Australian Government

Department of Health

Review of the Narcotic Drugs Act 1967

Discussion paper

4 March 2019

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Introduction

About this review

The *Narcotic Drugs Act 1967* (Cth) (**the ND Act**) establishes a regulatory framework with a dual purpose:

- to prevent the abuse and diversion of controlled narcotics, and
- to ensure that controlled narcotics are available for medical and research purposes within Australia.

The ND Act implements the United Nations *Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol* (**the Single Convention**), to which Australia is a party. The operation of the Single Convention is overseen by the International Narcotics Control Board (**INCB**).

Prior to 2016, the ND Act applied to the control of drugs obtained from the opium poppy and the regulation of the manufacture of licit narcotics, such as morphine.

Other Commonwealth laws at the time regulated the import and export and manufacture of cannabinoids and cannabis raw material. State and Territory laws permitted the cultivation of cannabis plants in Australia for industrial and horticultural purposes. Beyond those limited arrangements, cannabis was generally treated as an illegal narcotic in Commonwealth, State and Territory laws.

The ND Act was amended in February 2016 to establish a national regime permitting the cultivation and production of cannabis and cannabis resin in Australia, to enable a sustainable supply of medicinal products for therapeutic purposes and to facilitate scientific research. The existing provisions of the ND Act relating to manufacture of narcotic drugs were updated to mirror the new licence provisions permitting cannabis cultivation and production. The 2016 amendments also dealt with the risks associated with the potential for diversion of medicinal cannabis products. A central objective of the 2016 amendments was to ensure that Australia would remain compliant with its international treaty obligations under the Single Convention.

Why the review is being conducted

The 2016 amendments to the ND Act included a requirement in section 26A that the Minister cause a review of the operation of the Act to be undertaken as soon as possible after the second anniversary of the commencement of the 2016 amendments. The report of the review is to be tabled in both houses of Parliament before the third anniversary – in effect, by 29 October 2019. The requirement for the review recognises that the new regulatory framework for the cultivation, production and manufacture of medicinal cannabis opened an important but untested field of regulation in Australia.

The Hon Greg Hunt MP, Minister for Health, appointed Professor John McMillan AO to conduct an independent review of the operation of the ND Act, commencing in January 2019. Professor McMillan is an Emeritus Professor at the Australian National University and has relevant professional experience in administrative and constitutional law, as a legal practitioner and as a Commonwealth and State agency head. He has held appointments as Australian Information Commissioner, Commonwealth Ombudsman, New South Wales (**NSW**) Ombudsman (Acting), Integrity Commissioner for the Australian Commission for Law Enforcement Integrity (Acting) and member of the Australian Copyright Tribunal.

The scope of the review

The Minister for Health announced the Terms of Reference for this review:

> Noting that the object of the Narcotic Drugs Act, as set out in section 2A, is to give effect to certain of Australia's obligations under the Single Convention, the Review should inquire into and report on the *operation* of the Act, including considering whether the measures implemented are working efficiently and effectively or could be improved for the benefit of affected parties (being applicants and regulated entities as well as the department administering the Act).
>
> In particular, the Review should consider and make recommendations on:
>
> 1. 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.
> 2. 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.
> 3. The appropriateness of the compliance and enforcement regime in the Act, including in relation to the Secretary's functions and powers.

This Review is restricted to a review of the operation of the ND Act. It is not a review of cannabis regulation in Australia more broadly. Matters that do not fall directly within the scope of the review are the operation of Commonwealth, State and Territory laws dealing with:

- patient access to medicinal cannabis – for example, under the Special Access Scheme, the Authorised Prescriber Scheme and the Personal Importation Scheme established under the *Therapeutic Goods Act 1989* (Cth) (**TG Act**);
- subsidising the cost of medicinal cannabis products through the Pharmaceutical Benefits Scheme;
- scheduling of cannabis products by the Therapeutic Goods Administration (**TGA**) and adoption of scheduling decisions by State and Territory health departments;
- registration of cannabis products as prescription medicines on the Australian Register of Therapeutic Goods (**ARTG**); and
- decriminalisation of cannabis possession and for recreational uses.

The laws relating to those and other matters are referred to in this Discussion Paper, as laws that operate alongside the ND Act.

How the review is being conducted

The Review is required to invite public submissions, to conduct targeted consultations with interested stakeholders and through public forums, and to consult the Australian Advisory Council on the Medicinal Use of Cannabis.

Three public consultation forums have been held:

- Sydney – 5 February 2019
- Brisbane – 6 February 2019
- Melbourne – 8 February 2019.

The public forums enabled interested parties to raise issues that could be considered in the review. This discussion paper and invitation for written submissions continues the public consultation. The major issues raised in the public forums and that are taken up in this paper include:

- Does the ND Act establish a suitable framework for ensuring both a sustainable supply of safe medicinal cannabis products for therapeutic purposes, and the availability of cannabis products for research purposes?
- Does the ND Act establish a suitable framework for preventing the diversion of controlled narcotics to illegal uses?
- Is the regulatory scheme for medicinal cannabis efficient and effective, both in the ND Act and administratively?
- Is the compliance and enforcement regime for medicinal cannabis suitable, both in the ND Act and administratively?
- Is an appropriate and proportionate regulatory burden imposed on those making licence and permit applications and supplying information?
- Does the ND Act interact suitably with other Commonwealth, State and Territory legislation relating to the relating to the regulation of cannabis products and narcotic drugs?

Forum participants were encouraged to raise any other topics or issues which they thought the review should focus on, having regard to:

- the **key features of the regulatory framework** (for example, giving effect to Australia's international obligations; ensuring sufficient quantities of medicinal cannabis to meet local needs and export);
- the **risks to be managed** (for example, the risk of diversion; compliance risks); and
- the **terms of reference for the review**.

The Medicinal Cannabis Scheme

Cannabis regulation in Australia prior to 2016

Cannabis (*cannabis sativa*) is a narcotic drug that has been tightly controlled in Australia for many years. With limited exceptions, cannabis has been treated by Commonwealth, State and Territory laws as an illegal narcotic. Several laws prohibit the cultivation, possession and trafficking of cannabis, or make it an offence to operate a motor vehicle after using cannabis.[1]

The main exceptions to the general prohibition on cannabis handling were:

- a cannabis-derived product could be made available for patient use in accordance with the TG Act and the provisions related to the ARTG and the Poisons Standard;
- an application could be made under the ND Act to manufacture a cannabis compound as a narcotic drug;
- an application could be made under the *Customs Act 1901* (Cth) and *Customs (Prohibited Imports) Regulation 1956* (Cth) to import a narcotic drug, including cannabis;
- State and Territory law allowed cultivation of hemp obtained from the cannabis plant for industrial purposes, such as cloth and twine.

There were several instances prior to 2016 in which permission was granted through the TGA Special Access Scheme (discussed below) for the individual importation of medicinal cannabis products for approved use in the treatment of individual patients. The first such approval was granted as early as 1992.

There was growing public discussion in Australia and other countries prior to 2016 of proposals to provide easier patient access to cannabis for therapeutic purposes. A report of the Victorian Law Reform Commission in 2015 recommended legislative change to allow people to be treated with medicinal cannabis in exceptional circumstances.[2] The Commission's recommendations were largely accepted in the enactment of the *Access to Medicinal Cannabis Act 2016* (Vic).

Queensland undertook similar legislative reform in enacting the *Public Health (Medicinal Cannabis) Act 2016* (Qld) (Queensland Medicinal Cannabis Act). The Act and accompanying regulations lay down a comprehensive framework describing eligible prescribers, patients and medicinal cannabis products. The Health and Other Legislation Amendment Bill 2018, introduced into the Queensland Parliament in November 2018, will repeal the Queensland Medicinal Cannabis Act and Regulations.

In 2014 the NSW Government established a Terminal Illness Cannabis Scheme (later renamed the Medicinal Cannabis Compassionate Use Scheme), which enabled NSW police to exercise enforcement discretion in relation to the possession and use of cannabis products by certain terminally ill patients.

A legislative proposal introduced into the Australian Parliament in November 2014 by the Australian Greens with cross-party support was the Regulator of Medicinal Cannabis Bill 2014. A report on the Bill by the Senate Legal and Constitutional Affairs Legislation Committee in August 2015 did not recommend support of the Bill as drafted, nor the establishment of a free standing regulatory agency for medicinal cannabis, but expressed support in principle for legislative reform to enable patient

[1] Eg, Commonwealth laws include the *Crimes (Traffic in Narcotics and Psychotropic Substances) Act 1990* and Part 9.1 of the *Criminal Code Act 1995*.
[2] Victorian Law Reform Commission, *Medicinal Cannabis*, Report, August 2015.

access to cannabis products for use in treating particular medical conditions where the use of a product has been proven to be safe and effective.[3]

The Committee noted that many of the 261 submissions it received gave detailed individual patient accounts of their experience in using cannabis products (largely sourced illegally) to treat a variety of medical conditions.[4] The Committee also noted the strong popular support for medicinal use of cannabis that was reported in the Australian Institute of Health and Welfare 2013 National Drug Strategy Household Survey: 75 per cent of people supported clinical trials of cannabis products to treat medical conditions, and 69 per cent supported legislative reform to permit use of cannabis for medicinal purposes. The Committee report summarised the evidence before the Committee that pointed to difficulties posed by existing Australian laws in obtaining cannabinoid medications and conducting clinical research.[5]

A theme in the public debate in Australia at that time was that there was limited clear evidence from clinical trials and scientific research on the medicinal and therapeutic benefits of cannabinoid medications. There was acceptance nevertheless that a case had been established for cannabis to be more readily available to Australian patients, potentially including those with conditions such as terminal cancer, multiple sclerosis, epileptic seizures, chemotherapy-induced nausea control and chronic pain management. There was concern also that the existing obstacles to cannabis supply meant that people may obtain cannabis of unknown composition through the black market without appropriate medical supervision.

Key changes to the Narcotic Drugs Act in 2016

The Commonwealth Minister for Health announced on 17 October 2015 that it was the Government's intention to sponsor amendments to the ND Act to enable the cultivation of cannabis for medicinal and scientific purposes, consistently with Australia's international obligations relating to narcotic drugs. The proposed changes were introduced in the Narcotic Drug Amendment Bill 2016 which was enacted on 29 February 2016 and commenced operation on 29 October 2016.

The key features of the 2016 amendments are explained in more detail below, but in summary:

- Cannabis cultivation and production for medicinal purposes and research would be controlled through a licence and permit system. This would enable the Commonwealth to control the number and types of cannabis plants that would be cultivated and the size of cannabis crops, ensure that licence/permit holders would comply with regulatory requirements, and enable the Commonwealth to meet its reporting obligations under the Single Convention.
- The existing licence and permit system in the ND Act relating to the manufacturing of drugs was updated to mirror the new licence and permit system for cultivation and production.
- An applicant for a medicinal cannabis licence/permit must demonstrate that a supply arrangement exists with a licensed manufacturer, and the licensed manufacturer must demonstrate an authorised supply chain to a patient. These requirements would align production and supply with legitimate demand.
- The separate system of research licences and permits would enable expert research into such matters as growing conditions, strain selection and cannabis yields.

[3] Legal and Constitutional Legislation Committee, *Regulator of Medicinal Cannabis Bill 2014* (August 2015), Recommendation 1, p vii.
[4] Ibid, para 1.5.
[5] Ibid, para 2.29, and paras 4.4-30

- Regulatory objectives relating to the security of cannabis crops, control of cannabis yields and minimisation of criminal risks would be achieved through licensing conditions, monitoring and inspections, regulatory directions and infringement notices, and offence and penalty provisions.
- Internal review and external appeal opportunities would be available to aggrieved licence applicants and holders.

In the Second Reading Speech for the 2016 amendments the Minister for Health described it as a national licensing system to ensure that a safe, legal and sustainable supply of cannabis-derived products would be available to patients – a 'farm to pharmacy' cannabis supply chain.[6] The licensing and permit controls and regulatory requirements were said to strike 'the right balance between patient access, community protection and our international obligations'.[7] It was also a cooperative scheme that relied on the continuing operation of State and Territory legislation on many aspects of patient access and control of criminal risks.

Further changes were made to the ND Act in 2016 by the Narcotic Drugs Legislation Amendment Bill 2016. The amendments are largely picked up in other discussion in this paper and dealt with matters such as the protection of sensitive law enforcement information when an adverse decision is being reviewed, the grounds for refusal and revocation of licences and permits, and the scope of the regulation making power.

Australia's international obligations under the Single Convention

The ND Act declares that its object 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'.[8] Of particular importance is that the constitutional basis for the enactment of the ND Act by the Australian Parliament rests on it being an Act that implements an international obligation.[9]

The Single Convention applies generally to narcotic drugs including cannabis. The Preamble states the key concerns that underpin the provisions of the Convention. Among them:

> … the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and … adequate provision must be made to ensure the availability of narcotic drugs for such purposes
>
> … addiction to narcotic drugs constitutes a serious evil for the individual and is fraught with social and economic danger to mankind
>
> … effective measures against abuse of narcotic drugs require coordinated and universal action
>
> … [the parties to the Convention desire to conclude] a generally acceptable international convention … on narcotic drugs, limiting such drugs to medical and scientific use …

[6] House of Representatives, *Hansard*, 10 February 2016 at p 1165.
[7] Ibid, p 1166
[8] ND Act, s 2A.
[9] Commonwealth Constitution, s 51(xxix) ('external affairs').

The Single Convention specifies the obligations of state parties to carefully control, supervise and report on cultivation, production and manufacture of narcotic drugs. A party that permits the cultivation of cannabis plants is required to:

- establish a single government agency to exercise the functions of granting licences for cannabis cultivation, designating where cultivation is permitted, purchasing; and taking physical possession of licensed crops, and controlling import, export and wholesale trading of cannabis stocks;[10]
- adopt necessary measures to prevent misuse of and illicit traffic in leaves of the cannabis plant;[11]
- licence and control the manufacture of narcotic drugs;[12]
- prevent the accumulation of narcotic drugs by licensed manufacturers and authorised persons, in excess of the quantities required for the normal conduct of business;[13] and
- provide an annual report to the INCB on the quantities of cannabis to be consumed for medical or scientific purposes, areas of cultivation and annual stocks; and provide statistical returns as required by the Board regarding production, consumption, import, export and stocks of cannabis.[14]

The ND Act does not give effect to the obligation on state parties to purchase and take physical possession of cannabis crops.

The medicinal cannabis scheme in the Narcotic Drugs Act

The medicinal cannabis scheme in the ND Act is designed to implement and strike a balance between several objectives:

- facilitating the cultivation and manufacture of medicinal cannabis products in Australia for supply to patients through approved access and authorised prescriber mechanisms;
- supporting Australian research into cannabis cultivation for medicinal use and registration of medicinal cannabis products;
- cooperation between Commonwealth, State and Territory authorities to develop a safe, legal and sustainable supply of cannabis for medical and research purposes;
- protecting the community against the diversion to illegal purposes of cannabis products that are locally cultivated and manufactured; and
- implementing Australia's obligations under the Single Convention.

The main features of the medicinal cannabis scheme in the ND Act following the 2016 amendments will now be explained.

[10] Single Convention, Articles 23 and 28.
[11] Single Convention, Article 28(3).
[12] Single Convention, Article 29.
[13] Single Convention, Articles 21, 29.3, 30.2(a).
[14] Single Convention, Articles 19, 20.

Definitions

The ND Act uses the term 'cannabis' in referring to cannabis plants, cannabis resin, cannabis licences, cannabis permits and medicinal cannabis products.

The ND Act adopts the definitions of 'cannabis' and 'cannabis resin' in the Single Convention:[15]

> 'Cannabis' means the flowering of 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, by whatever name they may be designated.
>
> 'Cannabis resin' means the separated resin, whether crude or purified, obtained from the cannabis plant.

The Act contains a definition of 'cannabis plant' that expands the definition in the Single Convention:[16]

> ***cannabis plant*** means the following:
>
> (a) any plant of the genus cannabis
>
> (b) and part of a plant of the genus cannabis including, but not limited to, the seeds, stems or leaves of the plant.

The ND Act also contains definitions of other terms that are central to the operation of the medicinal cannabis scheme – such as 'cultivate', 'handling', 'premises', 'production' and 'supply'.

Licences and permits

The ND Act contains a licensing and permit scheme to regulate cannabis cultivation, production and manufacture for medicinal and scientific purposes.

Three different licences can be granted under the ND Act (the licensing criteria, procedure and conditions are discussed later):

- *Medicinal cannabis licence*:[17] This licence can variously authorise, for medicinal purposes, the cultivation (or growing) of cannabis plants, the production (or harvesting) of the cannabis flower or plant resin, and associated activities such as obtaining a cannabis plant, storage, packaging, transport and disposal of cannabis product. A single licence can apply to all or some only of those activities. A licence can be granted to an applicant who has not yet established a growing facility.
- *Cannabis research licence*:[18] This licence can authorise the same range of cultivation, production and associated activities, for the purpose of research relating to medicinal cannabis; and can be granted to an applicant prior to research commencing. A cannabis research licence may authorise cultivation or production only for research purposes.[19]
- *Manufacture licence*:[20] This licence can authorise the manufacture of a drug, including a drug that is a medicinal cannabis product.[21] The licence may authorise manufacture for

[15] ND Act s 4(1); Single Convention Art 1.1.
[16] Ibid.
[17] ND Act s 8E.
[18] ND Act s 9D.
[19] ND Act s 9H.
[20] ND Act s 11G.

patient supply, for research relating to medicinal cannabis products, and associated activities. An ND Act manufacture licence is different from a manufacturing licence under the TG Act, and manufacturers may require both for the production of certain medicinal cannabis products.

A licensee cannot commence activity under the licence until the licensee has been granted a permit to engage in cultivation, production, research or manufacture. These are correspondingly described in the ND Act as a 'medicinal cannabis permit', 'cannabis research permit' and 'manufacture permit'.[22]

Licences and permits are interrelated, and both are required before any cultivation, production, research or manufacture can be undertaken. They can be granted separately or together, though only a licence holder can apply for a permit. A medicinal cannabis licence will specify matters such as the name of the licence holder, the activities that are authorised by the licence in accordance with a permit, the premises at which cultivation or production or other activities can be undertaken, and the persons authorised to undertake those activities.[23] A medicinal cannabis permit will specify matters such as the types and strands of cannabis plant that may be cultivated, the number of cannabis plants a licensee can possess, the quantities of cannabis and cannabis resin that can be produced and the period during which cannabis plants may be cultivated.[24] There are corresponding provisions for cannabis research licences and permits and manufacture licences and permits.[25]

A licensee may require multiple permits to undertake the proposed range of cultivation, production, research or manufacturing activities under the licence. Equally, separate permits can be required for each supply chain arrangement.

The ND Act requires that licences and permits specify the period in which they are in force.[26] The Act does not specify the maximum allowable licence or permit period. There is no procedure in the Act for renewal of existing licences or permits – either a fresh application is required, or the period of the licence can be extended by a variation of the existing licence or permit. Nor can a licence be transferred to another person.[27]

The early practice of the Office of Drug Control (**ODC**), which is responsible for administering the regulatory framework for the cultivation and manufacture of medicinal cannabis in Australia (see below at page 23), was to grant medicinal cannabis licences for a period of one year, but they are now granted for up to three years. Research licences are typically granted for a longer period of three years. The term of a permit is tied, in practice, to the expected plant lifecycle or research period, and may consequently be granted for a shorter period than a licence.

A licence or permit may be varied, either on application or on the Secretary's initiative.[28] Variations that can be made include the variation or removal of an existing licence condition, imposition of a new condition, and variation of the activities or persons authorised by a licence. For example, a licensee may apply for a licence variation to the proposed scope or site of a cultivation or production operation; and for a permit variation because planting occurred later than planned. The variation power was used late in 2018 to extend the term of all existing licences for one year.

As noted below, there is also power to revoke a licence or permit.

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[21] The terms 'drug' and 'manufacture' are defined in the Single Convention, Art 1.1, and includes substances prescribed by regulation under the ND Act (see definition of 'drug' in ND Act s 4(1)).
[22] Respectively, ND Act ss 8P, 9N and 12.
[23] ND Act s 8M.
[24] ND Act s 9B.
[25] ND Act ss 9L, 10A (research); ss 11N, 12C (manufacture).
[26] ND Act ss 8N, 9C (medicinal cannabis licences and permits); ss 9M, 10B (cannabis research licences and permits); ss 11P, 12D (manufacture licences and permits).
[27] ND Act s 24C.
[28] ND Act s 10M (cannabis licences and permits); s 13 (manufacture licences and permits).

Requirements applying to all licence and permit applications

The ND Act specifies the requirements to be met for a licence or permit to be granted, as well as other matters that may be considered in assessing a licence or permit application. The requirements are framed in similar terms for all licences and permits with some contextual variations. There is considerable elaboration in the *Narcotic Drugs Regulations 2016* (**ND Regulations**) of many of the information requirements for a licence or permit application.

A licence cannot be granted unless the decision maker is satisfied on reasonable grounds of the following matters (among others):[29]

- the applicant is a fit and proper person to hold the licence or permit;
- each of the applicant's business associates in relation to the application is a fit and proper person to be associated with a licence or permit holder;
- the applicant (or, if it is a body corporate, its directors) has not engaged in conduct that constitutes a serious criminal offence in the previous ten years;
- the grant of the licence or permit would not be inconsistent with Australia's Single Convention obligations;
- the applicant will take reasonable measures to ensure the physical security of all cannabis products being handled by the applicant; and
- the proposed location, facility and security arrangements are suitable.

The key terms in those requirements are defined or elaborated in the ND Act, including:

- 'fit and proper person': matters that can be considered in deciding whether an applicant or business associate is a fit and proper person include the person's record in relation to criminal convictions, civil penalties, licence revocations or suspensions, connections and associations with other persons, previous business experience, capacity to comply with licence conditions, financial stability, and professional and personal integrity.30
- 'business associate': two or more persons are business associates if each person either:
  - can exercise a significant influence in the business by reason of having a share in the capital of the business, being entitled to receive income from the business, or being able to participate in managing the business or electing office holders; or
  - is a director, partner, trustee, manager, secretary or executive office holder in the business.
- 'serious criminal offence': these are offences involving dishonesty, fraud, drug cultivation or trafficking or that are punishable by imprisonment for five years or more.[31] A serious criminal offence may be disregarded in considering an application for a medicinal cannabis licence or a cannabis research licence if the conviction was for cannabis cultivation or supply and was fully disclosed in the licence application and 'that if the licence were granted, the applicant could comply with all the requirements of the licence' and the ND Act.[32]

[29] ND Act s 8G (medicinal cannabis licence), s 9F (cannabis research licence), s 11J (manufacture licence).
[30] ND Act s 8A and s 8B (whether a body corporate is a fit and proper person).
[31] ND Act s 4(1).
[32] ND Act ss 8H, 9G.

The decision maker may have regard to any other matter considered relevant, including matters that relate to the activities to be undertaken under the licence.[33]

The licencing requirements may have to be re-visited during the currency of a licence – for example, if there is a business restructure of a licensee, or a new issue arising as to the fitness and propriety of a licensee or business associate. As noted below, a standard condition imposed by the ND Act on all licences is a notification requirement about such matters.

The requirements applying to permit applications are comparatively limited, as permits can be granted only to licence holders.[34] The main requirements are:

- a permit application must relate to an activity that is authorised by the licence;
- an application may be refused if the applicant has breached a licence condition; and
- an application must be refused if the decision maker is not satisfied that any standards issued by the Minister under the ND Act[35] have been or will be met.

The ND Act also confers information gathering powers that a decision maker may utilise to supplement the information provided in an application. These include:

- requiring an applicant to allow inspection of the land or premises to which a licence application relates;[36]
- requiring an applicant to provide such further information or documents that are reasonably required;[37]
- requesting relevant information or documents from any source;[38] and
- requiring a State or Territory agency to provide relevant information or documents (subject to special restrictions applying to sensitive law enforcement information).[39]

Special licensing requirements

There are special requirements that apply separately to each category of licence application.

As to a medicinal cannabis licence application, there must be what is colloquially described as a ‘demonstrated supply arrangement’ between the licence applicant and a licensed producer or manufacturer. Specifically:

- a licence for the cultivation only of cannabis plants cannot be granted unless the decision maker is satisfied on reasonable grounds that the cultivated plant will be supplied to a licence holder for production
- a licence for the production of cannabis or cannabis resin cannot be granted unless the decision maker is satisfied on reasonable grounds that the product is to be supplied to a licensee for manufacture for medicinal cannabis or research purposes, or the applicant holds a manufacture licence.[40]

[33] ND Act ss 8F(3), 9E(3), 11H(3).
[34] ND Act ss 8P, 9N, 12.
[35] ND Act s 26B.
[36] ND Act ss 8F(3), 9E(3), 11H(3).
[37] ND Act s 14J.
[38] ND Act s 14K.
[39] ND Act s 14L.
[40] ND Act s 8J.

Correspondingly, it is a condition of a licence that authorises cultivation only that a contract is in existence with a licence holder who is authorised to undertake production; and it is a condition of a licence that authorises production only that a contract is in existence with the holder of a manufacture licence who is authorised to manufacture a drug for medicinal cannabis or research purposes.[41]

As to a cannabis research licence application, any cultivation or production that is permitted by the licence must be for the purposes of research relating to medicinal cannabis.[42]

As to a manufacture licence application to authorise the manufacture of a drug that is derived from the cannabis plant, the intended use of the drug must be for any one of the following:

- for use in research relating to medicinal cannabis products;
- for use in a clinical trial conducted in accordance with the TG Act;
- as a medicinal cannabis product that will be supplied in accordance with an approval or authority under the TG Act; or
- as a medicinal cannabis product that is a registered good under the TG Act.[43]

Licence and permit conditions

The ND Act imposes several standard conditions on all licences granted under the Act. There is elaboration of some of those conditions in the ND Regulations.[44] Additional conditions can also be imposed individually on licences. Breach of a licence condition is a ground for revocation of the licence, as discussed below.[45]

The conditions imposed by the ND Act upon all licences include:

- the licence holder must inform persons who are authorised to engage in activities under the licence of the conditions that are relevant to them and of any directions under the ND Act;[46]
- the licence holder must employ or engage suitable staff, such as adults who have not been convicted in the previous five years of a serious offence or a drug related offence and who have not used illicit drugs in that period;[47]
- activities undertaken under the licence must be authorised by a permit;[48]
- an authorised inspector can inspect the premises in which cultivation, production or manufacture is undertaken, and take samples;[49] and
- the licence holder must notify the Secretary of any matter that may affect whether the licence holder or a business associate is a fit and proper person as required by the ND Act, of any breach of the licence or any matter that is a ground for revocation of the licence.[50]

[41] ND Act s 10J.
[42] ND Act s 9H.
[43] ND Act s 11K(2).
[44] Eg, ND Regulations, ss 18, 19, 20.
[45] ND Act s 10P(2)(a).
[46] ND Act ss 10E, 12G.
[47] ND Act s 10F; ND Regulations s 18(2); s 12H.
[48] ND Act ss 10G, 12J.
[49] ND Act ss 10H, 12K.
[50] ND Act ss 10K, 12N.

Additional conditions that may be imposed individually on licences and permits can deal with matters such as the activities authorised by the licence, handling of cannabis plants and products, description of cannabis products, waste disposal and destruction, documentation and record keeping, security and access to premises, sampling, auditing and reporting, compliance with codes of practice, contingency planning, engagement of staff and contractors, advertising in relation to cannabis products and insurance.[51]

Special conditions are also imposed on manufacture licences to reinforce the special licensing requirement outlined in the previous section – namely, that the intended use of the drug to be manufactured is for research or a clinical trial relating to medicinal cannabis, or as a medicinal cannabis product that is supplied or is a registered good under the TG Act.[52]

Offences and civil penalties

The ND Act imposes a range of offences and civil penalties to ensure compliance with the requirements of the Act by licence holders.

A licence holder commits an offence, and is liable to a civil penalty, by

- engaging in cultivation or production that is not authorised by a medicinal cannabis licence or cannabis research licence;[53]
- breaching a condition of a medicinal cannabis licence that authorises cultivation;[54] and/or
- breaching a condition of a medicinal cannabis licence that authorises production.[55]

Compliance and enforcement powers

The ND Act provides for the appointment of authorised inspectors who may exercise the extensive range of regulatory enforcement powers listed in the *Regulatory Powers (Standard Provisions) Act 2014* (Cth) (**Regulatory Powers Act**).[56] These include powers of entry, inspection, search, seizure, monitoring, investigation and questioning. The powers can be exercised for the purposes of monitoring compliance with the offence and civil penalty and information gathering provisions of the ND Act. An authorised inspector may also issue an infringement notice, request and accept an enforceable undertaking, seek a civil penalty order, or apply for an injunction under the Regulatory Powers Act.

The ND Act confers a related power on authorised inspectors to enter licensed premises without consent or a warrant to monitor compliance with the Act.[57] It is also a condition imposed on licences that an authorised inspector can inspect the premises in which cultivation, production or manufacture is undertaken, and take samples.[58]

The practice implemented by the ODC is to undertake both planned and unannounced inspections of licensed premises. A planned inspection is ordinarily undertaken during the licence approval process, and the intention is to undertake at least one unannounced inspection of each licensee during each 12

[51] ND Act ss 10D, 12F.
[52] ND Act ss 12L, 12M.
[53] ND Act ss 11B, 11D.
[54] ND Act s 11C.
[55] ND Act s 11E.
[56] ND Act Chapter 4.
[57] ND Act s 14C.
[58] ND Act ss 10H, 12K.

month period. Inspections may also be undertaken for other purposes, such as monitoring site remediation and crop destruction.

There was mention earlier of the information gathering powers in the ND Act. These are exercisable in relation to consideration of licence and permit applications, but are also exercisable more generally in monitoring and enforcement. They include powers to require applicants to provide requested information, to request relevant information or documents from any source, and to require State and Territory authorities to provide relevant information or documents.[59]

A direction may be issued to a current or former licence holder on a range of issues. Failure to comply with a direction is both an offence and a civil penalty default.[60] Directions may:

- require a person to take specified measures to ensure the security of land or licensed premises, and to control entry or departure thereon;
- relate to the possession, control or handling of cannabis products;
- relate generally to a licence or permit, as considered appropriate;
- require the destruction of cannabis products that were cultivated, produced or manufactured in breach of a licence; and/or
- relate generally to the manufacturing or labelling of drugs or narcotic preparations.[61]

There are grounds specified in the ND Act on which a licence or permit *must* be revoked, and grounds on which a licence or permit *may* be revoked. The grounds on which a licence or permit *must* be revoked are that the Secretary is satisfied on reasonable grounds that:

- the licence holder has engaged in conduct that constitutes a serious offence since the licence was granted;
- the licence holder is no longer a fit and proper person to hold the licence; or
- a business associate is no longer fit and proper to be associated with the holder of the licence.[62]

The grounds on which a licence or permit *may* be revoked include that the Secretary is satisfied on reasonable grounds that:

- a condition of the licence has been breached;
- the licence holder has engaged in conduct that is an offence against the ND Act;
- false or misleading information was provided in support of the licence or permit application;
- a charge payable in respect of the licence is unpaid;
- the premises or security arrangements applying to the licence or cannabis products are not suitable;
- activities authorised by the licence have been undertaken at premises not covered by the licence; or
- the licence holder has not provided information as required.[63]

[59] ND Act ss 14J, 14K, 14L
[60] ND Act s 15C.
[61] ND Ac ss 14P, 15, 15A.
[62] ND Act ss 10P(1), 13B(1).

The ND Act requires that written notice of a proposed revocation must be given to a licence holder, and that procedural fairness steps be followed.[64]

Review and appeal mechanisms

Decisions under the ND Act that directly affect the interests of applicants and licence holders are generally classed as 'reviewable decisions', for which internal and external review rights are available.

The reviewable decisions include decisions to refuse to grant a medicinal cannabis, cannabis research or manufacture licence or permit; impose conditions on a licence or permit; vary or refuse to vary a licence or permit; revoke a licence or permit; give a direction to a current or former licence holder; suspend a licence or permit; and classify research as commercial rather than non-commercial for charging purposes.[65]

An applicant or licence holder is to be notified that a reviewable decision has been made, and of the terms and reasons for the decision.[66] The person may firstly seek internal review of the decision by applying to the Minister.[67] The Minister may review the decision personally or cause the decision to be reviewed by a person who was not involved in making the decision and is at least as senior as the decision maker.[68] The indicative timeframe for making an internal review decision is 60 days, exclusive of any time that elapses while the review applicant is required to provide further information.[69]

An application may be made to the Administrative Appeals Tribunal for review of an internal review decision, or of a reviewable decision that is deemed to have been affirmed after the elapse of the internal review timeframe. The appeal is to be determined by the Tribunal in accordance with the provisions of the *Administrative Appeals Tribunal Act 1975* (Cth).

The ND Act contains provisions directed to preserving the confidentiality of sensitive law enforcement information in both the internal and external review processes.[70]

Partial cost recovery[71]

The medicinal cannabis scheme implements a partial cost recovery scheme, in line with the *Australian Government Charging Framework* (July 2015) (**the Framework**). The Framework provides that identifiable groups that create a demand for a government activity should generally be charged for it. Part of the cost to government of establishing a regulatory scheme for medicinal cannabis is accordingly passed on to those who undertake cultivation, production and research activities that fall within the scheme.

Charges are imposed on licence holders pursuant to two Acts:

- The ND Regulations, made under the ND Act,[72] impose licence and permit application fees and inspection fees (as listed below).[73] These fees commenced on 30 October 2016. Lower

[63] ND Act ss 10P(2), 13B(2)
[64] ND Act ss 11, 13C.
[65] ND Act s 15D; ND Regulations, s 52.
[66] ND Act s 15G.
[67] ND Act s 15G
[68] ND Act s 15H.
[69] ND Act s 15J(2).
[70] ND Act ss 15F(2A), 15M(2), 15N.
[71] See Department of Health, 'Cost Recovery Implementation Statement: Regulation of Medicinal cannabis' (Version 1.1, January 2017).

fees are set for research licences and permits, with the intention of reducing the financial burden on the academic sector.

- The *Narcotic Drugs (Licence Charges) Regulation 2016*, made under the *Narcotic Drugs (Licence Charges) Act 2016* (Cth), imposes a charge on licence holders that is designed to partially recoup administration and regulatory costs, such as unannounced inspections, sampling, and ongoing monitoring and compliance activity. The charge is imposed annually on commercial licence holders, including a full charge for part only of a 12 month period in which a licence is in operation. It is imposed as a single licence charge on non-commercial cannabis research licence holders. The charge is imposed under a separate Act to meet Constitutional requirements as a law imposing taxation.[74] The charge commenced on 10 December 2016.

The scale of fees and charges is as follows:

Application fees	**Fee ($)**
Application for a medicinal cannabis licence	5,040
Application for a medicinal cannabis permit	1,830
Application for a cannabis research licence	5,040
Application for a cannabis research permit	1,830
Application for a variation of a medicinal cannabis licence	3,900
Application for a variation of a medicinal cannabis permit	1,730
Application for a variation of a cannabis research licence	3,900
Application for a variation of a cannabis research permit	1,730

An applicant may request that the application fee for either a medicinal cannabis licence or a cannabis research licence is reduced by up to 75% if the licence applications are made at the same time and relate to similar activities to be undertaken at the same licensed premises.[75]

Licence charges	**Charge ($)**
For a medicinal cannabis licence (annually)	27,380
For a commercial cannabis research licence (annually)	27,380
For a non-commercial cannabis research licence (single charge)	27,380

Inspection fees

The fee for an inspection conducted in relation to an application for a licence, permit or variation, is $470 in respect of each hour or part hour spent by each person conducting the inspection.

[72] ND Act s 28(1)(c).
[73] ND Act s 54 (inspection fees), Schedule 1 (application fees).
[74] *Commonwealth Constitution*, s 55.
[75] ND Regulations, s 53.

The full costs associated with the grant of licences and the costs of some related activities are not recovered through the mechanisms outlined above. They include:

- expenses associated with the grant of manufacture licences and permits under the ND Act;
- public education activities associated with the scheme;
- administration of the Australian Advisory Council for Medicinal Cannabis; and
- meeting Australia's commitments under the Single Convention.

Interaction of the Narcotic Drugs Act with other Commonwealth laws

The starting point in mapping the Commonwealth legislative framework relating to cannabis is the *Criminal Code 1995* (Cth), which makes it illegal to traffic, import, export, manufacture, cultivate or possess cannabis in any form, unless justified or excused under another law.[76] In short, cannabis can generally be described as an illegal narcotic.

For present purposes there are three relevant Commonwealth laws that authorise a cannabis-related activity that would otherwise be unlawful.

The first is the ND Act. As described in this paper, the ND Act authorises the lawful cultivation, production and manufacture of cannabis products for medicinal purposes, and the handling of cannabis products for the purposes of research into medicinal cannabis use.

The second is the TG Act. The TG Act provides pathways through which both approved and unapproved therapeutic goods can be accessed by or supplied to patients. An approved medicine is one that has been registered by the TGA and is included on the ARTG, following a process to assess the quality, safety and efficacy of the medicine. Once registered, a product can be prescribed through the long-established procedures that apply generally to therapeutic goods. The only product containing cannabinoids that is registered on the ARTG is an oral spray, SATIVEX (Nabiximols).

An unapproved medicinal cannabis product can be accessed through one of four means that are described in the next section – by an Authorised Prescriber, through the Special Access Scheme Category A or Category B, or through a clinical trial approved by an appropriate Human Research Ethics Committee and formally notified to the TGA.[77]

Thirdly, customs laws permit the controlled importation and exportation of cannabis products. It has long been possible to import cannabis products under the *Customs (Prohibited Imports) Regulations 1956* (Cth), with the approval or permission of the Secretary of the Department administering the Regulations.[78]

The exportation of cannabis and cannabis resin produced under a medicinal cannabis licence has been permitted since February 2018, following an amendment to the *Customs (Prohibited Exports) Regulations 1958* by the *Narcotic Drugs Amendment (Cannabis) Regulations 2018*. Exportation was permitted 'to allow for the Australian industry to expand and improve supply of medicinal cannabis within Australia'.[79] That Government policy is outlined in a Department of Health guidance document which explains that export approval may be granted following an assessment by the ODC that the export does not occur to the detriment of supply to Australian patients. The product to be exported must comply with a number of requirements administered by both the ODC and the TGA.

[76] See *Criminal Code 1995*, Chapter 9, Part 9.1; and *Criminal Code Regulations 2002*, reg 5B
[77] See TG Act s 19(1)(b); and https://www.tga.gov.au/clinical-trials.
[78] *Customs (Prohibited Imports) Regulations 1956*, reg 5.
[79] Department of Health, 'Export of medicinal cannabis: Guidance for cultivators and manufacturers of medicinal cannabis' (April 2018) p 4; available at: https://www.odc.gov.au/sites/default/files/guidance-on-export-of-medicinal-cannabis.pdf.

Two other areas of overlap between the medicinal cannabis scheme in the ND Act and the therapeutic goods framework in the TG Act should be noted. One relates to the manufacture of therapeutic goods. A manufacture licence holder under the ND Act will also require a Licence to Manufacture Therapeutic Goods (**GMP**) under the TG Act if the manufactured good is intended to be supplied for human use. A GMP licence is issued by the TGA, in accordance with standards that ensure the adoption of good manufacturing practices in Australia for therapeutic goods.[80]

The other area of overlap relates to the standards for medicinal cannabis. It is an offence under the TG Act to import, export or supply a therapeutic good (including an unapproved good) that does not conform to an applicable standard.[81] The standard applying to unapproved medicinal cannabis products is *Therapeutic Goods Order No. 93 (Standard for Medicinal Cannabis)* (**TGO 93**). TGO 93 imposes controls to ensure that the quality of the medicinal cannabis and ingredients used in the manufacture is of an acceptable standard and safe for consumers. A medicinal cannabis product manufacturer or supplier is required to declare that the product conforms to TGO 93. This requirement applies also to a medical practitioner prescribing a medicinal cannabis product through the Authorised Prescriber or Special Access Schemes.

Patient access under the Authorised Provider Scheme and the Special Access Schemes

The main pathways through which Australian patients can obtain reliable and ongoing access to medicinal cannabis products are through an Authorised Prescriber and the Special Access Schemes, Categories A and B. All three pathways apply to unapproved therapeutic products that are not listed on the ARTG.

A medical practitioner who has been approved as an Authorised Prescriber under the TG Act may prescribe a medicinal cannabis product for a patient in their immediate care for particular approved indications.[82] The conditions for approval as an Authorised Prescriber are that the medical practitioner is engaged in clinical practice, has the approval of an ethics committee or endorsement from an appropriate specialist college to prescribe the product, and the product is prescribed for a person suffering a life-threatening or serious illness or condition.

Special Access Scheme Category A (**SAS A**) is a notification pathway that allows a medical practitioner to access and prescribe a medicinal cannabis product for a patient who is seriously ill.[83] Only a notification to the TGA is required, and not an application. The main requirement for this access pathway is that the patient is seriously ill, which is defined to mean the patient has a condition from which death is reasonably likely to occur within a matter of months, or premature death is reasonably likely to occur in the absence of early treatment.

Special Access Scheme Category B (**SAS B**) is an application pathway through which a registered medical practitioner may apply to the TGA for approval to prescribe a medicinal cannabis product for a patient.[84] The prescribed product may be imported or locally manufactured.

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[80] *Therapeutic Goods (Manufacturing Principles) Determination 2018*, made under the TG Act s 36.
[81] TG Act s 14.
[82] TG Act s 19(5),(6); *Therapeutic Goods Regulations 1990* (**TG Regulations**), reg 12B. Further guidance material in relation to Authorised Prescribers is available on the TGA website (https://www.tga.gov.au/book-page/legal-basis-scheme) and (https://www.tga.gov.au/sites/default/files/authorised-prescriber-scheme.pdf).
[83] TG Act s 18(1); TG Regulations reg 12A. Further guidance material relating to the Special Access Scheme is available on the TGA website (https://www.tga.gov.au/form/special-access-scheme) and (https://www.tga.gov.au/sites/default/files/special-access-scheme-guidance-for-health-practitioners-and-sponsors.pdf).
[84] TG Act s 19(1)(a).

Interaction of the Narcotic Drugs Act with State and Territory laws

Subject to the following three qualifications, the ND Act does not override State and Territory laws relating to cannabis. The intention is that State and Territory laws can operate alongside the ND Act – for example, laws to prevent criminal activity associated with cultivation and trafficking outside the medicinal cannabis scheme.

First, the ND Act overrides any provision of a State or Territory law that is inconsistent with a provision of the ND Act, a regulation made under the Act or a direction given under the Act.[85]

Secondly, the licensing and permit provisions of the ND Act relating to cannabis cultivation, production and research operate to the exclusion of any State or Territory law that establishes similar licensing or permit arrangements or that would prevent a Commonwealth licensee from taking action under their licence or permit.[86] The intent is that the ND Act establishes a consistent national scheme in line with Australia's Single Convention obligations.

Provided there is no clash (inconsistency) with the ND Act scheme, State and Territory laws relating to cannabis cultivation and clinical trials can continue to operate. Alternatively, any inconsistency can be resolved by a regulation under the ND Act that preserves any prescribed State or Territory laws.[87]

Thirdly, section 25A of the ND Act authorises the Secretary of Health to grant an approval to a State or Territory agency to undertake an activity that otherwise requires a licence or permit under the ND Act.[88] Specifically, a State or Territory agency to which a section 25A approval is granted may itself undertake or authorise another person to undertake the cultivation, production or manufacture of cannabis-derived products for medicinal or research purposes. The approval operates to the exclusion of any inconsistent State or Territory law.[89]

A section 25A approval can only be issued if the Secretary is satisfied on reasonable grounds of three matters:

- the proposed State/Territory activity is not inconsistent with Australia's Single Convention obligations;
- the State/Territory agency to which the approval is granted will take all reasonable measures to ensure the physical security of the cannabis-derived products; and
- appropriate reporting arrangements are in place consistently with Australia's Single Convention reporting obligations.[90]

The section 25A approval mechanism was included in the ND Act against a background of some States having well-advanced plans to make medicinal cannabis products available to patients, and a projected time-lag in those products being available from Australian sources if required to wait for the new Commonwealth licensing system to commence on 30 October 2016. The Explanatory Memorandum to the Narcotic Drugs Amendment Bill 2016 explained that the intent of section 25A was 'to allow the earliest possible patient access', but 'is not intended to be used on a permanent basis'.[91] Authorisations were granted to both Victoria and NSW in July 2016 for a two year period to cultivate cannabis plants and produce cannabis or cannabis resin – in Victoria for medicinal purposes,

[85] ND Act s 7.
[86] ND Act s 7A(1).
[87] ND Act s 7A(2).
[88] ND Act s 25A.
[89] ND Act s 7A(1).
[90] ND Act s 25A(1).
[91] Narcotic Drugs Amendment Bill 2016, 'Explanatory Memorandum', p 97.

and in NSW for the purposes of research relating to medicinal cannabis. Victoria was granted a second authorisation in October 2016 for a two year period to manufacture cannabis extracts for medicinal purposes.

Another important intersection point between Commonwealth and State/Territory laws as regards cannabis has to do with poisons standards and scheduling. To promote a uniform national approach to the regulation of poisons, the TGA is responsible for administering a Poisons Standard that operates as a recommendation for adoption by Australian States and Territories, which in each jurisdiction is generally consistently adopted.[92] Cannabis (including seeds, extracts, resin and the plant) and THC (a psychoactive cannabinoid) are listed in Schedule 8 of the Standard for the Uniform Scheduling of Medicines and Poisons (**SUSMP**), which is scheduled to the current Poisons Standard. Schedule 8 informs State and Territory drugs and poison legislation that restricts the manufacture and availability of cannabis and THC to reduce abuse, misuse and physical or psychological dependence. CBD, a non-psychoactive cannabidoil, is listed in Schedule 4 of the SUSMP as a prescription only medicine.

Administration of the medicinal cannabis scheme

Most functions and powers in the ND Act are vested in the Secretary of the Department of Health (as the Secretary of the Department with portfolio responsibility for administering the *National Health Act 1953*).[93] The Secretary may delegate any power or function to any person, including (with State or Territory agreement) an officer or employee of a State or Territory agency.[94]

This arrangement fulfils the requirement of the Single Convention for a single government agency to regulate cannabis as a medicinal product.

The ODC is part of the Health Products Regulation Group of the Department of Health. The ODC is broadly responsible for regulating and providing advice to government on the import, export and manufacture of controlled drugs to support Australia's obligations under the Single Convention. A specific role of the ODC is to administer the regulatory framework for the cultivation and manufacture of medicinal cannabis in Australia, through licensing and permit decisions and undertaking compliance and enforcement activities. The ODC's responsibilities include ensuring that manufactured quantities of medicinal cannabis products are consistent with domestic requirements, engaging in cross-jurisdictional liaison to reduce the risk of illegal diversion of cannabis products, and fulfilling Australia's reporting obligations to the INCB.

The ODC was established in 2016 in recognition of the considerable work that would be required to implement and administer the medicinal cannabis scheme. The ODC received additional staff funding from Government in November 2018 in response to the greater-than expected workload generated by the scheme. There will be a time-lag in recruiting and training new staff; and, as noted above, the ODC's responsibilities extend wider than the administration of the medicinal cannabis scheme.

Senior Department of Health officials have acknowledged in industry and public consultations that the substantial workload and limited staffing to establish and administer the medicinal cannabis scheme has led to undesirable delays in licence and permit decision making. The resourcing for the medicinal cannabis scheme was based on a formal external analysis that suggested that the demand for licences would be about one-third of what it has turned out to be. The senior officials have outlined the administrative practices and reforms that have been adopted to deal with a growing workload, including the publication of administrative guidance on the licensing and permit scheme, and the introduction of new business processes such as screening for licence applications and fast-tracking procedures for permit applications.

[92] TGA Act ss 4(b), 52D.
[93] ND Act s 4(1) (definition of 'Secretary').
[94] ND Act s 25.

The TGA is also part of the Health Products Regulation Group within the Department of Health with responsibilities that intersect with the medicinal cannabis scheme. The TGA administers the TG Act. The TGA regulates good manufacturing practices for narcotics, and cannabis scheduling in conjunction with States and Territories. As explained earlier, the TGA plays a central role in administering the ARTG, the SUSMP, the current Good Manufacturing Practice requirements (**GMP**) and many other regulations, legislative instruments, standards and guidances.

The Department of Health provides administrative support to several relevant advisory and consultative bodies. The Australian Advisory Council on the Medicinal Use of Cannabis comprises 16 members appointed by the Minister for Health to provide advice to the Minister on the implementation and operation of the medicinal cannabis scheme. The members of the Council are drawn from government, the professions and the community, and have expertise in the fields of cancer, epilepsy, palliative care, toxicology, law, pharmacology, law enforcement and botany. It was envisaged that the Council would operate for two years until February 2019, but the Minister has extended its term for another two years.

The Medicinal Cannabis Access Working Group, the Cultivation and Production Working Group and the Law Enforcement Working Group are intergovernmental working groups comprised of representatives from all Australian governments. These Groups share information from each jurisdiction on jurisdictional administrative, policy and legislative changes relevant to their remit.

Operation of the medicinal cannabis scheme since 2016

Since the commencement of the medicinal cannabis scheme the ODC has received over 200 applications for medicinal cannabis, cannabis research and manufacture licences. At 25 February 2018, the ODC had granted 63 licences as follows:

- 26 Medicinal Cannabis Licences - authorising the cultivation and production of medicinal cannabis for commercial use
- 16 Cannabis Research Licences - authorising the cultivation and production of medicinal cannabis for non-human research purposes
- 21 Manufacture Licences -authorising the manufacture of medicinal cannabis products .

Also, 13 permits had been granted to permit cultivation by medicinal cannabis and cannabis research licence holders.

There are no limits on the number of medicinal cannabis licences and permits that can be granted. The licensing and permit scheme is premised on a market-based approach to licensing. The expectation is that the market will indirectly determine the number of licences and permits that will be current at any time: limited demand for the supply of medicinal cannabis products is expected to cause a decrease in the number of licence and permit applications, and a high market demand may correspondingly cause an increase in applications.

There is no conclusive data on the number of patients currently being supplied with medicinal cannabis in Australia through authorised channels. At 31 January 2019, the TGA had approved over 3,000 applications for the supply in Australia of unregistered medicinal cannabis products under SAS B.[95] The large majority of approvals have occurred since 2016. These numbers may include repeat applications for the same patient, as Special Access Scheme applications contain de-identified information. It is therefore difficult to estimate individual patient numbers, and the number of patients currently using medicinal cannabis in Australia is not clear. In addition there have been many hundreds of patients who have received cannabis through the Authorised Prescriber Scheme and through prescription of Sativex; there have also been several dozen SAS A notifications.

[95] https://www.tga.gov.au/access-medicinal-cannabis-products-1

Issues arising in this review

The Review invites written submissions in relation to the Terms of Reference for the Review (set out on page 5).

To assist the submission process, key themes and specific issues that have been raised in this Discussion Paper and in three public forums are set out below. You may address all or some only of those themes and issues in your submission. Or you may raise other issues relating to the ND Act and the implementation and administration of the medicinal cannabis scheme that fall within the Terms of Reference for this Review.

The Review is particularly interested in hearing about your practical engagement with the medicinal cannabis scheme in the ND Act. We welcome examples and case studies of issues you have encountered. Concrete proposals for legislative and administrative reform are also invited.

Key Themes

1. Does the *Narcotic Drugs Act 1967* establish a suitable framework for ensuring a sustainable supply of safe medicinal cannabis products for therapeutic purposes?

2. Does the *Narcotic Drugs Act 1967* establish a suitable framework for ensuring the availability of cannabis products for research purposes?

3. Does the *Narcotic Drugs Act 1967* establish a suitable framework for preventing the diversion of controlled narcotics to illegal uses?

4. Has the Commonwealth (and in particular the Office of Drug Control) implemented an efficient and effective regulatory scheme for medicinal cannabis? Is an appropriate and proportionate regulatory burden placed on those applying for or holding licences and permits? As to medicinal cannabis licences, is there duplication in the processes and information required in applying for a licence and a permit?

5. Has an appropriate compliance and enforcement regime been implemented, both in the *Narcotic Drugs Act 1967* and administratively? Are risks being appropriately managed? Is there excessive risk aversion?

6. Does the Act interact suitably with other Commonwealth, State and Territory laws relating to the regulation of cannabis products and narcotic drugs? Are the intersection points clear? Is there evidence of duplication?

Specific Issues

7. Are key terms appropriately defined in the *Narcotic Drugs Act 1967* having regard to Australia's obligation to adhere to the requirements and terms of the Single Convention – noting that among the terms defined in the Act and that are important in the operation of the medicinal cannabis scheme are 'cannabis', 'cultivate', 'handling', 'premises', 'production' and 'supply'?

8. The *Narcotic Drugs Act 1967* establishes a licensing and permit scheme that rests on three categories - medicinal cannabis licences and permits, cannabis research licences and permits, and manufacture licences and permits. Is that an appropriate structure, having regard to Australia's

obligation to adhere to the requirements and terms of the Single Convention? Is there a need to examine options for greater flexibility, for example, as to the activities (such as research) that can be conducted under a licence, or the uses that can be made of cannabis product that is covered by a licence and permit, or the 'demonstrated supply arrangement' that must form part of an application for a medicinal cannabis licence? Have the requirements of the Act been appropriately interpreted and applied by the Office of Drug Control?

9. The *Narcotic Drugs Act 1967* does not specify the period for which a licence or permit can be in force. Nor is there a procedure for renewal of an existing licence or permit. Should this be changed?

10. The *Narcotic Drugs Act 1967* provides an extensive list of matters that must and can be considered in deciding whether to grant a medicinal cannabis, cannabis research or manufacture licence. The requirement that a licence applicant and business associates meet a 'fit and proper' standard is of central importance. Extensive guidance is provided on those matters in the Regulations and by the Office of Drug Control. Does the *Narcotic Drugs Act 1967* appropriately frame the list of relevant matters? Is appropriate guidance provided in the Act, the Regulations and by the Office of Drug Control? Have the requirements of the Act and Regulations been applied appropriately by the Office of Drug Control?

11. Under s 11K of the *Narcotic Drugs Act 1967*, a licence to manufacture a drug derived from the cannabis plant can be granted only if the intended use of the drug falls within one of the categories in s 11K. Does s 11K impose appropriate restrictions on the grant of manufacture licences?

12. An applicant can be required under s 14J of the *Narcotic Drugs Act 1967* to provide additional information in support of an application. Is this information gathering mechanism being appropriately managed by the Office of Drug Control? Is the information that applicants are required to provide excessive?

13. A licence or permit may be varied either on the application of the licence holder or at the initiative of the Office of Drug Control. Has this power been appropriately managed?

14. The *Narcotic Drugs Act 1967* lists the standard conditions that apply to all licences, and other conditions that may be imposed on licences and permits. Does the Act provide an appropriate list of relevant conditions? Has the Office of Drug Control appropriately managed these provisions of the Act?

15. The Office of Drug Control can exercise a range of compliance and enforcement powers to ensure compliance with the *Narcotic Drugs Act 1967* and with licence and permit conditions. Have those powers been appropriately exercised? Do licence holders receive adequate guidance about the security standards they are expected to meet for premises and goods and the level of scrutiny that will be undertaken by the Office of Drug Control?

16. The Act and Regulations implement a cost recovery scheme, through which fees and charges are imposed on licence applicants and holders. Is the scale of fees and charges appropriate? Should the fee scale apply also to manufacture licences and permits?

17. Are there any concerns about the interaction of the Act with other Commonwealth laws, including in relation to the *Therapeutic Goods Act 1989* (Authorised Prescriber and Special Access Schemes)?

Have your say

The Review invites written submissions in relation to the Terms of Reference and the Key Themes and Specific Issues set out above.

If you are unsure whether a topic or issue fits within the Terms of Reference, the Review invites you to email the secretariat at ReviewNarcoticDrugsAct@health.gov.au, or call us on 1800 020 653, seeking clarification. The Secretariat will endeavour to respond as soon as possible.

The consultation period closes at 5.00PM on Tuesday 2 April 2019. Extensions will not be granted for receipt of submissions.

All submissions will be placed on this website unless marked confidential or indicated otherwise in the submission form. Please note that the Review collects your personal information in this submission in order to:

- contact you if the Review wants to seek clarification of issues raised in your submission or to check whether you consent to certain information that you have provided being made publicly available;
- help provide context about your submission (e.g. to determine whether you are an individual or a director of a company or representing an interest group); and/or
- seek feedback about how the consultation was undertaken.

Please do not include personal information about other individuals in the body of your submission. The Review notes that personal information in this context means information or an opinion about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion.

If you are unable to send the Review a submission via the online portal, submissions can be addressed to the Secretariat to the Review of the Narcotic Drugs Act 1967 and mailed to the following address:

Narcotic Drugs Act Review Secretariat
Health Products Regulation Group
Australian Government Department of Health
PO Box 100 Woden ACT 2606

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Professor John McMillan AO	March 2019