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CONSULTATION SUBMISSION

Date:	17 January 2020
To:	**Senate Community Affairs References Committee**
From:	Dr Teresa Nicoletti, Partner, Mills Oakley

Senate inquiry into the current barriers to patient access to medicinal cannabis in Australia

About Mills Oakley

1. Mills Oakley is an Australia-wide commercial law firm with offices in Sydney, Melbourne, Canberra, Brisbane and Perth.

2. Dr Teresa Nicoletti, who heads the Intellectual Property, Health and Life Sciences team, is both a lawyer and scientist with almost 25 years' experience in the Health and Life Sciences sector in Australia and New Zealand. She is a recognised leader in the sector, having won the Lawyers Weekly Partner of the Year for Health in 2016 and 2017, achieved a Band 1 individual ranking in the Life Sciences Category in Chambers Asia Pacific in 2018, 2019 and 2020, and listings in Legal 500 (Intellectual Property) and Best Lawyers (Health and Aged Care; Life Sciences; and Biotechnology).

3. Within the Australian therapeutic goods industry, Dr Nicoletti's practice is widely regarded as the industry leader in all aspects of Australian medicinal cannabis law and regulation. Having worked with the medicinal cannabis regulatory framework since its inception, Dr Nicoletti has a deep understanding as to how the Commonwealth and state/territory frameworks operate and their limitations. Her team has extensive experience advising a range of clients with respect to the various Commonwealth and state/territory laws and regulatory structures and processes applicable to the cultivation and production of cannabis plants, the manufacture and supply of medicinal cannabis products, and patient access to medicinal cannabis.

Introductory comments

4. We welcome the opportunity to make a submission to this inquiry into the current barriers to patient access to medicinal cannabis in Australia (**Inquiry**).

5. At a commercial level, we have advised several industry stakeholders including cultivators, manufacturers, importers, distributors, researchers, medical practitioners and advocacy groups.

6. In addition, we have assisted a number of individual Australian patients and/or their families, on a *pro bono* basis, to apply for and obtain medicinal cannabis for the treatment or management of a variety of medical conditions, in a range of clinical contexts. These include the following patients, whose stories will be referred to throughout the course of this submission:

   (a) Patient AA, who suffered from chronic debilitating pain of neuropathic origin, Lewy body Alzheimer's disease with anxiety (LBD), illusions and hallucinations, idiopathic Parkinson's disease, depression, suicidal ideation, progressive cognitive decline and movement problems.

(b) Patient BB, who suffered from chronic severe lower back pain associated with bilateral leg pain and a spinal fusion, which was the result of an injury that occurred when BB was seventeen years old.

(c) The parents of the late CC, a young girl who suffered from a complex (likely regressive) neurological disorder and severe refractory epilepsy. The obstruction of access to lawful medicinal cannabis for CC is an indictment on the Queensland health system.

(d) Patient DD, a young boy with autism and severe intractable epilepsy arising from 3 rare epilepsy syndromes. Any person who reads the story of DD would be horrified by the trauma that DD and his parents endured in their battle to obtain stable access to a medicinal cannabis product for DD.

7. Our submissions, including our detailed comments in respect of each of the Terms of Reference are set out below.

Background to the Inquiry

8. In order to put our submissions in the appropriate context, this Background section provides some information about the medicinal benefits of cannabis, its demand in Australia, and the relationship between cannabis and the law, both within Australia and internationally.

The Medicinal Benefits of Cannabis

Science, Cannabis and Medicinal Benefits

9. Cannabis, derived from the plant *Cannabis sativa*, contains approximately 140 chemical constituents called 'cannabinoids'. The most well-known cannabinoids are cannabidiol (**CBD**) and *delta*-9-tetrahydrocannabinol (**THC**), with THC being the first cannabinoid to have been isolated for scientific research in 1964 and the key psychoactive constituent.[1] Research throughout the 20th century uncovered the intricate endocannabinoid system which comprises several biochemical receptors throughout the human brain and body upon which cannabinoids were observed to act and produce a variety of therapeutic and psychoactive effects.[2] Different strains of cannabis contain different quantities and types of cannabinoids and thus different plant strains may offer different therapeutic benefits and/or psychoactive profiles.[3]

10. Cannabis for therapeutic or medicinal use comes in three distinct forms: pharmaceutical preparations, standardised herbal preparations and herbal (non-standardised) cannabis. Pharmaceutical preparations of cannabis contain specific, known quantities of synthetic or naturally-derived cannabinoids and have been developed and tested by pharmaceutical companies for approval by national regulatory bodies like the Therapeutic Goods Administration (**TGA**) in Australia. Although the therapeutic effects of pharmaceutical preparations are reliable and well-documented, pharmaceutical cannabis preparations are also likely to be very expensive for patients.

11. Standardised herbal preparations of cannabis are produced in controlled conditions from cultivation (so that the cannabinoid concentration of plants is kept constant) to manufacture (so that the final product strength and composition remains constant).[4] Herbal (non-standardised) cannabis, or illicit cannabis, contains unknown quantities and types of

[1] E Russo, 'Taming THC: potential cannabis synergy and phytocannabinoid-terpenoid entourage effects' (2011) *British Journal of Pharmacology* 1344.
[2] D Piomelle and E Russo, 'The cannabis sativa versus cannabis indica debate: an interview with Ethan Russo, MD' (2016) 1(1) *Cannabis and Cannabinoid Research* 44, 45.
[3] *Background on Cannabis and its medicinal use* (10 Feb 2016) Australian Government Department of Health <http://www.health.gov.au/internet/ministers/publishing.nsf/Content/5E437BF8715C3EBACA257F540078A07A/$File/Background%20on%20Cannabis%20and%20its%20medicinal%20use.pdf>, 1.
[4] A Hazekamp, 'An evaluation of the quality of medicinal grade cannabis in the Netherlands' (2006) 1(1) *Cannabinoids* 1, 4.

cannabinoids and may be contaminated with mould, heavy metals or pesticides.[5] On this basis, herbal cannabis is not recommended for medicinal use because such impurities and inconsistencies in its chemical profile may be dangerous for patients.

12. Pharmaceutical preparations of cannabis are generally designed for oral administration (*e.g.* capsules and tablets)[6] however studies involving medicinal cannabis have investigated administration by oromucosal spray,[7] tincture or ointment, or vaporisation.[8] Based on evidence of the adverse effects associated with smoking, smoking of cannabis is not recommended for medicinal use.[9]

13. There is clinical evidence which shows that THC and CBD can be used in the treatment of a range of medical conditions, including AIDS/HIV,[10] Alzheimer's disease,[11] chemotherapy-induced nausea and vomiting (**CINV**),[12] cancer,[13] diabetic peripheral neuropathy,[14] epilepsy,[15] multiple sclerosis (**MS**)[16] and anxiety and depression.[17] There is also some evidence that THC and CBD may assist in the symptomatic relief of chronic pain,[18] glaucoma,[19] Tourette syndrome[20] and sleep disorders.[21]

Patient Demand for Access to Medicinal Cannabis

14. There has been increasing social and political demand for access to medicinal cannabis by Australian patients, which has particularly intensified over the past decade. In 2013, a General Purpose Standing Committee established by New South Wales (**NSW**) Parliament published a report on the use of cannabis for medical purposes.[22] The report observed, *inter alia,* strong public support for the facilitation of access to cannabis for medicinal purposes. Similarly, the National Drug Strategy Household Survey observed that most Australians supported both the use of cannabis for medicinal purposes in a clinical trial (73.5 % in 2004, 73.6 % in 2007, 74.0 % in 2010 and 75 % in 2013)[23] and the introduction of legislation to permit the use of cannabis for medicinal purposes (67.5 % in 2004, 68.6 % in 2007, 68.8 % in 2010 and 69.0 % in 2013).[24] Subsequently, in late 2014, the NSW Government announced

[5] Ibid, 7.
[6] K Sharkey, N Darmani, and L Parker, 'Regulation of nausea and vomiting by cannabinoids and the endocannabinoid system' (2014) 722 *European Journal of Pharmacology* 134, 142; P Whiting et al., 'Cannabinoids for Medical Use: A Systematic Review and Meta-analysis' (2015) 313(24) *The Journal of the American Medical Association 2456,* 2459.
[7] M Lynch and M Ware, 'Cannabinoids for the Treatment of Chronic Non-Cancer Pain: An Updated Systematic Review of Randomized Controlled Trials' (2015) 10(2) *Journal of Neuroimmune Pharmacology* 293, 295.
[8] M Wallace et al., 'Efficacy of Inhaled Cannabis on Painful Diabetic Neuropathy' (2015) 16(7) *The Journal of Pain* 616, 625.
[9] A Gordon, J Conley and J Gordon, 'Medical Consequences of Marijuana Use: A Review of Current Literature' (2013) 15 *Current Psychiatry Reports* 419-430; L Zhang et al., 'Cannabis smoking and lung cancer risk: Pooled analysis in the International Lung Cancer Consortium' (2015) 136(4) *International Journal of Cancer* 893-904
[10] Victorian Law Reform Commission, *Medicinal Cannabis: Report*, Report No 32 (August 2015), 39 and 64.
[11] L Eubanks et al., 'A molecular link between the active component of marijuana and alzheimer's disease pathology' (2006) 3(6) *Molecular Pharmaceutics* 773, 775.
[12] Lynch and Ware, above n 7, 295 and 299.
[13] Whiting et al, above n 6, 2460.
[14] J Croxford and T Yamamura, 'Cannabinoids and the immune system: Potential for the treatment of inflammatory diseases?' (2005) 166(1) *Journal of Neuroimmunology* 3, 12.
[15] M Tzadok et al., 'CBD-enriched medical cannabis for intractable paediatric epilepsy: The current Israeli experience' (2016) 35 *Seizure* 41, 43.
[16] Croxford and Yamamura, above n 14; Whiting et al., above n 6, 2461 and 2465.
[17] Whiting et al., above n 6, 2463.
[18] Lynch and Ware, above n 7, 293-299.
[19] T Jarvinen, D Pate and K Laine, 'Cannabinoids in the treatment of glaucoma' (2002) 95 *Pharmacology & Therapeutics* 203, 215.
[20] Whiting et al., above n 6, 2464.
[21] Ibid.
[22] General Purpose Standing Committee No. 4, New South Wales Parliament, *The use of cannabis for medical purposes: Report,* No 27 of 2013, 15 May 2013.
[23] *AIHW National Drug Strategy Household Survey Detailed Report 2013* (2014) Australian Institute of Health and Welfare, 115.
[24] Ibid.

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that it would invest $9 million on clinical trials involving cannabis products over a period of five years.[25] In addition, NSW introduced the Terminally Ill Cannabis Scheme (**TICS**), under which police are not compelled to charge terminally ill patients or their carers who use cannabis to relieve symptoms.[26]

15. In February 2015, the Australian Senate referred the proposed Regulator of Medicinal Cannabis Bill 2014 to the Legal and Constitutional Affairs Legislation Committee. Shortly after, in June 2015, Sydney University received $33.7 million to commence a long-term scientific and clinical research program (the 'Lambert Initiative') which is dedicated to developing and testing standardised medicinal cannabis products for a variety of conditions and diseases.[27] Also in June 2015, NSW Premier Mike Baird pledged $12 million over four years to create the Centre for Medicinal Cannabis Research and Innovation.[28]

16. In August 2015, the Victorian Law Reform Commission issued a report on medicinal cannabis which considered, *inter alia,* testimonials from Australian patients who had used, or were using, cannabis for medicinal purposes. Among the testimonials, there was evidence that cannabis was already being used in Australia for chronic pain,[29] MS,[30] epilepsy[31] and in patients with terminal cancer.[32] At that time, Mrs Michelle Whitelaw was one of many Australians who shared her own positive experiences with the Commission because her son, who suffers from multiple forms of epilepsy, had reportedly suffered only three clinical seizures in over five months after beginning medicinal cannabis therapy – a reduction from approximately 75,000 seizures.[33]

Cannabis and the Law

International obligations

17. Australia is a party to three significant international agreements which concern the supply and use of narcotic drugs (including cannabis). Primarily, the *Single Convention on Narcotic Drugs 1961*[34] (**Single Convention**) requires signatories to prevent abuse and diversion of narcotic substances by limiting cultivation, production, manufacturing and other activities (including use and possession), but permits the provision of narcotic substances for medical and scientific purposes, subject to adequate controls, and specifically carves out of its scope of operation cannabis for industrial or horticultural purposes.[35] The Single Convention is implemented into Australian law by a number of instruments at the Commonwealth and state/territory level, primarily, at the former, by the Act.

18. In addition, Australia is a party to the *Convention on Psychotropic Substances 1971*[36] which describes the obligations of parties to facilitate the use of psychotropic substances for

[25] ABC, *Medical cannabis: Queensland, Victoria and New South Wales join forces on cannabis oil in medical trials* (19 April 2015) ABC News http://www.abc.net.au/news/2015-04-19/queensland-victoria-join-nsw-medicinal-cannabis-trial/6403760; and D Dumas, *World first as NSW trials medical cannabis on children with severe epilepsy* (27 October 2015) The Sydney Morning Herald (online) http://www.smh.com.au/nsw/world-first-as-nsw-trials-medical-cannabis-on-children-with-severe-epilepsy-20151027-gkjntb.html.
[26] *Terminal Illness Cannabis Scheme: Fact sheet for adults with a terminal illness and their carers* (2015) NSW Government http://www.nsw.gov.au/tics.
[27] *The Lambert Initiative for Cannabinoid Therapeutics* (2016) The University of Sydney http://sydney.edu.au/science/lambert.
[28] *Centre for Medical Cannabis Research and Innovation* (2015) NSW Ministry of Health http://www.health.nsw.gov.au/cannabis/Pages/research-and-innovation.aspx.
[29] Victorian Law Reform Commission, above n 10, 26 and 37.
[30] Ibid, 23.
[31] Ibid, 66; *Submission 71 to the Victorian Law Reform Commission*, Michelle Whitelaw (31 May 2015).
[32] Ibid, 7; *Submission 65 to the Victorian Law Reform Commission*, Robert Wisbey (21 May 2015).
[33] Submission 71, above n 31.
[34] *Single Convention on Narcotic Drugs 1961*, opened for signature 30 March 1961, 520 UNTS 204 (entered into force 13 December 1964), as amended by the *1972 Protocol amending the Single Convention on Narcotic Drugs 1961*.
[35] Ibid, Art 2; and Art 28 for cannabis cultivation specifically.
[36] *Convention on Psychotropic Substances 1971*, opened for signature 21 February 1971, 1019 UNTS 175 (entered into force 16 August 1976).

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medical and scientific purposes (and to limit their availability for other use(s)), and the *United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances 1988*,[37] which aims to promote cooperation between parties to address the illicit trafficking of narcotic drugs and psychotropic substances.

19. The Commonwealth Government is ultimately accountable for ensuring that any national, state or territory scheme for the cultivation, production, manufacture or supply of cannabis and products derived from cannabis is consistent with Australia's international obligations, including where responsibility for regulating aspects of the regime is devolved to the states and territories (as it is in relation to industrial cannabis). As a signatory to the Single Convention, Australia is obliged to regularly provide information to the International Narcotics Control Board (**INCB**), such as annual estimates of harvest areas and yields, amount of raw material and refined products in stock, amounts required for importation and relevant trends in use for medicinal purposes.[38] Failure to meet such international obligations poses certain diplomatic and economic risks, including potential damage to Australia's international reputation (in particular, for its progressive, balanced and comprehensive approach to dealing with the problems posed by the use and misuse of drugs in the community).[39]

20. Critically, the legal and policy issues that arise in relation to medicinal cannabis can be readily differentiated from those applying to the regulation of cannabis for non-medical purposes. The priorities, considerations and challenges which affect decisions in relation to medicinal cannabis differ significantly from those for non-industrial, recreational or other use.[40]

21. In our view, any discussion of medicinal cannabis should be underpinned by the *International Convention on Economic, Social and Cultural Rights* (**ICESCR**), which states that everyone has the right to the highest attainable standard of physical and mental health,[41] and to the *Australian Charter of Healthcare Rights,* which provides that all Australian patients have the right to receive safe and high quality care in an effective continuum.[42]

Regulation of Cannabis by the Commonwealth and States/Territores

22. Cannabis and cannabis-related activities are tightly controlled in Australia. The cultivation, production, manufacture, import, export, distribution, trade, possession, use and supply of cannabis and cannabis-derived products are, like other narcotic and non-narcotic drugs and their derived products, regulated by several Commonwealth and state/territory laws:[43]

    (a) As a starting point, the *Criminal Code 1995* (Cth) and separate state and territory crime, drug misuse and/or drug/poison control legislation generally make it illegal to traffic, import, export, manufacture, cultivate or possess cannabis or cannabis products.[44]

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[37] *United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances 1988*, opened for signature 20 December 1988, 2138 UNTS 214 (entered into force 11 November 1990).
[38] Ibid Arts 18-20; Explanatory Memorandum, Narcotic Drugs Amendment Bill 2016 (Cth), 7.
[39] Explanatory Memorandum, Narcotic Drugs Amendment Bill 2016 (Cth), 6.
[40] For example, see, R Pacula et al., 'Developing public health regulations for marijuana: Lessons from alcohol and tobacco' (2014) 104(6) *American Journal of Public Health* 1021.
[41] *International Covenant on Economic, Social and Cultural Rights*, opened for signature 16 December 1966, 993 UNTS 3(entered into force 3 January 1976)
[42] ACSQH, *Australian Charter of Healthcare Rights* (2008) Australian Commission on Safety and Quality in Health Care < https://www.safetyandquality.gov.au/wp-content/uploads/2012/01/Charter-PDf.pdf>; The University of Sydney Community Placement Program in Partnership and MGC Pharmaceuticals, *Medicinal Cannabis in Australia: Science, Regulation & Industry*, White Paper (2016).
[43] Ibid, 6.
[44] See, for example, *Drugs, Poisons and Controlled Substances Act 1981* (Vic) and *Therapeutic Goods Act 2010* (Vic); *Controlled Substances Act 1984* (SA); *Drugs of Dependence Act 1989* (ACT) and *Criminal Code Regulation 2005* (ACT); Misuse of Drugs Act 2001 (TAS) and *Poisons Act 1971* (TAS); *Cannabis Law Reform Act 2010* (WA) and *Misuse of Drugs Act 1981* (WA); *Drug Misuse and Trafficking Act 1985* (NSW); *Drugs Misuse Act* (QLD) and *Police Powers and Responsibility Act 2000* (QLD); and *Misuse of Drugs Act* (NT).

(b) On the other hand, the *Narcotic Drugs Act 1967* (**ND Act**) permits the cultivation and production of cannabis[45] and the manufacture of drugs comprising or derived from cannabis or its constituent parts,[46] but in so doing it inflexibly observes Australia's obligations under the Single Convention by ensuring those activities are closely controlled.

(c) The *Customs Act 1901* (Cth) addresses the import[47] and export[48] of narcotic substances generally, and the *Customs (Prohibited Imports) Regulations 1956* (Cth) and *Customs (Prohibited Exports) Regulations 1958* (Cth) provide a mechanism for the importation and exportation, respectively, of cannabis for medical and scientific purposes, subject to the appropriate licence and permit(s).[49]

(d) The *Therapeutic Goods Act 1989* (Cth) (TG Act), *Therapeutic Goods Regulations 1990* (Cth (TG Regulations) and other subordinate legislation and guidelines, and complementary state and territory legislation, regulate the availability of medicines and other therapeutic goods in Australia.[50]

(e) The states and territories, through drug misuse, poison/drug control and/or hemp-specific legislation, license and control the cultivation, production and manufacture of cannabis, including industrial hemp and its derivative products.[51]

[45] *Narcotic Drugs Act 1967* (Cth), Ch 2 Pt 2 Div 1-2.
[46] Ibid, Ch 3 Pt 2 Div 1-3.
[47] Ibid, s 49.
[48] Ibid, s 112.
[49] *Customs (Prohibited Imports) Regulations 1956*, r 5.
[50] *Therapeutic Goods Act 1989* (Cth), Pts 3-1 and 3-2.
[51] See, for example, the *Hemp Industry Act 2008* (NSW).

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Terms of Reference

Term of Reference (a)

To consider and make recommendations on the current barriers to patient access to medicinal cannabis in Australia, including the appropriateness of the current regulatory regime through the Therapeutic Goods Administration (TGA) Special Access Scheme (SAS), Authorised Prescriber Scheme and clinical trials.

The Regulatory Pathways

23. The current regulatory regime for patient access to medicinal cannabis provides the following "pathways" for obtaining patient access to medicinal cannabis:

    (a) Registration in the Australian Register of Therapeutic Goods (**ARTG**);

    (b) The Special Access Scheme (**SAS**);

    (c) The Authorised Prescriber Scheme (**APS**); and

    (d) Clinical trials, through the Clinical Trial Notification (**CTN**) and Clinical Trial Exemption (**CTX**) Schemes.

    (the **Regulatory Pathways**).

Registration in the ARTG

24. Therapeutic goods which are entered in the ARTG are lawfully able to be commercially supplied in Australia.

25. The only medicinal cannabis product currently registered in the ARTG is Sativex.[52] The pathway to registration is an onerous one, requiring the submission of a complex dossier of clinical, preclinical, chemistry and manufacturing data to the TGA. The investment into preparing such a dossier is prohibitive, running into tens of millions of dollars, and not commercially viable when it is weighed against the inability to obtain IP protection and the difficulties in obtaining PBS listing.

26. For example, after Sativex was registered in the ARTG, the sponsor applied for its listing on the Pharmaceutical Benefits Scheme (**PBS**), but the proposed price for Sativex, which was "cost minimised" against baclofen, was not commercially viable for the sponsor. Accordingly, in the absence of PBS listing, the only means by which patients have been able to access Sativex is under a private prescription, meaning a cost several orders of magnitude higher than the cost would be under a subsidised prescription.

27. The fact that there are no other cannabis-based pharmaceuticals registered in the ARTG for supply in Australia highlights the ineffectiveness of this pathway, as well as the conservative stance to accessing medicinal cannabis that is broadly taken in Australia.

The Appropriateness of the Regulatory Pathways

28. The current Regulatory Pathways under which medicinal cannabis may be accessed are grossly inadequate. To understand why this is so, it is necessary to understand the purpose of those schemes, and why they were introduced. We provide this information below.

<u>Special Access Scheme</u>

29. The SAS was introduced to provide a mechanism for patients to access therapeutic goods that are not entered in the ARTG. It is intended to facilitate the supply of a therapeutic good

[52] https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2017-PI-01866-1&d=202001141016933.

to a single patient on a case-by-case basis. The expectation is that a health practitioner seeking access to a medicine for their patient under the SAS will have considered all appropriate treatments that are entered in the ARTG and available in Australia before submitting an application for access under the SAS.

30. In its administration of the SAS as it concerns medicinal cannabis, the TGA has made it clear that:

    (a) it has a responsibility to encourage the use of medicines that are included in the ARTG, as these products have been evaluated to ensure they meet strict standards of safety, quality and effectiveness; and

    (b) for this reason, it is expected that medical practitioners (prescribers) will have considered all clinically appropriate treatment options that are included in the ARTG before applying to access an unapproved medicinal cannabis product under the SAS.

31. What this means, therefore, is that as far as the TGA is concerned, medicinal cannabis products should only be accessed by medical practitioners for their patients as last-line therapy, when it has quite clearly been shown to have benefit as an alternative treatment option that is not last line, or in adjunctive therapy.

32. An SAS approval provides a single approval to a health practitioner for a single medicine, for a single patient, for a single indication. If the patient does not derive sufficient benefit from that single medicine and requires, say, a medicine with a different composition of THC/CBD or a different strength or a different dosage form, then the health practitioner must submit another SAS application for each variant that would characterise the medicine as one that is separate and distinct from the original medicine for which an application was submitted.

33. Added to that, many medical practitioners have said that they simply do not have the time to spend on preparing SAS applications, which requires a clinical justification to be submitted to the TGA, along with evidence that all other ARTG-entered treatment options have been tried and have failed.

Authorised Prescriber Scheme

34. Authorised Prescribers (**APs**) are medical practitioners who are approved to prescribe unapproved therapeutic goods for a particular condition or class of patients in their immediate care.

35. To become an AP, a medical practitioner must:

    (a) have the training and expertise appropriate for the condition being treated and the proposed use of the product;

    (b) be able to best determine the needs of the patient; and

    (c) be able to monitor the outcome of therapy.

36. In order for a medical practitioner to become an AP, they must obtain approval from a Human Research Ethics Committee (**HREC**) or seek endorsement from a specialist college.

37. However, similar to the SAS, an APS authorisation is granted in respect of a single product, whose supply must only be to specified patients under the AP's immediate care (and not, for example, to other practitioners to prescribe/administer the product). This use in specified patients is also limited to the particular condition and/or class of patients specified in the authorisation, meaning that if the AP wants to administer the product to a patient for another condition or to a different class of patients, then another APS application is required.

Clinical Trials

38. Access to medicinal cannabis products under a clinical trial program is available where an approval for the trial has been obtained by an HREC and, where required, the TGA.

39. There are two schemes under which clinical trials involving therapeutic goods may be conducted:

    (a) the Clinical Trial Exemption (**CTX**) scheme; and

    (b) the Clinical Trial Notification (**CTN**) scheme.

40. The use of the clinical trial pathways as a means of accessing a medicinal cannabis product for treatment, rather than for the clinical investigation of a particular product for a particular medical condition, has an unreasonable regulatory burden attached to it, requiring a clinical trial protocol, investigator's brochure, patient information sheet and informed consent form, indemnity form and other documentation to be submitted to the HREC for assessment and approval. Once a clinical trial is approved, if there are any deviations required from the clinical trial protocol, a separate approval to vary the protocol must be obtained from the HREC.

41. Clinical trials are intended to investigate the safety and efficacy of a treatment for a particular indication, in a particular cohort of patients. They are certainly useful for gathering evidence for this purpose, but they are not appropriate in a mainstream setting where a patient sees their regular doctor or a specialist for the treatment of their condition.

Limited available pathways

42. As is evident from the above information, the current Regulatory Pathways for access to medicinal cannabis are seriously inadequate.

43. As noted in paragraphs 25 and 26 above, there is only one medicinal cannabis product – Sativex – currently registered in the ARTG, which has not been commercially marketed by its sponsor since its registration in 2014 because its PBS listing was not commercially viable, and most patients cannot afford to obtain it on a private prescription.

44. Another major issue affecting the entry of medicinal cannabis products in the ARTG is that all medicinal cannabis products are Schedule 8 medicines, apart from products containing CBD in at least 98% purity, which are Schedule 4 medicines. Even non-narcotic forms of medicinal cannabis, which have no psychotropic effects whatsoever, are Schedule 8 medicines, even though many of these would more appropriately be dealt with as herbal medicines under a complementary medicines regime.

45. The predominant pathway that patients and their treating medical practitioners have been accessing with some degree of success compared to other pathways (albeit itself limited) is the SAS. However, as explained in paragraphs 29 to 33 above, this pathway is severely limiting, and requires separate (and time-consuming) applications to be made for every patient and for every change in the medicine being used or medical condition being treated.

46. The APS is also a burdensome pathway in practice, because it requires a submission, containing an appropriate clinical justification (including evidence of other treatments used) to be made to a HREC or specialist college in order for a medical practitioner to become an Authorised Prescriber.

47. The limited utilisation of the APS as an available pathway is highlighted by the limited number of Authorised Prescribers nationally; according to the TGA, there were a mere 54 Authorised Prescribers as at 31 January 2019.[53] By comparison, there were approximately 119,926 medical practitioners registered in Australia, as at 30 September 2019.[54]

48. For the reasons stated in paragraphs 40 and 41 above, the use of clinical trial pathways for the mainstream treatment of patients is inappropriate.

[53] https://ajp.com.au/news/how-many-australians-are-accessing-unapproved-medicinal-cannabis/.
[54] https://www.medicalboard.gov.au/News/Statistics.aspx.

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49. Evidence that the SAS pathway is by far the predominantly utilised pathway for access to medicinal cannabis products is demonstrated in the table below, which provides a breakdown of SAS Category B approvals for medicinal cannabis products by month in 2019:

Month	Number of SAS Category B approvals
January 2019	670
February 2019	738
March 2019	1043
April 2019	1108
May 2019	1370
June 2019	1566
July 2019	2207
August 2019	2889
September 2019	2911
October 2019	3594
November 2019	3404
December 2019	3682

50. However, while the above information represents the number of SAS approvals, it does not indicate the number of patients that these approvals represent, or whether these approvals translate to product actually prescribed to the patient, which the patient is then administered. Whether or not a patient in respect of whom a medical practitioner obtains an SAS approval is actually treated with the medicinal cannabis product for which the approval was obtained depends very much on the cost of treatment and the continuity of supply, which are also critical factors in patient access. In this regard, although it may seem from the above table that the SAS is a mechanism that provides patients with adequate access to medicinal

cannabis products, it is estimated that there are more than 100,000 patients who are accessing black market medicinal cannabis; they appear to be doing so for the reasons we have stated above – *i.e.* that the current Regulatory Pathways are burdensome – but also because the cost of any medicines that can be accessed is prohibitive (including because their high cost is directly related to their limited availability and supply), a matter dealt with further below.

Term of Reference (b)

To consider and make recommendations on the current barriers to patient access to medicinal cannabis in Australia, including the suitability of the Pharmaceutical Benefits Scheme for subsidising patient access to medicinal cannabis products.

51. The PBS is entirely inappropriate for subsidising or facilitating patient access to medicinal cannabis products, as only products which are registered in the ARTG are eligible for PBS listing. Even then, as discussed in paragraphs 25 and 26 above, the only medicinal cannabis product currently registered in the ARTG is Sativex. PBS subsidies for every other medicinal cannabis product which is currently accessible as an unapproved therapeutic good are not possible under the current legislation, and will not be possible without legislative and regulatory reform.

52. The total absence of government subsidisation for medicinal cannabis products presents a major barrier to patient access in Australia, especially to patients with limited financial resources.

Term of Reference (c)

To consider and make recommendations on the current barriers to patient access to medicinal cannabis in Australia, including the interaction between state and territory authorities and the Commonwealth, including overlap and variation between state and territory schemes.

Encroachment on Commonwealth regime by the states and territories

53. The practical reality of the interplay between the existing Commonwealth regime and the emerging novel state and territory regulatory frameworks for medicinal cannabis is that patient access in every jurisdiction is characterised by obstruction and inefficiency.

54. Overall, the state and territory regimes ensure that approval or authority for supply at the Commonwealth level is effectively undermined and even neutered, and the numerous onerous requirements for the granting of access at the state and territory level operate more effectively to stifle, rather than facilitate, timely access to medicinal cannabis for patients, the vast majority of whom suffer from chronic and debilitating conditions which would benefit from treatment with medicinal cannabis.

55. Primarily, the state and territory regimes appear to unnecessarily duplicate and encroach on the Federal schemes administered by the TGA (*viz* the SAS and APS). This duplicative regulation has created unnecessary hurdles that patients and their prescribers have had to overcome in order to obtain access to medicinal cannabis. Medical practitioners, after having obtained SAS approval, have then had to tackle the state/territory regulatory authority and at times had to persevere for several months in order to obtain approval. In the patient cases discussed further below, access was obstructed at the state/territory level when, in our view, it is inappropriate for state/territory regulatory authorities to be intervening in matters relating to access (as opposed to matters controlling supply).

56. The additional barriers at the state/territory level which have been imposed on the supply of medicinal cannabis products have gone way beyond the restrictions that have been applied to any other unapproved medicine, and have been a major barrier to patient access, not to mention the deleterious effect this has had on the health and safety of patients. No evidence has been provided to date that state and territory intervention in the approval or authorisation of access to medicinal cannabis products has achieved any purpose other than to block or unnecessarily delay access and seriously compromise the health and safety of patients.

57. Under the existing legal and regulatory framework for therapeutic goods in Australia, each state and territory is free to regulate supply within its respective jurisdiction. In this regard, the regulation of the supply of medicinal cannabis products may be, and appears to be becoming, separate and distinct in every state and territory. This is despite Australia having common mechanisms which operate effectively for all other unapproved medicines, even those with highly significant risk profiles.

58. The story of patient AA below demonstrates where approval to access medicinal cannabis was granted by the TGA's Chief Medical Officer under the SAS but, based on the same clinical evidence, the patient was refused access by a decision maker at the state level who was a non-practising pharmacist with no clinical experience in medicinal cannabis.

59. It may be that the additional 'red tape' at the state/territory supply level, which fuelled refusals such as the above example, reflects the unique stigma that attaches to the prescription and supply of medicinal cannabis products at that level. If so, that only underscores the inappropriate interference and obstruction which is stifling access to medicinal cannabis. As such, public education and awareness, and perhaps greater intergovernmental liaison (between relevant Commonwealth and state/territory health agencies), are vital to ensuring that the Australian public, patients and health practitioners are free to utilise the developing framework for medicinal cannabis products in the absence of unwarranted scrutiny or cynicism from inappropriately qualified, state/territory 'gatekeepers' of medicinal cannabis access and supply.

Interference by state and territory policies

60. Further facilitating this interference, state and territory authorities are also able to introduce policies which undermine the effectiveness of the current Commonwealth regulatory regime. For example, in 2017, Children's Health Queensland (**CHQ**) introduced a "policy" which stated that medicinal cannabis products containing THC should not be administered to any person less than 25 years of age. This was regardless of any measured benefits experienced by any given patient who had previously been administered medicinal cannabis.

61. Whilst this policy and specific Queensland legislation relating to medicinal cannabis has been repealed, it is important that the Committee appreciate that that did not occur without strong and unrelenting advocacy, and sadly not before the tragic death of a patient while in the care of the Queensland public health system, to whose death the application of this policy is suspected to have contributed (as described in more detail below – see the case of patient CC).[55] In our view, any requirement that state/territory authorities must also approve a medicinal cannabis product undermines and erodes the functionality of the current regulatory regime. We recommend that action is taken to remove all state/territory requirements for approval to access medicinal cannabis products, by ensuring that the Commonwealth government regime 'covers the field' on any matter which bears on approval to access such products.

62. Another issue we are aware of which is obstructing access to medicinal cannabis is the intermittent requirement by at least some state/territory authorities for specialist doctors to

[55] This matter is currently the subject of a coronial investigation and will become the subject of a coronial inquest; the extent to which the CHQ policy contributed to Patient CC's death is a matter for determination as part of that inquiry/inquest.

prescribe medicinal cannabis or endorse a general practitioner's prescription of medicinal cannabis. This implies that such specialists have a greater knowledge of medicinal cannabis than other medical practitioners, when this is often not the case. This unnecessary requirement highlights some of the illogical approaches which create further barriers to patient access. Rather than imposing such a mandatory requirement, it would make more sense to provide proper education to medical practitioners about the endocannabinoid system, medicinal cannabis generally and specific medicinal cannabis products, so that they are reasonably equipped with the information they need to comfortably prescribe medicinal cannabis.

Patient Cases

63. The examples below of patients we have represented illustrate how bureaucratic requirements at the state/territory level have stifled access to medicinal cannabis products.

Patient AA

64. Patient AA suffered from chronic debilitating pain of neuropathic origin, LBD with anxiety, illusions and hallucinations, idiopathic Parkinson's disease, depression, suicidal ideation, aggression, paranoia, progressive cognitive decline and movement problems. Her condition and its management placed considerable strain on both her quality of life and her family, who were her primary carers.

65. AA was being administered an industrial hemp oil containing CBD, prior to the changes to legislation which outlawed the use of those products. Importantly, patient AA profoundly benefited from the hemp oil treatment, and many of the unpleasant and challenging symptoms she was exhibiting, such as aggression, paranoia, illusions, hallucinations and movement disorder, subsided whilst she was on treatment. AA's GP monitored AA's condition and progress during this administration and was overwhelmingly impressed with the improvements in AA's symptoms and general wellbeing. AA was able to perform tasks that, prior to cannabis treatment, she was unable to perform independently.

66. After the hemp oil treatment that patient AA was taking was outlawed, her family sought to obtain access to medicinal cannabis under the SAS. Accordingly, on 16 July 2017, AA's GP submitted an application for access to a medicinal cannabis product for AA under Category B of the SAS.

67. The Category B Application was for a product containing 1.0 mg/ mL THC and 20.0 mg/mL CBD. The GP recommended an initial dose of 1 mL three times daily, titrated up as required to achieve an optimal response. The GP was of the view that a low-THC and high-CBD dose would be beneficial to improve AA's condition and slow her degenerative decline.

68. The GP attached to the Category B Application a summary of numerous studies demonstrating the safety and efficacy of medicinal cannabis in the treatment of chronic pain. Following contact with a pharmacist at the TGA, who requested further information in relation to the Category B Application, the GP referred AA to a neurologist, who considered AA's past treatment and dose regimens in detail and determined the medicinal cannabis treatment was appropriate to assist with AA's clinical symptoms.

69. On 14 September 2017, the pharmacist at the TGA provided the GP with a Notification of Approval of the Category B application, on the grounds that there was no alternative therapy currently supplied in Australia. This decision was affirmed by the Delegate of the Secretary, who also provided (on 15 September 2017) the GP with a Notification of Approval of the Category B Application (subject to the conditions in the 14 September letter). The approval provided by the TGA's pharmacist contained explicit reference to the requirement that the GP must comply with any relevant State or Territory legislation in order to secure access for AA.

70. On 18 September 2017, the GP lodged an application to NSW Health for authority to supply a cannabis product for human therapeutic use by AA. On 5 October 2017, this application was refused on the basis that the GP had failed to provide sufficient rationale for the use of

the proposed medicinal cannabis product for AA's condition, and adequate assessment of the benefits and harms to appropriately justify the treatment of AA in such an experimental context.

71. The TGA's approval of the Category B Application indicated that the TGA was satisfied, on the evidence provided by the GP, that the prescription and supply of the proposed medicinal cannabis product to AA was clinically justified in the circumstances. Despite this, NSW Health exercised a power which infringed on the TGA's jurisdiction and made a decision to the contrary, effectively blocking AA's access to treatment which substantially improved her and her carers' quality of life.

72. We commenced acting for the GP and AA on a *pro bono* basis following NSW Health's refusal to grant access. It was, quite frankly, an unnecessarily arduous task to overcome NSW Health's refusal, and it took us another 6 months of ongoing and relentless advocacy to procure an approval from NSW Health on behalf of AA's GP.

73. Since then, pleasingly, NSW has moved to a streamlined model, which now only requires an SAS approval by the TGA in order for a patient to obtain access. However, it highlights a history of unacceptable interference at the state/territory level which must be excised from any future iterations of the scheme.

Patient BB

74. Patient BB suffers from chronic severe lower back pain associated with bilateral leg pain, which is the result of an injury that occurred when BB was seventeen years old. BB had three lumbar spinal operations, and was treated with a number of non-pharmacological and pharmacological interventions. Previous medications BB used include Endone, Panadeine Forte, Lyrica, Palexia, Endep, Valium and NSAIDs. BB had not experienced any significant relief from opioid or non-opioid pain medication. In fact, when we met BB, he scored his pain at an 8 or 9 on an 11-point VAS pain scale.

75. After several failed attempts over almost a year by BB's treating doctor to obtain access to medicinal cannabis, we decided to assist BB on a *pro bono* basis in July 2017 to obtain access to an unapproved medicinal cannabis product by way of a Category B Application under the SAS.

76. In the first instance, we accompanied BB to a consultation with his specialist, who agreed that it would be appropriate for BB to trial a medicinal cannabis product to treat his chronic severe pain.

77. As many medical practitioners are too busy to devote the time required to prepare an SAS application, and due to the unfamiliarity that BB's specialist had with the SAS application requirements, we assisted BB's specialist to prepare a comprehensive Category B application to the TGA, which included the following:

    (a) Clinical evidence supporting the prescription of medicinal cannabis as a safe and effective treatment for the relief of chronic non-cancer pain when used alone or in conjunction with other pain medication;

    (b) The dosage specifications for the particular medicinal cannabis product recommended by BB's specialist; and

    (c) A monitoring regime to be followed by BB's specialist, which comprised regular appointments with BB with the object of assessing the efficacy of the product and any adverse side effects.

78. In November 2017, after almost 18 months, BB's access to medicinal cannabis was finally approved, but then BB had to wait another two months before obtaining the required authorisation from NSW Health, following an administrative burden of substantial, ongoing correspondence between the TGA, NSW Health, BB and his specialist.

79. BB's case demonstrates the inordinate delays that patients have been forced to endure because of the burdensome regulatory regime and the administrative hurdles it creates.

Patient CC

80. We represent the parents of patient CC, a young child who died suddenly on 21 October 2017 while she was an in-patient in a Queensland hospital.

81. Prior to her death, the precise nature of CC's condition remained undiagnosed, but it is accepted that she suffered from a complex (likely regressive) neurological disorder and severe refractory epilepsy. Despite having tried numerous anticonvulsant medications, CC continued to experience uncontrolled seizures and was regularly admitted to hospital from 2010 to 2017. CC developed tolerance to most medications and when dosages were increased to combat the rising tolerance, she experienced severe and debilitating side effects, evidencing a requirement for new therapeutic approaches.

82. These significant side effects included, but were not limited to, excessive body hair, bleeding stomach ulcers, bone density problems, vertigo, inability to sweat and control body temperature, over-sedation, respiratory failure, constipation, severe irritability, loss of ability to swallow and loss of eye control. Notably, CC's parents were informed by CC's treating practitioners in or around April 2015 that all therapeutic options had been exhausted. It is at this point in time that CC's parents decided to turn to a combination medicinal cannabis product (containing predominantly THC), which they sourced illicitly. Her parents administered this product to CC for just over two and a half years and had been identified as doing so in CC's hospital records. The medicinal cannabis product that CC's parents sourced for CC allowed her to maintain a reasonable quality of life, reducing the frequency of seizures by approximately 90% with few, if any, observable side effects. CC's parents firmly believe that medicinal cannabis saved CC's life at least twice in circumstances where prescription medicines had failed.

83. In October 2017, CC was again admitted to hospital. Even though CC was entitled under the Commonwealth regime to obtain medicinal cannabis on just the prescription of a treating medical practitioner (as a Category A patient under the Special Access Scheme), and was found to be an "eligible patient" for medicinal cannabis under the Queensland legislation that was in force at the time, CC's specialist Queensland hospital clinicians refused her parents' requests to prescribe to her a licit combination medicinal cannabis product equivalent to the illicit cannabis product her parents had been administering, despite the dramatic reduction in seizures experienced by CC using the illicitly sourced product; the clinicians maintained the position that they would not support the use of any medicinal cannabis product other than Epidiolex®, an investigational CBD-only medicinal cannabis product which has a vastly dissimilar cannabinoid profile to the combination product that CC had been using. Although the reason for the hospital clinicians' refusal to prescribe a combination product was not (and has not since been) made known to CC's parents, the CHQ policy (referred to in paragraph 60 above) that medicinal cannabis products containing THC should not be administered to any person less than 25 years of age is suspected to have been a significant factor.

84. CC's case illustrates how the Queensland public health system blocked the attempts by CC's parents to access a lawful supply of a particular kind of medicinal cannabis product for CC. This matter is currently the subject of a coronial investigation and will, according to the requirements of Queensland legislation, become the subject of a coronial inquest, Whether the Queensland health system's blocking of access caused, or materially contributed to, the decline in CC's health and her ultimate death, and the extent to which CHQ's policy contributed to those events, is a matter to be determined in the course of those coronial processes.

85. Regardless of the outcome of the coronial processes, it is imperative that any changes that are made to improve the existing regulatory regime remove the opportunity for interference or intervention by state and territory authorities in any decision relating to patient access. This can be achieved by establishing a model that solely regulates access to medicinal

cannabis at the Commonwealth level and prohibits interference by state and territory authorities.

Patient DD

86. It is our understanding that the case of DD is the subject of a separate submission by DD's mother. We do not propose to repeat her poignant submissions in ours. However, we would like to emphasise the following particular points in the submission from DD's mother, which are highly relevant to the Inquiry:

(a) Between January 2010 and December 2014, DD spent more time as an inpatient in hospital than he did at home, and experienced chronic seizure activity.

(b) In desperation, in December 2014, DD's mother sourced an illicit medicinal cannabis product, and observed an immediate improvement in his condition.

(c) Between December 2014 and June 2017, DD experience a total of only 4 tonic clonic seizures, representing an enormous reduction in seizure activity.

(d) Unfortunately, in June 2017, due to a suspect batch of medicinal cannabis, DD experienced what his mother describes as a "horrific tonic clonic seizure". She was told to immediately cease administering medicinal cannabis to DD and he was not administered any other medications, causing his seizures to spiral out of control.

(e) In March 2018, DD was approved for treatment with Epidiolex, but had to wait several months for a prescription to be issued, during which time he had many Code 1 experiences.

(f) Not only did DD not improve on Epidiolex treatment, but his condition dramatically deteriorated.

(g) In October 2018, DD obtained approval for treatment with another CBD product. He did not initially improve on this product and his seizures continued to worsen.

(h) On 19 November 2018, DD experienced 3 tonic clonic seizures and presented twice to the Emergency Department via ambulance. He was weak and had minimal 'fight' left in him.

(i) On 20 November 2018, against the advice of DD's neurologist, DD's mother split the dose of DD's medication. She did not administer more than the daily dose, but administered the daily dose in divided amounts over the course of the day. This was the last time that DD experienced a tonic clonic seizure.

87. The questions that DD's mother has asked in her submission are demanding of answers:

(a) Why wasn't DD prescribed a medicinal cannabis product other than Epidiolex when his neurologists had EEG evidence that the product he was taking worked?

(b) Why was DD's access to a suitable medicinal cannabis product delayed, making him suffer unnecessarily for months?

(c) Why is it that families who take their children to see the same neurologists are being refused the right to try and/or are refused access to lawful medicinal cannabis, leaving those families with no option but to access black market product?

88. Questions arise in DD's case as to what the main barrier to his access to a medicinal cannabis product was – whether it was bureaucratic interference, the ignorance of his clinicians or their prejudices against the use of medicinal cannabis notwithstanding its demonstrated benefits. This is a difficult issue for the Committee to address. Doctors are expected to make decisions which are in the best interests of their patients, but what rights do patients or their carers have when they believe that doctors' prejudices are clouding their judgement, to the point where the health and safety of patients is at serious risk? Surely, addressing the barriers to patient access must consider a patient's right to access medicinal

cannabis, particularly in circumstances, as in the case of DD, where compelling evidence is available of its benefit.

Term of Reference (d)

To consider and make recommendations on the current barriers to patient access to medicinal cannabis in Australia, including Australia's regulatory regime in comparison to international best practice models for medicinal cannabis regulation and patient access.

89. Other international best practice models provide for more accessible access to medicinal cannabis, meeting these countries' obligations under the International Covenant on Economic, Social and Cultural Rights and under human rights charters to a much higher standard. This is plainly evident when comparing the numbers of patients who are accessing medicinal cannabis products in different countries.

90. In 2019, the TGA approved approximately 25,000 SAS Category B applications for unapproved medicinal cannabis products in Australia.[56] For the reasons stated earlier in this submission, is not known whether this number of approvals represents approvals in respect of 25,000 individual patients, or whether these approvals translate to 25,000 products actually prescribed to patients.

91. By comparison, Canada, which takes a more progressive approach to medicinal cannabis use and cannabis use generally, had approximately 369,614 medical client registrations with federally licensed sellers at the end of September 2019.[57]

92. Effective international best practice models are those which deal with medicinal cannabis outside of the framework used for conventional medicines. It is our view that the regulation of medicinal cannabis needs to occur under a separately developed framework and separate legislation, which is fit for purpose. Experience has shown us that the current regulatory model, which has sought to fit the square peg of medicinal cannabis into the round hole of conventional medicine, is wholly inadequate.

Term of Reference (e)

To consider and make recommendations on the current barriers to patient access to medicinal cannabis in Australia, including the availability of training for doctors in the current TGA regulatory regime for prescribing medicinal cannabis to their patients.

Term of Reference (f)

To consider and make recommendations on the current barriers to patient access to medicinal cannabis in Australia, including the education of doctors in the Endogenous Cannabinoid System (ECS), and the appropriateness of medicinal cannabis treatments for various indications.

93. University training prior to the advent of medicinal cannabis was devoid of any mention of the endocannabinoid system or its functions. Accordingly, it is understandable that the lack of education on this subject and on the use of medicinal cannabis products has a direct bearing on the level of comfort which medical practitioners will have in prescribing them. Indeed, a

[56] See paragraph 49 above.
[57] https://www.canada.ca/en/health-canada/services/drugs-medication/cannabis/research-data/medical-purpose.html.

survey undertaken in 2017 found that only 28.8% of GPs felt comfortable discussing medicinal cannabis with patients.[58]

94. There are an increasing number of medicinal cannabis education and training courses available to doctors who wish to obtain knowledge about the endocannabinoid system and the use of medicinal cannabis treatments. For example, there are currently four RACGP-accredited webinars available for RACGP members and their colleagues about the use of medicinal cannabis,[59] and there are a number of industry-developed courses which provide comprehensive theoretical and practical information to health practitioners who are treating, interested in treating or involved in the treatment of patients with medicinal cannabis. These education and training courses are not mandatory, but any doctor may access education and training that will give them sufficient knowledge and understanding of medicinal cannabis as a treatment modality.

95. We continue to receive feedback about doctors who are not comfortable to prescribe medicinal cannabis products to their patients. We believe that this is simply a symptom of the stigma that still attaches to medicinal cannabis, and those doctors not having received adequate education and training on this topic. Added to that are concerns about the liability risk that the use of an "unapproved" product presents, which has not been helped by the positioning of the majority of medicinal cannabis products as Schedule 8 medicines (which are regarded as high-risk medicines) which should only be used as last-line therapy.

96. Further education and training of medical practitioners is clearly required so that they understand and accept medicinal cannabis as a treatment option (not last line) which may be appropriate for their patients in certain circumstances. There is an opportunity to mandate such education and training if a separate regime that is fit for purpose is created administer medicinal cannabis.

Term of Reference (g)

To consider and make recommendations on the current barriers to patient access to medicinal cannabis in Australia, including sources of information for doctors about uses of medicinal cannabis and how these might be improved and widened.

97. It is clear from the patient cases discussed above that attitudes towards medicinal cannabis amongst medical practitioners can vary greatly.

98. In the case of patient AA, the patient's treating GP and neurologist both supported the use of medicinal cannabis, and it was the state regulatory authority who was unnecessarily blocking access.

99. In the case of the late CC, her specialist clinicians did not support the use of a medicinal cannabis product other than Epidiolex, despite the undeniable, overwhelmingly positive benefits observed from her treatment with the combination medicinal cannabis product illicitly sourced by her parents.

100. These differing views undoubtedly undermine access to medicinal cannabis, and are a strong source of frustration for those patients who believe that their doctors are ignorant about the potential uses and benefits of medicinal cannabis, and do not invest the time to participate in education and training programs which will give them the knowledge and understanding they need to make informed decisions about whether medicinal cannabis may be an appropriate treatment for their patients.

[58] https://bmjopen.bmj.com/content/8/7/e022101
[59] https://www.racgp.org.au/education/professional-development/online-learning/webinars/medicinal-cannabis.

Term of Reference (h)

To consider and make recommendations on the current barriers to patient access to medicinal cannabis in Australia, including delays in access, and the practice of product substitution, due to importation of medicinal cannabis and the shortage of Australian manufactured medicinal cannabis products.

Term of Reference (i)

To consider and make recommendations on the current barriers to patient access to medicinal cannabis in Australia, including the current status of the domestic regulated medicinal cannabis industry.

101. We provided an extensive submission in relation to the review of the Narcotic Drugs Act (**ND Act Review Submission**), which provided feedback about our experience with the legislation, and ways in which the regime regulating the cultivation, production and manufacture of medicinal cannabis could be improved.

102. For the Committee's benefit, we have appended a copy of our ND Act Review submission to this submission, at **Attachment 1**.

103. As the Committee may be aware, the 2016 amendments to the ND Act introduced a licensing and permit scheme for the cultivation, manufacture and supply of medicinal cannabis. The TG Act operates concurrently to regulate the manufacture of medicinal cannabis products, which must be manufactured in accordance with good manufacturing practice (**GMP**).

104. The domestic medicinal cannabis scheme is administered by the Office of Drug Control (**ODC**), which is appallingly under-resourced and incapable of managing the regulatory burden that comes with the overly prescriptive requirements that applicants for licences and permits must meet before they are able to commence operations in Australia.

105. Added to that, medicinal cannabis active ingredients and medicinal cannabis products under the domestic scheme must be manufactured in GMP-licensed premises, a requirement which does not apply to in-bound (imported) products, which are only required to be manufactured in accordance with the requirements that apply in the country of origin. There is thus an unlevel playing field between imported medicinal cannabis and domestically manufactured medicinal cannabis, which gives preference to imported medicinal cannabis and medicinal cannabis products which may be of compromised quality.

106. The overly burdensome requirements of the domestic scheme are a major barrier to a viable medicinal cannabis industry in Australia. One of our clients has spent more than $30 million establishing its operations in Australia, expenditure which is in large part directly related to the regulatory burden that Australian industry stakeholders must bear.

107. This expenditure is exacerbated by the unreasonable delays in obtaining the necessary regulatory approvals required to commence medicinal cannabis activities. One industry player had to wait more than 2 years to obtain a cannabis research licence. On any level, one would regard such delays as grossly unacceptable.

108. ODC has said that it requires further resources in order to speed up the timeframes for regulatory approvals. It has said that to procure further resources, it proposes to increase the current fees charged under the licensing and permit scheme, but it admits that all revenue obtained under the scheme is pooled under the Consolidated Revenue Fund and it is up to the Finance Minister to decide how that revenue will be disbursed. In other words, ODC has made it clear that there is no guarantee whatsoever that any increases in fees under the scheme will be allocated towards the procuring of additional resources, and therefore there is no guarantee that the present administrative burden will be relieved.

109. For industry players that have invested substantially in the establishment of cultivation, production and manufacturing facilities, but are waiting idly 'in the queue' for the licences and

permits they require to commence operations, the burn rate and risk of collapse is significant. The present state of play cannot continue; it is destroying an industry before it has even had the chance to get off the ground.

110. In our view, part of the problem with the domestic scheme is this government's anally retentive, and excessively narrow, interpretation of its obligations under the *Single Convention on Narcotic Drugs 1961,* which is enacted under Australian law in large part through the ND Act, and which is apparently relied upon as the "reason" why the scheme has to be so restrictive, notwithstanding the fact that the Australian scheme is more restrictive and burdensome than any other market that is also a signatory to, and has obligations under, the Convention.

111. The TGA says that the requirements pertaining to imported medicinal cannabis are not as onerous because it is necessary to ensure that patients in Australia have facilitated access to imported medicinal cannabis products until the domestic scheme is up and running. With respect, the way to facilitate access to medicinal cannabis for Australian patients is to facilitate a domestic scheme that is not overly burdensome, and is administered by a regulatory authority that is adequately resourced.

112. The current framework is burdensome and confusing, and discourages investment in Australia, which is essential for the long-term viability of the local industry, and for assuring that patients have access to high-quality domestic product.

113. In our view, the regulatory framework has stifled the growth of Australia's domestic medicinal cannabis industry, with most cannabis companies being import-oriented. Further, because of the burdensome access schemes in Australia, domestic players are looking at the export market for their long-term viability, as domestic supply is so restrictive that a business looking solely at the domestic market is more than likely to fail. Indeed, we are aware of a number of corporate clients that are so frustrated by the complex and costly regulatory framework that they have chosen to move their operations overseas.

114. The impact of this is that the price of accessing medicinal cannabis is increased as patients are having to rely on imported product rather than accessing high quality and affordable domestic medicinal cannabis, and demand is far outstripping supply, resulting in a distorted market with inflated prices. Consequently, Australian patients, including some of our clients, are being forced to turn to the black market to obtain affordable access to cannabis for medicinal purposes.

Term of Reference (j)

To consider and make recommendations on the current barriers to patient access to medicinal cannabis in Australia, including the impacts on the mental and physical wellbeing of those patients struggling to access medicinal cannabis through Australia's regulatory regime.

115. From the patient cases referred to above, it is apparent that the current barriers to patient access to medicinal cannabis in Australia have severely detrimentally impacted the mental and physical wellbeing of patients and their families struggling to access medicinal cannabis.

Impact on patients' mental wellbeing

116. The impact on mental wellbeing arising out of the current flawed Regulatory Regime is not limited to patients, but also extends to their families and loved ones.

117. Firstly, both patients and their families are being forced to incriminate themselves by resorting to sourcing black-market cannabis, as a result of the high barriers to them accessing legal medicinal cannabis (cost, regulatory burden, attitudes of medical practitioners).

118. Families should not be forced to put themselves at legal risk in order to source effective healthcare for loved ones. As noted above, in the case of CC, the family was reported to

DOCS by the hospital where CC was being treated, simply because her parents were administering illicit medicinal cannabis to their child, and regardless of the enormous benefit that it was evident that CC derived from that treatment. This demonstrates an attitude held by many that the use of medicinal cannabis is akin to drug abuse, which we can only assume derives from antiquated social values and the lack of education as to the medicinal value of cannabis.

119. We have observed first-hand that patients and their families endure feelings of helplessness, frustration and severe distress when desperately trying to obtain access to medicinal cannabis. It is incredibly distressing for families to observe their loved ones' conditions deteriorating, when they know of the benefits of medicinal cannabis.

120. In the case of CC, her death was incredibly traumatic for her parents, and they continue to be haunted by the events leading to her death. Her father, in particular, has suffered enormously from her death, and was recently diagnosed with post-traumatic stress disorder, which is a direct result of the sustained mental and emotional trauma he endured when he desperately tried to obtain legal access to medicinal cannabis for his child, and her senseless death which very likely would not have occurred had she not been denied access to medicinal cannabis.

Impact on patients' physical wellbeing

121. The inability to source high-quality medicinal cannabis has resulted in deteriorating medical conditions and the inability to manage painful and debilitating symptoms of disease.

122. In the case of CC, as stated above, despite numerous attempts – including with our intervention – CC's parents were unable to obtain access to a lawfully available medicinal cannabis product, even though there were clear legislative pathways which allowed it.

123. From the point in time that CC had commenced treatment with a medicinal cannabis product, she experienced a 90% reduction in her seizures with few, if any, observable side effects. The product her parents requested, at the time, to be obtained lawfully as a suitable alternative to the treatment CC was using had a similar concentration of THC to the combination she was already taking, but it would obviously have been subject to much greater quality control. It is therefore likely that CC would have obtained similar, if not better, safety, efficacy and quality of life outcomes from a lawfully-sourced, well-controlled product.

124. CC's parents were also often prevented from administering medicinal cannabis to CC when she was hospitalised, resulting in an increase in her number of seizures, causing her and her family significant physical, mental and emotional distress.

125. Further, her parents believe that the extent to which CHQ and Queensland Health refused their repeated attempts to access a lawful supply of medicinal cannabis for their child materially contributed to the decline in CC's health and her ultimate death – this is a matter to be further determined through the coronial processes.

Term of Reference (k)

To consider and make recommendations on the current barriers to patient access to medicinal cannabis in Australia, including the particular barriers for those in rural and remote areas in accessing medicinal cannabis legally.

126. We consider that patients in rural and remote areas will face even greater difficulty in accessing medicinal cannabis legally, which should be a consideration when evaluating future reform.

MILLS OAKLEY

Term of Reference (l)

To consider and make recommendations on the current barriers to patient access to medicinal cannabis in Australia, including the significant financial barriers to accessing medicinal cannabis treatment.

Term of Reference (m)

To consider and make recommendations on the current barriers to patient access to medicinal cannabis in Australia, including the number of Australian patients continuing to rely on unregulated supply of medicinal cannabis due to access barriers and the impacts associated with that.

127. Patients have reportedly been quoted up to $34,000 per year (*i.e.* approximately $93 per day) to access medicinal cannabis following TGA approval. On this basis, many patients simply cannot afford treatment under the proposed arrangements and, in such circumstances, patients are most likely to resort to (or continue) sourcing cannabis for medicinal use through illegal channels.

128. Having regard to the already significant approval, operational and other costs associated with cultivating, producing and manufacturing medicinal cannabis under present scheme, it is unlikely that industry participants will be able to address issues of costs on their own, and we anticipate that fiscal policies such as price ceilings and government subsidies will be necessary to facilitate patient access to legal medicinal cannabis in Australia. Given that the PBS is not available for medicines that are not registered in the ARTG, and will not be available unless the legislation which administers the scheme is changed, other avenues for subsidisation need to be explored, such as subsidisation under the Medicare Benefits Scheme (which could, for example, explore the feasibility of a 'medicinal cannabis service' which includes as part of that service a consultation with a medical practitioner and the supply of a medicinal cannabis product), or subsidisation by private health insurers.

129. If the issue of cost is not addressed, black market cannabis will continue to remain considerably more inexpensive than lawfully manufactured medicinal cannabis, which continues to deter patients from accessing medicinal cannabis lawfully.

Term of Reference (n)

To consider and make recommendations on the current barriers to patient access to medicinal cannabis in Australia, including any related matters.

130. One final issue that is worth mentioning is that in some states, it is a strict liability offence for the presence of THC to be detected in any person driving a vehicle, regardless of whether the person has a legitimate reason (*e.g.* the person has a medical prescription) for its use.

131. For example, in NSW, the *Road Transport Act 2013* (**RT Act**) defines delta-9-tetrahydrocannabinol (*i.e.* THC) as a "prescribed illicit drug",[60] along with methylamphetamine (also known as speed), 3,4-methylenedioxymethylamphetamine (also known as ecstasy) and cocaine. Section 111 of the RT Act makes it an offence for a person to drive whilst a prescribed illicit drug is present in that person's oral fluid (saliva), blood or urine.[61]

132. In the case of hard drugs such as speed, ecstasy and cocaine, such a prohibition makes sense, but the same approach cannot be justified in respect of drivers who are using cannabis for medicinal purposes. Further, it makes no sense that the mere detection of THC,

[60] Section 4 of the RT Act.
[61] Section 111 of the RT Act.

even if it is present in such low concentrations that it could not possibly cause any impairment, gives rise to an offence.

133. The penalty for an offence is a fine, which may be up to $2,200 in the case of a first offence and up to $3,300 if it is a repeat offence. People using medicinal cannabis daily to manage their symptoms are therefore be staring down the barrel of a minimum $2,200 fine if THC is detected in their system whilst driving, and $3,300 fine for every subsequent time that THC is detected.

134. Notably, there is a carve-out in the RT Act for morphine when taken for medicinal purposes. Accordingly, whilst it is an offence under the RT Act for a person to drive with the presence of morphine in their blood or urine, if that person proves to the court's satisfaction that at the time of their offending conduct the presence of morphine in their blood or urine was caused by the consumption of a substance for medicinal purposes, then this is considered a defence.

135. The RT Act is clearly out of step with, and wholly inconsistent with, the regulatory scheme for medicinal cannabis. It should have been amended in 2016, when the amendments to the Narcotic Drugs Act were introduced. To this day, it has still not been amended, meaning that a patient in NSW who has taken all the required steps to obtain medicinal cannabis lawfully is still at risk of committing an offence if they happen to drive a vehicle and THC is detected in their system.

136. These issues are putting unnecessary fear into patients, to the point where some patients are unwilling to access medicinal cannabis for fear of being caught with THC in their system while driving.

137. Proper access to medicinal cannabis requires ancillary issues such as this to be addressed, as they present additional barriers which unnecessarily deter patients from seeking access to medicines which may otherwise be of significant benefit to them.

MILLS OAKLEY

ATTACHMENT 1
MILLS OAKLEY SUBMISSION TO NARCOTIC DRUGS ACT REVIEW

MILLS OAKLEY

CONSULTATION SUBMISSION

Date:	2 April 2019
To:	Professor John McMillan AO **Australian Government Department of Health**
From:	Dr Teresa Nicoletti, Partner; Julian Grover, Special Counsel; Helaena Short, Lawyer **Mills Oakley**

Review of the Narcotic Drugs Act 1967

About Mills Oakley

1. Mills Oakley is an Australia-wide commercial law firm with offices in Sydney, Melbourne, Canberra, Brisbane and Perth.
2. Dr Teresa Nicoletti, the head of our Intellectual Property, Health and Life Sciences team, is both a lawyer and scientist with almost 25 years' experience in the Health and Life Sciences sector in Australia and New Zealand. She is a recognised leader in the sector, having won the Lawyers Weekly Partner of the Year for Health in 2016 and 2017, achieved a Band 1 individual ranking in the Life Sciences Category in Chambers Asia Pacific, a listing in the 2018 Legal 500 (Intellectual Property) and in Best Lawyers (Life Sciences).
3. Within the Australian therapeutic goods industry, Dr Nicoletti's expert team is widely regarded as leading the field in all aspects of Australian medicinal cannabis law and regulation. In particular, the team has extensive experience advising a range of clients with respect to the various Commonwealth and state/territory laws and regulatory structures and processes applicable to the cultivation and production of cannabis plants, and the manufacture and supply of medicinal cannabis products.

Introductory comments

4. We appreciate the opportunity to make submissions to this review (**Review**) of the *Narcotic Drugs Act 1967* (**Act**).
5. At a commercial level, we act for several industry stakeholders including cultivators, manufacturers, importers, distributors, researchers, medical practitioners and advocacy groups. In addition, we have assisted a number of individual Australian patients and/or their families on a *pro bono* basis, to apply for and obtain medicinal cannabis for the treatment or management of a variety of medical conditions, in a range of clinical contexts.
6. Having worked with the medicinal cannabis regulatory framework since its inception, we have a deep understanding as to how the framework operates and its limitations.
7. Our submissions, including our detailed comments in respect of each of the Terms of Reference are set out below.

Background to the Review

8. In order to put our submissions in the appropriate context, this section provides some background information in relation to the medicinal benefits of cannabis, its demand in Australia, and the relationship between cannabis and the law, both within Australia and internationally.

The Medicinal Benefits of Cannabis

Science, Cannabis and Medicinal Benefits

9. Cannabis, derived from the plant *Cannabis sativa*, contains approximately 100 chemical constituents named 'cannabinoids'. The most well-known cannabinoids are cannabidiol (**CBD**) and *delta*-9-tetrahydrocannabinol (**THC**), with THC being the first cannabinoid to have been isolated for scientific research in 1964 and the key psychoactive constituent.[1] Research throughout the 20th century uncovered the intricate endocannabinoid system which comprises several biochemical receptors throughout the human brain and body upon which cannabinoids were observed to act and produce a variety of therapeutic and psychoactive effects.[2] Different strains of cannabis contain different quantities and types of cannabinoids and thus different plant strains may offer different therapeutic benefits and/or psychoactive profiles.[3]

10. Cannabis for therapeutic or medicinal use comes in three distinct forms: pharmaceutical preparations, standardised herbal preparations and herbal (non-standardised) cannabis. Pharmaceutical preparations of cannabis contain specific, known quantities of synthetic or naturally-derived cannabinoids and have been developed and tested by pharmaceutical companies for approval by National regulatory bodies like the Therapeutic Goods Administration (**TGA**) in Australia. Although the therapeutic effects of pharmaceutical preparations are reliable and well-documented, pharmaceutical cannabis preparations are also likely to be very expensive for patients.

11. Standardised herbal preparations of cannabis are produced in controlled conditions from cultivation (so that the cannabinoid concentration of plants is kept constant) to manufacture (so that the final product strength and composition remains constant).[4] Herbal (non-standardised) cannabis, or illicit cannabis, contains unknown quantities and types of cannabinoids and may be contaminated with mould, heavy metals or pesticides.[5] On this basis, herbal cannabis is not recommended for medicinal use because such impurities and inconsistencies in chemical profile may be dangerous for patients.

12. Pharmaceutical preparations of cannabis are generally designed for oral administration (*e.g.* capsules and tablets)[6] however studies involving medicinal

[1] E Russo, 'Taming THC: potential cannabis synergy and phytocannabinoid-terpenoid entourage effects' (2011) *British Journal of Pharmacology* 1344.
[2] D Piomelle and E Russo, 'The cannabis sativa versus cannabis indica debate: an interview with Ethan Russo, MD' (2016) 1(1) *Cannabis and Cannabinoid Research* 44, 45.
[3] *Background on Cannabis and its medicinal use* (10 Feb 2016) Australian Government Department of Health <http://www.health.gov.au/internet/ministers/publishing.nsf/Content/5E437BF8715C3EBACA257F540078A07A/$File/Background%20on%20Cannabis%20and%20its%20medicinal%20use.pdf>, 1.
[4] A Hazekamp, 'An evaluation of the quality of medicinal grade cannabis in the Netherlands' (2006) 1(1) *Cannabinoids* 1, 4.
[5] Ibid, 7.
[6] K Sharkey, N Darmani, and L Parker, 'Regulation of nausea and vomiting by cannabinoids and the endocannabinoid system' (2014) 722 *European Journal of Pharmacology* 134, 142; P Whiting et al., 'Cannabinoids for Medical Use: A Systematic Review and Meta-analysis' (2015) 313(24) *The Journal of the American Medical Association 2456,* 2459.

cannabis have investigated administration by oromucosal spray,[7] tincture or ointment, or vaporisation.[8] Based on evidence of the adverse effects associated with smoking, smoking of cannabis is not recommended for medicinal use.[9]

13. There is clinical evidence which shows that THC and CBD can be used in the treatment of AIDS/HIV,[10] Alzheimer's disease,[11] chemotherapy-induced nausea and vomiting (CINV),[12] cancer,[13] diabetic peripheral neuropathy,[14] epilepsy,[15] multiple sclerosis (MS)[16] and anxiety and depression.[17] There is also some evidence that THC and CBD may assist in the symptomatic relief of chronic pain,[18] glaucoma,[19] Tourette syndrome[20] and sleep disorders.[21]

Patient Demand for Access to Medicinal Cannabis

14. There has been increasing social and political demand for access to medicinal cannabis by Australian patients, which has particularly intensified over the past decade. In 2013, a General Purpose Standing Committee established by New South Wales (**NSW**) Parliament published a report on the use of cannabis for medical purposes.[22] The report observed, *inter alia,* strong public support for the facilitation of access to cannabis for medicinal purposes. Similarly, the National Drug Strategy Household Survey observed that most Australians supported both the use of cannabis for medicinal purposes in a clinical trial (73.5 % in 2004, 73.6 % in 2007, 74.0 % in 2010 and 75 % in 2013)[23] and the introduction of legislation to permit the use of cannabis for medicinal purposes (67.5 % in 2004, 68.6 % in 2007, 68.8 % in 2010 and 69.0 % in 2013).[24] Subsequently, in late 2014, the NSW Government announced that it would invest $9 million on clinical trials involving cannabis products over a period of five years.[25] In addition, NSW introduced the

[7] M Lynch and M Ware, 'Cannabinoids for the Treatment of Chronic Non-Cancer Pain: An Updated Systematic Review of Randomized Controlled Trials' (2015) 10(2) *Journal of Neuroimmune Pharmacology* 293, 295.
[8] M Wallace et al., 'Efficacy of Inhaled Cannabis on Painful Diabetic Neuropathy' (2015) 16(7) *The Journal of Pain* 616, 625.
[9] A Gordon, J Conley and J Gordon, 'Medical Consequences of Marijuana Use: A Review of Current Literature' (2013) 15 *Current Psychiatry Reports* 419-430; L Zhang et al., 'Cannabis smoking and lung cancer risk: Pooled analysis in the International Lung Cancer Consortium' (2015) 136(4) *International Journal of Cancer* 893-904
[10] Victorian Law Reform Commission, *Medicinal Cannabis: Report*, Report No 32 (August 2015), 39 and 64.
[11] L Eubanks et al., 'A molecular link between the active component of marijuana and alzheimer's disease pathology' (2006) 3(6) *Molecular Pharmaceutics* 773, 775.
[12] Lynch and Ware, above n 7, 295 and 299.
[13] Whiting et al, above n 6, 2460.
[14] J Croxford and T Yamamura, 'Cannabinoids and the immune system: Potential for the treatment of inflammatory diseases?' (2005) 166(1) *Journal of Neuroimmunology* 3, 12.
[15] M Tzadok et al., 'CBD-enriched medical cannabis for intractable paediatric epilepsy: The current Israeli experience' (2016) 35 *Seizure* 41, 43.
[16] Croxford and Yamamura, above n 14; Whiting et al., above n 6, 2461 and 2465.
[17] Whiting et al., above n 6, 2463.
[18] Lynch and Ware, above n 7, 293-299.
[19] T Jarvinen, D Pate and K Laine, 'Cannabinoids in the treatment of glaucoma' (2002) 95 *Pharmacology & Therapeutics* 203, 215.
[20] Whiting et al., above n 6, 2464.
[21] Ibid.
[22] General Purpose Standing Committee No. 4, New South Wales Parliament, *The use of cannabis for medical purposes: Report,* No 27 of 2013, 15 May 2013.
[23] *AIHW National Drug Strategy Household Survey Detailed Report 2013* (2014) Australian Institute of Health and Welfare, 115.
[24] Ibid.
[25] ABC, *Medical cannabis: Queensland, Victoria and New South Wales join forces on cannabis oil in medical trials* (19 April 2015) ABC News http://www.abc.net.au/news/2015-04-19/queensland-victoria-join-nsw-medicinal-cannabis-trial/6403760; and D Dumas, *World first as NSW trials medical cannabis on children with severe epilepsy* (27 October 2015) The Sydney Morning Herald (online) http://www.smh.com.au/nsw/world-first-as-nsw-trials-medical-cannabis-on-children-with-severe-epilepsy-20151027-gkjntb.html.

Terminally Ill Cannabis Scheme (**TICS**) under which police are not compelled to charge terminally ill patients or their carers who use cannabis to relieve symptoms.[26]

15. In February 2015, the Australian Senate referred the proposed Regulator of Medicinal Cannabis Bill 2014 to the Legal and Constitutional Affairs Legislation Committee. Shortly after, in June 2015, Sydney University received $33.7 million to commence a long-term scientific and clinical research program (the 'Lambert Initiative') which is dedicated to developing and testing standardised medicinal cannabis products for a variety of conditions and diseases.[27] Also in June 2015, NSW Premier Mike Baird pledged $12 million over four years to create the Centre for Medicinal Cannabis Research and Innovation.[28]

16. In August 2015, the Victorian Law Reform Commission issued a report on medicinal cannabis which considered, *inter alia,* testimonials from Australian patients who had used, or were using, cannabis for medicinal purposes. Among the testimonials, there was evidence that cannabis was already being used in Australia for chronic pain,[29] MS,[30] epilepsy[31] and in patients with terminal cancer.[32] Michelle Whitelaw was one of many Australians who shared her own positive experiences with the Commission because her son, who suffers from multiple forms of epilepsy, had reportedly suffered only three clinical seizures in over five months after beginning medicinal cannabis therapy – a reduction from approximately 75,000 seizures.[33]

Cannabis and the Law

International obligations

17. Australia is a party to three significant international agreements which concern the supply and use of narcotic drugs (including cannabis). Primarily, the *Single Convention on Narcotic Drugs 1961*[34] (**Single Convention**) requires signatories to prevent abuse and diversion of narcotic substances by limiting cultivation, production, manufacturing and other activities (including use and possession), but permits the provision of narcotic substances for medical and scientific purposes, subject to adequate controls, and specifically carves out of its scope of operation cannabis for industrial or horticultural purposes.[35] The Single Convention is implemented into Australian law by a number of instruments at the Commonwealth and state/territory level, primarily, at the former, by the Act.

18. In addition, Australia is a party to the *Convention on Psychotropic Substances 1971*[36] which describes the obligations of parties to facilitate the use of psychotropic substances for medical and scientific purposes (and to limit their availability for

[26] *Terminal Illness Cannabis Scheme: Fact sheet for adults with a terminal illness and their carers* (2015) NSW Government http://www.nsw.gov.au/tics.
[27] *The Lambert Initiative for Cannabinoid Therapeutics* (2016) The University of Sydney http://sydney.edu.au/science/lambert.
[28] *Centre for Medical Cannabis Research and Innovation* (2015) NSW Ministry of Health http://www.health.nsw.gov.au/cannabis/Pages/research-and-innovation.aspx.
[29] Victorian Law Reform Commission, above n 10, 26 and 37.
[30] Ibid, 23.
[31] Ibid, 66; *Submission 71 to the Victorian Law Reform Commission*, Michelle Whitelaw (31 May 2015).
[32] Ibid, 7; *Submission 65 to the Victorian Law Reform Commission*, Robert Wisbey (21 May 2015).
[33] Submission 71, above n 31.
[34] *Single Convention on Narcotic Drugs 1961*, opened for signature 30 March 1961, 520 UNTS 204 (entered into force 13 December 1964), as amended by the *1972 Protocol amending the Single Convention on Narcotic Drugs 1961*.
[35] Ibid, Art 2; and Art 28 for cannabis cultivation specifically.
[36] *Convention on Psychotropic Substances 1971*, opened for signature 21 February 1971, 1019 UNTS 175 (entered into force 16 August 1976).

other use(s)), and the *United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances 1988*,[37] which aims to promote cooperation between parties to address the illicit trafficking of narcotic drugs and psychotropic substances.

19. The Commonwealth Government is ultimately accountable for ensuring that any national, state or territory scheme for the cultivation, production, manufacture or supply of cannabis and products derived from cannabis is consistent with Australia's international obligations, including where responsibility for regulating aspects of the regime is devolved to the states and territories (as it is in relation to industrial cannabis). As a signatory to the Single Convention, Australia is obliged to regularly provide information to the International Narcotics Control Board (**INCB**) such as annual estimates of harvest areas and yields, amount of raw material and refined products in stock, amounts required for importation and relevant trends in use for medicinal purposes.[38] Failure to meet such international obligations poses certain diplomatic and economic risks, including potential damage to Australia's international reputation (in particular, for its progressive, balanced and comprehensive approach to dealing with the problems posed by the use and misuse of drugs in the community).[39]

20. Critically, the legal and policy issues that arise in relation to medicinal cannabis can be readily differentiated from those applying to the regulation of cannabis for non-medical purposes. The priorities, considerations and challenges which affect decisions in relation to medicinal cannabis differ significantly from those for non-industrial, recreational or other use. [40]

21. In our view, any discussion of medicinal cannabis should be underpinned by the *International Convention on Economic, Social and Cultural Rights* (**ICESCR**), which states that everyone has the right to the highest attainable standard of physical and mental health,[41] and to the *Australian Charter of Healthcare Rights* which provides that all Australian patients have the right to receive safe and high quality care in an effective continuum.[42]

Regulation of Cannabis by the Commonwealth

22. Not surprisingly having regard to Australia's international obligations, cannabis and cannabis-related activities are tightly controlled in Australia. The cultivation, production, manufacture, import, export, distribution, trade, possession, use and supply of cannabis and cannabis-derived products are, like other narcotic drugs and their derived products, regulated by several state/territory and Commonwealth laws:[43]

    (a) As a starting point, the *Criminal Code 1995* (Cth) and separate state and territory crime, drug misuse and/or drug/poison control legislation generally

[37] *United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances 1988*, opened for signature 20 December 1988, 2138 UNTS 214 (entered into force 11 November 1990).
[38] Ibid Arts 18-20; Explanatory Memorandum, Narcotic Drugs Amendment Bill 2016 (Cth), 7.
[39] Explanatory Memorandum, Narcotic Drugs Amendment Bill 2016 (Cth), 6.
[40] For example, see, R Pacula et al., 'Developing public health regulations for marijuana: Lessons from alcohol and tobacco' (2014) 104(6) *American Journal of Public Health* 1021.
[41] *International Covenant on Economic, Social and Cultural Rights*, opened for signature 16 December 1966, 993 UNTS 3(entered into force 3 January 1976)
[42] ACSQH, *Australian Charter of Healthcare Rights* (2008) Australian Commission on Safety and Quality in Health Care < https://www.safetyandquality.gov.au/wp-content/uploads/2012/01/Charter-PDf.pdf>; The University of Sydney Community Placement Program in Partnership and MGC Pharmaceuticals, *Medicinal Cannabis in Australia: Science, Regulation & Industry*, White Paper (2016).
[43] Ibid, 6.

make it illegal to traffic, import, export, manufacture, cultivate or possess cannabis or cannabis products.[44]

(b) On the other hand, the Act permits the cultivation and production of cannabis[45] and the manufacture of drugs comprising or derived from cannabis or its constituent parts,[46] but in so doing it observes Australia's obligations under the Single Convention by ensuring those activities are closely controlled.

(c) The *Customs Act 1901* (Cth) addresses the import[47] and export[48] of narcotic substances generally, and the *Customs (Prohibited Imports) Regulations 1956* (Cth) provides a mechanism for the importation of cannabis for medical and scientific purposes subject to the appropriate licence and permit(s).[49]

(d) The *Therapeutic Goods Act 1989* (Cth) and complementary state and territory legislation regulates the availability of medicines and other therapeutic goods in Australia.[50]

(e) The states and territories, through drug misuse, poison/drug control and/or hemp-specific legislation, license and control the cultivation, production and manufacture of industrial cannabis / hemp and its derivative products.[51]

[44] See, for example, *Drugs, Poisons and Controlled Substances Act 1981* (Vic) and *Therapeutic Goods Act 2010* (Vic); *Controlled Substances Act 1984* (SA); *Drugs of Dependence Act 1989* (ACT) and *Criminal Code Regulation 2005* (ACT); Misuse of Drugs Act 2001 (TAS) and *Poisons Act 1971* (TAS); *Cannabis Law Reform Act 2010* (WA) and *Misuse of Drugs Act 1981* (WA); *Drug Misuse and Trafficking Act 1985* (NSW); *Drugs Misuse Act* (QLD) and *Police Powers and Responsibility Act 2000* (QLD); and *Misuse of Drugs Act* (NT).
[45] *Narcotic Drugs Act 1967* (Cth), Ch 2 Pt 2 Div 1-2.
[46] Ibid, Ch 3 Pt 2 Div 1-3.
[47] Ibid, s 49.
[48] Ibid, s 112.
[49] *Customs (Prohibited Imports) Regulations 1956*, r 5.
[50] *Therapeutic Goods Act 1989* (Cth), Pts 3-1 and 3-2.
[51] See, for example, the *Hemp Industry Act 2008* (NSW).

MILLS OAKLEY

Submissions

Term of Reference #1

To consider and make recommendations on the efficiency and effectiveness of the structure of the licensing and permit regimes and other restrictions in the Act in controlling the supply of narcotic drugs and options to reduce the regulatory burden on affected parties, whilst still achieving the object of the Act.

Licensing, Permits and Supply

23. The 2016 amendments to the Act established a national licensing scheme for the cultivation of cannabis plants, and the production of cannabis and cannabis resin, for medicinal and scientific purposes. In addition, the amendments consolidated the existing licensing scheme for the manufacture of all narcotic drugs, including cannabis.

24. In particular, the Act provides for three types of licences:

    (a) 'Medicinal Cannabis Licences', which authorise cannabis cultivation and production for therapeutic use;

    (b) 'Cannabis Research Licences', which authorise cannabis cultivation and production for the purpose of research relating to medicinal cannabis (including research into growing conditions, cannabinoid yields from different strains and other matters relating to producing safe and predictable medicinal cannabis for human use); and

    (c) 'Manufacture Licences', which authorise the manufacture of narcotic drugs, including medicinal cannabis products, for use in research and/or supply for therapeutic use.

25. Prior to undertaking an authorised activity, a licence holder under the Act must also obtain a permit which may specify matters such as the type and quantity of cannabis plant that may be cultivated or medicinal cannabis products which may be manufactured.[52]

26. Licences and permits are both issued by (or under the delegated authority of) the Secretary of the Department of Health (**Secretary**), having regard to the matters and subject to the conditions outlined in the Act and *Narcotic Drugs Regulation 2016* (Cth) (**ND Regulation**).[53]

27. Criminal penalties, including up to 10 years imprisonment, apply to a breach of the Act or a licence condition.[54]

28. Essentially, the Act ensures the Department of Health, particularly the Office of Drug Control (**ODC**), can regulate (or at least co-regulate with other Government authorities) every step in the medicinal cannabis supply chain.

Cultivation and Production licence categories

29. Cannabis cultivated and/or produced under a Cannabis Research Licence may not be used in humans (experimentally or otherwise). This, understandably, allows persons who intend only to cultivate and produce cannabis for use other than in humans certain advantages, such as less expensive application fees and fewer, less onerous requirements in relation to the activities permitted under the licence.

[52] ss 9B, 10A and 12C.
[53] See, for example, ss 8F, 8G, 9E, 9F, 11H and 11J.
[54] Ibid, ss 11C and 11E.

30. The approval criteria applicable for obtaining, and the conditions imposed upon the holder of, a Medicinal Cannabis Licence are far more stringent. However, even where an applicant satisfies the criteria to be granted a Medicinal Cannabis Licence, in order to supply cannabis material just for research purposes, that licensee is required to obtain a separate Cannabis Research Licence and permits thereunder. In our view, this is an unnecessary duplication of time, effort, funds and resources by licensees and the ODC.

31. First, beyond the additional costs, the significant amount of time and required to complete an additional licence application is likely to discourage commercial industry participants from considering and thus engaging in research.

32. In our experience, research licensees are able to progress their applications and commence their operations more quickly (because the complementary state and territory requirements are less onerous and because the TGA is not involved). As a result, Cannabis Research Licensees with finished facilities are able to cultivate and produce cannabis with relative ease, compared to Medicinal Cannabis Licensees who may also have finished facilities, but are awaiting state, territory and/or TGA approvals, either for themselves or in respect of the persons to whom they propose to supply cannabis or cannabis resin.

33. By way of example, in New South Wales, in order to obtain a Cannabis Research Permit, a Cannabis Research Licensee requires:

    (a) a contract with a researcher or institution who holds a NSW authority (under the *Poisons and Therapeutic Goods Act 1966* (NSW) or the *Drug Misuse and Trafficking Act 1985* (NSW)) to possess and use cannabis (S9) for research; and

    (b) a NSW authority to supply cannabis (S9) for research.

34. A NSW authority does not incur a fee and is ordinarily processed in 4 to 6 weeks. Alternatively, a Cannabis Research Licensee can conduct in-house research without obtaining any external authorities.

35. In contrast, in order to obtain a Medicinal Cannabis Permit, a Medicinal Cannabis Licensee requires:

    (a) a Manufacture Licence under the Act, or a contract with another person who has one; and

    (b) a NSW Manufacture and Wholesale Supply licence to possess, manufacture and supply cannabis (S8) for therapeutic purposes, or a contract with a person who has one.

36. Importantly in this regard, a person with a Manufacture Licence under the Act cannot enter into an arrangement with a Medicinal Cannabis Licensee unless there is an arrangement in place for the manufacture and supply of a finished medicinal cannabis product to consumers (*i.e.* patients). However, the significant barriers to access to medicinal cannabis products in Australia have prevented the proliferation of any such agreements and in turn, the granting of any Medicinal Cannabis Permits.

37. Furthermore, to the best of our knowledge, there is no person in NSW with a Manufacture and Wholesale Supply licence, and the process for obtaining one of these requires, among other things, the preparation of a Drugs and Poisons Control Plan which includes a finished product specification. Having regard to the lack of patient demand described above, the development of a product specification in the absence of apparent interest in such a product is commercially premature and as

such, it is unlikely that the number of Manufacture and Wholesale Supply licences in NSW will grow in the foreseeable future.

38. Our more detailed comments in respect of the Manufacture Licence regime are set out in the following section.

39. Notwithstanding these broader issues, the availability and supply of cannabis for research purposes would improve considerably if Medicinal Cannabis Licensees were able to cultivate and produce cannabis or cannabis resin for either commercial or research purposes. For example, if a Medicinal Cannabis Licensee was able to cultivate cannabis for the interim period after obtaining a licence under the Act but before satisfying all other requirements to obtain a Medicinal Cannabis Permit, the licensee would benefit from being able to trial its facility and the resulting cannabis could be supplied for promising pre-clinical research.

40. Although mixed use crops are not presently permitted under the Act, in our view, this should not prevent Medicinal Cannabis Licensees from being able to cultivate and produce cannabis or cannabis resin for research purposes only, if they so choose. On this basis, we recommend that Medicinal Cannabis Licensees should be able to apply for both Cannabis Research Permits and Medicinal Cannabis Research Permits under the Act.

Manufacture Licences and demonstrating legitimate supply

41. As foreshadowed above, in our view, there are serious issues arising from the jurisdictional overlap of the TGA, ODC and state and territory governments in respect of manufacture, such that the regime for Manufacture Licences under the Act is effectively unserviceable in isolation.

42. Under the Act, in its application for a permit, a licence holder must specify the details of the next party in their proposed supply chain by providing a copy of the agreement between those two parties.[1]

43. Although this requirement appears to mandate the organisation of only one party, being the one party ahead of the applicant in the proposed supply chain, the roll-on effect is that an applicant is required to demonstrate an entire supply chain (*e.g.* from cultivation to distribution to patients/consumers) before it will be issued a medicinal cannabis permit.

44. In our view, to do this (establish a complete supply chain) for cannabis for research purposes is not unduly onerous. This is likely because:

    (a) the provisions of the Act which relate to cultivation and production operate to the exclusion of all of state and territory laws which purport to regulate the same. As such, the ODC has sole jurisdiction over Medicinal Cannabis Licensees and Cannabis Research Licensees; and

    (b) as described above in respect of NSW, the requirements at the state and territory level are not particularly numerous or complex. Namely, each party in the supply chain (other than a Cannabis Research Licensee) may require, at a maximum, an authority or permit from the state or territory government to possess, use and possibly even manufacture cannabis for research purposes.

45. By way of comparison, to establish a complete supply chain for medicinal cannabis products which are intended for therapeutic use, whether domestically or overseas, is overwhelmingly complex.

[1] Memorandum – Importing cannabis seeds or nursery stock for cultivation

46. In order to obtain a permit under a Manufacture Licence under the Act to manufacture a medicinal cannabis product (*e.g.* cannabis oil) for therapeutic use, we have established that the applicant must have:

    (a) a Medicinal Cannabis Licence, or an agreement with a person with one, which authorises the supply of cannabis to the Manufacture Licensee;

    (b) a state or territory Manufacture and Wholesale Supply Licence to manufacture medicinal cannabis in their relevant state or territory; and

    (c) an agreement in respect of its supply of the oil for a prescribed purpose.

47. In relation to (c) above, the Act requires that a medicinal cannabis product be supplied in accordance with the TG Act. Within Australia, this includes supply under the Special Access or Authorised Prescriber schemes, however, supply through these avenues relies on the particular prescriptions of individual practitioners to their patients and, as such, has not, and is unlikely to, generate sufficient demand to warrant a Manufacture Licensee under the Act fulfilling the requirements of (a) to (c) above for the purpose of obtaining a permit.

48. In order to obtain a permit to supply medicinal cannabis outside of Australia (by export), in addition to the requirements in (a) to (c) above, the Manufacture Licensee must have:

    (a) a GMP Licence granted under the TG Act, or a contract with a person who has one;

    (b) an export licence (and eventually a permit) under the *Customs (Prohibited Exports) Regulations 1958*; and

    (c) eventually, a listing in the Australian Register of Therapeutic Goods for the medicinal cannabis product which is intended for export – whether as a starting material (ingredient) or a finished product.

49. Having regard to all of the above, the effect of a Manufacture Licence under the Act is overwhelmingly stifled by the surrounding laws and regulations which separately apply to cannabis as a therapeutic good, schedule 8 poison (when for therapeutic use) and prohibited export. In turn, as Medicinal Cannabis Licensees are unable to obtain a permit to cultivate and produce cannabis until they have an established relationship with a manufacturer (ordinarily being the next party in their proposed supply chain), all commercial cultivation, production and manufacture activities are hamstrung.

50. In this regard, it is critical that the Review acknowledges the interaction of the Act, particularly with respect to commercial supply activities, with the various existing legal and regulatory regimes which inescapably influence the operation of the Act in practice, despite falling outside the Terms of Reference.

51. On the one hand, this has caused smaller industry participants to reach a standstill, and on the other hand it has driven the more sophisticated industry participants to develop ‘closed loop’ supply chains, whereby they intend to retain responsibility and control over cannabis from initial cultivation, through manufacture under the Act and manufacture into a finished product under the TG Act. Having regard to the lack of domestic demand described above, these industry participants will most likely be targeting supply by way of export.

52. If it is intended that the Act continues to operate concurrently with the other regimes, cooperation between the relevant regulators must improve. The requirements listed above are mandated by the legislation and, accordingly, the

regulators should be familiar with their role in the overall process and prepared to handle enquiries in respect of them.

53. To the contrary, in our experience, the Drug Control Section of the ODC has been unable to provide guidance on the GMP requirements for manufacturers – despite that requirement arising under the Act and, in turn, the GMP section of the TGA has been unable to provide advice on their expectations in respect of cannabis – which is unique to any other pharmaceutical starting material ordinarily under assessment.

54. Furthermore, the expectations at each 'level' have been frustratingly circular. For example, in order to obtain a NSW Manufacture and Wholesale Supply licence an applicant must provide a finished product specification for the product which they propose to manufacture. However, the cannabinoid concentration of cannabis plants varies for a number of reasons and to develop a finished product specification, in many cases, a person needs to cultivate cannabis and manufacture a batch to characterise the specification. However, in order to cultivate or manufacture cannabis under the Act, a licensee requires a permit – which they cannot obtain without a NSW Manufacture and Wholesale Supply licence.

55. Similarly, a finished product specification is required to obtain a listing in the ARTG for export, however, a person is required to enter into an agreement to supply a product by export, even before it can obtain a licence to manufacture the product. This kind of contract is undoubtedly premature in a commercial context and has the potential to leave Australian parties liable if they are unable to arrange all of the other requirements they need to fulfil their obligations under such a contract.

56. In our view, as all of the above-described requirements arise under the Act, being preconditions to a Manufacture Licensee being granted a permit, we are of the view that the Drug Control Section should be able to communicate directly with the TGA and state and territory health departments (as applicable) and provide guidance on the requirements for applicants. If the Drug Control Section is not in a position to do so, in our view, it should not be a precondition to a permit that these separate requirements are satisfied – acknowledging that the obligations will persist at law nonetheless.

Licence requirements and conditions

Authorised Persons

57. The activities which a person may obtain a licence to undertake are set out in general terms sections 8E, 9D and 11G of the Act (as applicable). A licence granted under the Act ordinarily replicates these activities (as applicable) on its face, indicating that the licence holder is authorised ('licensed') to undertake those activities, in accordance with the conditions of the licence.

58. Relevantly, one condition of a licence under the Act is that the licence-holder will take all reasonable steps not to employ or engage persons who are not suitable.[55] This includes, among other things, persons who are under 18 years of age, have not been convicted of a serious offence or who have a drug addiction, or are being treated for such.

59. In our view, it follows that a licence holder is authorised to conduct the activities stated on their licence and to employ suitable staff, in accordance with the Act, to assist the licence holder in doing so, including when the licence holder is not physically present.

[55] ss 10F and 12H.

60. Unfortunately, the ODC has taken the contrary view that only 'authorised persons' who are specifically listed by name on a licence may undertake licensed activities when the licence holder is not physically present.

61. By way of example, one of our clients has a cultivation and production licence under the Act which states, after the list of authorised persons:

> *'…any other person/s conducting or undertaking activities authorised under the licence must do so under the supervision of a person authorised to engage in such activities at the licenced premises.'*

62. In our view, in a modern world where people and communications are mobile, '*supervision'* in this context can sensibly – and should – be construed to mean that a person (already required to have been employed in accordance with the licence and the Act) may conduct activities authorised by the licence under the guidance and oversight of an authorised person, which may involve a reasonable degree of remoteness, and should not involve the constant physical presence of the supervisor.

63. Notably, this interpretation is consistent with that taken by the ODC in respect of manufacture licences – see the following note in comparison:

> *'Note that other persons may undertake the authorised activities if they are employed or engaged under the processes provided by the licence holder to the Office of Drug Control, and that such employment or engagement complies with the condition of a manufacture licence that the licence holder employ or engage suitable staff, as prescribed in the circumstances under section 12H of the Act and section 39 of the Regulation' (**Qualification**).*

64. It would therefore appear that the ODC is of the inconsistent view that the obligations of 'authorised persons' are different under cultivation and production licences, compared to manufacture licences, despite no specific wording in the legislation to support this.

65. In our view, requiring a list of 'authorised persons' to be stated on every licence under the Act is not practically or commercially feasible. Having regard to the fluid employment environment to which developing businesses are generally exposed (i.e. the retention of personnel), it is far too onerous and impractical for licensees to require all personnel who are involved, or may be involved, in undertaking licensed activities unaccompanied to be named on the licence, especially having regard to the protracted timelines for making changes.

66. In our view, as a matter of sense and commercial practicality, any person employed by a licensee in accordance with the Act should be lawfully able to conduct activities authorised by a licence, in accordance with the terms of their employment, under the guidance and oversight of an 'authorised person' as stated on the licence, including where the supervising person is not physically present but provides sufficient guidance and oversight through other communication and monitoring mechanisms.

<u>Export</u>

67. The ND Regulation was amended in early 2018 to create three possible pathways for cultivators, producers and manufacturers licensed under the Act to supply 'simple' cannabis products (*e.g.* dried flower and resin) or 'refined' cannabis products (*e.g.* cannabis oil) by way of, or for the purpose of, export.

68. In particular, the ND Regulation presently anticipates the following possible export pathways:

Pathway 1: s 7B	Cultivators and producers licensed under the Act may supply cannabis or cannabis resin to the holder of a GMP licence for use in the manufacture by the GMP licensee of a medicine for export from Australia;
Pathway 2: s 37(b)	Manufacturers licensed under the Act may manufacture a medicinal cannabis product and supply it by way of export; and
Pathway 3: s 37(c)(ii)	Manufacturers licensed under the Act may manufacture a medicinal cannabis product and supply it to the holder of a GMP licence for use in the manufacture by the GMP licensee of a medicine for export.

Note: A 'GMP licence' is a manufacture licence granted under Part 3-3 of the *Therapeutic Goods Act 1989* (Cth) (**TG Act**).

69. The legal basis for each of the pathways summarised above is deceptively more complex than the ND Regulation suggests and this, among other things, is likely to have contributed to the lack of progress across the Australian industry to commence export, despite significant international interest.

70. Some aspects of the export scheme of particular concern, in our view, are set out below.

71. Firstly, all of the possible export pathways require the involvement of a GMP licensee. Although this is obvious in Pathways 1 and 3 above, a closer analysis of the relevant legislation reveals that Pathway 2 also requires the application of GMP licensing requirements – despite the fact that the ND Regulation does not specify it.

72. This is because any medicinal cannabis product under the Act is necessarily also a 'therapeutic good' for the purposes of the TG Act (being, or intended to be, a therapeutic good, or ingredient thereof).[56] Part 3-3 of the TG Act provides that a person must hold a GMP licence to carry out any step in the manufacture of a medicine unless the medicine and/or the manufacturer are/is exempt.

73. Although medicines which are supplied under exemption schemes such as the Authorised Prescriber scheme and Special Access scheme are exempt, there is no relevant exemption for medicines supplied by export. Accordingly, any person who 'manufactures' (for the purposes of the TG Act) a medicinal cannabis product is required to hold a GMP licence (unless they will supply to another person with a GMP licence).[57]

74. This is significant because:

    (a) GMP requirements are extremely onerous – as far as we are aware there is no one with an appropriate GMP licence for cannabis yet;

[56] Section 3 of the TG Act provides: "therapeutic goods means goods: (a) that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be: (i) for therapeutic use; or (ii) for use as an ingredient or component in the manufacture of therapeutic goods…" and "therapeutic use means use in or in connection with: (a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons; or (b) influencing, inhibiting or modifying a physiological process in persons; or…".

[57] Item 2 of Schedule 7 of the *Therapeutic Goods Regulations 1990* (Cth) provides that "herbs… or oils extracted from herbs, the sole therapeutic use of which is as starting materials for use by [GMP] licensed manufacturers" are exempt from Part 3-3 of the TG Act (**HSM Exemption**). It is our view that cannabis would be a 'herb' for the purposes of the HSM Exemption.

(b) The standard is inconsistent – GMP standards are not required for domestic patients (under the exempt schemes) yet they are required for export;

(c) Many countries do not regulate cannabis as a medicine and for the purpose of exporting to those countries GMP is not relevant and not required.

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Provision of information and administration

Term of Reference #2

To consider and make recommendations on the efficiency and effectiveness of the obligations in the Act relating to the provision of information and other administrative requirements and options for reducing the regulatory burden on affected parties, whilst still achieving the object of the Act.

Application processes

75. Under section 14J of the Act, the ODC may, by notice in writing, require an applicant for a licence or a permit, or for a variation of such a licence or permit, to give such further information or documents in relation to the application as the ODC reasonably requires.

76. We often assist our clients in drafting their responses to such requests and compiling the relevant information or documents. In our experience, the requests that our clients have received under s 14J, if in respect of the same kind of licence, have contained the same questions, usually in two or three tranches following submission of the original application. For example, the first request under s14J in relation to a Medicinal Cannabis Licence application under the Act will ordinarily contain the same, or similar questions for several clients.

77. On this basis, in our view, it is unclear why applicants cannot, at least, have the opportunity to supply as much of the information and documents which it is expected to hold at the initial application stage – rather than waiting for the subsequent requests.

78. In this regard, we note that it is increasingly popular to submit an application, regardless of its initial shortcomings, in order to secure a place in the "queue" of applications before the ODC. This is because the ODC assesses applications in the order in which they are received – notwithstanding the quality of the application.

79. It is becoming increasingly apparent, in our view, that applicants who submit a poor application in the first instance benefit in the longer term from additional guidance by the ODC, including by way of more detailed s 14J requests and responses. In our view, the time and resources required throughout this process, although potentially warranted for some applicants, should not be expended to the detriment of applicants who have dedicated their time and resources to preparing a robust application in the first instance.

80. In our view, the initial application process should require applicants to provide all of the information and documents presently required, in addition to the vast majority documents and information ordinarily requested through s 14J requests. Instead, we recommend that requests under s 14J are reserved for clarification on specific issues arising from the applicant's more comprehensive initial application.

81. Where the overall requirements for a licence application are clearly defined, applicants will be able to ensure that their initial applications are suitably comprehensive and robust. In turn, we are of the view that this would facilitate the lodgement and assessment of applications in an order which more appropriately reflects applicant readiness to commence activities.

82. Although the regulatory burden at the initial application may be understood to be higher, in totality, the substantive requirements would be identical, whereas the administrative burden would likely be reduced. In our view, this would enable applicants to plan their business activities more confidently and to prepare more consolidated applications.

Licence requirements and conditions

Fit and Proper Person Criteria

83. Generally, the Secretary has broad discretion as to whether to grant a Medicinal Cannabis Licence, Cannabis Research Licence or Manufacture Licence, however, the Secretary must refuse to grant a licence if they are not satisfied on reasonable grounds that the applicant, and each business associate of the applicant, is a "*fit and proper person"*.[58]

84. This decision is at the Secretary's discretion, although the ND Regulation states that the Secretary may have regard to matters such as any previous convictions, associations (including relatives), previous business experience or financial background of the applicant and whether they are generally of 'good repute' having regard to their character, honesty and professional and personal integrity (**Fit and Proper Person Criteria**).[59]

85. In practice, licence applicants under the Act are required to demonstrate that the Fit and Proper Person Criteria are satisfied by their company directors, officers, significant shareholders, business and/or otherwise relevant associates (as applicable)[60] each time they lodge an application with the ODC.

86. In our experience, several industry participants have applied for, or intend to apply for, multiple licences under the Act either at the outset or as additional resources and information become available to them. In these cases, the requirement to reproduce the same information on multiple occasions is unnecessarily onerous for the applicant and almost certainly contributes to the protracted processing periods which most applicants have experienced in the last 2 years.

87. Furthermore, it is a condition of all licences granted under the Act that the licence holder notifies the ODC upon becoming aware of any event or information which may affect their status as a fit and proper person to hold a licence under the Act, including events or information which affect the licence holder's relatives, business associates or similar.

88. In our experience, this has included, for example, the occasion of minor traffic offences after a licence has been granted and the revelation of a historical offence (more than 10 years previous) on a National Police Check produced by one agency but not another.

89. The process for notifying these matters to the ODC is not specified in the legislation but in any event, the management of such notifications has been poor. After notifying the ODC on behalf of a client of one matter in August 2018, we are still yet to receive formal confirmation that the ODC is of the view that the person concerned remains a fit and proper for the purposes of the Act.

90. Although we are confident that the ODC will not conclude otherwise in the above example, in other circumstances the absence of a formal reply from the ODC may:

    (a) cause persistent uncertainty for the stakeholders involved; and/or

    (b) create an opportunity for a licence holder to inadvertently continue to operate their business unlawfully, for potentially a long period of time, if the Secretary formed the view that a notification related to conduct of sufficient

[58] ss 8G and 9F.
[59] *Narcotic Drugs Regulation 2016* (Cth), rr 5(3) and 11(3); esp. rr 5(3)(l) and 11(3)(l).
[60] *Narcotic Drugs Act 1967* (Cth), ss 8G(1)(a)(ii) and 9F(1)(a)(ii).

seriousness to diminish that person's status as a fit and proper person under the Act – but did not advise the licence holder as such immediately.

91. In our view, there should be scope for applicants under the Act, whether a natural person or corporation, to only be required to comprehensively demonstrate satisfaction of the Fit and Proper Person Criteria, including by providing such documents as National Police Check certificates and/or Informed Consent forms (as appropriate) once. Thereafter, the ODC and applicants should be able to refer to and, if appropriate, rely on, information and documents which have already been provided to the ODC. If, despite this submission, an additional mechanism is considered necessary, we consider it sufficient for updated information to be provided by way of a simple declaration (e.g. that there have been no criminal charges or convictions since the provision of the original information).

92. Furthermore, in our view, a clear process for notifying the Secretary of matters, such as under sections 10K and 12N of the Act, is required to give proper effect to those obligations and allow other industry participants to operate with confidence.

Import

93. A Medicinal Cannabis Licence or a Cannabis Research Licence granted under the Act will authorise the licence holder to obtain a specified quantity of cannabis plants or seeds from a specified source, in order to commence cultivation or production.

94. In this regard, before applying for a Cannabis Permit, a Medicinal Cannabis Licence holder or Cannabis Research Licence holder must have made all commercial arrangements for the purchase and supply of cannabis seeds or nursery stock and obtained the corresponding licence(s) and/or authority(ies).

95. Where a licence holder intends to obtain seeds or nursery stock from overseas (which is, in our experience, most of the time), the licence holder must have obtained an import licence under regulation 5 of the *Customs (Prohibited Imports) Regulations 1956*. In order to be granted this kind of licence, the applicant must establish, among other things:

(a) that he/she is a fit and proper person to be granted a licence to import drugs;

(b) the persons (if any) that the Licence holder:

(i) has appointed, or proposes to appoint, as agents; or

(ii) has employed or proposes to employ;

for the purposes of the business carried on by him in relation to drugs, are fit and proper persons to be so appointed as agents or so employed; and

(c) the premises on which the Licence holder proposes to keep the drugs that will come within his possession during the currency of the licence are secure for that purpose.

96. These requirements clearly duplicate the requirements under the Act in respect of Medicinal Cannabis Licences and Cannabis Research Licences.

97. Therefore, in the relevant circumstances, the same information must be provided to the Medicinal Cannabis Section (of the ODC) under the Act as to the Drug Control Section (of the ODC) under the *Customs (Prohibited Imports) Regulations 1956*. In our view, this duplication only serves to waste time and prolong what could be a more efficient and effective process. Nevertheless, this could be overcome by improving the sharing of information within the ODC as described above.

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Other relevant matters

98. Although, strictly speaking, they fall outside the express Terms of Reference, we consider the following matters to be relevant to the review:

    (a) legal and regulatory barriers to the supply of medicinal cannabis to patients;

    (b) the proper operation of the industrial (low-THC) cannabis / hemp regime.

Supply of medicinal cannabis to patients

99. Although supply of medicinal cannabis remains outside the scope of the Act, the framework established by the Act is relevant to the framework(s) for supply, and we consider the following issues to be relevant to any Review of the Act and its operation.

100. Under the existing legal and regulatory framework for therapeutic goods in Australia, each state and territory is free to regulate supply within its respective jurisdiction. In this regard, the regulation of the supply of medicinal cannabis products may be, and appears to be becoming, separate and distinct in every state and territory. This is despite Australia having common mechanisms which operate effectively for all other unapproved medicines, even those with highly significant risk profiles.

101. We have previous experience with a client who was granted approval by the TGA's Chief Medical Officer under the Special Access scheme to obtain medicinal cannabis but was refused access by a decision maker in NSW Health (who was a non-practicing pharmacist with no clinical experience in medicinal cannabis whatsoever), on the basis of the same clinical evidence.

102. It may be that the additional 'red tape' at the state/territory supply level reflects a unique stigma attached to the prescription and supply of medicinal cannabis. As such, public education and awareness, and perhaps a greater measure of intergovernmental liaison (between relevant Commonwealth and state/territory health agencies), are vital to ensuring that the Australian public, patients and health practitioners are free to utilise the developing framework for medicinal cannabis in the absence of unwarranted scrutiny or cynicism from well-meaning, but inappropriately qualified, state/territory 'gatekeepers' of medicinal cannabis supply.

103. Furthermore, patients have reportedly been quoted up to $34,000 per year (*i.e.* approximately $93 per day) to access medicinal cannabis following TGA approval. On this basis, many patients could simply not afford treatment under the proposed arrangements and in such circumstances patients are most likely to resort to (or continue) sourcing cannabis for medicinal use through illegal channels. Having regard to the already substantial approval, operational and other costs associated with cultivating, producing and manufacturing medicinal cannabis under the Act however, it is unlikely that industry participants will be able to address issues of costs on their own and we suspect that fiscal policies such as price ceilings and government subsidies may be necessary to enhance patient access to legal medicinal cannabis in Australia.

104. However characterised, the barriers to patient access to medicinal cannabis have severely limited the domestic market thus far and will necessarily obstruct growth of the industry. Some consideration of these matters is thus critical to the Review in its broader context and necessary, among other reasons, to ensure that such barriers won't persist and undermine any modifications made to the Act in isolation as a result of the present Review.

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Regulation of industrial uses of low-THC cannabis / hemp

105. As a result of recent dialogue with the ODC, we are concerned that the ODC is taking an unnecessarily restrictive view of the proper scope of the exemption in the relevant international agreements – particularly the Single Convention – for the cultivation, production and manufacture of cannabis and cannabis products for industrial or horticultural purposes. In particular, we are concerned that the ODC appears to be taking a view that the supply by way of export of products lawfully produced/manufactured in accordance with applicable state/territory hemp regimes is not permitted by the Single Convention and/or the Act.

The Purpose of the Single Convention and its application under Australian law

106. The Preamble to the Convention states (emphasis added):

> ***"THE PARTIES,***
> ***CONCERNED*** *with the health and welfare of mankind,*
> ***RECOGNIZING*** *that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes,*
> ***RECOGNIZING*** *that addiction to narcotic drugs constitutes a serious evil for the individual and is fraught with social and economic danger to mankind,*
> ***CONSCIOUS*** *of their duty to prevent and combat this evil,*
> ***CONSIDERING*** *that effective measures against abuse of narcotic drugs require coordinated and universal action,*
> ***UNDERSTANDING*** *that such universal action calls for international cooperation guided by the same principles and aimed at common objectives,*
> ***ACKNOWLEDGING*** *the competence of the United Nations in the field of narcotics control and desirous that the international organs concerned should be within the framework of that Organization,*
> ***DESIRING*** *to conclude a generally acceptable international convention replacing existing treaties on narcotic drugs, limiting such drugs to medical and scientific use, and providing for continuous international cooperation and control for the achievement of such aims and objectives,*
> ***HEREBY AGREE as follows:***
> **…."**

107. It is clear from the preamble that the purpose of the Single Convention is to create a system of *"international cooperation and control"* for "*narcotic drugs, limiting such drugs to medical and scientific use", "recognising that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs "* but *"effective measure against abuse of narcotic drugs require co-ordinated and universal action" (*our emphasis added).

108. That being the case, it is our view that the giving of legal effect to the Single Convention under Australian law should recognise what aims and objectives the Single Convention was intended to achieve and not seek to place unnecessary and unwarranted controls on cannabis that is not narcotic.

109. The Single Convention is given legal effect under Australian law by the enactment of the *Narcotic Drugs Act 1967* which states, under section 2A:

> *The object of this Act is to give effect to certain of Australia's obligations under the Single Convention on Narcotic Drugs, 1961, as in force, from time to time.*

110. Giving effect to Australia's obligations under the Single Convention means, according to the preamble to the Single Convention, introducing measures by which narcotic drugs may be made available for medical or scientific use while ensuring effective measures against their abuse.

111. The *Narcotic Drugs Amendment Act 2016* (Cth) introduced a system of controls regulating the cultivation, production of medicinal cannabis in Australia. The Act relevantly provides that a person will not be granted a licence to cultivate, produce or manufacture cannabis if it is not intended to be used for medicinal cannabis.

112. That being the case, the Act does not, and is not intended to, regulate the cultivation, production and manufacture of cannabis for non-medicinal purposes, and the legal effect given to the Single Convention under Australian law does not extend to cannabis for non-medicinal cannabis purposes.

113. Irrespective of the above, the ODC has been fettering access to non-medicinal cannabis by, for example, refusing to grant export licences for cannabis that has not been manufactured under a manufacture licence issued under the Act.

114. The issue appears to stem from Schedule 1 of the Single Convention, which refers to 'extracts of cannabis' but does not define what those extracts cover. Further, the Single Convention defines 'cannabis' as "*the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted*", but does not differentiate between narcotic and non-narcotic forms of cannabis.

115. The simplistic view put forward by ODC is that pursuant to the Single Convention and its operation by virtue of the Act, a licence to extract a non-medicinal cannabis extract (other than an extract from seed) cannot be granted unless the extract is manufactured under a manufacture licence issued by ODC.

116. However, Article 28 paragraph 2 of the Single Convention says that the Single Convention "*shall not apply to the cultivation of the cannabis plant exclusively for industrial purposes (fibre and seed) or horticultural purposes*".

117. Further, Article 2 paragraph 9 of the Single Convention says that "*Parties are not required to apply the provisions of this Convention to drugs which are commonly used in industry for other than medical or scientific purposes*", provided that (among other things), the Parties "*ensure by appropriate methods of denaturing or by other means that the drugs so used are not liable to be abused or have ill effects… and that the harmful substances cannot in practice be recovered*".

118. Since, by their definition, non-narcotic forms of cannabis such as low-THC hemp are not "liable to be abused or have ill effects", then it would seem logical that the Single Convention was never intended to apply *"to drugs which are commonly used in industry for other than medical or scientific purposes*".

119. Taking this issue further, if the Single Convention does not to apply to certain substances, then it is irrelevant whether a term in Schedule 1 of the Single Convention would, on its face, include those substances.

120. Taking the above provisions together, it is clear that while 'extracts of cannabis' are drugs under schedule 1 of the Single Convention, the following extracts of cannabis are not:

(a) extracts of cannabis seeds only (because cannabis seeds not accompanied by the tops are not 'cannabis' in the first place);

(b) extracts of cannabis leaves only (because cannabis leaves not accompanied by the tops are not 'cannabis' in the first place);

(c) extracts of cannabis tops from which the resin has been extracted (because cannabis tops from which the resin has been extracted are not 'cannabis' in the first place);

(d) extracts of any part of the cannabis plant where used exclusively for industrial purposes or horticultural purposes (by virtue of paragraph 2 of Article 28);

(e) extracts of any part of the cannabis plant which are commonly used in industry for other than medical or scientific purposes, provided they are not liable to abuse or to cause ill effects and harmful substances cannot be recovered (by virtue of paragraph 9 of Article 2).

121. In relation to the types of extracts referred to in items (D) and (E) above, where an extract of any part of the plant is exclusively for industrial purposes (e.g. as a non-therapeutic, nutritional product, or food additive), and/or where it is used in industry other than for medical or scientific purposes (e.g. hemp oil as a non-therapeutic, nutritional product, or food additive which, because of its very low THC content is not liable to abuse/ill effects or the recovery of the THC), then it is simply not an 'extract of cannabis' for the purposes of schedule 1 of the Single Convention, and the question of whether export would be permitted under the Single Convention does not even arise.

122. Extract type (D) above is not limited to extracts of fibre or seed. On a proper reading of paragraph 2 of Article 28, the reference to "fibre and seed" in parentheses is not intended to limit the scope of the permitted industrial purposes by limiting the parts of the plant in relation to which the industrial purposes are permitted, but is just included by way of example of material in common industrial use at the time the Single Convention was made.

123. Support for this reading can be found in regimes at the state/territory level which govern the way that industrial and horticultural uses of cannabis and cannabis extracts are regulated. While ODC has acknowledged that:

> "*a person, under state/territory Hemp schemes, may…cultivate the cannabis for industrial uses (specifically fibre and seed), which is not captured under the Narcotic Drugs Act 1989* [sic]",

it purports to limit the scope of the permitted industrial uses to only fibre and seed. To the contrary, there are state regimes for industrial cannabis/hemp cultivation and use which do not adopt the same definitions of cannabis and related terms as the Single Convention or use the same language regarding permitted industrial or horticultural use. For example, the definition of the relevant material ('low-THC hemp') in the relevant NSW legislation (the *Hemp Industry Act 2008* (NSW) (**HI Act**)) is not limited in the way ODC seeks to characterise it. In the NSW legislation, the definition reads:

> *"**low-THC hemp** means any plant of the genus Cannabis, by whatever name that plant may be called, that has a concentration of THC in its*

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leaves and flowering heads of no more than 1%, and includes the seed of any such plant and any product (such as oil or fibre) derived from any such plant."

124. Further, significantly, the HI Act does not limit the scope of the permitted industrial and horticultural activities to "specifically fibre and seed", but allows the supply and use of 'low-THC hemp' (as broadly defined) for a variety of industrial purposes. In particular, there is nothing in the HI Act which would prohibit the export of low-THC hemp for the purposes permitted by the HI Act.

125. Similarly, the industrial cannabis/hemp regime in Western Australia permits the cultivation and use of 'industrial hemp' (defined to mean "cannabis, the leaves and flowering heads of which do not contain more than 1% of tetrahydrocannabinol", where cannabis is again defined broadly as "plant of the genus Cannabis… or part of that plant" – see the *Industrial Hemp Act 2004* (WA))" and the supply of 'processed industrial hemp', which is defined (see the *Misuse of Drugs Act 1981* (WA)) as:

"any product made from industrial hemp or industrial hemp seed that —
(a) does not contain more than 1% of tetrahydrocannabinol; and
(b) does not contain viable whole cannabis seed; and
(c) is not manufactured in a form to be inhaled",

from which it is evident that the permitted purposes go beyond the use of fibre and seed for industrial purposes.

126. The existence and scope of these examples is consistent with our understanding of the proper reading of the phrase "(fibre and seed)" in paragraph 2 of Article 28 of the Single Convention, as outlined above.

127. Accordingly, the position promulgated by ODC that "*Export* [of all extracts of cannabis (excluding seed extracts)] *for non-medical use would not be permitted under the convention*" is not correct insofar as there are other 'extracts of cannabis' in addition to seed extracts that are not regulated by the Single Convention, notably because they are for industrial or horticultural purposes.

128. The Single Convention's exclusion of these products flows through consistently to the way in which the Single Convention is given force in Australia, as follows:

(a) Insofar as the Act, which implements many of the most important aspects of the Single Convention in Australia, permits the cultivation, production and manufacture of cannabis and cannabis products, it clearly applies only to cannabis for medicinal purposes. Importantly, it explicitly does not purport to override state or territory legislation regarding the cultivation, production or manufacture of cannabis plants / cannabis for non-medicinal (or related scientific) purposes (see sections 7 and 7A of the Act), leaving room for the operation of state and territory regimes to regulate the cultivation and use of cannabis (including extracts of cannabis) for industrial and horticultural purposes.

(b) The *Criminal Code 1995 (Cth)* (**Criminal Code**) similarly carves out of its operation the state and territory industrial cannabis/hemp regimes. Part 9.1 of the Criminal Code (Serious drug offences) specifically implements and gives effect to the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, done at Vienna on 20 December 1988 (**TINDAPS Convention**) (see section 300.1 of the Criminal Code). Article 3 of the TINDAPS Convention requires the Parties (including Australia) to adopt measures to criminalise certain conduct in

relation to any narcotic drug contrary to the provisions of the Single Convention, including production, manufacture, extraction or exportation of such drugs, and the cultivation of cannabis plant for the purpose of the production of such narcotic drugs.

(c) Part 9.1 of the Criminal Code is directed squarely at implementing Australia's obligations under the TINDAPS Convention and the Single Convention regarding, relevantly, the cultivation of cannabis and the export of cannabis. It does this by creating offence provisions in respect of the unlawful trafficking, manufacture and export of cannabis (defined more broadly than in the Single Convention), cannabis plants and related substances. However, significantly, it provides exemptions from those provisions in relation to conduct which occurs in a state or territory where that conduct is justified or excused by or under a law of that state or territory (section 313.1 of the Criminal Code), the most obvious and relevant example of which would be the cultivation and use of cannabis/hemp for industrial or horticultural purposes under state/territory industrial cannabis/hemp legislation.

(d) Australia complies with other aspects of the Single Convention by its implementation of the export licence/permit controls that exist under Division 2 of Part 3 of the *Customs (Prohibited Export) Regulations 1958* (**CPE Regulations**) and by observing those controls. In particular, the combined operation of regulations 10A, 10C and 10E of the CPE Regulations explicitly requires the grant of an export licence to be consistent with the requirements of the Single Convention that are appropriate to the drug. It is tolerably clear that if a product is not a drug for the purposes of the Single Convention (including if it is not such a drug because the Convention is not intended to apply to it), then there are no applicable requirements of the Single Convention that even arise for consideration under regulation 10A.

129. Accordingly, if a product is properly within the scope of the 'industrial and horticultural purposes' exemption from the operation of the Single Convention, and it is lawfully able to be produced and supplied by way of export pursuant to state/territory industrial cannabis/hemp legislation, then neither the Single Convention nor any of the above Commonwealth instruments apply to make that supply unlawful, and there is no barrier to the grant of an export licence based on any such consideration.

130. It follows that the export of an extract of cannabis which is not a seed extract (such as hemp oil produced from the flowering tops of the low-THC cannabis plant), which may be lawfully produced and exported pursuant to NSW hemp legislation, and which is for an industrial purpose to which the Single Convention does not purport to apply (which we say is not limited to the use of fibre and seed by virtue of both Article 28 paragraph 2 and Article 2 paragraph 9), is not prohibited by the Single Convention, the Act, the Criminal Code or the CPE Regulations, or any other Commonwealth (or international) instrument to which the Department is permitted to have regard in making a decision to issue an export licence.

131. Noting the above, it is imperative that it further amendments to the Act make it clear that the legal effect given to the Convention under the Act is to introduce a system of controls regulating the cultivation, production and manufacture of medicinal cannabis only (and, even then, only narcotic forms of medicinal cannabis) and not non-medicinal cannabis intended for industrial or horticultural purposes. Whilst the cultivation, production and manufacture of low-THC medicinal cannabis and

medicinal cannabis products should adhere to the same GAP and GMP standards required in relation to any other medicinal cannabis, the stringent levels of control and scrutiny that apply to high-THC medicinal cannabis are not warranted for low-THC medicinal cannabis. In this regard, we see no reason why security arrangements applying to the cultivation and production of low-THC medicinal cannabis should not align with the security arrangements expected of cultivators and producers of industrial hemp (noting that, on the other hand, the quality of low-THC medicinal cannabis needs to meet a higher standard than that which would be expected for industrial hemp.

Timing

132. As the Department would be aware, there are important international developments occurring in relation to the regulation of medicinal and non-medicinal cannabis. Most significantly, in November 2018 the World Health Organisation's Expert Committee on Drug Dependence (**WHO ECDD**) carried out critical reviews of cannabis and cannabis-related substances to determine the most relevant level of international control for those substances, and in January 2019 made recommendations to the United Nations' Commission on Narcotic Drugs (**CND**) according to its remit under the Single Convention and the Convention on Psychotropic Substances. Those recommendations, as you would no doubt know, were to effectively 'downschedule' cannabis and cannabis-related substances. In particular, the ECDD recommended that:

- Cannabis and cannabis resin be deleted from Schedule IV of the Single Convention (the category of substances subject to the most stringent controls);
- Extracts and tinctures of cannabis be deleted from Schedule I of the Single Convention (*i.e.* deleted from the operation of the Single Convention altogether);
- Pharmaceutical preparations produced by chemical synthesis or from cannabis, containing one or more other ingredients such that the THC cannot be readily recovered or in a yield that would be a risk to public health, be added to Schedule III of the Single Convention (allowing them to be subject to a lower level of control than if not included in that Schedule);
- Preparations containing or consisting of pure CBD (containing no more than 0.2% THC) be confirmed to be outside the scope of the Single Convention;
- THC and other tetrahydrocannabinols be deleted from Schedule II of the Convention on Psychotropic Substances and added to Schedule I of the Single Convention.

133. Although the timing of the recommendations was insufficient to allow the CND to consider and vote on them at its 62nd regular session in March 2019, and consideration and voting were postponed, it is anticipated that the CND will make a decision regarding acting on the recommendations at its 63rd regular session in March 2020 (if not at its reconvention of the 62nd session in December 2018).

134. These changes, which are consistent with the other submissions we have made regarding the proper scope of regulation of cannabis/hemp for industrial purposes, would represent a fundamental shift in the international attitude to and regulation of cannabis and cannabis-related substances, and in our submission, any decision to review and revise the Act must take into account the likelihood of these changes being effected and ensure that any changes to the regime are consistent with the

WHO ECDD's recommendations. Otherwise, the Government risks going to the trouble of making changes which are quickly rendered obsolete by a change in the international landscape, leaving Australia at a significant commercial/industrial disadvantage in a rapidly-growing global industry, which is plainly counterproductive to the national interest.