STATUS OF THC AND CBD	
THC	Any product that contains greater than 0.3% THC is illegal; low-THC (less than 0.5% THC) exceptions granted for medical purposes as per below.
CBD	CBD products with less than 0.3% THC are legal.
MEDICAL CONDITIONS FOR WHICH MEDICAL CANNABIS IS PERMITTED	
Epilepsy, seizure disorder, multiple sclerosis, spasticity, amyotrophic lateral sclerosis (ALS), autism, terminal cancer, incurable neurodegenerative disease	
All conditions: the physician determines the risk of the medical use of low-THC cannabis by the patient is reasonable in light of the potential benefit for the patient.	
ENROLMENT STATISTICS	
Number of applicants approved	2,405 patients (July 2020); no limitation on age, under 18 may require legal guardian; must be a resident of Texas. 208 physicians (July 2020)
REQUIREMENTS FOR USE - PRESCRIBING	
Prescribing authority	Physician, patient under care of. Required to be licensed, board certified in a medical specialty relevant to the treatment of the patient's medical condition by a specialty board approved by the American Board of Medical Specialties or the Bureau of Osteopathic Specialists, and dedicates a significant portion of clinical practice to the evaluation and treatment of the patient's particular medical condition.[44] Applications made by physician via Compassionate Use Registry of Texas (CURT); once physician is approved, patients can be added to profile, treatment plan is described, safety and efficacy information is added, and a prescription can be used.
REQUIREMENTS FOR USE - DISPENSING	
Licensed dispensaries	Three dispensaries licensed by DPS
Cost	Prices are set by the licensed dispensing organizations, based on the market. DPS does not regulate the cost of the product. Not covered by insurance.

[43] Compassionate Use Program: https://www.dps.texas.gov/rsd/cup/index.htm
[44] Occupations Code: https://statutes.capitol.texas.gov/Docs/OC/htm/OC.169.htm

TABLE 3.32 PERMITTED MEDICINAL CANNABIS PRODUCTS AND LEGISLATIVE FRAMEWORK

TYPE OF CANNABIS PERMITTED (TREATMENT) AND DISPENSING (INCLUDING LIMITS)	
Certification of cannabis products required	No, Texas Health and Safety Code Ch.487 regulates the cultivation, processing, and dispensing of low-THC cannabis and does not specifically address the licensing of low-THC cannabis testing laboratories. Only licensed dispensing organizations may test low-THC products.
Registry of approved products	No, licensed dispensaries create medical cannabis products. Prescription lists which formulation doctor prescribes. Only inhaler, tincture, and oil ingestion methods are legal. Licensees in this state are only allowed to produce cannabis extracts containing 0.5% THC by weight.
Example products	
High-CBD (20:1) Pure Tincture	Oral tincture THC: 0.5% w/v (5 mg/ml) CBD: 10% w/v (100 mg/ml)
High-CBD (20:1) Spray	Oral spray THC 0.5% w/v (5 mg/ml) CBD: 10% w/v (100 mg/ml)
Balanced (3:1) Tincture	Oral tincture THC 0.5% w/v (5 mg/ml) CBD: 1.5% w/v (15 mg/ml)
Other approved THC-substance	Epidiolex: legal throughout US. Approved by Food and Drug Administration (FDA; Schedule V); CBD-only prescription medication (100 mg/ml) Marinol (Dronabinol), approved by FDA, is a medication which contains a synthetic version of THC.
PROGRESS TOWARDS MEDICAL CANNABIS PROGRAM	
Rohrabacher-Farr amendment	At Federal level, cannabis is classified as Schedule I drug. After six failed attempts, in December 2014, the Rohrabacher-Farr amendment was signed into law, prohibiting the Justice Department from spending funds to interfere with state implementation of medical cannabis laws.
Early approvals	None
LEGISLATION	
Legislative instruments	June 2019, House Bill 3703 expanded the Compassionate Use Act to include additional medical conditions and physician specialties for which low-THC (less than 0.5% THC) cannabis may be prescribed. June 2019, House Bill 1325 authorized the production, manufacture, retail sale, and inspection of industrial hemp crops and products in Texas. This includes products for consumable hemp products which contain cannabidiol. Agency with oversight is the Texas Department of Health and Human Services. The Agriculture Improvement Act of 2018 legalized the commercial production of hemp (less than 0.3% THC) in the US. The law legalized growing and cultivating hemp and is regulated at the state level (i.e. Texas Department of Agriculture). Removed hemp-derived products from Schedule I status under the Controlled Substances Act. June 2015, Senate Bill 339, the Texas Compassionate Use Act, legalized the use of low-THC (less than 0.5% THC) cannabis for treatment of epilepsy patients.

TABLE 3.33 DRIVING AND MEDICINAL CANNABIS AND PROVISIONS RELATING TO DRUG DRIVING AND TESTING

DRIVING WHILST PRESCRIBED MEDICINAL CANNABIS	
Driving permitted by prescription cannabis users	No. Driving while intoxicated (DWI) offence applies for any detectable amount of cannabis in body regardless of medical or recreational use.
LEGISLATION	
Legislative instruments	Texas Penal Code 49.04: DWI law. Includes prescription drugs / medications (https://statutes.capitol.texas.gov/Docs/PE/htm/PE.49.htm)
DRIVING LAWS CONCERNING MEDICINAL CANNABIS AND CANNABIS	
Detection of drugs	Police observation; standard field sobriety tests
Impairment	Impaired driving provisions, *including for drivers suspected positive for medicinal cannabis* If Police believe impaired, can require blood/urine sample for laboratory testing Impairment tests are: horizontal gaze nystagmus test; walk and turn test; one-leg stand.
Roadside oral fluid test introduced	N/A
Drugs tested for at roadside	None
Test device	N/A
Laboratory test / confirmation	Blood or urine sample Initial screening test for amphetamines, barbiturates, benzodiazepines, carisoprodol, cocaine, opiates, PCP, THC. Additional screening test includes anti-depressants, pain relievers, muscle relaxers, anti-convulsants, sleep aids, MDPV.
Penalties	Arrest First offense: confinement in jail 3-180 days, fine not to exceed $2,000, loss of driver licence up to 1 year Second offense: confinement in jail 30-365 days, fine not to exceed $4,000, loss of driver licence up to two years Third offense: imprisonment 2-10 years, fine not to exceed $10,000, loss of driver licence up to two years Criminal record Refusal of blood or breath test results in automatic suspension of driver license for 180 days

TABLE 3.34 DRINK-DRIVING LAWS, RELEVANT AGENCIES AND FITNESS-TO-DRIVE

DRIVING LAWS CONCERNING ALCOHOL (BAC LIMITS) AND DRIVING	
Fully licenced, 21 years and older	0.08 BAC
Fully licenced, under 21 years	0.00 BAC
Learner permit	0.00 BAC
Professional (commercial driver)	0.04 BAC
ENFORCEMENT (TRAFFIC, ROAD)	
Police service	Department of Public Safety / Texas Highway Patrol
Forensic services (for drug testing)	Department of Public Safety Crime Laboratory Service, Toxicology Section. Function is to analyse biological specimens in order to detect alcohol, volatiles, and/or drugs in investigations related to driving while intoxicated (DWI), sexual assault, and homicide.
LICENSING AUTHORITY	
Licensing authority	Department of Public Safety (https://www.dps.texas.gov/DriverLicense/)
OTHER ROAD RELEVANT GOVERNMENT ROAD SAFETY AGENCIES	
Government	Department of Transportation (https://www.txdot.gov/)
Government	National Highway Traffic Safety Administration (https://www.nhtsa.gov/)
MEDICAL FITNESS TO DRIVE (MFtD)	
Texas Medical Evaluation Process for Driver Licensing	https://www.dps.texas.gov/DriverLicense/MedicalRevocation.htm
Medical Review Practices for Driver Licensing	https://www.nhtsa.gov/sites/nhtsa.dot.gov/files/documents/812402_medicalreviewdriverlicense.pdf (p. 353-371 relating to Texas)

TABLE 3.35 IMPACTS ON ROAD SAFETY OF MEDICINAL CANNABIS PROGRAM

IMPACTS OF DRUG-DRIVING ON ROAD CRASHES IN TEXAS	
Prevalence in fatal crashes	Number of fatalities due to drug-impaired driving in 2017: 630 (16.9%) Total fatalities: 3,726
Positive rate, OFT	Of killed drivers with positive drug tests, percent that tested positive for cannabinoids was 36%; 32% stimulants; 12% narcotics; 14% depressants (Trueblood, n.d., p. 11-12)[45]
ROAD SAFETY IMPACTS OF MEDICINAL CANNABIS	
Crashes involving Medicinal Cannabis Certificate	Unknown
Number detected at roadside	N/A

[45] https://www.county.org/TAC/media/TACMedia/Education/Event%20Presentation%20Materials/2019/Impaired-Driving-Symposium/6-Trueblood-Drug-Impaired-Driving.pdf

3.7 MEDICINAL CANNABIS PROGRAM CHARACTERISTICS AND DRIVING REQUIREMENTS IN OREGON, USA

This section provides details concerning aspects of drug-driving in Oregon, United States of America (USA). The following Tables provide a detailed outline of aspects relating to the medicinal cannabis program and associated drug-driving considerations.

TABLE 3.36 FEATURES OF THE MEDICINAL CANNABIS PROGRAM IN OREGON

PROGRAM CHARACTERISTIC	DETAIL
ADMINISTRATIVE	
Name of Scheme	Oregon Medical Marijuana Act[46]
Legislation approved	3 November 1998
Date of commencement	3 December 1998
Government Department responsible for medical cannabis oversight	Oregon Health Authority
Pilot program	No
Evaluation planned	No
STATUS OF THC AND CBD	
THC	**Medical** and **recreational** cannabis use and possession by people aged 21 and older is legal with limits on quantities.
CBD	No legal impediment. Any CBD only product can be sold without restriction
MEDICAL CONDITIONS FOR WHICH MEDICAL CANNABIS IS PERMITTED	
Cancer, glaucoma, a degenerative or pervasive neurological condition, HIV/AIDS, post-traumatic stress disorder (PTSD), or a medical condition or treatment for a medical condition that produces one or more of the following: cachexia (a weight loss disease than can be caused by HIV or cancer), severe pain, severe nausea, seizures (including but not limited to seizures caused by epilepsy), and persistent muscle spasm (including but not limited to spasms caused by multiple sclerosis)	
Physician must state in writing that the patient has a qualifying medical condition and that medical marijuana may mitigate the symptoms or effects of that condition annually.	
ENROLMENT STATISTICS	
Number of applicants approved	23,278 (July 2020)[47]; no limitation on age, under 18 requires caregiver; must be Oregon resident. Oregon Medical Marijuana Program (OMMP) requires all patients to have an established, bona fide doctor/patient relationship. Once the patient has been certified, the patient must register with the OMMP Patient Registry. Registration is mandatory in order for patients to ensure protection under Oregon's medical marijuana law. 58% Male Age # of patients 0-17 164

46 Oregon Medical Marijuana Program (OMMP): https://www.oregon.gov/oha/PH/DISEASESCONDITIONS/CHRONICDISEASE/MEDICALMARIJUANAPROGRAM/Pages/index.aspx

47 https://www.oregon.gov/oha/PH/DISEASESCONDITIONS/CHRONICDISEASE/MEDICALMARIJUANAPROGRAM/Documents/OMMP_Statistical_Snapshot_07_2020.pdf

	18-29 2,529 30-49 8,464 50-69 9,653 70+ 2,468 1,275 physicians associated with patients (July 2020)
By medical condition	Not mutually exclusive; one patient may report one or more conditions Condition % of patients Severe pain 88.2 Spasms 21.9 PTSD 14.4 Nausea 10.2 Cancer 6.0 Neurological 5.3 Seizures 3.2 Glaucoma 1.7 Cachexia 1.2 HIV/AIDS 1.1
REQUIREMENTS FOR USE - PRESCRIBING	
Prescribing authority	Attending Physician's may recommend the use of medical marijuana for the aforementioned medical conditions. An Attending Physician is defined as a Doctor of Medicine (MD) or Doctor of Osteopathy (DO) licensed under ORS chapter 677 who has the primary responsibility for the care and treatment of a person diagnosed with a debilitating medical condition. Primary responsibility means that the physician: • Provides primary health care for the patient; or provides medical specialty care and treatment for the patient as recognized by the American Board of Medical Specialties; or • Is a consultant who has been asked to examine and treat the patient by the patient's primary care physician licensed under ORS Chapter 677, the patient's physician assistant licensed under ORS Chapter 677, or the patient's nurse practitioner licensed under ORS Chapter 678 • AND has reviewed a patient's medical records at the patient's request and has conducted a thorough physical examination of the patient, has provided or planned follow-up care, and has documented these activities in the patient's medical record.
REQUIREMENTS FOR USE - DISPENSING	
Licensed dispensaries	OMMP is responsible for registration, regulation and oversight of medical marijuana facilities in Oregon, including medical marijuana dispensaries. Inspected annually to ensure compliance. Required to use the Cannabis Tracking System.
Cost	A dispensary is permitted to seek reimbursement for immature plants and medical marijuana products based on its normal and customary costs of doing business. Not covered by insurance. Can be sold tax free.

TABLE 3.37 PERMITTED MEDICINAL CANNABIS PRODUCTS AND LEGISLATIVE FRAMEWORK

TYPE OF CANNABIS PERMITTED (TREATMENT) AND DISPENSING (INCLUDING LIMITS)	
Certification of cannabis products required	All marijuana and marijuana products intended to be sold at a dispensary or retail shop must have been sampled and tested according to Division 7 Marijuana Labelling, Concentration Limits, and Testing rules[48]. Any laboratory that tests marijuana items must be accredited by the Oregon Environmental Laboratory Accreditation Program and licensed by the Oregon Liquor Control Commission.
Limits	A dispensary may not transfer at any one time to a patient or caregiver, within one day, more than: 24 ounces of usable marijuana; 16 ounces of a medical cannabinoid product in solid form; 72 ounces of a medical cannabinoid product in liquid form; 16 ounces of a cannabinoid concentrate whether sold alone or contained in an inhalant delivery system; 5 grams of a cannabinoid extract whether sold alone or contained in an inhalant delivery system; 4 immature marijuana plants; and 50 seeds.
Home grown	A patient (and their caregiver, if applicable) may possess up to 6 mature plants, which must be grown at a registered grow site address, and up to 24 ounces of usable marijuana.
Registry of approved products	No. To meet legal requirements, medical cannabis products must meet the following concentration and serving size limits.

Type of Marijuana Item	Maximum concentration or amount of THC per serving	Maximum concentration of amount of THC in container
Cannabinoid Edibles	N/A	100 mg
Cannabinoid Topicals	N/A	6%
Cannabinoid Tinctures	N/A	4,000 mg
Cannabinoid Capsules	100 mg	4,000 mg
Cannabinoid Suppositories	100 mg	4,000 mg
Cannabinoid Transdermal Patches	100 mg	4,000 mg
Cannabinoid Concentrates or Extracts	N/A	4,000 mg

PROGRESS TOWARDS MEDICAL CANNABIS PROGRAM	
Decriminalization of marijuana	Prior to the legalisation of medical cannabis, in 1973 Oregon became the first state to decriminalize cannabis, abolishing criminal penalties for possession of up to one ounce of marijuana.
Early approvals	None
LEGISLATION	
Legislative instruments	Oregon Administrative Rules (OAR) 333-007 establishes minimum compliance testing standards for marijuana items. Oregon Revised Statute (ORS) 475B Cannabis Regulation / Oregon Medical Marijuana Act states patients and doctors have found marijuana to be an effective treatment for suffering caused by debilitating medical conditions and, therefore, marijuana must be treated like other medicines. Since 2013, over a dozen legislative bills pertaining to medical marijuana have been passed to amend laws governing regulations with regard to, e.g. program administration, testing, labelling, advertising, tracking, dispensaries, growers, and growing facilities.[49]

[48] https://oregon.public.law/rules/oar_chapter_333_division_7

[49] https://www.oregon.gov/oha/PH/DISEASESCONDITIONS/CHRONICDISEASE/MEDICALMARIJUANAPROGRAM/Pages/legal.aspx

TABLE 3.38 DRIVING AND MEDICINAL CANNABIS AND PROVISIONS RELATING TO DRUG DRIVING AND TESTING

DRIVING WHILST PRESCRIBED MEDICINAL CANNABIS	
Driving permitted by prescription cannabis users	No. Driving under the influence of intoxicants (DUII) refers to operating a motor vehicle while intoxicated or drugged, including impairment from the use of marijuana regardless of medical or recreational use.
LEGISLATION	
Legislative instruments	ORS 813.010 – DUII (https://www.oregonlaws.org/ors/813.010)
DRIVING LAWS CONCERNING MEDICINAL CANNABIS AND CANNABIS	
Detection of drugs	Police observation; standard field sobriety tests; use of Drug Recognition Experts (DRE), police officers with specialised training in drug-impaired driving
Impairment	Impaired driving provisions, including for drivers suspected positive for medicinal cannabis If Police believe impaired, can require urine sample for laboratory testing. A police officer may not request a urine test unless the officer is certified by the Department of Public Safety Standards and Training as having completed at least eight hours of training in recognition of drug impaired driving and the officer has a reasonable suspicion that the person arrested has been driving while under the influence of cannabis. If a DRE is used, will execute 12-step DRE protocol (https://www.theiacp.org/12-step-process) which includes e.g., breath test, horizontal and vertical gaze nystagmus test, walk and turn test, one-leg stand, and vital signs.
Roadside oral fluid test introduced	N/A
Drugs tested for at roadside	None
Test device	N/A
Laboratory test / confirmation	Urine sample; blood tests used only if the person is receiving medical care in a health care facility after a crash. The laboratory performs a qualitative analysis of biological fluids (e.g., urine) for controlled substances, common pharmaceuticals and poisons. Quantitative analysis of drugs in blood is performed on post-mortem toxicology cases. Volatiles analysis (e.g., blood alcohol determination) is provided for ante-mortem and post-mortem cases.
Penalties	Arrest First offense: confinement in jail 2-365 days, may be required to perform up to 160 hours of community service, minimum fine $1,000 not to exceed $6,250, minimum 30-day license suspension Second offense: confinement in jail 2-365 days, may be required to perform up to 160 hours of community service, minimum fine $1,500 not to exceed $6,250, minimum 60-day license suspension Third offense: confinement in jail 2-365 days, may be required to perform up to 160 hours of community service, minimum fine $2,000 not to exceed $6,250 Fourth offense (within 10 years): imprisonment up to 5 years, minimum fine $2,000 not to exceed $125,000, minimum 1-year license suspension Refusal of urine test for intoxicants punishable by minimum fine of $500, not more than $1,000 and license suspension

TABLE 3.39 DRIVING AND MEDICINAL CANNABIS AND PROVISIONS RELATING TO DRUG DRIVING AND TESTING

DRIVING LAWS CONCERNING ALCOHOL (BAC LIMITS) AND DRIVING	
Fully licensed, 21 years and older	0.08 BAC
Fully licensed, under 21 years	0.00 BAC
Learner permit	0.00 BAC
Professional (commercial driver)	0.04 BAC
ENFORCEMENT (TRAFFIC, ROAD)	
Police service	Oregon State Police
Forensic services (for drug testing)	Oregon State Police Forensic Services Division
LICENSING AUTHORITY	
Licensing authority	Oregon Driver and Motor Vehicle Services (https://www.oregon.gov/odot/DMV/Pages/index.aspx)
OTHER ROAD RELEVANT GOVERNMENT ROAD SAFETY AGENCIES	
Government	Department of Transportation (https://www.oregon.gov/odot/Pages/index.aspx/)
Government	National Highway Traffic Safety Administration (https://www.nhtsa.gov/)
MEDICAL FITNESS TO DRIVE (MFtD)	
Medical Review Practices for Driver Licensing	https://www.nhtsa.gov/sites/nhtsa.dot.gov/files/documents/812402_medicalreviewdriverlicense.pdf (p. 301- 318 relating to Oregon)

TABLE 3.40 IMPACTS ON ROAD SAFETY OF MEDICINAL CANNABIS PROGRAM

IMPACTS OF DRUG-DRIVING ON ROAD CRASHES IN OREGON	
Prevalence in crashes	Study found that there was no statistically significant increase in cannabinoid prevalence among fatal-crash-involved drivers in Oregon between 1992-2009 following the 1999 legalization of medical marijuana (Masten & Guenzburger, 2014)[50]. Note: this study did not examine the crash-involvement of prescribed cannabis users, but was a population-level fatality crash analysis. The crude average of all fatal-crash-involved drivers with positive cannabinoid test results increased from 2.5% Pre-law to 2.9% Post-law. For fatally injured drivers only, the average decreased from 2.0% Pre-law to 1.2% Post-law. Data are from crashes that involved a death within 30 days of crash. Overall estimates of cannabinoid prevalence while driving is likely to be underestimated because drug testing is completed only if the driver passes BAC test. Of samples taken from people arrested for driving under the influence of intoxicants, 1,020 tested positive for cannabis in 2016. By comparison, more than 10,000 drivers had a BAC over the legal limit in 2016 (Oregon State Police). Note: the average test rate for drivers involved in fatal crashes prior to the medical cannabis law was 14.0% and 20.9% from 2009 onwards. For killed drivers, the drug test rate was 9.5% pre- and 14.5% post-legislation. The statistical ARIMA model also adjusted for prevalence trends in other US States as a way to isolate any changes due to the medical cannabis law. No information was provided on the number of prescribed medical cannabis users or use characteristics, nor were there any statistics presented on the proportion of cannabis users in the community. This is relevant as latest statistics show over 23,278 in July 2020 people have accessed the medical cannabis program in Oregon in July 2020.[51] The authors point to significant limitations of the data and state that "the cannabinoid prevalence estimates likely do not reflect prevalence among drivers in general" [50 (p.49)] Drug tests are also poorly captured in FARS and not standardized across the US. These represent significant data limitations, particularly the low proportion of tested drivers for drug and/or alcohol. For completeness, it is noted that the *FARS* data represents a Census of fatal crashes reported by each US State.[52] In the *FARS 2018 Data Coding Manual,* alcohol is preferentially assumed where a Driving While Impaired (DWI) offence is indicated and no other test results are available. Drugs screening test also used.
ROAD SAFETY IMPACTS OF MEDICINAL CANNABIS	
Crashes involving Medicinal Cannabis Certificate	Unknown
Number detected at roadside	N/A

[50] Masten, S. V., & Guenzburger, G. V. (2014). Changes in driver cannabinoid prevalence in 12 U.S. states after implementing medical marijuana laws. Journal of safety research, 50, 35–52. https://doi.org/10.1016/j.jsr.2014.03.009
Note: Research used the US National Fatality Accident Reporting Sample (FARS) system to assess prevalence of cannabinoids in crash-involved drivers and killed drivers in 14 US States where medical cannabis was legalised. This paper reported increased driver cannabinoid prevalence associated with following the implementation of medical marijuana laws was detected in California (crashes: +2.1%; killed drivers: +5.7%), Hawaii (crashes: +6.0%; killed drivers: +9.6%) and Washington (crashes: +3.4%; killed drivers: +4.6%). Other US States showed no change.

[51] https://www.oregon.gov/oha/PH/DISEASESCONDITIONS/CHRONICDISEASE/MEDICALMARIJUANAPROGRAM/Documents/OMMP_Statistical_Snapshot_07_2020.pdf

[52] https://www.nhtsa.gov/research-data/fatality-analysis-reporting-system-fars

4 EXAMINATION OF AUSTRALIAN MEDICINAL CANNABIS PROGRAMS WITH RESPECT TO DRIVING PERMISSIONS AND ASPECTS RELATING TO ROAD SAFETY

All Australian States and the Australian Capital Territory (ACT) and the Northern Territory (NT) have implemented a medicinal cannabis program. The Australian Government, through the Therapeutic Goods Administration (TGA) and the Office of Drug Control, set procedures for the prescribing and supply of cannabis medicines. State and Territory Governments play a role in the approval process depending on the medicinal cannabis product in question, however in 2020 this has become streamlined into a single approver process in select jurisdictions.

In relation to driving, the following statements can be made based on the information presented in the Tables that follow:

- A medical doctor has the ability to prescribe medicinal cannabis, with this dispensed through pharmacies.
- There is a robust approval and oversight process through the TGA and in some instances additional State-Territory approvals for use.
- Recreational cannabis is not permitted and remains a criminal offence in Victoria, NSW, QLD and Tasmania, however is decriminalised in the ACT, with *effective decriminalisation for possession of small amounts* in SA, the NT and Tasmania, noting however criminal penalties apply for cultivation/sale trafficking in all jurisdictions. Depending on the jurisdiction (e.g., Victoria, NSW, QLD, WA, Tasmania), cannabis possession is de-penalised for small quantities.
- In **every jurisdiction**, a zero-tolerance per se approach to drug-driving applies.
- Road-side Oral Fluid Tests are used in each jurisdiction for assessment of drug-driving. A second OFT is used for evidential purposes (lab-tested) in all jurisdictions **except** the NT where an evidential blood sample is required and only one OFT test (screen) is performed.
- All jurisdictions test for the presence of THC (cannabis), Methamphetamine (MA) and MDMA (Ecstasy). NSW also tests for cocaine and morphine (for heroin; also the NT).
- In addition to the per-se / presence offence, all jurisdictions have a Driving-under-influence (DUI) offence, while Victoria and WA **also** have a Driving-while-impaired (DWI) offence.
- For the DUI offence, driving behaviour and other driver demeanour / physical and mental cues are relevant, however there is no formal test battery. For DWI, in Victoria and WA there are specific requirements for Police to undertake to pursue this charge; for example, in Victoria a formal Driving Impairment Assessment (DIA) is conducted (and video-taped).
- Penalties are higher for DUI and DWI offences than per-se (presence) offences. Victoria also has a *combination offence* of blood and drugs with respect to penalties that includes provision for vehicle impoundment
- **A medical cannabis prescription *does not act* as a defence to drug-driving, as per-se (presence), DUI or DWI.**
- **No formal evaluation of the impact of medicinal cannabis programs on road safety outcomes has been conducted in Australia.**
- Note: For consideration by legal experts in relation to medical cannabis, in Victoria, WA and the N.T, 'defence' provision exists in the relevant *Acts* when a drug was detected but was used under prescription in accordance direction of the medical practitioner, per directions. Victoria and WA stipulate that "he driver was not aware, and could not reasonably have been expected to be aware, that those drugs were likely to render him incapable of having proper control of a motor vehicle". This defence is not applicable to alcohol or drug and alcohol offences. This remains for the defence to satisfy. It is a requirement of prescribing medicinal cannabis that all associated risks, including relating to driving are known, and is also described in the Consumer / Patient Information Leaflet. This is noted here only because if may bear on a defence process in the future to an offence.

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TABLE 4.1 MEDICAL CANNABIS PROGRAMS IN AUSTRALIAN STATES AND TERRITORIES – BASE FEATURES AND RIGHTS TO PRESCRIBE

	Victoria	NSW	ACT	QLD	NT	WA	SA	Tasmania
Medical cannabis permitted	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Date	2017	2016 (August)	2016 (November)	2017	2019 (Feb 1)	2016 (November)	2016 (November)	2017
Name scheme	Medical Cannabis Scheme	Medicinal Cannabis Compassionate Use Scheme. www.medicinalcannabis.nsw.gov.au	Medicinal Cannabis Scheme	Medical Cannabis Scheme	Medical Cannabis Access Scheme	Medical Cannabis Scheme	Medical Cannabis Scheme	Controlled Access Scheme (CAS)
Agency / Office **State Regulator**	Medicines and Poisons Regulation Branch, Department of Health and Human Services[53]	Centre for Medicinal Cannabis Research and Innovation, NSW Health	Health Protection Service, ACT Heath.	Queensland Health	Dept. Health	Department of Health	SA Health	Department of Health, TAS Health
Prescribing authority – Medical Doctor authorised under SAS[54] via TGA or be registered under APS[55]	Medical Doctor (SafeScript procedures apply, April 2020)	Medical Doctor	Medical Doctor	Medical Doctor	Medical Doctor (based in NT)	Medical Doctor	Medical Doctor	Medical Specialist (GP must refer; GP unable to prescribe)

[53] As at October 2020, The Office for Medicinal Cannabis (OMC) is responsible for policy aspects of medicinal cannabis; previously, the OMC was also responsible for regulatory approvals however this is now the responsibility of the Medicines and Poisons Regulations Branch of DHHS. The OMC is scheduled to close in December 2020.
[54] SAS – Special access scheme (for individual patient approvals), Category A (patient is seriously ill) and Category B (application pathway, if not fit Cat. A; requires clinical justification)
Approvals under SAS Category B – 12-months to August 2020: 50,089 in Australia
[55] Authorised Prescriber Scheme – broad approval, prescriber needs to demonstrate clinical expertise in medicinal cannabis; do not need individual patient approval, but do need to report on patient numbers each 6-months.

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TABLE 4.2 MEDICAL CANNABIS PROGRAMS IN AUSTRALIAN STATES AND TERRITORIES – APPLICABLE MEDICAL CONDITIONS AND S.8 (THC) APPROVALS

	Victoria	NSW	ACT[56]	QLD	NT	WA	SA	Tasmania
Medical conditions **Note:** In all jurisdictions, in determining whether medicinal cannabis use if permitted, consideration is given to the efficacy of other therapies, and in particular, whether 'conventional' pharmacotherapies have failed.	Any condition clinically appropriate.	Any condition clinically appropriate.	Spasticity in MS. Nausea and vomiting due to chemotherapy. Pain and/or anxiety in patients with active malignancy of a life limiting disease where (in either case) the prognosis might reasonably be expected to be 12 months or less. Refractory pediatric epilepsy.	Any condition clinically appropriate.	Conditions specified, where evidence to support therapeutic use (where no equal alternative) MS chronic non-cancer pain, chemo-induced nausea/vomiting (CINV), palliative care.	Any condition clinically appropriate.	Any condition clinically appropriate.	No specific condition identified, but where conventional treatment has failed.
THC	S.8 prescription only product – Note Sativex is the only approved S.8 product in Australia – for use of any other, require S8 (or S.4) TGA approval							
THC: Schedule 8 (S.8) (all unapproved S.8 products must have Clth / TGA approval)	Vic & Clth application needed for any unapproved S8 product Vic only approval if S8 ARTG approved (Sativex)	Clth approval only needed (single approver) for unapproved S.8 product	Approval from ACT Chief Health Officer, under "Category 6 – Medicinal Cannabis in the ACT Controlled Medicines Prescribing Standards" Plus Clth (TGA)	Approval from Clth and for person considered drug dependent approval for S8 (unapproved TGA) also required from Chief Executive of Qld Health.	Clth (TGA) approval Health Dept pre-authorisation not required, inform Chief Health Officer if > 2 months (& treatment successful)	Clth approval only needed (single approver) for S.8	Clth approval only needed (single approver)	Application to the Secretary of the Tasmanian Department of Health (DoH) (under s.59e of the Poisons Act 1971; TGA approval

[56] https://www.act.gov.au/cannabis/home; see: Drugs of Dependence (Personal Cannabis Use) Amendment Bill 2018; related: Simple Cannabis Offence Notice Scheme (SCON)

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TABLE 4.3 MEDICAL CANNABIS PROGRAMS IN AUSTRALIAN STATES AND TERRITORIES –S.4 (CBD) APPROVALS, REGULATORS, DISPENSING AND COST

	Victoria	NSW	ACT[57]	QLD	NT	WA	SA	Tasmania
CBD	Yes (THC<1%), S.4 product (prescription only))							
CBD: Schedule 4 (S.4), SAS-B	Clth (TGA) approval only	Clth (TGA) approval only	Clth (TGA) approval only.	Clth (TGA) approval only	Clth (TGA) approval only	Clth (TGA) approval only	Clth (TGA) approval only	Application to the Secretary of the Tasmanian Department of Health (DoH) (under Regulation 87 of the Poisons Regulations 2018.; TGA approval
Regulator (therapeutic)	TGA, [58] Department of Heath Where approved or exemption under Therapeutic Goods Act 1989							
Regulator (supply)	Office of Drug Control[59], administers *Narcotics Act.*							
Dispensing	Pharmacy	Pharmacy	Pharmacy	Pharmacy	Pharmacy	Pharmacy	Pharmacy	Tas. Health Service Hospital pharmacy
Subsidised	No, not listed on Pharmaceutical Benefits Scheme (PBS)							
Co-payment	Compassionate access scheme funds product for a limited number of children with severe intractable epilepsy	N/A	N/A	N/A	N/A	N/A	N/A	Potential for PBS co-payment as hospital dispensed

57 https://www.act.gov.au/cannabis/home; see: Drugs of Dependence (Personal Cannabis Use) Amendment Bill 2018; related: Simple Cannabis Offence Notice Scheme (SCON)
58 https://www.tga.gov.au/
59 https://www.odc.gov.au/medicinal-cannabis

TABLE 4.4 MEDICAL CANNABIS PROGRAMS IN AUSTRALIAN STATES AND TERRITORIES – PRODUCT APPROVALS AND USE OF CANNABIS FLOWER

	Victoria	NSW	ACT	QLD	NT	WA	SA	Tasmania
Medical cannabis products (approved products)	Approved pharmaceutical products TGA approval needed to prescribe unapproved *Nabiximols (Sativex) is the only TGA approved product & listed on ARTG*							
Medical cannabis products (unapproved products)	TGA approval required for unregistered product to be prescribed (raw flower, vaporised, oils, liquids, gels, sprays) Can permit imported products							
Medical use of cannabis flower permitted	Requires TGA approval as 'unapproved product'							

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TABLE 4.5 LAWS CONCERNING RECREATIONAL USE OF CANNABIS

	Victoria	NSW	ACT	QLD	NT	WA	SA	Tasmania
Recreational use	No (criminal offence for possession / use) Depenalisation: For persons 17 and older, Police can issue a caution for up to 50 g possession and attend Victoria Cannabis Cautioning Program; maximum of 2 cautions. (see: https://www2.health.vic.gov.au /alcohol-and-drugs/aod-treatment-services/forensic-aod-services	No (criminal offence for possession / use) Depenalisation: Police can exercise discretion with up to two cautions if in possession of amounts up to 15 g. Drug diversion and Cannabis Caution Scheme (NSW Police)	Decriminalised (Effective from Jan 31, 2020) Permitted for 18 years+: possess up to 50 grams of dried cannabis or up to 150 grams of fresh cannabis; grow up to two cannabis plants per person, with a maximum of four plants per household; use cannabis in your home (personal use). Offence to: smoke or use cannabis in a public place; expose a child or young person to cannabis smoke; store cannabis where children can reach it grow cannabis; using hydroponics or artificial cultivation; grow plants where they can be accessed by the public.	No (criminal offence for possession / use) Depenalisation: Police can exercise discretion with up to one caution if in possession. THC listed as Schedule 2 (max. prison: 20 years)	No Effectively decriminalised Fines apply for up to 50g cannabis, small amounts of hash (1 g), seed (10 g) or 2 plants	No Criminal offence for possession / use) Depenalisation: < 10 g results in diversion through a Cannabis Intervention Requirement, which includes counselling session Significant penalties apply for greater amounts.	No Decriminalised / no criminal conviction recorded for possession of small quantities (s.45 of Controlled Substances Act 1984) Police Drug Diversion Initiative (PDDI) Trafficking / cultivation and/or sale is a criminal offence (fine: $50,000) and/or prison (up to 15 years). See: https://lsc.sa.gov.au for detail (Ch.12, includes Penalty summary per *Act (below)*	No (criminal offence for possession / use) Depenalisation: Police can exercise discretion with up to three cautions if in possession of amounts up to 50g

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TABLE 4.6 LEGISLATIVE INSTRUMENTS RELEVANT TO CANNABIS (MEDICINAL AND/OR OTHER USE)

	Victoria	NSW	ACT	QLD	NT	WA	SA	Tasmania
Federal offences (cannabis)	Narcotics Drugs Act 1967 (Clth) Commonwealth Criminal Code 1995.							
State-based legislation	Drugs, Poisons and Controlled Substances Act 1981 Crimes Act 1958 Sentencing Act 1991 Summary Offences Act 1966 Access to Medicinal Cannabis Act 2016	Poisons and Therapeutic Goods Act 1966 No 31 Drug Misuse and Trafficking Act 1985 No 226 Children and Young Persons (Care and Protection) Act 1998 No 157 – Section 175 Guardianship Act 1987 No 257 Poisons and Therapeutic Goods Amendment (Cannabis Medicines) Regulation 2019	Drugs of Dependence Act 1989; Criminal Code 2002; Medicines, Poisons and Therapeutic Goods Act 2008	Drugs Misuse Act 1986 Health (Drugs and Poisons) Regulation 1996 describes the requirements for prescribing and dispensing restricted drugs (S4) and controlled drugs (S8).	NT Misuse of Drugs Act 1990 NT Medicines, Poisons and Therapeutic Goods Act 2012	Misuse of Drugs Act Young Offender's Act.	Controlled Substances Act 1984 (s.45) Controlled Substances (Poisons) Regulations 2011 (SA), s.18A.	Misuse of Drugs Act 2001 (Tas) Youth Justice Act 1997
Legislation (international obligations)	Single Convention on Narcotic Drugs 1961							

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TABLE 4.7 ROAD SAFETY RELATED ASPECTS OF ALCOHOL CONSUMPTION (BAC LIMITS) AND DRUG-DRIVING, INCLUDING TESTED DRUGS AND LIMITS

	Victoria	NSW	ACT	QLD	NT	WA	SA	Tasmania
BAC levels	Full: 0.05 Learner / P: 0.00 Commercial: 0.00	Full: 0.05 Learner / P: 0.00 Commercial: 0.00	Full: 0.05 Learner / P: 0.00 Commercial: 0.00	Full: 0.05 Learner / P: 0.00 Commercial: 0.00	Full: 0.05 Learner / P: 0.00 Commercial: 0.00	Full: 0.05 Learner / P: 0.00 Commercial: 0.00	Full: 0.05 Learner / P: 0.00 Commercial: 0.00	Full: 0.05 Learner / P: 0.00 Commercial: 0.00
OFT (RDT)	Yes, since 2003	Yes, since 2007	Yes, since 2011	Yes, since 2007	Yes, since 2008 for HV; all vehicles since 2016	Yes, since 2007	Yes, since 2006	Yes, since 2005
OFT (2nd, evidentiary)	Yes	Yes	Yes	Yes	-	Yes	Yes	Yes* (since 2018)
Blood (evidentiary)	Not required	Not required	Not required	Not required	Yes, required	Not required	Not required	Pre-2018 required
Drugs tested for	Cannabis Methamphetamine MDMA	Cannabis Methamphetamine MDMA Cocaine Morphine (illicit)	Cannabis Methamphetamine MDMA	Cannabis Methamphetamine MDMA	Cannabis Methamphetamine MDMA (& MDA) Heroin	Cannabis Methamphetamine MDMA	Cannabis Methamphetamine MDMA	Cannabis Methamphetamine MDMA
Per se law	Yes, presence only needed	Yes, presence only needed	Yes, presence only needed	Yes, presence only needed	Yes, presence only needed (s.27)	Yes, presence only needed	Yes, presence only needed	No, per se

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TABLE 4.8 OFFENCES RELATED TO DRUG-DRIVING – DRIVING WHILE UNDER INFLUENCE (DUI) AND DRIVING WHILE IMPAIRED (DWI)[60]

	Victoria	NSW	ACT	QLD	NT	WA	SA	Tasmania
Driving under Influence (DUI) **"noticeable signs of impaired driving" / behaviour / demeanor**	Yes (includes impairment test process), s.49(1), Road Safety Act (under influence of,): no set process for this	Yes	Yes	Yes	Yes	Yes Per 63 of Road Traffic Act, 1974: drive under influence of; (behaviour / demeanor) – incapable of proper control of vehicle. OFT not relevant to this offence.	Yes	Yes
Provisions for Offence Driving While Impaired / (DWI)	s.49(1)(ba), RSA 1986, 'driving whilst impaired; has a defined Drug Impairment Assessment (DIA), inclusive of BAC; focus is on drugs as reason for impairment. No requirement to prove person incapable of having proper control of vehicle.	No	No	No	No	s.64v – driving while impaired. Reason to believe impaired. If prescribed, can request Pharmacological Opinion Report; full BAC/OFT, assessment, blood test applies. No requirement to prove 'incapable of proper control'	No	No

[60] Note: Penalties are higher with DUI and DWI compared to 'per-se' offences

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TABLE 4.9 MEDICAL CANNABIS AND DRIVING – NO EXEMPTIONS AND FITNESS-TO-DRIVE ASSESSMENT

	Victoria[1]	NSW	ACT	QLD	NT[2]	WA[3]	SA	Tasmania
Medical cannabis exemption to drive / ride	No exemption to from per se law applies See Note 1 in relation to s.49(3B) of Act	No exemption to from per se law applies Driving is explicitly not covered by the Compassionate Use Scheme, which is focussed on people with terminal illness (police discretion for possession, for persons registered under the medical cannabis scheme)	No exemption to from per se law applies	No exemption to from per se law applies	No exemption to from per se law applies See Note 2	No exemption to from per se law applies See Note 3	No exemption to from per se law applies	No exemption to from per se law applies
Fitness-to-drive	Per Austroads / NTC *Assessing Fitness to Drive (2017).* These guidelines exist to ensure common practice and guidance on assessing a person's ability to drive safely. Note: this Edition was updated in 201/2017, and published 2017 and prior to implementation of medicinal cannabis programs. See S. 2.2.8 for prescription medication – no mention of THC. See S.9, Substance Misuse: includes THC.							
Other considerations	As none of the jurisdictions permit an exemption for users of prescribed medicinal cannabis to drive, there are no requirements relating to licensing conditions or proof of prescribed use. Patients prescribed medicinal cannabis are advised by the prescribing medical practitioner of the inability to drive per drug-driving laws. The Patient Information Leaflet of medicinal cannabis products states: "You must not drive or use machinery when you are taking *xxx*".[61]							

Note 1: Victoria - Note, 49 (3B): If on an analysis carried out in accordance with this Part, no drug other than a permissible non-prescription drug **or a prescription drug** was found present in the person's body, it is a defence to a charge under paragraph (ba) of subsection (1) for the person charged to prove that—(a) he or she did not know and could not reasonably have known that the permissible non-prescription drug or the prescription drug, or the combination of those drugs, so found would impair driving if consumed or used in accordance with advice given to him or her by a registered medical practitioner, a dentist or a pharmacist in relation to the drug or combination of drugs; and (b) he or she consumed or used that drug or combination of drugs in accordance with that advice

Note 2: A defence exists against use of Prohibited Drug (19A) in relation to s.28 (driving with certain drugs in body), per s.29: that if detected, the defendant must satisfy the court that:(a) the defendant was, at the time of the alleged offence, under treatment by a medical practitioner and had taken the drug as part of that treatment; and(b) the defendant had taken the drug in accordance with the directions of the medical practitioner. Note: defence not apply if seen to be impaired

Note 3 WA: s.63(1b) – Offence, if under the influence of drugs to such an extent as to be incapable of having proper control of the vehicle. However, note: In any proceedings for an offence against subsection (1)(b), it is a defence for the accused to prove — (a) that the drugs, under the influence of which the accused is alleged or appears on the evidence to be, were — (i) taken by him pursuant to a prescription of a medical practitioner, nurse practitioner or dentist; or (ii) administered to him by a medical practitioner, nurse practitioner or dentist, for therapeutic purposes; and (b) that he was not aware, and could not reasonably have been expected to be aware, that those drugs were likely to render him incapable of having proper control of a motor vehicle. Not applicable to alcohol or drug and alcohol offences.

61 In non-Australian jurisdictions where driving exemptions are permitted, patients are advised: "You must not drive or use machinery when you first start to take xxx and until you are established on a stable daily dose", noting further advice not to drive/use machinery is side effects are present (e.g., sleepiness).

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TABLE 4.10 POLICE AND LEGISLATIVE INSTRUMENTS RELEVANT TO ROAD SAFETY IN AUSTRALIAN STATES AND TERRITORIES

	Victoria	NSW	ACT	QLD	NT	WA	SA	Tasmania
Police Service	Victoria Police	NSW Police Force	Australian Federal Police	Queensland Police Service	Northern Territory Police Force	WA Police Force	South Australia Police	Tasmania Police
Road / license authority	DOT (VicRoads)	Roads and Maritime Services, Transport for NSW	Road Transport Authority ACT	Transport and Mains Roads	Department of Infrastructure, Planning and Logistics	Department of Transport Main Roads	Department for Infrastructure and Transport (DIT)	Transport Tasmania
Legislation	Road Safety Act 1986 (Vic), s.49 (Part 5 – offences involving alcohol or other drugs plus associated Regulations: Road Safety (General) Regulations 2009 Road Safety (Drivers) Regulations 2009 Road Safety (Vehicles) Regulations 2009 Road Safety Road Rules 2009 Road Rules Victoria (Road Safety Road Rules 2009)	Road Transport Act 2013 (NSW), s 111) s.112: DUI s.148	Road Transport (General) Act 1999, s47B, s.20, s.24, s.22 Road Transport (Safety and Traffic Management) Act 1999 Road Transport (Road Rules) Regulation 2017 Road Transport (Alcohol and Drugs) Act 1977, s.20 Road Transport (Alcohol and Drugs) Legislation Amendment Act 2010, Road Transport (Alcohol and Drugs) (Random Drug Testing) Amendment Act 2010	Transport Operations (Road Use Management) Act 1995 (Qld), s.79, Plus: Transport Operations (Road Use Management—Road Rules) Regulation 2009 Transport Operations (Road Use Management Driver Licensing) Regulation 2010 Criminal Code Act 1899 (Qld). In addition, the Police Powers and Responsibilities Act 2000 (Qld)	Traffic Act 1987 Division 3 (offence driving with drug in body), s.28 Division 4: Drive under influence, s.29	Road Traffic Act 1974, s.63, s.64ab, s.64ac Road Traffic Code 2000 Road Traffic (Authorisation To Drive) Regulations 2014	Road Traffic Act 1961 (s.47), s40, s.47	Road Safety (Alcohol and Drugs) Act 1970, s.4, s.6, s.14 Traffic Act, 1925, s.41a.

TABLE 4.11 PENALTIES ASSOCIATED WITH DRUG-DRIVING IN AUSTRALIAN STATES AND TERRITORIES

Penalty	ACT	NSW	NT	Qld	SA	Tas	Vic	WA
Maximum Fine ($AUD)								
1st offence	1,600	572*	400*	1,868	1,300	1,570	496*	500
2nd offence	4,000	2,200	400*	2,438	1,600	3,140	1,983	1,000
3rd offence	4,000	3,300	400*	3,413	2,200	3,140	19,826	1,000
Minimum License Cancellation Period (months)								
1st offence	6	3*	n/a	n/a	3	3	6*	n/a
2nd offence	12	6	3	9	6	6	6	6
3rd offence	12	12	6	12	12	6	12	6
Maximum Prison Sentence (months)								
1st offence	n/s	n/s*	3	3	n/s	3	n/s*	n/s
2nd offence	3	n/s	6	6	n/s	6	n/s	n/s
3rd offence	3	n/s	6	9	n/s	6	n/s	n/s

Key: AUD = Australian Dollar, n/s = not specified in the legislation

* The first offence in Vic, NSW and the NT can be dealt with as an "infringement" as opposed to a criminal offence and via payment of "traffic infringement" (Vic or NT) or "penalty notice" (NSW). The infringement in Vic and NSW involves license "suspension" instead of licence "cancellation."

Source: Moxham-Hall, V Hughes, C. Drug driving laws in Australia: What are they and why do they matter? Drug Policy Modelling Program, UNSW Social Policy Research Centre. (at May 2020)

TABLE 4.12 PENALTIES ASSOCIATED WITH DUI IN AUSTRALIAN STATES AND TERRITORIES

Penalty	ACT	NSW	NT	Qld	SA	Tas	Vic*	WA*
Maximum Fine ($AUD)								
1st offence	4,800	3,300	1,570	3,737	1,600	1,884	4,130	2,500
2nd offence	4,800	5,500	3,140	7,314	2,900	9,420	19,826	3,500
3rd offence	4,800	5,500	3,140	7,314	2,900	9,420	29,740	5,000
Minimum License Cancellation Period (months)								
1st offence	6	36	6	6	12	12	24	10
2nd offence	12	60	12	24	36	24	48	30
3rd offence	12	60	12	24	36	24	48	Life
Maximum Prison Sentence (months)								
1st offence	6	18	12	9	3	12	3	n/s
2nd offence	12	24	12	18	6	24	12	9
3rd offence	12	24	12	18	6	24	18	18

Key: AUD = Australian Dollar, n/s = not specified in the legislation

* VIC and WA both have an offence of "Driving While Impaired" (DWI) law as well as a DUI law. The penalties for a DWI in WA are the same as for a DUI. In VIC the maximum fine is $1,983 for a first offence, $19,826 for a second and $29,739 for a third or subsequent offence. The minimum license cancellation is 12 months for a first offence and 24 for a second or subsequent offence. The maximum prison sentence is 0 months for a first offence, 12 months for a second offence and 18 months for a subsequent offence.

Source: Moxham-Hall, V Hughes, C. Drug driving laws in Australia: What are they and why do they matter? Drug Policy Modelling Program, UNSW Social Policy Research Centre. **(at May 2020)**

TABLE 4.13 PENALTIES ASSOCIATED WITH COMBINATION BAC OFFENCES IN VICTORIA (ONLY STATE WHERE RELEVANT)

Penalty	Blood Alcohol Concentration 0.05–<0.1 + drugs			Blood Alcohol Concentration 0.1–<0.15 + drugs			Blood Alcohol Concentration ≥0.15 + drugs		
	1st offence	2nd offence	3rd offence	1st offence	2nd offence	3rd offence	1st offence	2nd offence	3rd offence
Maximum fine ($AUD)	4,664	13,991	27,983	4,664	13,991	27,983	4,664	27,983	41,974
Minimum license disqualification (months)	12	24–30	24–30	16–20	32–40	32–40	21–30	42–60	42–60
Maximum prison sentence (months)	n/a	6	12	n/a	6	12	n/a	12	18
Minimum alcohol interlock (months)	6	12	48	6	12	48	6	48	48
Vehicle impoundment (days)	0	30	30	30	30	30	30	30	30
Minimum requirement for zero BAC (months)	36	36	48	36	36	48	36	48	48
Complete Drink and Drug Driver Behaviour Change Program	✓	✓	✓	✓	✓	✓	✓	✓	✓

Source: Moxham-Hall, V Hughes, C. Drug driving laws in Australia: What are they and why do they matter? Drug Policy Modelling Program, UNSW Social Policy Research Centre. (at May 2020)

5 DISCUSSION AND KEY POINTS OF COMPARISON WITH VICTORIA

This report set out to document the characteristics of drug-driving programs in selected jurisdictions in the Europe Union (Ireland, Germany), Switzerland, Canada (British Columbia, Quebec), the United States (Texas, Oregon) and Australia. The international jurisdictions were selected on the basis of geographic spread and representing a mix of drug-driving enforcement programs coupled with medicinal cannabis programs.

The purpose of this report was to provide insight into how these jurisdictions managed the driving of those permitted to use medicinal cannabis by way of medical prescription.

The report also set out to document any evaluation of the impact of medicinal cannabis on road safety; notably, only one was found and no demonstrable dis-benefit on road safety was evident notwithstanding a number of technical limitations of the dataset upon which the findings were based.

An extensive series of Tables were used to present program characteristics, legislation, and processes associated with drug-driving regimes. To facilitate a comparison with regulations and processes in other jurisdictions with in Victoria to be made, Table 5.1 is used to highlight key features and points of differences. It is first useful to capture commonalities and differences across the jurisdictions.

Commonalities (base state) among all jurisdictions (not noted in Table)

- All jurisdictions examined have medicinal cannabis provisions under government approved process with medical doctor permitted to prescribe medicinal cannabis.
- All have extensive drug-driving penalties for THC (as well as other illicit drugs).
- All have extensive drink-drive provisions, with roadside breath testing.
- None of the jurisdictions examined are yet to conduct an evaluation of the impact of prescribed medicinal cannabis use and access programs on the driving behaviour and crash-involvement rates of prescribed users.[62]

Differences

- For medicinal cannabis, qualifying conditions (indications) vary from very strict with limited medical conditions (Ireland) to any medical condition being eligible for medicinal cannabis use. This is important as it has an impact on the number of people who may be driving while prescribed and using medical cannabis.
- Differences are evident in available THC and CBD products, including pharmaceutical raw flower–used via vaporiser–through to oils, oral-mucosal sprays, extracts, tablets and gels.
- Exemptions from THC drug-driving offences apply in Ireland, Germany and Switzerland on the proviso the driver is not impaired nor shows any detrimental impact of the drug on driving performance. No such exemption applies to any jurisdiction in Australia.
- No jurisdiction permits an exemption for the use of medical cannabis for a driving-under-the-influence (DUI) or driving-while-impaired offence.
- Jurisdictions that have medical exemptions for cannabis to drive have extensive provisions and procedures for the assessment of driver impairment and fitness-to-drive, supported by toxicological results. Driver Impairment Assessments using a pre-determined test battery are well-defined and conducted. These however take extensive time, resource commitment and training.
- A number of jurisdictions test for a range of prescription and illicit substances not currently tested for routinely in Victoria.
- While a number of international jurisdictions use oral fluid tests, blood (or urine) is used for evidential purposes.
- Penalty / offences differ in their quantum, and procedures to re-license post-licence or prove fitness-to-drive are extensive (e.g., Germany).

[62] The US-based study cited in Table 3.40 (Oregon) was a before-after population level examination of the presence of cannabinoids among drivers killed in 14 US States that had implemented a medicinal cannabis program. The study demonstrated mixed results and a number of important data limitations were noted by the authors. Prescribed medicinal cannabis users were not specifically examined.

- While recreational cannabis is illegal in all Australian jurisdictions, noting recent decriminalisation in the ACT, the legal status of recreational cannabis was seen to differ.

While the reader is referred to the body of the Report for detail, Table 5.1 highlights some of the core characteristics of the programs.

TABLE 5.1 COMPARISON OF SELECTED DRUG-DRIVING PROGRAM CHARACTERISTICS IN SELECTED JURISDICTIONS COMPARED TO VICTORIA

Jurisdiction	Roadside Oral Fluid Test (OFT) (Evidential, EV:)	Per se law (presence)	DUI / DWI offence	Formal Driver Impairment assessment	Medical cannabis exemption on per se offence	Recreational cannabis use permitted
Australia						
Victoria	OFT	Yes	DUI + DWI	For DWI (DIA)	No	No
NSW	OFT	Yes	DUI	No	No	No
ACT	OFT	Yes	DUI	No	No	De-criminalised
QLD	OFT	Yes	DUI	No	No	No
NT	OFT EV:blood	Yes	DUI	No	No	No (small amounts de-criminalised)
WA	OFT	Yes	DUI + DWI	For DWI	No	No
SA	OFT	Yes	DUI	No	No	No (small amounts de-criminalised)
TAS	OFT	Yes	DUI	No	No	No
European Union (EU)						
Republic of Ireland	OFT Ev: blood / urine	Yes	DWI	Formal, fit-to-drive	**Yes**	No
Germany	OFT Ev: blood	Yes	DWI	Impairment procedures plus Fit-to-drive assessment	**Yes**	No (small amounts de-criminalised)
Europe						
Switzerland	OFT Ev: blood	Yes	DWI	Formal, incapacitation, Fit-to-drive	**Yes**	No (small amounts de-criminalised
Canada						
British Columbia	OFT Ev: blood	Yes	DWI	SFST† DRE‡	No	Yes
Quebec	OFT Ev: blood	Yes	DWI	SFST† DRE‡	No	Yes
United States						
Texas	**No OFT** Ev: blood/urine	Yes	DWI	Impairment battery, includes DRE tests	No	No (if THC >0.3%)
Oregon	**No OFT** Ev: blood/urine	Yes	DWI	Impairment battery, includes DRE tests‡	No	Yes

Note: †SFST – Standard Field Sobriety Test; ‡DRE: Drug Recognition Expert process (12 step process); Ev: evidential.

6 CONCLUSION AND IMPLICATIONS

This report highlights important differences in the way drivers in Victoria (and all other Australian jurisdictions) and selected international jurisdictions are managed with respect to medicinal cannabis use.

Exemptions for users of prescribed medical cannabis is permitted at roadside drug tests

A number of international jurisdictions (Switzerland, Germany, Ireland) apply an exemption for drivers who are prescribed medicinal cannabis and who return a positive drug-driving test. This exemption status is limited to drivers and riders who are prescribed medical cannabis by their medical practitioner and who are not impaired with respect to driving (see below). In the event of a positive roadside drug test, proof of this treatment relationship and care is required; indeed, this may include the direct involvement of the prescribing doctor. Drivers must present a prescription or a more formal medical cannabis certificate for this exemption to apply.

In practical terms, a driver stopped at a random roadside check-point who tests positive to THC but does not demonstrate any impairment or inability to drive safely is not subject to a drug-driving offence upon providing a prescription for medical cannabis or a medical cannabis certificate to the police officer.

The remaining jurisdictions (North America, Australia) examined do not permit any exemption from their drug-driving laws based on prescribed medicinal cannabis use

Prescribed use is no defence to impaired driving: Impairment assessment and fitness-to-drive protocols are robust

However, the exemption to permit users of medicinal cannabis to drive **only applies** where a driver is **not impaired** in any way nor demonstrates any safety risk to themselves of other drivers.

To enable this exemption, the relevant jurisdictions have implemented detailed regulations and processes concerning the assessment of driver impairment. This assessment can range from observation of a driver error or violation through to extensive driver impairment assessment protocols. Any demonstration of impairment or a driver / rider presenting as a safety risk results in the driver / rider being subjected to the drug-driving offence process. In short, a prescription of medical cannabis is not a defence to observed risky or impaired driving. In the event impairment is shown, a full fitness-to-drive assessment along with a full physical and mental health examination may be also required either immediately or upon re-licensing.

Following from above, it is notable that the jurisdictions where a medical exemption to cannabis is applicable also test for a range of prescription medications and illicit substances. In these jurisdictions, it is considered imperative to have provisions that permit users of prescription medications to drive whilst ensuring that the safety of all road users is adequately balanced against any impaired driving from any driver / rider that may result from use of any prescribed medications. The regulations and associated processes aim to achieve this balance have evolved over many years.

It remains important to point out that overseas jurisdictions take drug-driving extremely seriously. This is reflected by their extensive penalty regimes and in the well-established impairment assessment, fitness-to-drive, and associated licensing and post-offence protocols. The use of an impairment-based process permits a full range of substances (prescription/illicit) to be tested. It appears that these processes are well accepted by the communities that they are designed to protect.

Take outs for Victoria and future research questions

This report has highlighted a range of approaches in managing the safe driving of prescribed medicinal cannabis users. With the State of Victoria having recently introduced a prescription medical cannabis program, the insights gained from these jurisdictions may inform Victoria's response to the question of driving (riding) by individuals prescribed medicinal cannabis in relation to current drug-driving laws.

Given the recency of medicinal cannabis programs and the international experience on managing driving, there are a number of questions that remain outstanding. These relate to the pharmacokinetics of medicinal cannabis and detection of THC at the roadside, as well as measures of impairment and fitness-to-drive assessment procedures specific to this group. Further research to identify the most appropriate model for Victoria with respect to managing safe driving of prescribed medicinal cannabis users is recommended. An important input to this would be an assessment of the driving behaviour and crash-involvement rates of medicinal cannabis users now and in the future.

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