Australian Medicinal Cannabis Association
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PARLIAMENTARY INQUIRY INTO CANNABIS AND HEMP
CONSULTATION SUBMISSION
AUSTRALIAN MEDICINAL CANNABIS ASSOCIATION

Introductory comments

1. The Australian Medicinal Cannabis Association (**AMCA**) welcomes the opportunity to make a submission to this inquiry into cannabis and hemp in Western Australia (**Inquiry**).

2. We represent numerous industry stakeholders including cultivators, manufacturers, importers, distributors, researchers, medical practitioners, nurses, pharmacists, patients and consumers, and broader advocacy groups.

3. Our submissions, which address Terms of Reference 2(a) - 2(c) are set out below.

Background to the Inquiry

4. 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

5. 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]

6. 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 relatively expensive for patients because they are not eligible for subsidisation.

[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.

7. 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 its chemical profile may be dangerous for patients.

8. 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]

9. 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,[12] cancer,[13] diabetic peripheral neuropathy,[14] epilepsy,[15] multiple sclerosis,[16] 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]

Industrial Hemp

10. In Western Australia, industrial hemp is defined in the *Industrial Hemp Act 2004* (WA) (**IH Act**) to mean cannabis (*Cannabis sativa*), the leaves and flowering heads of which do not contain more than 1.0% of THC. With these low levels of THC, industrial hemp plants are non-psychoactive, compared with plants that contain higher levels of THC.

11. At present, industrial hemp is cultivated in WA for both fibre and seed production. Fibre and hurd can be extracted from the stem and can be used to manufacture textiles, rope and building materials. On the food side, the seeds can be hulled and packaged, or pressed to produce protein-rich powders or oils that are rich in omega 3, 6 and 9.

Cannabis and the Law

International obligations

12. 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*

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[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.
[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.

Drugs 1961[22] (**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.[23] 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.

13. In addition, Australia is a party to the *Convention on Psychotropic Substances 1971*[24] which describes the obligations of parties to facilitate the use of psychotropic substances for 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*,[25] which aims to promote cooperation between parties to address the illicit trafficking of narcotic drugs and psychotropic substances.

14. 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.[26] 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).[27]

15. 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.[28]

16. 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,[29] 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.[30]

Regulation of Cannabis by the Commonwealth and States/Territories

17. 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:[31]

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[22] *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*.
[23] Ibid, Art 2; and Art 28 for cannabis cultivation specifically.
[24] *Convention on Psychotropic Substances 1971*, opened for signature 21 February 1971, 1019 UNTS 175 (entered into force 16 August 1976).
[25] *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).
[26] Ibid Arts 18-20; Explanatory Memorandum, Narcotic Drugs Amendment Bill 2016 (Cth), 7.
[27] Explanatory Memorandum, Narcotic Drugs Amendment Bill 2016 (Cth), 6.
[28] 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.
[29] *International Covenant on Economic, Social and Cultural Rights*, opened for signature 16 December 1966, 993 UNTS 3(entered into force 3 January 1976)
[30] 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).
[31] Ibid, 6.

(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.[32]

(b) On the other hand, the *Narcotic Drugs Act 1967* (**ND Act**) permits the cultivation and production of cannabis[33] and the manufacture of medicines comprising or derived from cannabis or its constituent parts.[34] However, the consensus is that the ND Act narrowly and inflexibly observes Australia's obligations under the Single Convention and the tight controls are, in at least some respects, unnecessary.

(c) The *Customs Act 1901* (Cth) addresses the import[35] and export[36] 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).[37]

(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.[38]

(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.[39]

(f) The IH Act and *Industrial Hemp Regulations 2004* (WA) (**IH Regs**) regulate the production of industrial hemp in WA, and these are administered by the Department of Primary Industries and Regional Development. Legislation regulating the production and supply of industrial hemp exists in each state and territory in Australia.

Terms of Reference

The Select Committee is to inquire into and report on the potential to amend the current legislation and regulations which apply to cannabis and hemp in Western Australia, with particular reference to:

(a) the current barriers to pharmaceutical and nutraceutical use of cannabinoid products;
(b) medicinal cannabis, its prescription, availability and affordability; and
(c) the potential benefits and risks of permitting industrial hemp for human consumption.

[32] 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).
[33] *Narcotic Drugs Act 1967* (Cth), Ch 2 Pt 2 Div 1-2.
[34] Ibid, Ch 3 Pt 2 Div 1-3.
[35] Ibid, s 49.
[36] Ibid, s 112.
[37] *Customs (Prohibited Imports) Regulations 1956*, r 5.
[38] *Therapeutic Goods Act 1989* (Cth), Pts 3-1 and 3-2.
[39] See, for example, the *Hemp Industry Act 2008* (NSW).

Term of Reference (a)

To inquire into and report on the potential to amend the current legislation and regulations which apply to cannabis and hemp in Western Australia, with particular reference to the current barriers to pharmaceutical and nutraceutical use of cannabinoid products

18. Before discussing the barriers to pharmaceutical and nutraceutical use of cannabinoid products, it is useful to differentiate between the "pharmaceutical" and "nutraceutical" use of cannabinoid products.

Cannabinoid products for pharmaceutical use

19. Cannabinoids are chemical constituents found in the *Cannabis sativa* plant. Of some 140 cannabinoids contained in the plant, the two most commonly known for their therapeutic benefit are delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD).

20. Pharmaceutical preparations of cannabis contain specific, known quantities of synthetic or naturally-derived cannabinoids and have been developed by various medicinal cannabis companies, both in Australia and Overseas, for restricted supply under the medicinal cannabis regulatory framework which commenced in 2016.

Cannabinoid products for nutraceutical use

21. In the context of nutraceutical use, the term "nutraceutical" was introduced by Dr. Stephen DeFelice in 1989 to mean "food or part of a food that provides medical or health benefits, including the prevention and/or treatment of a disease. (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8326690/). The term is not formally recognised in any country, although it is generally understood to refer to a product that has been extracted or derived from food and is usually sold as a formulated preparation. (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4336979/).

22. In Australia, a product derived from ingredients which are traditionally consumed as food may be classified as a food or a therapeutic product depending on various factors such as (but not limited to) the dosage form and whether any therapeutic claims are made in relation to the product.

23. For the purposes of this Inquiry, we have taken "nutraceutical use" with respect to industrial hemp to mean the production of food products which are intended for human consumption, and have certain health benefits.

24. Hemp products intended for consumption as food products would be regulated under food legislation, including the *Australia New Zealand Food Standards Code* (Food Standards Code) whereas hemp products intended to be marketed as therapeutic goods would be regulated under the *Therapeutic Goods Act 1989* (Cth).

The Barriers to the Pharmaceutical and Nutraceutical Use of Cannabinoid Products

Cannabinoid products used for pharmaceutical use:

25. Although the therapeutic effects of cannabis preparations are reasonably well documented, there are significant costs associated with the cultivation, production and manufacture of medicinal cannabis products under the current regulatory framework in Australia. These include costs associated with:

    (a) obtaining the licences, permits, authorisations and/or approvals prescribed under the regulatory regime;

    (b) the infrastructure required to establish cultivation, production and manufacturing facilities which meet stringent regulatory requirements;

    (c) the actual cultivation, production and manufacture of medicinal cannabis products for supply to Australian patients; and

    (d) the supply of medicinal cannabis products to patients, which the patient bears the entire burden for because of the absence of any subsidisation schemes for prescribed medicinal cannabis products.

Cannabinoid products used for nutraceutical use:

26. Industrial hemp (*Cannabis sativa*) is a versatile crop which is currently used to, among other things, make nutritious food products for human consumption. As stated above, the industrial hemp industry in Western Australia is regulated under the IH Act and IH Regs.

27. The manufacture of food made from industrial hemp is currently permitted in Australia in very limited circumstances. Under the IH Act, a *Cannabis sativa* plant is considered to fall within the definition of 'industrial hemp' if the leaves and flowering heads do not contain more than 1.0% of THC. Currently, only the seeds of the plant can be used in the manufacture of products for human consumption as foods, as the seeds contain negligible – if any – amounts of cannabinoids. It is the leaves and flowering heads of the plant that contain cannabinoids (as well as other compounds such as flavonoids and terpenes which also have therapeutic properties), and it is currently prohibited to use these components of the plant in the preparation of any food products.

28. Incongruously, hemp growers are subject to strict security requirements to prevent the diversion of any hemp-derived products into illicit markets, even though hemp has no real value in the illicit market (because it is not subject to misuse or abuse). There are many controls that are applied to industrial hemp which, in our view, are time-consuming and unnecessarily costly for the grower, and such costs will inevitably be passed down the supply chain, eventually to the consumer.

29. For example, the most maligned aspect of producing industrial hemp products under the current state and territory industrial hemp regimes is the wastage of the leaves and flowering heads of the plants, which are not permitted to be used for any other industrial purpose and must therefore be destroyed once the seeds (for food products) or fibre (for other industrial purposes) are used. This is a substantial financial loss to the grower and could be avoided if the leaves and flowering heads of the plant were able to be used, if not in food then for other purposes such as the extraction of cannabinoids and other compounds in the flowering heads and leaves for pharmaceutical use.

A. Limited Access Pathways for Pharmaceutical Use of Cannabinoid Products

30. Another major barrier to the use of cannabinoids for pharmaceutical use is the difficulty that patients have in accessing medicinal cannabis. This is due to the overly burdensome nature of the regulatory pathways in Australia and results in very limited patient access to medicinal cannabis.

The Regulatory Pathways

31. Under the current regulatory regime, patients can only access medicinal cannabis via one of the following "pathways":

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

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

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

    (d) Clinical trials, through the Clinical Trial Notification (**CTN**) and Clinical Trial Approval (**CTA**) Schemes.

32. A brief description of these pathways and their limitations follows.

Registration in the ARTG

33. Only therapeutic goods which are entered in the ARTG are lawfully able to be commercially supplied in Australia.

34. Currently there are only two medicinal cannabis products registered on the ARTG. These are Sativex (nabiximols) and Epidyolex (cannabidiol).

35. 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.

36. 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. In the absence of PBS listing, the only means by which patients are able to access medicines is through a private prescription, at a cost that is usually several orders of magnitude higher than the cost would be under a subsidised prescription.

37. The fact that there are no other cannabis-based pharmaceuticals registered in the ARTG for supply in Australia highlights its ineffectiveness or unattractiveness as an access pathway.

Access Schemes (SAS and APS)

38. Due to the limited access to medicinal cannabis for patients provided by the above pathways (i.e. registered products and clinical trials), the primary means of accessing medicinal cannabis are the "Access Schemes" (SAS and APS).

39. However, both schemes are unduly burdensome for the prescriber with the result that they do not deliver the benefits that were intended with respect to medicinal cannabis. 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.

Special Access Scheme

40. 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 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.

41. 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.

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

Authorised Prescriber Scheme

43. 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.

44. 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.

45. 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.

46. However, an APS authorisation is granted 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

47. 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. Hence, this pathway is of limited use for patients to access medicinal cannabis and is not appropriate in a mainstream setting where a patient sees their regular doctor or a specialist for the treatment of their condition.

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

    (a) the Clinical Trial Approval (**CTA**) scheme; and

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

49. 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 or specialist college 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.

50. Generally, 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.

Summary of Limitations of Existing Pathways

51. As is evident from the above information, the current Regulatory Pathways for access to medicinal cannabis have significant limitations.

52. As noted in paragraph 34 above, there are only two medicinal cannabis products – Sativex and Epidyolex that are currently registered in the ARTG. Sativex has been registered since 2012 but never succeeded in obtaining PBS listing and therefore has not been commercially viable as most patients would be unable to afford it on a private prescription.

53. Epidyolex, on the other hand, was registered on 21 September 2020 and has been able to obtain PBS listing for severe myoclonic epilepsy in infancy (Drave syndrome), but only for patients with generalised tonic-clonic seizures or generalised clonic seizures that are not adequately controlled with at least two other anti-epileptic drugs AND the treatment must be

as adjunctive therapy to at least two other anti-epileptic drugs. This simply highlights the ongoing stigma associated with the acceptance of medicinal cannabis as an alternative, legitimate first-line treatment.

54. Notwithstanding the above, the predominant pathway that patients and their treating medical practitioners have been accessing with a high degree of success compared to other pathways (albeit itself limited) is the SAS. The APS is a more 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, which will consider the medical practitioner's eligibility to become an Authorised Prescriber.

55. 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 from the time of legalisation of medicinal cannabis (2016) until the end of 2021:[40]

Year	Number of SAS Category B approvals
2016	15
2017	231
2018	2560
2019	25,160
2020	57,710
2021	122,560

56. 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 viable mechanism that provides patients with adequate access to medicinal cannabis products, there are still a significant number of patients who are accessing black market medicinal cannabis, and they appear to be doing so mainly because the cost of medicines that can be accessed is prohibitively high.

B. Scheduling of Cannabis Products

57. Another major consideration when it comes to the use of cannabinoids for pharmaceutical or nutraceutical use, or food production more generally, is the scheduling of cannabis and products containing cannabinoids.

Background to Scheduling

58. Scheduling is a national classification system that controls how medicines and poisons are made available to the public. Medicines and poisons are classified into Schedules according to the level of regulatory control over the availability of the medicine or poison required to protect public health and safety. (https://www.tga.gov.au/scheduling-basics)

59. The Schedules are:

[40] https://www.tga.gov.au/medicinal-cannabis-special-access-scheme-category-b-data, accessed 7 January 2022.

Schedule 1	Not currently in use
Schedule 2	Pharmacy Medicine
Schedule 3	Pharmacist Only Medicine
Schedule 4	Prescription Only Medicine OR Prescription Animal Remedy
Schedule 5	Caution
Schedule 6	Poison
Schedule 7	Dangerous Poison
Schedule 8	Controlled Drug
Schedule 9	Prohibited Substance
Schedule 10	Substances of such danger to health as to warrant prohibition of sale, supply and use

60. The Australian Department of Health determines the scheduling of all medicines and poisons in Australia.

61. The Schedules are published in the Poisons Standard and are given legal effect through state and territory legislation. The Poisons Standard is the legal title of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).

62. The current version of the Poisons Standard is the SUSMP No. 34 (Poisons Standard October 2021).

63. Western Australia automatically adopts the Poisons Standard via the *Medicines and Poisons Act 2014* (WA) (**MP Act**) and *Medicines and Poisons Regulations 2016* (WA) (**MP Regs**).

64. Interestingly, however, under the MP Act, the Minister can recommend that a substance be identified in the regulations in any way they see fit,[41] and the Governor, based on that recommendation, may classify a substance as a poison included in schedule 2, 3, 4, 5, 6, 7, 8, or 9.

65. Additionally, the MP Act seems to suggest a set of criteria that the Minister can use as a reference to classify a substance by. This set of criteria is explicitly mentioned to not limit the Minister's powers.[42] A substance may be classified by reference to any of the following[43]:

(a) an adopted code;

(b) the way in which it is, or is intended to be, used;

(c) the purpose for which it is, or is intended to be, used;

(d) the quantity in which it is supplied;

(e) its packaging or labelling;

(f) its physical or chemical state or form;

(g) any other factor.

[41] Subsection 4(2) of the MP Act.
[42] Subsection 4(3) of the MP Act.
[43] *Ibid*.

66. Most importantly, the MP Act provides that industrial hemp or industrial hemp seed[44] and processed industrial hemp[45] cannot be classified as Poisons, nor can they be classified as strictly controlled substances.[46]

67. Accordingly, the interaction between the definitions of hemp in the IH Act and MP Regs appears to confer power on the WA State Government to control the scheduling of hemp products, and it would appear that hemp products are not caught by the Poisons Standard in WA as long as fall within the definition of 'industrial hemp' under state legislation. In any event, it appears that hemp products can be reclassified and regulated less stringently, based on a recommendation from the Minister, or perhaps by reference to 'any other factor' that the Minister deems to be relevant.

Scheduling of cannabinoid products for pharmaceutical use

68. Cannabinoid preparations for pharmaceutical use are subject to very strict criteria. They must comprise at least 98 per cent of CBD and no more than 1 per cent of THC.

69. All medicinal cannabis products are Schedule 8 medicines, apart from products containing CBD in at least 98% purity (which are Schedule 4 medicines), or products containing CBD that are registered in the ARTG in doses not exceeding 150 mg/day (which are Schedule 3 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 lower risk medicines.

70. These extreme restrictions on the legitimate pharmaceutical use of cannabinoid products have a number of significant consequences. Firstly, sponsors are deterred from applying for registration of their products on the ARTG, as a Schedule 8 classification would severely restrict their ability to sell and market their products. Secondly, many doctors are simply too uncomfortable 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.

71. Lastly, patients are deprived of the opportunity to access the forms of therapeutic and medical cannabis that would give them real benefits for serious conditions that are not adequately controlled by existing medications.

Scheduling of cannabinoid products for nutraceutical use

72. The IH Act defines industrial hemp as cannabis, the leaves and flowering heads of which do not contain more than 1.0% per cent of tetrahydrocannabinol (THC). These low levels of THC mean that industrial hemp plants do not have the psychoactive effects associated with cannabis varieties that have higher (psychotropic) levels of THC.

73. Currently in Australia, including in Western Australia, medicinal cannabis products are classified as Schedule 8 (S8) medicines (controlled drugs), apart from products containing cannabidiol only in ≥98% purity, which are classified as Schedule 4 (S4) medicines (prescription only medicines) and products containing cannabidiol only in doses ≤150 mg/day that are registered in the Australian Register of Therapeutic Goods (**ARTG**). The only medicinal cannabis products currently registered in the ARTG are Sativex (which is a Schedule 8 medicine) and Epidyolex (which is a Schedule 4 medicine).

74. Products that are included in any Schedule under the Poisons Standard are not permitted to be used in the manufacture of foods.

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[44] Subsection 3(1) of the IH Act provides that 'industrial hemp' means cannabis, the leaves and flowering heads of which do not contain more than 1% of tetrahydrocannabinol.

[45] Subsection 3(1) of the *Misuse of Drugs Act* 1981 provides that 'processed industrial hemp' means any product made from industrial hemp or industrial hemp seed that does not contain more than 1% THC, does not contain viable whole cannabis seed, and is not manufactured to be inhaled):

[46] A strictly controlled substance is a substance classified by regulations made under subsection 5(1) as a strictly controlled substance.

75. Medical practitioners in Western Australia are able to prescribe medicinal cannabis products, however prescribing S8 products requires approval from the Department of Health for each patient that a medical practitioner intends to prescribe to. Obtaining approval is not always straightforward for medical practitioners in Western Australia, and the lack of an easy and straightforward approval process may be a significant barrier which deters a medical practitioner from prescribing medicinal cannabis products as an alternative to conventional treatments.

76. When approval is given, and when cannabis products are prescribed, prescriptions for medicinal cannabis can be dispensed at any pharmacy in Western Australia, which can obtain medicinal cannabis products from licensed manufacturers and wholesalers

The Poisons Standard in Western Australia

77. Under the MP Act and MP Regs, Western Australia automatically adopts the Poisons Standard into state law.[47] However, under the MP Act, the Minister can recommend that a substance be identified in the regulations in any way they see fit[48] and the Governor, based on that recommendation, may classify a substance as a poison included in schedule 2, 3, 4, 5, 6, 7, 8, or 9.

78. Additionally, the Act prescribes a set of criteria that the Minister can use as a reference to classify a substance by. This set of criteria is explicitly mentioned to not limit the Minister's powers.[49]

79. A substance may be classified by reference to any of the following:[50]

- an adopted code;
- the way in which it is, or is intended to be, used;
- the purpose for which it is, or is intended to be, used;
- the quantity in which it is supplied;
- its packaging or labelling;
- its physical or chemical state or form;
- any other factor.

80. Most importantly, however, the Act provides that industrial hemp or industrial hemp seed[51] and processed industrial hemp[52] cannot be classified as Poisons, nor can industrial hemp or industrial hemp seed be classified as strictly controlled substances.[53]

81. It appears that this qualification in the MP Act carves out any industrial hemp products, including industrial hemp products derived from the flowering heads and leaves of the plant, from the Poisons Standard, and therefore industrial hemp products manufactured using the flowering heads and leaves would not be classified as poisons under the Poisons Standard in WA as long as fall within the definition of 'industrial hemp' under the IH Act. Otherwise, based on a recommendation from the Minister, or by redefining industrial hemp under the IH Act, hemp products can be reclassified and regulated less stringently.

[47] Section 4 of the MP Act and regulation 6 of the MP Regs.
[48] Section 4(2) of the MP Act..
[49] Medicines and Poisons Act 2014 (WA) s 4(3).
[50] Ibid.
[51] Industrial hemp means cannabis, the leaves and flowering heads of which do not contain more than 1% of tetrahydrocannabinol: subsection 3(1) of the IH Act.
[52] Processed industrial hemp means any product made from industrial hemp or industrial hemp seed that does not contain more than 1% THC, does not contain viable whole cannabis seed, and is not manufactured to be inhaled): subsection 3(1) of the *Misuse of Drugs Act.*
[53] A strictly controlled substance is a substance classified by regulations made under subsection 5(1) as a strictly controlled substance and is, in essence, a Schedule 10 substance.

Term of Reference (b)

To inquire into and report on the potential to amend the current legislation and regulations which apply to cannabis and hemp in Western Australia, with particular reference to medicinal cannabis, its prescription, availability and affordability.

Background to Medicinal Cannabis

82. To provide some context to our response to Term of Reference 2(b), reference should be made to information about the medicinal benefits of cannabis and its demand in Australia in the "Background to the Inquiry" provided in Clauses 4 and 17 at the beginning of this submission.

Medicinal Cannabis – Prescription, Availability and Affordability

83. The restrictive scheduling, lack of availability to and affordability of medicinal cannabis are all major barriers to access for patients in Australia.

Medicinal Cannabis – Prescription

84. As stated above, a major barrier against the use of cannabinoids for pharmaceutical use is the restrictive scheduling of these products.

85. 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 lower risk registered medicines or listed medicines.

86. Cannabinoid products contain only CBD at dosages less than 150 mg/day and are registered in the ARTG are classified as Schedule 3 (over-the-counter) medicines. However, these formulations are of limited benefit in the treatment of serious conditions.

87. The restrictive scheduling of medicinal cannabis products, especially medicines in Schedule 8, is a significant barrier to patients trying to access these products. Many doctors are already reluctant to prescribe medicinal cannabis products, and their predominant inclusion in Schedule 8 categorises them as high-risk medicines that must be strictly controlled, even though many medicinal cannabis products which fall into Schedule 8 do not have the safety concerns that would justify their inclusion in Schedule 8.

88. The consensus amongst AMCA members is that the restrictive regulatory framework for medicinal cannabis is symptomatic of the stigma that still attaches to medicinal cannabis, and doctors not having received adequate education and training on its use. 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 and recommendations that they be only used as last-line therapy, or at least not used as first-line medicines.

Medicinal Cannabis – Access and Affordibility

89. As is evident from the table in paragraph 55 above, access to medicinal cannabis products appears to have improved to a significant degree in recent years, evidenced by the exponential growth in SAS Category B approvals between 2016 and 2021.

90. However, the affordability of medicinal cannabis is still a major deterrent to access, and an SAS Category B approval for a medicinal cannabis product does not necessarily mean that the patient to whom the approval relates will have that product dispensed. Because medicinal cannabis products are unapproved products, they are not eligible for reimbursement and a product is not reimbursed, then the patient must pay the full cost.

91. Although medicinal cannabis supplied under a clinical trial is (generally) free of charge, products supplied under SAS or APS are **not** free of charge, although it is at each product sponsor's discretion as to whether it will supply its products to patients at a subsidised cost or free of charge.

92. The cost of accessing medicinal cannabis can be substantial, particularly in patients who require medicinal cannabis for long-term treatment, and the cost of treatment can therefore quickly become unaffordable for patients and their families. Patients have reportedly been quoted up to $34,000 per year or more (*i.e.* approximately $93 per day) to access medicinal cannabis following an SAS approval. Many patients can 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 illicit channels ('black market' cannabis).

93. Having regard to the already significant regulatory burden and operational and other costs associated with cultivating, producing and manufacturing medicinal cannabis products under the present regime, it is unlikely that affordable access to medicinal cannabis products will be achievable without substantial regulatory change and other government action which will facilitate lawful access. 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 (which we accept is highly unlikely, 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 treatment with medicinal cannabis), or subsidisation by private health insurers.

94. It is plain that if the issue of cost is not addressed, black market cannabis will continue to remain considerably more inexpensive than lawfully manufactured medicinal cannabis, which patients will be diverted towards, at potentially significant risk to their health and safety.

Term of Reference (c)

To inquire into and report on the potential to amend the current legislation and regulations which apply to cannabis and hemp in Western Australia, with particular reference to the potential benefits and risks of permitting industrial hemp for human consumption.

95. Noting that industrial hemp is not classified as a poison in Western Australia, it appears that industrial hemp products are lawfully able to be manufactured in Western Australia, but the ability to supply these products is nevertheless limited by other legislation that is in force, which effectively prohibits supply through other means. For example, only hemp seed products are currently permitted in foods in Australia, and hemp products that are derived from the flowering heads and/or leaves are prohibited. Such products may be permissible as medicinal cannabis products, but they would be subject to the federal regime that regulates such products, requiring compliance with the *Narcotic Drugs Act 1967*, the *Therapeutic Goods Act 1989* and related subordinate legislation.

96. Accordingly, even though the MP Act does not classify industrial hemp products as poisons, their supply either as nutraceuticals (foods) or pharmaceuticals (therapeutic goods) would be subject to compliance with the laws regulating the supply of those types of products.

97. That being the case, AMCA would support any government proposal to amend legislation to broadly permit industrial hemp products (not limited to products derived from hemp seed) for human consumption as foods ('nutraceuticals') or medicines that are not subject to the stringent federal framework regulating such products. As Western Australia is the only jurisdiction in Australia that has not formally adopted the *Therapeutic Goods Act 1989* into its state law, there may be scope to explore whether industrial hemp products that are cultivated, produced and manufactured under the IH Act could be supplied intrastate under the sole trader provisions, which exempt a natural person from the operation of the TG Act as long as supply only occurs within the state.

98. The impetus on Western Australia taking the initiative to create a regulatory scheme that facilitates broad access to industrial hemp products in Western Australia is that it will likely precipitate other state and territory governments, and the federal government, to facilitate similar changes, under mounting pressure from the general public. There is sufficient experience globally with the use of industrial hemp products as food products or nutraceuticals to demonstrate that the potential risks associated with the use of these products is outweighed by the nutritional and health benefits, and the evidence supporting the safety of these products can no longer be regarded as anecdotal due to their widespread use globally.