



**Australian Government**  
**Department of Health**

# Review of the Narcotic Drugs Act 1967

## *Final Report*

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# Acronyms and Abbreviations

<b>AAT or Tribunal</b>	Administrative Appeals Tribunal
<b>ADJR Act</b>	<i>Administrative Decisions (Judicial Review) Act 1977 (Cth)</i>
<b>ARC</b>	Administrative Review Council
<b>ARTG</b>	Australian Register of Therapeutic Goods
<b>CBD</b>	Cannabidiol
<b>Customs Export Regulations</b>	<i>Customs (Prohibited Exports) Regulations 1958 (Cth)</i>
<b>Customs Import Regulations</b>	<i>Customs (Prohibited Imports) Regulations 1956 (Cth)</i>
<b>DCS</b>	Drug Control Section in the ODC
<b>GMP</b>	Good Manufacturing Practice
<b>INCB</b>	International Narcotics Control Board
<b>MCIA</b>	Medicinal Cannabis Industry Australia
<b>MDS</b>	Medicinal Cannabis Section in the ODC
<b>ND Act</b>	<i>Narcotic Drugs Act 1967 (Cth)</i>
<b>ND Regulation</b>	<i>Narcotic Drugs Regulation 2016 (Cth)</i>
<b>NSW</b>	New South Wales
<b>ODC</b>	Office of Drug Control
<b>PBS</b>	Pharmaceutical Benefits Scheme
<b>Poisons Standard or SUSMP</b>	Standard for the Uniform Scheduling of Medicines and Poisons which is scheduled to the current Poisons Standard
<b>Regulatory Powers Act</b>	<i>Regulatory Powers (Standard Provisions) Act 2014 (Cth)</i>
<b>SAS A</b>	Special Access Scheme Category A
<b>SAS B</b>	Special Access Scheme Category B
<b>Single Convention</b>	United Nations <i>Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol</i>
<b>THC</b>	Tetrahydrocannabinol
<b>THCA</b>	Tetrahydrocannabinolic acid
<b>TGA</b>	Therapeutic Goods Administration
<b>TG Act</b>	<i>Therapeutic Goods Act 1989 (Cth)</i>
<b>TG Regulations</b>	<i>Therapeutic Goods Regulations 1990 (Cth)</i>
<b>WHO</b>	World Health Organisation

# List of Recommendations

<b>Recommendation 1</b>	The objects clause (section 2A) in the <i>Narcotic Drugs Act 1967</i> be amended to include a statement along the lines that an object of the <i>Narcotic Drugs Act 1967</i> is to enable cannabis cultivation, production, manufacture and research, in order to ensure that medicinal cannabis products are available to Australian patients for therapeutic purposes.
<b>Recommendation 2</b>	The <i>Narcotic Drugs Regulation 2016</i> be amended by deleting paragraph 4A(b) (specifically ‘cannabidiol (including all isomers and salts)’).
<b>Recommendation 3</b>	The <i>Narcotic Drugs Act 1967</i> be amended by deleting paragraph (b) from the definition of ‘cannabis plant’ in section 4(1) of the <i>Narcotic Drugs Act 1967</i> (specifically, ‘(b) any part of a plant of the genus cannabis including, but not limited to, the seeds, stems or leaves of the plant’).
<b>Recommendation 4</b>	The Australian Government Department of Health continue to monitor and advise the Australian Government on options (if any) for altering the operation of the <i>Narcotic Drugs Act 1967</i> , consistently with the provisions of the Single Convention, to remove any unintended obstacles to the cultivation and commercial sale of low-THC hemp under State and Territory law.
<b>Recommendation 5</b>	<p>The Office of Drug Control publish more extensive guidance than is currently published on:</p> <ul style="list-style-type: none"> <li>• the meaning of ‘manufacture’ in the <i>Narcotic Drugs Act 1967</i></li> <li>• the relationship of that term to other relevant terms in the <i>Narcotic Drugs Act 1967</i> (such as ‘cultivation’, ‘production’ and ‘research’) the comparison between the manufacture licence provisions in the Act and manufacture requirements in the Therapeutic Goods Act 1989 and State and Territory laws</li> </ul>
<b>Recommendation 6</b>	<p>The Office of Drug Control consider publishing more extensive guidance than is currently published on:</p> <ul style="list-style-type: none"> <li>• the meaning of the term ‘research’ in the <i>Narcotic Drugs Act 1967</i>: the activities of a research or product development nature that can be authorised by a medicinal cannabis licence or manufacture licence in the absence of a separate cannabis research licence</li> </ul>
<b>Recommendation 7</b>	The <i>Narcotic Drugs Act 1967</i> be amended to establish a new licence structure applying to medicinal cannabis products. The <i>Narcotic Drugs Act 1967</i> should provide for the issue of a single licence to authorise all or some of cultivation, production, manufacture and research of such products.

<b>Recommendation 8</b>	<p>The requirements imposed by the <i>Narcotic Drugs Regulation 2016</i> on licence and permit applicants to provide information and documents in support of applications be revised, with the following objectives:</p> <ul style="list-style-type: none"> <li>• to delete requirements that are no longer necessary to attaining the objectives of the licensing or permit decision</li> <li>• to merge or consolidate requirements that are similar in nature, so as to reduce the number of separate requirements that applicants are required to meet</li> <li>• to reduce the number and breadth of mandatory requirements imposed on applicants</li> <li>• to frame the requirements in more general terms that can, in appropriate circumstances, be elaborated in guidelines issued by the Australian Minister of Health under section 26C(1) of the <i>Narcotic Drugs Act 1967</i> or in informal guidance published by the Office of Drug Control</li> </ul>
<b>Recommendation 9</b>	<p>The <i>Narcotic Drugs Act 1967</i> be amended by repealing section 11K, on the basis that it imposes an unnecessary and counterproductive constraint on the permitted uses of medicinal cannabis products that are manufactured pursuant to licences under the <i>Narcotic Drugs Act 1967</i>.</p>
<b>Recommendation 10</b>	<p>The <i>Narcotic Drugs Act 1967</i> be amended to provide:</p> <ul style="list-style-type: none"> <li>• a medicinal cannabis licence, cannabis research licence or manufacture licence applying to cannabis products shall be granted for a term of maximum term of five years</li> <li>• a licence holder may apply for renewal of the licence at the expiration of the licence term, in accordance with the <i>Narcotic Drugs Regulation 2016</i></li> <li>• the renewal of the licence may be refused on a ground on which the Secretary must or may revoke a licence</li> </ul>
<b>Recommendation 11</b>	<p>The information and document requirements in the <i>Narcotic Drugs Regulation 2016</i> applying to an application for a medicinal cannabis permit, cannabis research permit or manufacture permit be reviewed to reduce the level of detail and specificity required in applications, as part of the review proposed in Recommendation 8 to reduce the detailed prescriptive requirements in the Regulation.</p>
<b>Recommendation 12</b>	<p>The <i>Narcotic Drugs Act 1967</i> (sections 10M, 10N, 13, 13A) and the <i>Narcotic Drug Regulation 2016</i> be amended to provide:</p> <ul style="list-style-type: none"> <li>• that a licence holder must obtain the formal written approval of the Secretary for a variation of a permit, if the variation is of a kind listed in the Regulation</li> <li>• as to any other variation of a permit that is not listed in the Regulation as one that requires the Secretary's written approval – the licence holder shall notify the variation to the Secretary before acting on the basis of the variation</li> </ul>

<b>Recommendation 13</b>	The Office of Drug Control review the standard licence conditions that are imposed on medicinal cannabis, cannabis research and manufacture licences, to ensure that conditions are not imposed unnecessarily and that conditions are appropriately framed.
<b>Recommendation 14</b>	The <i>Narcotic Drugs Regulation 2016</i> , regulations 18 and 39 be amended: <ul style="list-style-type: none"> <li>• to delete the condition that a licence holder take reasonable steps not to employ a person who has sought treatment for drug addiction</li> <li>• to amend the condition that a licence holder take reasonable steps not to employ a person who has used illicit drugs during the previous five years, by providing instead (in terms similar to sections 8H and 9G of the <i>Narcotic Drugs Act 1967</i>) that the Secretary may excuse reliance on that condition if the licence holder has taken reasonable steps to ascertain drug usage by employees and has disclosed any relevant knowledge to the Office of Drug Control</li> </ul>
<b>Recommendation 15</b>	Sections 8M(e), 9L(e) and 11N(e) of the <i>Narcotic Drugs Act 1967</i> be amended to require that a licence specify the persons who are required by the <i>Narcotic Drugs Regulation 2016</i> to be specified as persons who can engage in activities authorised by the licence.
<b>Recommendation 16</b>	The Office of Drug Control include guidance on the operation of the notification requirements in sections 10K and 12N of the <i>Narcotic Drugs Act 1967</i> , when undertaking a review of the ODC publication, <i>Guidance: Compliance, Enforcement and Inspections</i> , as proposed in Recommendation 20.
<b>Recommendation 17</b>	The Office of Drug Control take account of the best practice principles on coercive information gathering powers published by the Administrative Review Council, when undertaking a review of the ODC publication, <i>Guidance: Compliance, Enforcement and Inspections</i> , as proposed in Recommendation 20.
<b>Recommendation 18</b>	The Office of Drug Control initiate discussion with Commonwealth, State and Territory law enforcement agencies: <ul style="list-style-type: none"> <li>• to ensure there is a shared understanding of the protections in the <i>Narcotic Drugs Act 1967</i> for sensitive law enforcement information</li> <li>• to ascertain if there is a need for an administrative protocol regarding the operation of those protections, especially as they apply to sensitive law enforcement information that may be provided to the Administrative Appeals Tribunal in proceedings before the Tribunal for the review of a decision under the <i>Narcotic Drugs Act 1967</i></li> </ul>
<b>Recommendation 19</b>	Sections 10P and 13B of the <i>Narcotic Drugs Act 1967</i> be amended to provide that the relationship between a business associate and a licence holder is a discretionary ground for the revocation of a licence (subsections 10P(2) and 13B(2)) and not a mandatory ground for revocation (subsections 10P(1) and 13B(1)).
<b>Recommendation 20</b>	The Office of Drug Control review its publication, <i>Guidance: Compliance, Enforcement and Inspections</i> , with a view to developing and publishing more comprehensive and contemporary regulatory guidance. Public consultation be a part of this review.

<b>Recommendation 21</b>	The Office of Drug Control review the information presented on its website to evaluate if further helpful information or links can suitably be provided on the interaction of the medicinal cannabis scheme in the <i>Narcotic Drugs Act 1967</i> with relevant Commonwealth, State and Territory laws. This review be undertaken in consultation with the Australian Advisory Council on the Medicinal Use of Cannabis and the three intergovernmental Working Groups.
<b>Recommendation 22</b>	The Australian Government Department of Health arrange for the interaction of the <i>Narcotic Drugs Act 1967</i> and other relevant Commonwealth, State and Territory laws relating to cannabis to be a standing agenda item in the meetings of the Australian Advisory Council on the Medicinal Use of Cannabis and the three intergovernmental Working Groups.
<b>Recommendation 23</b>	Section 25A of the <i>Narcotic Drugs Act 1967</i> be repealed if, at the expiration of current approvals under the section, it becomes a spent provision that is no longer required.
<b>Recommendation 24</b>	The Office of Drug Control develop a risk management framework dealing with the exercise of its regulatory functions, drawing from the <i>Commonwealth Risk Management Policy and the Australian Standard, Risk Management – Guidelines</i> .
<b>Recommendation 25</b>	The Office of Drug Control review its administrative procedures to identify changes that can be implemented to provide an enhanced level of client service to existing licence holders.
<b>Recommendation 26</b>	The Office of Drug Control undertake a review, every six months, of a sample of notices issued during the previous six months under section 14J of the <i>Narcotic Drugs Act 1967</i> requiring the provision of specified information, to evaluate the Office of Drug Control’s reliance on section 14J and the quality of section 14J notices. The review include participation of at least one independent representative from elsewhere in the Australian Government Department of Health or another Commonwealth agency.

# Executive Summary

## Adoption of a national medicinal cannabis scheme in Australia

Australia ratified the United Nations *Single Convention on Narcotic Drugs, 1961* in 1967.<sup>1</sup> The same year the Commonwealth Parliament enacted the *Narcotic Drugs Act 1967* (Cth) (ND Act) to give effect to certain of Australia's obligations under the Convention.

The Single Convention declares that the medical use of narcotic drugs is indispensable for the relief of pain and suffering and that they should, accordingly, be available for medical and scientific use. At the same time, the Single Convention recognises that effective measures are necessary, both nationally and internationally, to guard against addiction to and abuse of narcotic drugs. Among the measures that will be necessary are national control and licensing of the cultivation, production and manufacture of narcotic drugs.

The ND Act initially gave effect to the Single Convention in a limited way. The Australian Government Minister for Health (the Minister) administering the ND Act could grant licences to manufacture narcotic drugs, and the ND Act regulated the movement of narcotic drugs through Australia (for example, on vessels). Until 2016 the manufacture licensing provisions in the ND Act were applied to the control of narcotic drugs obtained from the opium poppy.

In 2016 the ND Act was extensively amended to establish a national regime permitting the cultivation and production of cannabis and cannabis resin in Australia (described in this report as the medicinal cannabis scheme). This came after an active debate that had been occurring both publicly and in Australian legislatures to allow expanded patient access to medicinal cannabis products.

The central feature of the medicinal cannabis scheme established in 2016 was a licensing scheme applying to the cultivation of cannabis plants, the production of cannabis flower and plant resin, the conduct of research relating to medicinal cannabis, and the manufacture of medicinal cannabis drugs. Licences could be granted separately for each of those processes – cultivation and production (combined), research and manufacture. An allied feature of the three-licence scheme was that the specific activity a licence holder could undertake would be spelt out in one or more permits, for which an application would be separately made.

The licensing and permit system enabled the Commonwealth to control the number and types of cannabis plants that could be cultivated, the size of cannabis crops, research activities, the permitted uses of manufactured drugs, the eligibility and conduct of licence holders, and the overall security and integrity of licensed activities. Commonwealth regulatory control enabled it to meet its obligations under the Single Convention to report on Australian activity to the International Narcotics Control Board.

Commonwealth regulatory functions and powers were formally vested by the ND Act in the Secretary of the Australian Government Department of Health (the department), but would be exercisable by a new office established within the department – the Office of Drug Control (ODC). The ODC became part of the Health Products Regulation Group in the department, alongside the Therapeutic Goods Administration (TGA). The TGA was an established part of the Department that regulates therapeutic goods to ensure they are of an acceptable standard.

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<sup>1</sup> The current full title of the Single Convention is *Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol*.

## Review of the operation of the medicinal cannabis scheme in the ND Act

The 2016 amendments to the ND Act required the Minister to cause a review of the operation of the ND Act to be carried out during the third year of operation of the medicinal cannabis scheme. This Review commenced in January 2019. The Terms of Reference for the Review are in **Appendix A** to this report. The report of the review is to be tabled by the Minister in both houses of the Commonwealth Parliament by 29 October 2019.

Public consultation with key stakeholders has been a major element of this Review. This has included the publication of a Discussion Paper in March 2019, consultation forums in three cities, receipt of written submissions (many of which are published on the TGA and ODC websites), and meetings with industry bodies, government working groups and the Australian Advisory Council on the Medicinal Use of Cannabis.

This report makes 26 recommendations for:

- amendment of the *Narcotic Drugs Act 1967* (the ND Act) and the *Narcotic Drugs Regulation 2016* (ND Regulation)
- publication by the ODC of expanded guidance on key features of the ND Act and ND Regulations and the ODC's regulatory approach
- ongoing review of specified issues by the department, the Australian Advisory Council on the Medicinal Use of Cannabis and government working groups

This Review is restricted to the operation of the ND Act. It is not a review more broadly of cannabis regulation in Australia, patient access to medicinal cannabis or scheduling and other decisions of the TGA in relation to cannabis products. There is nevertheless a mention of those issues at various points in the report as they are aspects of the broader setting in which the medicinal cannabis scheme operates.

### Key findings of this Review

The establishment of the medicinal cannabis scheme in the ND Act in 2016 was an important milestone in the Australian Government's approach to the treatment of personal pain and suffering.

The medicinal cannabis scheme built on steps that had already been taken both at national and at State and Territory level to allow patient access to medicinal cannabis products and to support research. The ND Act amendments, however, went much further in establishing a comprehensive framework to facilitate and support an Australian industry dedicated to the supply of medicinal cannabis therapies.

It was described by the Minister at the time as a scheme that would ensure patient availability of a safe, legal and sustainable supply of cannabis-derived products – a 'farm to pharmacy' cannabis supply chain. The establishment of the Commonwealth scheme also led to State governments drawing back from plans already partially legislated to establish State-level schemes regulating cultivation, manufacture and supply of medicinal cannabis products.

A great deal has occurred since October 2016 when the new ND Act scheme commenced. An administrative structure and procedures have been developed and administered by the ODC and the department. The framework is notable for the careful balance it strikes between facilitating cultivation and production of medicinal cannabis products, implementing Australia's obligations under the Single Convention to safeguard against illegal practices, and facilitating cooperation with State and Territory governments to administer safe and sustainable pathways for patient access to medicinal cannabis therapies.

The ODC has received (at 30 June 2019) 246 licence applications, and granted 63 licences (24 medicinal cannabis licences, 16 cannabis research licences and 23 manufacture licences). This is a far higher number than expected. It points to strong commercial interest in the Australian medicinal cannabis industry. This is supported by an active research program in Australia, and the formation of two representative industry organisations. Informal indications point to firm international confidence in the integrity and effectiveness of Australian regulatory processes and the reliability of Australian medicinal cannabis products.

A direct correlation cannot be drawn between, on the one hand, increased cultivation and manufacturing activity by ND Act licence holders and, on the other hand, improved patient access in Australia to medicinal cannabis therapies. There has, nevertheless, been a steady and accelerating increase in patient access that points to a parallel and consistent trend. For example, under one of the patient access pathways described in this report (Special Access Scheme Category B) the number of monthly approvals for the supply of a medicinal cannabis product rose from 132 approvals in May 2018 to 1,374 in May 2019. Increased patient access is also recorded under other pathways.

The medicinal cannabis scheme was established in the ND Act in 2016 and is still in its early days. To date, the establishment of the scheme has overall been resoundingly successful. The ODC has played a central role in this success. It is well respected throughout government and industry for its expertise and professionalism. Additional budgetary funding was provided to the department in 2018 to administer the medicinal cannabis scheme.

These developments are encouraging for Australia. There is growing public and international interest in medicinal cannabis therapies. Proposals have also been developed by the World Health Organisation (WHO) (but not yet considered by the United Nations Commission on Drugs) to adjust the cannabis settings in the Schedules of the Single Convention.

## **Improvement of the medicinal cannabis scheme in the ND Act**

Strong interest was expressed in submissions and consultations during this Review for legislative and administrative reforms to improve the operation of the medicinal cannabis scheme. There was an equally keen interest in the ODC and the TGA to evaluate the reform proposals. An independent business review of ODC administration was commenced internally during this review and is considering many options for administrative improvement.

Generally, there is an aspiration at different levels within government to ensure that the medicinal cannabis scheme functions according to best practice principles of regulation that are consistent with Australia's obligations under the Single Convention.

Five themes stand out in the analysis undertaken by this Review.

### **Unexpected administrative challenges**

Numerous unexpected challenges have been encountered in implementing and administering the medicinal cannabis scheme.

Partly this stems from receipt of a substantially larger number of licence applications than was anticipated from the independent expert modelling that was done at a preparatory stage. Licence applications can be lengthy and intricate and require time-consuming consultation with applicants. The ODC was not resourced to process so many applications. This has contributed to processing delays in the ODC and to frustration and criticism on the part of licence applicants and holders.

Another contributory factor to the unexpected administrative challenges was the phrasing of some of the legislative standards in the ND Act and ND Regulation. Some standards are ambiguous, inexact or inordinately demanding. This, too, adds to the ODC's administrative burden and to the obligations imposed on licence applicants and holders.

Similarly, a couple of provisions in the ND Act and ND Regulation go further than the Single Convention requires (for example, on the definitions of ‘cannabis plant’ and ‘drug’). This has extended the regulatory reach of the medicinal cannabis scheme further than seems necessary.

Recommendations are made in this report to address those unexpected challenges. There are recommendations to amend the ND Act and the ND Regulation to delete or rephrase some legislative standards and to introduce simpler administrative processes (for example, to allow notification rather than formal approval of permit variations that are not substantive in nature or do not pose a material risk).

It is also recommended that the ODC provide extended guidance on the meaning of some terms in the legislation that have given rise to queries and uncertainty in the licensing process (such as the terms ‘manufacture’ and ‘research’).

## **Regulatory focus on risk minimisation**

The first two years of the medicinal cannabis scheme were marked by a strong focus on minimising the risk of criminal incursion in the scheme. This was to be expected initially, because of the requirements of the Single Convention and the improbabilities faced in regulating a new industry that is handling a narcotic drug that is susceptible to abuse. The risk minimisation focus runs through the ND Act, the ND Regulation and the regulatory method of the ODC.

A view forcefully expressed during this Review is that the same intensity is no longer required on risk minimisation in the design and administration of the medicinal cannabis scheme. The risk of criminal infiltration and diversion within the scheme has been controlled. Licence holders have a strong commercial interest to manage risks effectively and to safeguard the integrity of the industry. The ND Act operates alongside other Commonwealth, State and Territory laws that control the risks. There is general acceptance of those points within the department.

This report makes recommendations of two types dealing with the risk minimisation focus. First, the report recommends that the number and breadth of requirements imposed by the ND Regulation on licence applicants to provide information and documents in support of applications be reduced. An alternative regulatory approach is for some of the application requirements to be phrased more generally and to be supplemented by either formal guidelines issued by the Minister under s. 26C of the ND Act, instructions issued by the Secretary under similar statutory powers, or informal guidelines published by the ODC.

Second, the report recommends that the ODC, following public and stakeholder consultation, develop and publish a more contemporary and comprehensive regulatory guide. The purpose of the guide would be to explain the ODC’s regulatory powers, when and how they can be exercised, regulatory goals and priorities, and procedural fairness and other protections available to those affected by regulatory action.

## **Licence and permit system**

The medicinal cannabis framework in the ND Act is structured around three separate licence categories – for cultivation and production (jointly), research and for manufacture. Permits are also issued separately for each licence.

The three licence structure is not a requirement of the Single Convention. It requires only that cultivators be licensed by a government agency and that the parties to the Convention control under licence the establishments and premises in which the manufacture of drugs takes place.

The current three licence structure has been vexing for licence applicants and holders, and adds to the ODC's administrative and regulatory compliance burdens. Licence applicants must submit separate applications for each licence, provide information and documents of a similar kind in support of each application and liaise with the ODC (and possibly different ODC staff) on each application. Doubts can arise as to which activities (such as research and product development) fall within each licence category.

Separate licence categories can also add complexity for licence holders in other ways – such as demonstrating the supply chain arrangements for medicinal cannabis product, transferring or supplying product from one licence or permit to another, or applying for a variation of a licence permit or condition.

This report recommends that the ND Act be amended to establish a single licence structure. A single licence could authorise some or all of cultivation, production, manufacture and research. This would enable adoption of a simpler and more streamlined process for licence application and approval. There would be more flexibility for licence applicants and holders to tailor a required licence to their business intentions and development plans. Managing medicinal cannabis product under a single licence and complying with licence and permit conditions and notification requirements may also be more straightforward.

A single licence structure will require supplementary changes to the ND Regulation and to administrative procedures and forms. The restructure would also provide an opportunity to review how licences and permits interrelate in achieving the objectives of the medicinal cannabis scheme in the ND Act.

## **Hemp cultivation and supply**

The report notes many cross-over points between the medicinal cannabis scheme in the ND Act and activities occurring in the cultivation and commercial sale of low-THC hemp.

For the most part those other activities are controlled by State and Territory laws. Hemp, a specially cultivated cannabis plant that contains little or no psychoactive cannabinoid content, is usually cultivated for industrial and horticultural purposes and as a food ingredient.

The Single Convention declares that it does not apply to the cultivation of the cannabis plant exclusively for industrial or horticultural purposes. The focus of the Convention is upon the control of narcotic drugs for medical and scientific purposes. Commonwealth laws can nevertheless apply to low-THC hemp products. An example discussed in the report is that an extract of a cannabis plant that is used in a non-therapeutic product may need to be covered by a ND Act manufacture licence if it is to be exported from Australia.

The potential cross-over of Commonwealth law and State / Territory law in relation to hemp cultivation was an issue that was frequently discussed in the consultations and submissions in this Review. A general complaint was that Commonwealth law can have an overlapping and inhibiting effect on the cultivation and production of low-THC hemp.

It was not within the scope of this Review to examine those complaints. The report observes that the issues can be more complex and nuanced than at first glance. That said, it is important that the distinctions drawn in the Single Convention between the regulation of narcotic and non-narcotic cannabis derivatives is not blurred.

The report recommends, as a precautionary measure, that the department continue to monitor and advise Government on the options (if any) for altering the operation of the ND Act to remove any obstacles to the cultivation and commercial sale of low-THC hemp under State and Territory law. A related recommendation is that the definition of 'drug' in the ND Regulation, that applies to the manufacture licence provisions in the ND Act, be amended to remove pure cannabidiol from the definition.

## Patient access

Patient access to medicinal cannabis therapies does not fall within the scope of this Review of the ND Act. It is a broad subject that is controlled by other Commonwealth, State and Territory laws and administrative arrangements.

The submissions to this Review understood that limited scope. They nevertheless took the opportunity to point out that a declared expectation when the medicinal cannabis scheme was being introduced into the ND Act in 2016, was that medicinal cannabis would be more readily and easily available to Australian patients. There are statements on the parliamentary record that confirm that expectation.

It was claimed in some submissions that the expectation has not been fulfilled. A relatively small number of patients are receiving prescribed medicinal cannabis, it is mostly imported and it is expensive. There are also claims that obtaining medicinal cannabis through illicit channels is the easier path for many patients.

This Review has not examined those claims and cannot express a view. However, the Review is aware that industry regulation has been a dominating focus in the establishment of the medicinal cannabis scheme in the ND Act since 2016. Further, the objects clause in the ND Act provides no illumination beyond declaring that the object of the ND Act is to give effect to certain of Australia's obligations under the Single Convention.

The statutory objects clause should be an important element in signifying how the ND Act should be understood, administered and construed. To achieve that purpose, the report recommends that the objects clause include a statement that an object of the ND Act is to enable cannabis cultivation, production, manufacture and research, in order to ensure that medicinal cannabis products are available to Australian patients for therapeutic purposes.

## Implementation of recommendations

The 26 recommendations in this report span amendment of the ND Act, amendment of the ND Regulation, and administrative-level reforms.

The most far-reaching recommendation – and, in that sense, the prominent recommendation – is to replace the current three licence structure in the ND Act with a single licence structure. Implementation of that recommendation would require extensive changes not only to the ND Act but also to the ND Regulation and to ODC publications, forms and administrative procedures.

It is important that other improvements to the medicinal cannabis scheme are not postponed until a new licence structure is adopted. To do so would maintain practices that detract from the opportunity to make a well-regarded medicinal cannabis scheme work far better.

The licence and permit application requirements in the ND Regulation could be amended and simplified ahead of any change to the three licence structure. Some application requirements in the Regulation could be deleted or revised, and others could be merged or consolidated so that single forms could be used for multiple application purposes.

Many other recommendations in this report could be implemented in a short timeframe by amendment of the ND Regulation or administrative reforms – for example, to extend the standard licence terms, reduce the number and difficulty of licence conditions, institute simpler procedures for notifying and approving routine permit variations, and lessening the frequency and scope of the reporting obligations on licence holders.

Early steps could also be taken within the ODC and the department to act on other recommendations that require publication of an expanded regulatory guide and guidance material, and refinement of existing review and consultation arrangements.

## Acknowledgements

This Review has benefited greatly from the input and assistance of many people.

The discussion at three public consultation forums attended by over 200 people was lively and constructive. Many thoughtful submissions were received that provided commentary and examples that were drawn from heavily in preparing this report.

Staff in the department, particularly the ODC and the TGA, gave excellent support to the Review and readily shared their considerable knowledge and experience in the regulation of therapeutic substances. Many other officers in Commonwealth, State and Territory government agencies were similarly keen to be consulted and to render valuable assistance during the Review.

The Australian Advisory Council on the Medicinal Use of Cannabis took great interest in the Review and held lengthy and constructive discussions with the Reviewer at three meetings of the Council.

Special acknowledgement and thanks are owed, most importantly, to a small and talented team within the TGA who provided expert assistance throughout – Danielle Chifley, Tristan Dimmock and (for part of the review) Kieran Proctor. They brought to the Review great energy, enthusiasm and a deep intellectual grasp of complex issues.

# Chapter 1: Why and how this Review was conducted

## Why this Review was conducted

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
- to ensure that controlled narcotics are available for medicinal 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 contained a basic framework for regulating narcotic drugs, principally through licensing the manufacture of narcotic drugs. The main application of the ND Act prior to 2016 was to control narcotic drugs obtained from the opium poppy and 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. The new medicinal cannabis scheme was tailored to the specific objective of making available within Australia a sustainable supply of medicinal cannabis products for therapeutic purposes, and to facilitate scientific research into medicinal cannabis. The existing provisions of the ND Act relating to the manufacture of narcotic drugs were updated to align with the new licence provisions permitting cannabis cultivation and production. New provisions dealt with potential criminal risks of medicinal cannabis products being diverted to unlawful purposes and to criminal infiltration of the industry. A central aim of the 2016 amendments was to ensure that Australia would remain compliant with its international treaty obligations under the Single Convention.

The 2016 amendments required the Minister to initiate a review of the operation of the ND Act as soon as possible after the second anniversary of the commencement of the 2016 amendments.<sup>2</sup> 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, Australian Minister for Health (the Minister), 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 Ombudsman (Acting), Integrity Commissioner for the Australian Commission for Law Enforcement Integrity (Acting) and member of the Australian Copyright Tribunal.

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<sup>2</sup> ND Act, s 26A.

## The scope of this Review

The Minister announced the Terms of Reference for this Review:

Noting that the object of the ND 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 ND 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 ND 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 more broadly of cannabis regulation in Australia or patient access to medicinal cannabis. 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 (SAS), 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 or compassionate schemes
- scheduling of cannabis products by the 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)
- decriminalisation of cannabis possession for recreational uses.

Those who took an interest in this Review understood that it is limited in scope and would not directly examine the issues just listed. That said, some submissions criticised the limited scope of the review and questioned whether the central purpose of the 2016 ND Act amendments – patient access to medicinal cannabis – was obscured by a limited review.

This report can only deal directly with issues that fall within the terms of reference and that are covered by the ND Act. Broader questions of patient access and the affordability and accessibility of medicinal cannabis are controlled by other legislative and administrative arrangements that would require government initiation of a separate and different process of examination.

A review of the ND Act separately from other cannabis-related issues is an important subject of inquiry. The ND Act contains a new and comprehensive licensing and regulatory regime for medicinal cannabis cultivation and manufacture that has attracted considerable commercial, research and policy interest in Australia and abroad. A great deal has happened in the short period the new scheme has been operating. A diversity of views has been expressed, as captured in this report, about how the scheme should be revised or fine-tuned. Those matters warrant early consideration, which this Review may facilitate.

This inquiry has nevertheless benefitted from issues raised in submissions that did not fall squarely within the terms of reference. For the most part the views expressed have influenced the discussion in this report, especially in the summary in Chapter 5 of responses to the Key Themes. It is clear from that summary that some submissions felt the objective of making medicinal cannabis more readily available to Australian patients had not been realised. This was for a variety of reasons to do with product cost, complex access pathways, the reluctance of medical practitioners to prescribe medicinal cannabis, delays in approving Australian licences to produce and manufacture medicinal cannabis products and lack of integration of Commonwealth, State and Territory laws and regulatory activities. In one way or another those and similar points are picked up throughout this report.

## How this Review was conducted

Consultation both publicly and with key stakeholders was a major element of this Review. The consultation was underpinned by publication of a Discussion Paper<sup>3</sup> on 4 March 2019 that invited submissions by 2 April 2019 on 17 Key Themes and Specific Issues.

The Key Themes have been prominent in all consultations in this Review. They are:

- Does the ND Act establish a suitable framework for ensuring a sustainable supply of safe medicinal cannabis products for therapeutic purposes?
- Does the ND Act establish a suitable framework for ensuring 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?
- Has the Commonwealth (and in particular the ODC) implemented an efficient and effective regulatory scheme for medicinal cannabis? Is an appropriate and proportionate regulatory burden imposed 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?
- Has an appropriate compliance and enforcement regime been implemented, both in the ND Act and administratively? Are risks being appropriately managed? Is there excessive risk aversion?
- Does the ND 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?

The Specific Issues listed in the Discussion Paper raised similar matters to do with the terms of the ND Act, the licensing and permit scheme, decision-making criteria and processes, regulatory controls, the exercise of compliance and enforcement powers, fees and charges, and the interaction of the ND Act with the TG Act.

Three public consultation forums were held (prior to the publication of the Discussion Paper) in Sydney, Brisbane and Melbourne between 5 - 8 February 2019. The forums were attended by over

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<sup>3</sup> *Review of the Narcotic Drugs Act 1967*, Discussion Paper (Department of Health, 4 March 2019) (the **Discussion Paper**).

120 people including interested members of the public, licence holders and applicants, consultants, researchers, Commonwealth and State officials and health professionals. Senior officials from the department attended and addressed the public forums.

The Review received 25 submissions. Parties could request non-publication of either their submission or their identity. The public website established for this Review publishes 16 submissions (two anonymously) and lists three other parties that made submissions.<sup>4</sup> The submissions principally came from those having a commercial, public health, public policy or patient access interest in the medicinal cannabis scheme.

Other consultation activities the Review undertook included:

- attending three meetings of the Australian Advisory Council on the Medicinal Use of Cannabis<sup>5</sup>
- attending meetings of three Working Groups convened by the department and comprising Commonwealth, State and Territory government officials – specifically, the Medicinal Cannabis Access Working Group, the Cultivation and Production Working Group and the Law Enforcement Working Group
- consulting with Queensland and Victorian Government public health officials about the medicinal cannabis legislation applying in those States, and with Western Australian police representatives
- consulting with two industry bodies – the Medicinal Cannabis Industry Association (MCIA) and the Medicinal Cannabis Council Inc.
- holding numerous consultations with Commonwealth officials from the department, including the ODC and the TGA
- consulting with the Australian Government Solicitor
- visiting the premises of a licensed cannabis cultivation facility
- consulting with a New Zealand Government official about proposed legislation in that country.

## **The approach adopted in this report**

The medicinal cannabis scheme based in the ND Act is a new scheme that was operating for just over two years when this Review commenced. A central focus of the Review has been whether the scheme is operating efficiently and effectively.

A clear message in the three public consultation forums held as part of this Review was that many unanticipated issues had arisen in the administration of the medicinal cannabis scheme that were the subject of regular discussion between the department and interested parties. The number of licence applications made to the department was roughly three times higher than forecast by a formal external analysis that was undertaken prior to the scheme commencing. The Government has since acknowledged, through extra funding in the last year and other steps, that constant review is needed of potential administrative practice changes that can be made as required.<sup>6</sup>

Other issues requiring attention that have been highlighted in the first couple of years concern matters such as the interaction of the federal medicinal cannabis scheme with State and Territory laws, and intersection points between the scheme and industry practices regarding the cultivation, manufacture and export of cannabis-derived products.

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<sup>4</sup> [www.odc.gov.au/consultation-review-narcotic-drugs-act-1967](http://www.odc.gov.au/consultation-review-narcotic-drugs-act-1967).

<sup>5</sup> The Council's role is explained in Chapter 2.

<sup>6</sup> See the Discussion Paper, at p 23.

Views have been expressed to this Review in submissions and public forums about administrative and legislative reforms that could be implemented to address supposed problems with the scheme. The constructive response has been for the department to consider some of those suggestions as they arise (particularly suggestions for administrative reform). There has been ongoing discussion between the department and many parties while this Review was underway. The additional funding the department received enabled it to commission an independent business review of administration within the ODC. The business review is due to be completed before this report will be published and is expected to consider the public submissions that have been made to this Review.

It is in the interest of all parties that necessary improvements be implemented as early as practicable and not await the outcome of this Review. This has implications for the approach adopted in this report. The report summarises all criticisms of the medicinal cannabis scheme that were expressed in submissions and consultations but does not always reach a finding or make a recommendation that could be overtaken in the interim. A substantial number of recommendations are nevertheless made for legislative and administrative reform. The summary of views expressed also provides a reference point for subsequent appraisal of whether effective progress has been made in improving the operation of the medicinal cannabis scheme.

This report does not quote from or refer specifically to individual submissions. Most of the points that are taken up in this report were expressed in multiple submissions, and it can be misleading to refer to one only of them. Often too a point was made in unpublished as well as published submissions.

# Chapter 2: Cannabis regulation in Australia

## Introduction

This chapter provides background information on the medicinal cannabis scheme that was introduced in 2016 into the ND Act. Six topics are covered:

- the elements of the cannabis plant, to inform an understanding of the elements regulated by the ND Act and those regulated, for example, by State and Territory industrial hemp laws
- examples of Australian laws that prohibit or regulate activities involving cannabis, with a focus on laws enacted prior to the commencement of the medicinal cannabis scheme in 2016
- Australian developments leading up to the creation of a medicinal cannabis scheme in 2016, and the main features of the new scheme
- the implementation and administration of the scheme within the department, and the role of the ODC within the department
- the pathways in the TG Act by which Australian patients can obtain access to medicinal cannabis products
- scheduling of controlled substances in Australian statutes.

The last two of those topics (patient access and scheduling) are not part of this Review. They are, however, an important adjunct to an objective of the ND Act of facilitating the supply of medicinal cannabis products to patients in Australia through authorised prescriber mechanisms. They will be noted in that context.

## The cannabis plant<sup>7</sup>

The cannabis plant is an annual flowering plant that contains various components – roots, stem, leaves, flowering (or fruiting) tops and seeds. Resin can be extracted from the plant, principally from the flowers and adjacent leaves but also from other leaves and the stem.

The plant contains over 500 compounds (cannabinoids), including 120 phytocannabinoids. The two most important naturally occurring cannabinoids that have medicinal qualities are delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD). THC is a psychotropic substance (or intoxicant); CBD is non-psychoactive.

THC and CBD are both derived from the flowering tops and resin of the plant. The cannabinoid concentration can vary across varieties or strains of the plant, with higher concentrations in the resin. Different concentrations of compounds can have different therapeutic benefits and psychoactive effects. The dried stem, leaves and seeds of the cannabis plant are almost devoid of psychoactive cannabinoids.

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<sup>7</sup> Sources relied on for this description include State Government website material relating to hemp regulation, and the report of the World Health Organisation Expert Committee on Drug Dependence, *Fortieth Report* (2018), WHO Technical Report Series, No 1013.

The cannabis flowering tops and resin can be administered in different ways, that include smoking or as a pharmaceutical or herbal preparation. Pharmaceutical preparations are mostly administered orally as capsules, tablets, and extracts or tinctures, but can be administered as a spray, ointment or by vaporisation.

Hemp is a cannabis plant that is bred to contain low (or zero) concentration of THC – that is, a cultivar, or specially cultivated plant. A hemp extract may have little or no psychoactive effect; a higher concentration of CBD in the plant may inhibit or counteract the psychoactive effects of THC. It is generally grown for industrial and horticultural uses. For example, the leaves and stem can be used as fibre, rope, fabric, insulation, and as a component of paper, fibreboard, plastic and compost; and the seeds can be used as a food ingredient, nutritional supplement or cosmetic.

Laws that regulate industrial hemp (also called low-THC hemp/cannabis) define the maximum THC content of the plant. A standard in many State and Territory laws in Australia is that the concentration of THC in the leaves and flowering heads must be no more than 1%<sup>8</sup>, though the level is set lower in Victoria at 0.35%.<sup>9</sup>

Research is being conducted (increasingly) in Australia and internationally on the therapeutic benefits of cannabinoid medications. Some of the research is government sponsored. There was acceptance in Australia in adopting a medicinal cannabis scheme in 2016, 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. Support has been expressed for research and clinical trials to be conducted on the therapeutic benefits for other conditions for which there is limited or no clinical evidence, such as depression, Alzheimer’s disease, AIDS/HIV and post-traumatic stress disorder.

## Australian legal regulation of cannabis products

To explain the broader setting in which the medicinal cannabis scheme operates, this section gives examples of Australian laws that either prohibit or regulate activities involving cannabis. The laws referred to were mostly enacted prior to the creation of the Commonwealth scheme in 2016. The term ‘cannabis’ will be used, though many of the laws provide more specific definitions of the derivatives of the cannabis plant or the composition of the drug to which the law applies.

These examples of Australian laws are arranged in four groups that are broad generalisations – many laws fit in more than one group. The approach adopted in each Australian jurisdiction is that cannabis is treated as an illegal narcotic unless an activity such as possession, cultivation, manufacture or supply is authorised by another law.

The first group of laws to note are those that treat cannabis as an illegal narcotic or illicit substance. Following are some examples:<sup>10</sup>

- *Criminal Code Act 1995* (Cth): Cannabis is in a scheduled list of ‘Controlled drugs’ and ‘Controlled plants’.<sup>11</sup> The *Criminal Code Act 1995* (Cth) contains many separate offences that make it illegal to traffic, import, export, manufacture, cultivate or possess a controlled drug or plant, unless justified or excused under another law.<sup>12</sup>

<sup>8</sup> *Hemp Industry Act 2008* (NSW) s 3(1); *Industrial Hemp Act 2015* (Tas) s 4; *Industrial Hemp Act 2017* (SA) s 3; *Industrial Hemp Act 2004* (WA) s 3; *Hemp Fibre Industry Facilitation Act 2004* (ACT) Dictionary.

<sup>9</sup> *Drugs, Poisons and Controlled Substances Act 1981* (Vic) s 61(1).

<sup>10</sup> Generally, see Parliament of Australia, Law and Bills Digest Group, ‘Illicit Drugs, their Use and the Law in Australia’, Background Paper 12, 1996-97; and Senate Economic References Committee, *Personal choice and community impacts*, Interim report on the sale and use of marijuana and associated products (May 2016).

<sup>11</sup> *Criminal Code Regulations 2019* (Cth), Schedule 1

<sup>12</sup> See *Criminal Code 1995* (Cth), Chapter 9, Part 9.1.

- *Crimes (Traffic in Narcotics and Psychotropic Substances) Act 1990* (Cth): Cannabis is in a scheduled list of ‘Narcotic Drugs’.<sup>13</sup> It is an offence under the *Crimes (Traffic in Narcotics and Psychotropic Substances) Act 1990* (Cth) to deal in one of those drugs on board an Australian aircraft or ship or in another country that has similar laws to Australia.
- *Drug Misuse and Trafficking Act 1985* (NSW): This Act prohibits the cultivation, manufacture, supply, possession and use of various drugs including cannabis.
- *Criminal Code 2002* (ACT): The focus of the offence provisions of this Act is upon ‘Serious Drug Offences’, such as cultivation and manufacture of commercial quantities of controlled drugs (including cannabis), drug trafficking and selling drugs to children.
- *Transport Operations (Road Use Management) Act 1995* (Qld): It is an offence under this Act to drive a motor vehicle while under the influence of a drug (such as cannabis) or while a drug is present in blood or saliva.<sup>14</sup>

A qualification on those examples is that the penalty attached to a specific offence will generally vary according to the quantity of drug involved. A common example is that simple possession of a small quantity of cannabis may attract either a warning, referral to a diversion or drug treatment program, or a low fine or penalty notice that if paid does not result in a recorded conviction.

The next group to note are the Australian laws that regulate supply or access to cannabis as a therapeutic medicine. Some examples:

- *Therapeutic Goods Act 1989* (Cth): This Act imposes controls on the quality, safety and efficacy of therapeutic substances that are used in or exported from Australia. Two important elements of the Act are the ARTG which is a register of ‘approved’ medicines that can be supplied in Australia; and the Poisons Standard<sup>15</sup> which classifies drugs and poisons in schedules, as recommendations for adoption by States and Territories. One cannabis product is registered in the ARTG; cannabis is listed in Schedule 8 of the Poisons Standard as a ‘Controlled Drug’; and cannabidiol is listed in Schedule 4 of the Standard as a ‘Prescription Only Medicine’.
- *Customs Act 1901* (Cth): Cannabis is listed in both the *Customs (Prohibited Imports) Regulations 1956* and the *Customs (Prohibited Exports) Regulations 1958* as a drug that cannot be imported to or exported from Australia without a licence and permit under those Regulations.<sup>16</sup>
- *Drugs, Poison and Controlled Substances Act 1981* (Vic): This Act establishes a comprehensive framework applying to medicines and poisons, in line with the Schedules in the Poisons Standard. Activities that are controlled include possession, manufacture, storage, supply, labelling, packaging, medical prescription and pharmacy dispensing.
- *Controlled Substances Act 1984* (SA): This Act is a public health and safety Act that applies to medicines, poisons and prohibited substances (including cannabis) that are used in health care, industry, agriculture or in the home, and the Act controls activities such as manufacture, sale, supply and possession.

<sup>13</sup> *Crimes (Traffic in Narcotics and Psychotropic Substances) Act 1990* (Cth), Schedule 2.

<sup>14</sup> *Transport Operations (Road Use Management) Act 1995* (Qld) s 80.

<sup>15</sup> The Standard for the Uniform Scheduling of Medicines and Poisons (**SUSMP**) is scheduled to the current Poisons Standard (**current Poisons Standard**). The current Poisons Standard is a non-disallowable legislative instrument for the classification of medicines and poisons (see s 52A of the TG Act). Medicines and poisons are classified under the SUSMP into Schedules, which state the level of control which should be exercised over the availability of the medicines and poisons in each Schedule. This Report refers to the more commonly used term ‘Poisons Standard’. These references should be read as being to the SUSMP or relevant Schedule thereof.

<sup>16</sup> Respectively, regulation 5 and Schedule 4 of the Customs Import Regulations; and reg 10 and Schedule 8 of the Customs Export Regulations.

A third group of laws comprises the Acts in two States that aimed to establish a comprehensive framework for regulating the supply of medicinal cannabis to patients. Both Acts were enacted prior to the establishment of the Commonwealth medicinal cannabis scheme in 2016, but neither Act was implemented following the Commonwealth development:

- *Access to Medicinal Cannabis Act 2016* (Vic): The Act was designed to enable Victorian patients to access medicinal cannabis in exceptional circumstances. Allied provisions in the Act dealt with cultivation and manufacture of medicinal cannabis products, research and supply. The Victorian Government announced in 2018 that it would not implement a stand-alone regulatory scheme following Commonwealth action to licence cultivation and manufacture.<sup>17</sup> It is understood that the Victorian Act may be repealed.
- *Public Health (Medicinal Cannabis) Act 2016* (Qld): This was an analogous Act to the Victorian Act and laid down a comprehensive framework describing eligible prescribers, patients and medicinal cannabis products. The Queensland Act was repealed from 1 July 2019<sup>18</sup>, to be replaced by a new scheme under the Medicines and Poisons Bill 2019 (Qld). The Bill is intended to make it easier for patients and doctors to access medicinal cannabis, including prescription of medicinal cannabis by non-specialist medical practitioners.<sup>19</sup>

A fourth group of laws are those relating to industrial hemp:

- *Industrial Hemp Act 2015* (Tas): A licence can be granted under this Act to authorise cultivation, supply, manufacture or research involving industrial hemp for non-therapeutic purposes. This can include use in textiles, paper and building materials (for hemp fibre and pulp) and cosmetics and food (for hemp seed and oil). Industrial hemp is classified under the Act as cannabis that contains less than 1% THC.
- Acts in other jurisdictions that deal exclusively with industrial hemp are the *Hemp Industry Act 2008* (NSW), *Industrial Hemp Act 2017* (SA), *Industrial Hemp Act 2004* (WA) and *Hemp Fibre Industry Facilitation Act 2004* (ACT).<sup>20</sup>

One other important framework item to note is the *National Drug Strategy 2017-2026*. This is endorsed by the Ministerial Drug and Alcohol Forum. The Strategy lays down a national framework to minimise the harm associated with drug use, including both illicit and pharmaceutical drugs. Cannabis is listed as a priority substance in the Strategy.

## Introduction of the medicinal cannabis scheme in 2016

Access to cannabis products for therapeutic or medicinal purposes was possible prior to 2016, principally under the pathways in the TG Act (discussed below). The first approval granted through the Special Access Scheme (SAS) to import a medicinal cannabis product occurred as early as 1992. Cannabidiol was also re-classified by the TGA in the Poisons Standard in July 2015 from being a Schedule 9 ‘prohibited substance’ to a Schedule 4 ‘prescription medicine’.

<sup>17</sup> Media Release, ‘Victorian Medicinal Cannabis Industry Powers Ahead, 17 January 2018: [www.premier.vic.gov.au/wp-content/uploads/2018/01/180117-Victorian-Medicinal-Cannabis-Industry-Powers-Ahead.pdf](http://www.premier.vic.gov.au/wp-content/uploads/2018/01/180117-Victorian-Medicinal-Cannabis-Industry-Powers-Ahead.pdf). As to the inoperative status of the Victorian Act, see also Victorian Department of Health and Human Services, *Annual Report 2017-18*, p 90 (‘Timeliness’).

<sup>18</sup> *Health and Other Legislation Amendment Act 2019* (Qld), s 57.

<sup>19</sup> Medicines and Poisons Bill 2019 (Qld) - [https://www.legislation.qld.gov.au/view/html/bill\\_first/bill-2018-004/lh](https://www.legislation.qld.gov.au/view/html/bill_first/bill-2018-004/lh); See also statement from The Honourable Steven Miles, Minister for Health and Minister for Ambulance Services (Qld) - <http://statements.qld.gov.au/Statement/2019/4/3/queensland-streamlines-medicinal-cannabis-access>.

<sup>20</sup> The Northern Territory Government introduced a *Hemp Industry Bill 2019* into the Legislative Assembly on 16 May 2019.

From 2016 onwards there was also the prospect of expanded access to medicinal cannabis products in Victoria and Queensland under new State Acts that year.<sup>21</sup> Related developments in some States were that penalties for possession of cannabis were downgraded or transformed. An example was the Terminal Illness Cannabis Scheme established in New South Wales in 2014 (later renamed the Medicinal Cannabis Compassionate Use Scheme), which enabled New South Wales police to exercise enforcement discretion in relation to the possession and use of cannabis products by certain terminally ill patients.

Prior to 2016 there was growing public discussion in Australia and other countries 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.<sup>22</sup> The Commission's recommendations were largely accepted in the enactment the following year of the *Access to Medicinal Cannabis Act 2016* (Vic).<sup>23</sup>

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 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.<sup>24</sup> The Senate 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.<sup>25</sup>

The Senate 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 Senate Committee report summarised the evidence before the Senate Committee that pointed to difficulties posed by existing Australian laws in obtaining cannabinoid medications and conducting clinical research.<sup>26</sup>

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.<sup>27</sup> 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.

The Minister 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 enacted on 29 February 2016 and commenced operation on 29 October 2016.<sup>28</sup>

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<sup>21</sup> *Access to Medicinal Cannabis Act 2016* (Vic); *Public Health (Medicinal Cannabis) Act 2016* (Qld).

<sup>22</sup> Victorian Law Reform Commission, *Medicinal Cannabis*, Report, August 2015.

<sup>23</sup> As noted above at footnote 16, the Act has been inoperative following the establishment of a Commonwealth medicinal cannabis scheme in 2016.

<sup>24</sup> Legal and Constitutional Legislation Committee, *Regulator of Medicinal Cannabis Bill 2014* (August 2015), Recommendation 1, p vii.

<sup>25</sup> *Ibid*, para 1.5.

<sup>26</sup> *Ibid*, para 2.29, and paras 4.4-30.

<sup>27</sup> See TGA, 'Medicinal cannabis – guidance documents' (May 2018): [www.tga.gov.au/medicinal-cannabis-guidance-documents](http://www.tga.gov.au/medicinal-cannabis-guidance-documents)

<sup>28</sup> *Narcotic Drug Amendment Act 2016* (Cth).

The lead-up to the 2016 amendments included extensive and targeted consultation with the States and Territories, including through the Intergovernmental Committee on Drugs. The consultation aimed to develop a 'nationally agreed approach' to the development of the new scheme.<sup>29</sup> This was seen to be important to ensure that patient access to cannabis-derived products for medicinal use was consistent around Australia, and that there were no regulatory gaps that could be exploited by organised criminal groups. Support for improved patient access to medicinal cannabis was expressed by professional and support bodies such as the Australian Medical Association, Royal College of Physicians, Multiple Sclerosis Australia, MS Research Australia and Palliative Care Australia.

The key features of the 2016 amendments are explained in later chapters of this report, 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 manufacture 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.
- 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 applicants and licence holders.
- The ND Act would not override State and Territory laws except to the extent that any such law was inconsistent with the licensing and permit provisions of the ND Act or would prevent a Commonwealth licence holder acting under their ND Act licence or permit. The State/Territory laws that would continue to operate included laws dealing with medicines, industrial hemp, land use, and cannabis possession and supply.

In the Second Reading Speech for the 2016 amendments the Minister 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.<sup>30</sup> The licensing and permit controls and regulatory requirements were said to strike 'the right balance between patient access, community protection and our international obligations'.<sup>31</sup> 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.

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<sup>29</sup> See Explanatory Memorandum, Narcotic Drugs Amendment Bill 2016, 'Sections. 5: Consultation' (p 14).

<sup>30</sup> House of Representatives, *Hansard*, 10 February 2016 at p 1165.

<sup>31</sup> *Ibid*, p 1166

Further changes were made to the ND Act later in 2016.<sup>32</sup> The amendments 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.

Another relevant legislative change in February 2018 was the amendment of the *Customs (Prohibited Exports) Regulations 1958* to permit the export for therapeutic use of certain cannabis products cultivated or manufactured in Australia.<sup>33</sup> A department guidance document explained at the time that the purpose in allowing export was ‘to allow for the Australian industry to expand and improve supply of medicinal cannabis within Australia’<sup>34</sup>. The product to be exported must comply with several requirements administered by both the ODC and the TGA, including an ODC assessment that the export would not occur to the detriment of supply to Australian patients.

## Implementation and administration of the medicinal cannabis scheme

### Office of Drug Control

The ND Act vests functions and powers in the Secretary of the Department of Health (as the Secretary of the Department with portfolio responsibility for administering the *National Health Act 1953*).<sup>35</sup> 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.<sup>36</sup>

In recognition of the considerable work that would be required to implement and administer the medicinal cannabis scheme, the ODC was established in 2016 within the Department of Health, with two sections. An existing section, the Drug Control Section (DCS), retained its role of regulating the manufacture and import/export of narcotic drugs including cannabis, and fulfilling Australia’s reporting obligations under the international drug conventions; and a new section, the Medicinal Cannabis Section (MCS), would regulate cannabis cultivation and production.

The ODC is part of the Health Products Regulation Group in the department. The ODC received additional staff funding from the Australian Government in November 2018 in response to the greater-than expected workload generated by the scheme.

The ODC is broadly responsible for regulating and providing advice to the Australian 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 monitoring stock levels to ensure that manufactured quantities of medicinal cannabis products are consistent with domestic requirements and export commitments, engaging in cross-jurisdictional liaison to reduce the risk of illegal diversion of cannabis products, and fulfilling Australia’s reporting obligations to the INCB.

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<sup>32</sup> *Narcotic Drugs Legislation Amendment Act 2016* (Cth).

<sup>33</sup> *Narcotic Drugs Amendment (Cannabis) Regulations 2018*. The precise scope of the export provisions is explained in Department of Health, ‘Export of medicinal cannabis: Guidance for cultivators and manufacturers of medicinal cannabis’ (April 2018), available at: <https://www.odc.gov.au/sites/default/files/guidance-on-export-of-medicinal-cannabis.pdf>.

<sup>34</sup> *Ibid* at p 4.

<sup>35</sup> ND Act, s 4(1) (definition of ‘Secretary’).

<sup>36</sup> ND Act, s 25.

Since the commencement of the medicinal cannabis scheme the ODC (at 30 June 2019) had received 246 applications for medicinal cannabis, cannabis research and manufacture licences. The ODC had granted 63 licences:

- 24 Medicinal Cannabis Licences - authorising the cultivation and production of cannabis for commercial use as a therapeutic product
- 16 Cannabis Research Licences - authorising the cultivation and production of medicinal cannabis for non-human research purposes
- 23 Manufacture Licences -authorising the manufacture of drugs (including medicinal cannabis products that are drugs) for therapeutic use.

Thirty three permits had been granted to permit cultivation by medicinal cannabis and cannabis research licence holders.

Licence holders can voluntarily elect to have their name published on the ODC website. Twenty licence holders were listed in June 2019.

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.

While there is no direct limit on licences or permits, a Party to the Single Convention is required to report each year to the INCB on the quantity of drugs the Party intends to cultivate, manufacture, import and export.<sup>37</sup> A limit is set by the INCB, and it can call on a Party to adopt remedial measures to ensure that the provisions of the Convention are observed.<sup>38</sup>

## Other government bodies

Other regulatory and advisory bodies within or supported by the department also play a role in relation to medicinal cannabis.

The TGA is also part of Health Products Regulation Group in the department. The TGA administers the TG Act, which embraces Good Manufacturing Practice (GMP) requirements for narcotics, the ARTG for registered and listed medicines, the Poisons Standard as a scheduling recommendation to the States and Territories, the Special Access Scheme (SAS), the Authorised Prescriber Scheme and the Personal Importation Scheme.

The department provides administrative support to the Australian Advisory Council on the Medicinal Use of Cannabis. The Australian Advisory Council comprises 16 members appointed by the Minister to provide advice to the Minister on the implementation and operation of the medicinal cannabis scheme. The members of the Australian Advisory Council are drawn from the Australian 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 Australian Advisory 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 comprising representatives from all Australian governments. These groups share information from each jurisdiction on administrative, policy and legislative changes relevant to their remit.

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<sup>37</sup> Single Convention, Articles 12-21.

<sup>38</sup> Single Convention, Article 14.1(b).

## Patient access pathways

Commonwealth law provides five main pathways through which a medicinal cannabis product can be lawfully supplied to a patient under the TG Act.<sup>39</sup>

First, any medicine that is included in the ARTG can (in accordance with State or Territory law) be prescribed by a medical practitioner for a patient and dispensed through standard pharmacy procedures. Inclusion in the ARTG is done by the TGA following evaluation of the quality, safety and efficacy of the medicine.<sup>40</sup> A registered medicine that is included in the ARTG can be a subsidised medicine under the Pharmaceutical Benefits Scheme (PBS).

The only product containing cannabinoids that is included in the ARTG is ‘SATIVEX® (Nabiximols) (Sativex). It was registered in November 2012. Sativex contains a 1:1 ratio of THC and CBD, extracted from botanical medicinal cannabis. It is an oral spray that is indicated as a treatment for symptom improvement in patients with moderate to severe spasticity due to multiple sclerosis. Sativex is not currently a PBS medicine.

Second, a medical practitioner who is an Authorised Prescriber under the TG Act may prescribe a specified medicinal cannabis product for a class of patients in their immediate care for approved indications.<sup>41</sup> The practitioner has to report six monthly to the TGA on the number of patients who are newly prescribed the medicinal cannabis product in the six monthly period and the number of patients continuing on the product.

The prescribed product may be locally manufactured or imported; if the latter, an import permit must be obtained by the importer of the product who may import bulk product that is held for supply.<sup>42</sup>

The conditions to be 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 cannabis product, and the product is prescribed for a person suffering a life-threatening or serious illness or condition. At 30 April 2019 there were 57 Authorised Prescribers.

Third, 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.<sup>43</sup> Only a notification to the TGA is required before prescribing the relevant good, 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.

A medicinal cannabis product cannot be manufactured domestically for supply directly through the SAS A pathway, as this is not listed in s 11K of the ND Act as a permitted use of a manufactured drug. Consequently, in practice, drugs that can be supplied under SAS A are those either imported by a

<sup>39</sup> It is also lawful to access a medicinal cannabis product as an extemporaneously compounded product or via the personal importation scheme. These pathways fall under the TG Act and the *Therapeutic Goods Regulations 1990* (Cth) and are not considered further in this report.

<sup>40</sup> Therapeutic goods supplied in Australia are required to be included in the Register or, if not, to be covered by an exemption, approval, or authority. Criminal offences apply if a person imports, exports, manufactures or supplies therapeutic goods in Australia that are not registered, listed, exempt or the subject of an approval or authority under the TG Act (see ss 19B of the TG Act).

<sup>41</sup> TG Act, s 19(5),(6). 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>).

<sup>42</sup> *Customs (Prohibited Imports) Regulations 1956* (Cth), reg 5.

<sup>43</sup> 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>).

doctor or pharmacy or manufactured in Australia under a GMP licence using cannabis or cannabis extract starting material that has been imported.

Fourth, Special Access Scheme Category B (SAS B) is an application pathway through which a registered health practitioner may apply to the TGA for approval to prescribe a medicinal cannabis product for a patient.<sup>44</sup> The application must outline the patient diagnosis, the clinical justification for use of a product that is not included in the ARTG, and the proposed course of treatment.

Fifth, a person may access medicinal cannabis by participating in a clinical trial approved by an appropriate Human Research Ethics Committee and formally notified to the TGA.<sup>45</sup>

The great majority of medicinal cannabis products supplied to Australian patients through these pathways were imported. The first domestically produced product became available in August/September 2018 and only in small volumes.

Only the first pathway provides access to a registered medicine in the ARTG – that is, a medicine registered in the ARTG after evaluation by the TGA (currently Sativex is the only such medicine). Therapeutic goods, including medicinal cannabis products, that are not included in the ARTG can be accessed through the other four main pathways. The TGA advises that ‘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’.<sup>46</sup>

All therapeutic goods that are supplied in Australia or imported or exported must conform to applicable standards.<sup>47</sup> The principal standard applying with respect to medicinal cannabis products is *Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017* (TGO 93).<sup>48</sup> 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 medicinal cannabis products a medical practitioner may prescribe through the Authorised Prescriber or Special Access Schemes, and in clinical trials. Evaluation of a medicine to be listed in the ARTG looks more rigorously at the quality, safety and efficacy of the product.

There are no definitive figures on the number of patients currently being supplied with medicinal cannabis in Australia through these authorised pathways. The number of patients currently using medicinal cannabis in Australia is not clear, although the following figures are indicative:

- At 31 May 2019, the TGA had approved over 7,700 applications for the supply in Australia of unregistered medicinal cannabis products under SAS B.<sup>49</sup> The large majority of approvals have occurred since 2016. The number of SAS B approvals has risen sharply over the past year: the number of monthly approvals between May 2018 to May 2019 has been 132, 146, 188, 229, 237, 331, 567, 490, 671, 738, 1041, 1110 and 1374. These numbers may include repeat applications for the same patient, as SAS applications contain de-identified information.
- At 17 May 2019, 135 notifications had been made to the TGA under SAS A – an increase from 45 notifications five months earlier in December 2018.
- Over 500 patients have received medicinal cannabis products through the Authorised Prescriber scheme. Hundreds of patients have also been prescribed Sativex.

<sup>44</sup> TG Act, s 19(1)(a).

<sup>45</sup> See TG Act, s 19(1)(b); and <https://www.tga.gov.au/clinical-trials>.

<sup>46</sup> <https://www.tga.gov.au/access-medicinal-cannabis-products-1>.

<sup>47</sup> TG Act, s 14.

<sup>48</sup> TGO 93, determined under s 10 of the TG Act, constitutes a standard for medicinal cannabis products (see TGO 93, s 5).

<sup>49</sup> <https://www.tga.gov.au/access-medicinal-cannabis-products-1>.

A final point to note about patient pathways is that access to both the registered and unregistered medicinal cannabis products – the latter including through the Authorised Prescriber and Special Access Schemes – can require approval within the relevant State or Territory. This is to comply with State and Territory drugs and poisons legislation.

The Commonwealth, States and Territories have worked to streamline access to medicinal cannabis products by agreeing to a TGA portal through which a single application can be lodged by a medical practitioner for Commonwealth and State/Territory approval where required. The protocol is that the evaluation of an application will be completed and the applicant notified within two days of all required information being received. Tasmania does not participate in this procedure, requiring separate applications to the Commonwealth and to the Tasmanian Department of Health and Human Services.

## Scheduling

A common feature of the legal instruments (laws and conventions) that regulate controlled substances such as narcotic drugs, medicines and poisons is that the instruments list the substances to which they apply in multiple schedules. The level of control of a substance will vary according to the schedule it is in.

Instruments that are discussed in this report that adopt scheduling are the Single Convention, the Poisons Standard, the Customs Import and Export Regulations, and the *Criminal Code Act 1995* (Cth). The main point to be noted at this stage is that there are differences between those instruments in Schedule classification/definition and numbering. In part that is because the scheduling in each instrument is set in a different context or for a different purpose. For example, the Single Convention establishes an international framework for narcotic drugs to be available for the relief of pain and suffering, while coordinating international measures against abuse of narcotic drugs; and the Poisons Standard sets a domestic framework for the availability of medicines and drugs.

The Single Convention contains four Schedules and specifies different controls to be applied to the narcotic drugs in each Schedule. Schedule I lists cannabis, cannabis resin and extracts and tinctures of cannabis. Schedule IV lists cannabis and cannabis resin. Higher standards of control apply to Schedule IV drugs. There is further discussion of the Single Convention in Chapter 3.

The Poisons Standard includes (as a schedule) the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP). The SUSMP in turn contains Schedules that state the level of control to be exercised over the availability of the medicines and poisons in each Schedule. The Schedules embody the decisions of the Secretary of the Department of Health (or delegates) regarding the classification of poisons. The Schedule classifications are a recommendation to be given legal effect by the Australian States and Territories in legislation that regulates medicines and poisons and their availability to the public.<sup>50</sup> The objective of the SUSMP is to promote a uniform approach throughout Australia to the availability, accessibility and safe handling of medicines and poisons. (In this Report, a reference to the Poisons Standard should be read as being a reference to the SUSMP.)

There are nine active Schedules in the Poisons Standard – Pharmacy Medicine (Sch 2), Pharmacist Only Medicine (Sch 3), Prescription Only Medicine (Sch 4), Caution (Sch 5), Poison (Sch 6), Dangerous Poison (Sch 7), Controlled Drug (Sch 8), Prohibited Substance (Sch 9), and Substances of such danger to health as to warrant prohibition of sale, supply and use (Sch 10).

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<sup>50</sup> TGA Act, ss 4(1)(b), 52D.

Schedule 8, which applies to drugs that should be available by prescription but subject to controls to reduce abuse, misuse and physical or psychological dependence, includes the following two items: ‘Cannabis (including seeds, extracts, resin and the plant, and any part of the plant) when prepared or packed for human therapeutic use’ in accordance with ND Act or TG Act requirements; and THC ‘when extracted from cannabis for human therapeutic use’ in accordance with ND Act or TG Act requirements. Cannabis was changed from a Schedule 9 drug to a Schedule 8 drug in November 2016.

CBD is listed in Schedule 4 of the Poisons Standard as a Prescription Only Medicine under the following description: ‘Cannabidiol in preparation for therapeutic use where cannabidiol comprises 98 per cent or more of the total cannabinoid content of the preparation; and any cannabinoids, other than cannabidiol, must be only those naturally found in cannabis and comprise 2 per cent or less of the total cannabinoid content of the preparation’.

Cannabis is also listed in Schedule 9 as a prohibited substance, except as covered by Schedule 4 or 8, or as processed hemp fibre or hemp seed oil with a prescribed minimum THC content.

The *Customs (Prohibited Imports) Regulations 1956* contains 15 schedules that list items that are prohibited for import or to which special import requirements and permissions apply. ‘Drugs’ are listed in Schedule 4, and include ‘Cannabinoids’, ‘Cannabis’ and ‘Cannabis resin’. A Schedule 4 substance can only be imported by the holder of both a licence and a permit – which, in the case of drugs listed in Schedule I or II of the Single Convention, can only be granted in specified circumstances designed to ensure Australia’s compliance with the Convention.<sup>51</sup>

The *Customs (Prohibited Exports) Regulations 1958* adopts a similar approach. Schedule 8 of the eight schedules in the *Customs (Prohibited Exports) Regulations 1958* applies to ‘Drugs the exportation of which is prohibited if specified conditions, restrictions or requirements are not met’. ‘Cannabis’ and ‘Cannabis resin’ are listed in Schedule 8. Among the requirements to be met for export are that the exportation is by a licensed exporter and the export is for a purpose specified in the *Customs (Prohibited Exports) Regulations 1958*.<sup>52</sup>

The *Criminal Code Regulations 2019*, Schedule 1, lists ‘Controlled drugs’, ‘Controlled plants’ and the quantities that, for the purposes of the offence provisions in the *Criminal Code Regulations 2019*, are a ‘Commercial quantity’, a ‘Marketable quantity’ and a ‘Trafficable quantity’. Among the drugs listed in Schedule 1 are ‘Cannabis (in any form, including flowering or fruiting tops, leaves, seeds or stalks, but not including Cannabis fibre)’ and ‘Cannabis resin’. Among the controlled plants listed in regulation 12 is ‘any plant of the genus *Cannabis*’. The interaction of the Criminal Code and the ND Act is discussed in Chapter 4.

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<sup>51</sup> *Customs (Prohibited Imports) Regulations 1956*, reg 5(10).

<sup>52</sup> *Customs (Prohibited Exports) Regulations 1958*, reg 8(1).

# Chapter 3: Single Convention on Narcotic Drugs

## Introduction

Australia is a party to three United Nations conventions relating to narcotic drugs – the *Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol* (the Single Convention),<sup>53</sup> the *Convention on Psychotropic Substances 1971*<sup>54</sup> and the United Nations *Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances 1988*.<sup>55</sup>

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*’.<sup>56</sup> The Single Convention is, accordingly, directly relevant to this Review.

Implementation of Australia’s obligations under the Single Convention provides the constitutional basis for the enactment of the ND Act by the Australian Parliament.<sup>57</sup> This means that it is not open to the Commonwealth – as suggested in some submissions and consultations – to work from a different standpoint than embodied in the Single Convention regarding the classification of cannabis as a narcotic drug that poses social and health risks.

This chapter briefly outlines the terms of the Single Convention and recommendations that are presently under consideration to reschedule the classification of cannabis in the Convention.

## The Single Convention

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 ...’

The operation of the Single Convention is overseen by the INCB.

<sup>53</sup> *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*.

<sup>54</sup> *Convention on Psychotropic Substances 1971*, opened for signature 21 February 1971, 1019 UNTS 175 (entered into force 16 August 1976).

<sup>55</sup> *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).

<sup>56</sup> ND Act, s 2A.

<sup>57</sup> Commonwealth Constitution, s 51(xxix) (‘external affairs’).

An important structural feature of the Single Convention is that it lists the narcotic drugs to which it applies in four Schedules to the Convention. Different obligations apply to the drugs in each Schedule. Cannabis is listed in Schedules I and IV, under the following descriptions:

- **Schedule I:** ‘CANNABIS and CANNABIS RESIN and EXTRACTS and TINCTURES of cannabis’.
- **Schedule IV:** ‘CANNABIS and CANNABIS RESIN’.

The drugs in all four Schedules are subject to the controls listed below, with additional obligations applying to opium and cannabis and cannabis resin,<sup>58</sup> and exceptions applying to drugs listed in Schedule II and preparations listed in Schedule III. Higher standards of control are required for drugs listed in Schedule IV.<sup>59</sup>

The overriding obligation of parties under the Single Convention is 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<sup>60</sup>
- adopt necessary measures to prevent misuse of and illicit traffic in leaves of the cannabis plant<sup>61</sup>
- licence and control the manufacture of narcotic drugs<sup>62</sup>
- prevent the accumulation of narcotic drugs by licensed manufacturers and authorised persons, in excess of the quantities required for the normal conduct of business<sup>63</sup>
- 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.<sup>64</sup>

Schedule IV drugs are those regarded as posing the greatest health, welfare and social dangers (for example, heroin is another Schedule IV drug). The higher standards of control applying to Schedule IV drugs are as follows:

- a Party shall adopt any special measures of control which in its opinion are necessary having regard to the particularly dangerous properties of a drug so included
- a Party shall, if in its opinion the prevailing conditions in its country render it the most appropriate means of protecting the public health and welfare, prohibit the production, manufacture, export and import of, trade in, possession or use of any such drug except for amounts which may be necessary for medical and scientific research only, including clinical trials therewith to be conducted under or subject to the direct supervision and control of the Party.

The Single Convention draws two important distinctions, between:

- narcotic drugs to which the Convention applies, and non-narcotic substances that may fall outside the Convention

<sup>58</sup> Eg, Single Convention, Articles 23 and 28.

<sup>59</sup> Single Convention, Article 2.5.

<sup>60</sup> Single Convention, Articles 23 and 28.

<sup>61</sup> Single Convention, Article 28(3).

<sup>62</sup> Single Convention, Article 29.

<sup>63</sup> Single Convention, Articles 21, 29.3, 30.2(a).

<sup>64</sup> Single Convention, Articles 19, 20.

- the use of narcotic drugs for medical and scientific purposes, which is permitted by the Convention in accordance with the controls that it outlines, and the use of narcotic drugs for other purposes that are not permitted.

Those distinctions are taken up in Articles 2.9, 4.1(c) and 28.2 of the Convention:

- 2.9. Parties are not required to apply the provisions of this Convention to drugs which are commonly used in industry for other than medical or scientific purposes, provided that:
- (a) They ensure by appropriate methods of denaturing or by other means that the drugs so used are not liable to be abused or have ill effects ... and that the harmful substances cannot in practice be recovered; and
  - (b) They include in the statistical information ... furnished by them the amount of each drug so used.
- 4.1 The Parties shall take such legislative and administrative measures as may be necessary:
- (a) To give effect to and carry out the provisions of this Convention within their own territories;
  - (b) To cooperate with other States in the execution of the provisions of this Convention; and
  - (c) Subject to the provisions of this Convention, to limit exclusively to medical and scientific purposes the production, manufacture, export, import, distribution of, trade in, use and possession of drugs.
- 28.2 This Convention shall not apply to the cultivation of the cannabis plant exclusively for industrial purposes (fibre and seed) or horticultural purposes.

## Proposals to reschedule cannabis in the Single Convention

A review of cannabis scheduling under the Single Convention was undertaken in 2018 by the Expert Committee on Drug Dependence of the World Health Organisation (WHO) (the Committee) at its 40th and 41st meetings. The review was prompted in part by recognition of an increased use of cannabis for medical purposes and the emergence of new cannabis-related pharmaceutical preparations for therapeutic use.<sup>65</sup>

Based on the Committee's work, the WHO has put forward recommendations to the United Nations Commission on Drugs to amend the listing of items in the Schedules of the Single Convention. These are only at proposal stage and are yet to be supported by the INCB.

The recommendations (based on the Committee's findings) can be summarised as follows:<sup>66</sup>

- **Cannabidiol:** The Committee accepted that there are no case reports of abuse or dependence relating to the use of pure CBD, or public health problems associated with CBD. Research is underway on the therapeutic applications of CBD.

CBD is not separately listed in the Single Convention, but if prepared as an extract or tincture of cannabis it currently falls within the listing of cannabis in Schedule I. The WHO made separate recommendations that preparations considered to be pure CBD should not be scheduled in the Single Convention; and that a footnote be added to the entry for cannabis and cannabis resin in Schedule I to read: 'Preparations containing predominantly cannabidiol and not more than 0.2 percent of delta-9-tetrahydrocannabinol are not under international control'.

<sup>65</sup> World Health Organisation Expert Committee on Drug Dependence, *Fortieth Report* (2018), WHO Technical Report Series, No 1013, at p 1.

<sup>66</sup> The following summary is taken principally from the Fortieth Report, supplemented by a letter conveying the recommendations from the Director-General of the World Health Organisation to the Secretary-General of the United Nations, dated 24 January 2019.

- ***Cannabis and cannabis resin:*** The Committee accepted that cannabis with a high concentration of THC can cause adverse health effects (particularly for children) and can impair motor control and cognitive function and be a drug of physical dependence. Those adverse effects stem mostly from acute or chronic use. The Committee also recognised the growing interest and research into the medical applications of cannabis, and that medical use was permitted in a growing number of countries.

The WHO agreed that cannabis and cannabis resin should continue to be listed in Schedule I of the Single Convention, noting it is liable to abuse and to produce ill-effects, and is the most widely illicitly produced drug worldwide. However, the proposal is that cannabis and cannabis resin not be listed in Schedule IV as the ill-effects are not similar to those of other Schedule IV listed drugs, which do not have compensating therapeutic benefits.

The Committee also made the following observation about hemp:

Low potency (0.2-0.3% THC) cannabis plants (hemp) are cultivated to produce paper, textiles, rope or twine, and construction materials based on fibre from stalks. Grain from industrial hemp is used in food products, cosmetics, plastics and fuels. Cannabis plants grown for these purposes are excluded from control under the 1961 Convention<sup>67</sup>

- ***Extracts and tinctures of cannabis:*** The WHO recommended that ‘extracts and tinctures of cannabis’ be deleted from the listing of cannabis in Schedule I.

The Committee noted that an extract or tincture may contain different quantities of both THC and CBD. An example is Sativex an oral spray that is registered in the ARTG. While the abuse potential and public health risks of THC and CBD are separately known from other studies, there is limited research on extracts and tinctures that contain mixed substances.

- ***Other THC substances:*** The WHO recommended that THC/dronabinol and other tetrahydrocannabinols be moved from Schedule II of the *Convention on Psychotropic Substances 1971* to Schedule I of the Single Convention and listed with other cannabis substances.
- ***Pharmaceutical preparations produced by chemical analysis or from cannabis that contain one or more other ingredients such that the THC cannot be readily recovered or in a yield that would be a risk to public health:*** The WHO recommended that this item be added to Schedule III, which lists preparations.

The United Nations Commission on Narcotic Drugs noted the recommendations at its 62nd regular session in March 2019. A formal response was postponed to a later meeting to allow the Commission further time to consider and whether to adopt the recommendations. This could occur at a reconvened meeting of the 62<sup>nd</sup> session in December 2019, or at the 63rd regular session in March 2020.

A few of the submissions to this Review pointed to these developments and the possibility of cannabis substances in the Single Convention being rescheduled – or ‘down-scheduled’ as it was sometimes described. The view was expressed that the adoption of the recommendations would represent a marked shift in the international attitude to the regulation of cannabis and related substances.

On the other hand, the TGA observed in a statement in December 2017 following a WHO pre-assessment report that Australian practice already mirrored the rescheduling proposal in relation to CBD.<sup>68</sup> Specifically, the TGA had re-classified CBD in the Poisons Standard in July 2015 from being a Schedule 9 ‘prohibited substance’ to being a Schedule 4 ‘prescription medicine’. This was based on a recommendation in 2014 from the Advisory Council on Medicines Scheduling.

The department is closely monitoring the international developments and participating in the meetings of the relevant international bodies.

<sup>67</sup> Fortieth Report, p 22.

<sup>68</sup> Therapeutic Goods Administration, ‘TGA recognised WHO findings on cannabidiol three years ago’ (media statement, 15 December 2017).

# Chapter 4: Overview of the Act and the key issues

## Introduction

This chapter covers three topics:

- The first part explains the medicinal cannabis scheme that was introduced into the ND Act in 2016. The focus of discussion is the new licensing and permit provisions that were designed to balance several objectives of the new scheme, and the activities involving cannabis to which the scheme applies.

A more detailed discussion of the licensing and permit provisions occurs in Chapter 6, where it is recommended that a new licensing approach be adopted based around a single licence that would authorise some or all activities regulated by the ND Act. Key terms that are used in the licensing provisions (such as ‘cannabis’, ‘cultivation’, ‘research’ and ‘manufacture’) are discussed in Chapter 5. The mechanisms in the ND Act for enforcing compliance with licence and permit conditions and requirements are discussed in Chapter 7.

- The Discussion Paper that formed part of this Review identified six Key Themes on which submissions were invited. A summary of the submissions is given in this third part of the chapter. The discussion overlaps with that of other chapters, but also presents a larger-scale picture of the views expressed in submissions.
- The fourth part of the chapter recommends that the ND Act include a clearer statement of the objects of the medicinal cannabis scheme.

## The medicinal cannabis scheme in the ND Act

### Objectives of the medicinal cannabis scheme

Prior to the enactment of a medicinal cannabis scheme within the ND Act in 2016,<sup>69</sup> the ND Act contained a basic framework for regulating narcotic drugs, in two ways. The Minister could grant an applicant a licence to manufacture narcotic drugs, provided this would be consistent with Australia’s obligations under the Single Convention.<sup>70</sup> There were allied powers in the ND Act to grant manufacturing permits, inspect licensed premises, give directions to licensees, and to make it an offence to manufacture narcotic drugs except as authorised by a licence under the ND Act. The second way the ND Act regulated narcotic drugs was to regulate the movement of drugs through Australia (for example, on vessels).<sup>71</sup>

The medicinal cannabis scheme retained and built on the existing features of the ND Act, but overall was more extensive and far reaching. Some parts of the amended ND Act (such as some licensing provisions) apply only to cannabis regulation. Other parts (such as monitoring and enforcement powers) apply generally to narcotic drugs but are more detailed to reflect the greater regulatory role the Commonwealth would thereafter play as a result of the ND Act including a new medicinal cannabis scheme.

<sup>69</sup> *Narcotic Drugs Amendment Act 2016* (Cth).

<sup>70</sup> ND Act s 9 (prior to 2016 amendments).

<sup>71</sup> ND Act s 22 (prior to 2016 amendments).

The medicinal cannabis scheme was 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
- facilitating 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
- implementing Australia's obligations under the Single Convention.

The medicinal cannabis scheme is framed around a licensing and permit scheme to regulate cannabis cultivation, production and manufacture for medicinal and scientific purposes.

## The licensing and permit scheme

Three different licences can be granted under the ND Act:

1. *Medicinal cannabis licence:*<sup>72</sup> This licence can variously authorise, for medicinal purposes,<sup>73</sup> the cultivation (or growing) of cannabis plants, the production (or separation) 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.
2. *Cannabis research licence:*<sup>74</sup> This licence can authorise the same range of cultivation, production and associated activities, for research relating to medicinal cannabis; and can be granted to an applicant prior to research commencing. A cannabis research licence may only authorise cultivation or production for research purposes.<sup>75</sup>
3. *Manufacture licence:*<sup>76</sup> This licence can authorise the manufacture of a drug, including a drug that is a medicinal cannabis product.<sup>77</sup> A licence to manufacture a drug that includes any part of the cannabis plant cannot be granted unless the Secretary is satisfied that the intended use of the drug is for research relating to medicinal cannabis products, for use in a clinical trial, or for patient supply or as a registered good in accordance with the TG Act.<sup>78</sup> A manufacturer may require both a manufacture licence under the ND Act and a manufacturing licence under the TG Act if the drug is for human use. The broad difference is that the ND Act licence will control the type and quantity of a drug obtained from a cannabis plant and held by the manufacturer, while the TG Act licence will control the quality, safety and efficacy of the manufactured drug.

<sup>72</sup> ND Act s 8E.

<sup>73</sup> The term 'medicinal cannabis product' is defined in the ND Act s 4(1), and is discussed below under 'Interaction of the ND Act and the Criminal Code'.

<sup>74</sup> ND Act s 9D.

<sup>75</sup> ND Act s 9H.

<sup>76</sup> ND Act s 11G.

<sup>77</sup> The term 'drug' is defined in the ND Act s 4(1) as including a drug covered by the Single Convention. Section 4(1A) of the Act further provides that, to avoid doubt, the term 'drug' includes 'a medicinal cannabis product that is a drug'. The meaning of 'medicinal cannabis product' is discussed below under 'Interaction of the ND Act and the Criminal Code'.

<sup>78</sup> ND Act s 11K.

A licence holder 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’.<sup>79</sup>

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.<sup>80</sup> 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 licence holder can possess, the quantities of cannabis and cannabis resin that can be cultivated and produced and the period during which cannabis plants may be cultivated.<sup>81</sup> There are corresponding provisions for cannabis research licences and permits and manufacture licences and permits.<sup>82</sup>

A licence holder 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<sup>83</sup> – though the ND Act does not provide guidance as to the minimum or maximum term of a licence or permit. There is no procedure in the ND 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.

A licence cannot be transferred to another person.<sup>84</sup> This means that a fresh licence application may be required if there is a corporate takeover or restructure.

A licence or permit may be varied, either on application by the licence holder or on the Secretary’s initiative.<sup>85</sup> 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 licence holder 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.

## Requirements to be granted a licence or permit

The requirements an applicant must meet to be granted a licence or permit are spelt out in both the ND Act and the ND Regulation. The requirements are framed in similar terms for all licences and permits, with some contextual variations.

A licence cannot be granted unless the decision maker is satisfied on reasonable grounds of the following matters (among others):<sup>86</sup>

- 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

<sup>79</sup> Respectively, ND Act, ss 8P, 9N and 12.

<sup>80</sup> ND Act, s 8M.

<sup>81</sup> ND Act, s 9B.

<sup>82</sup> ND Act, ss 9L, 10A (research); ss 11N, 12C (manufacture).

<sup>83</sup> 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).

<sup>84</sup> ND Act, s 24C.

<sup>85</sup> ND Act, s 10M (cannabis licences and permits); s 13 (manufacture licences and permits).

<sup>86</sup> ND Act, s 8G (medicinal cannabis licence), s 9F (cannabis research licence), s 11J (manufacture licence).

- 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
- the proposed location, facility and security arrangements are suitable.

Three key terms in those requirements are discussed in Chapter 5 – 'fit and proper person', 'business associate' and 'serious criminal offence'. The information and documents an applicant must provide are discussed in Chapter 6.

In deciding a licence application the decision maker may also have regard to any other matter considered relevant, including matters that relate to the activities to be undertaken under the licence.<sup>87</sup>

A change in circumstances may trigger a need to re-visit the licensing requirements 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 in Chapter 7, 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.<sup>88</sup> 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
- an application must be refused if the decision maker is not satisfied that any standards issued by the Minister under the ND Act<sup>89</sup> have been or will be met.

## 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.<sup>90</sup> Correspondingly, the ND Act imposes a licence condition that a contract is in existence with a licence holder who is authorised to undertake production.<sup>91</sup>
- A licence to produce cannabis or cannabis resin cannot be granted unless the decision maker is satisfied on reasonable grounds that the applicant holds a manufacture licence or the cannabis product is to be supplied to a manufacture licence holder either to manufacture a medicinal cannabis product or for research relating to such products.<sup>92</sup> Correspondingly, the ND Act imposes a licence condition that a contract is in existence with a manufacture licence holder relating to those purposes.<sup>93</sup>

<sup>87</sup> ND Act, ss 8F(3) (medicinal cannabis licence), 9E(3) (cannabis research licence), 11H(3) (manufacture licence).

<sup>88</sup> ND Act, ss 8P (medicinal cannabis permit), 9N (cannabis research permit), 12 (manufacture permit).

<sup>89</sup> ND Act, s 26B.

<sup>90</sup> ND Act, s 8J(1).

<sup>91</sup> ND Act, s 10J(1).

<sup>92</sup> ND Act, s 8J(2).

<sup>93</sup> ND Act, s 10J(2).

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.<sup>94</sup>

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
- as a medicinal cannabis product that is a registered good under the TG Act
- by a pharmacist in a public hospital in accordance with the TG Act
- for export as approved under the Customs Export Regulations
- for manufacture in accordance with the TG Act for one of the foregoing uses.<sup>95</sup>

### **Interaction of the ND Act and the Criminal Code**

The ND Act has a limited sphere of operation in relation to cannabis. The activities that can be licensed under the ND Act (cultivation, production, research and manufacture) must relate to the use of cannabis for a medicinal or research purpose.<sup>96</sup> The term ‘medicinal cannabis product’ is defined in the ND Act as meaning a product (including a substance, composition, preparation or mixture) that is wholly or partly derived from the cannabis plant and is used ‘for the purposes of curing, or alleviating the symptoms of, a disease, ailment or injury’.<sup>97</sup>

The use of a cannabis plant for a non-therapeutic purpose – such as an industrial or horticultural purpose – is not controlled by the ND Act. The relevant offence provisions in the ND Act apply only to the conduct of licence holders, in undertaking cultivation, production or manufacture that is not authorised by their ND Act licence.<sup>98</sup>

The Commonwealth Criminal Code applies more generally to the cultivation of cannabis plants and the manufacture of controlled drugs derived from cannabis, cannabis resin or THC.<sup>99</sup> It is an offence under the Code to undertake those activities unless the cultivation or manufacture is justified or excused by a Commonwealth, State or Territory law.<sup>100</sup> However, the Code, too, has a limited sphere of operation, in two respects: it does not apply to cannabidiol, which does not fall within the definition of ‘controlled drug’; and the Code only applies to cultivation or manufacture of commercial, marketable or trafficable quantities above a specified weight or number of plants.

Two points can be drawn from that legislative framework. The first is that it may be necessary to consult the ND Act, the Code and State/Territory law to ascertain the applicable rules regarding cultivation, production, research or manufacture relating to a cannabis plant. The second is that the particular activity may not be covered by a Commonwealth law and may be regulated only by a State or Territory law. An example would be some activities relating to industrial or low-THC hemp.

<sup>94</sup> ND Act, s 9H.

<sup>95</sup> ND Act, s 11K(2) (as to the first four uses), ND Regulation, reg 37 (as to the latter three uses).

<sup>96</sup> ND Act, ss 8E, 9D, 11G.

<sup>97</sup> ND Act, s 4(1).

<sup>98</sup> ND Act, ss 11B, 13E.

<sup>99</sup> As to cultivation: Criminal Code ss 303.4, 303.5, 303.6. As to manufacture: ss 305.3, 305.4, 305.5.

<sup>100</sup> Criminal Code, ss 10.5, 313.1.

## Commentary on Key Themes in the Discussion Paper

A major focus of the public consultation for this Review, noted in Chapter 1, was discussion of six Key Themes regarding the terms and operation of the ND Act. Many submissions were tailored to those themes and expressed views directly on each theme.

Following is a summary of those responses. The individual submissions are not quoted or referred to, as this summary is designed to synthesise the diverse views expressed in submissions, and some submissions requested non-publication of either the author's details, or the specific content of the submission.

It is important to stress that the following summary does not evaluate or endorse the views expressed in submissions. Later chapters of this report contain findings and recommendations.

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

The submissions generally acknowledged that the ND Act was designed to implement the Single Convention and was appropriately framed as a licensing scheme that tightly regulated cannabis production and supply for therapeutic purposes. It was acknowledged too that the ND Act had made a large difference in stimulating development of a vigorous domestic industry, particularly in the fields of cultivation, production and research.

There was, on the other hand, a strong view that the new medicinal cannabis scheme – in the first two years of operation – had not fulfilled the expectation of making medicinal cannabis more readily and easily available to Australian patients. The limited number of patients who are receiving prescribed medicinal cannabis are obtaining it from imported sources and not from Australian production and manufacture. The cost of medicinal cannabis products is high and unaffordable for many patients, and the procedure to obtain a prescription can be complex and time-consuming. There is an uneven pattern of prescriptions around Australia.

It was said to be easier for many people to obtain a cannabis product through illicit channels, and they are following that path. This exposes them to legal action and to obtaining a medicinal product that may be unsafe or ineffective. Higher numbers of patients have lawfully obtained medicinal cannabis in countries such as Canada, the Netherlands and Germany, which have different schemes that have been in place for many years.

There was also a strong view that the requirements of the ND Act and its administration had hampered the development of a vibrant local industry that could support a sustainable supply channel of affordable and effective cannabis medicines. A paramount problem, noted below, is said to be the regulatory focus – or overemphasis – on security and integrity vetting to combat potential criminal risks of infiltration and cannabis products being diverted to illicit use. Under-resourcing of administration of the new scheme by the ODC was also nominated as a major contributory factor in delay and inefficiency at the administrative level.

Many suggestions were made to correct the supposed failure of the new scheme to meet the needs of patients – ranging from adopting an entirely different framework for cannabis regulation, to improving and streamlining the present scheme. Prominent suggestions for targeted reform include the introduction of a simpler licensing and permit scheme, and expansion of the objects clause in the ND Act to spell out the aim of ensuring there is a sustainable supply of medicinal cannabis products to Australian patients.

Another recurring theme in many submissions was a claim that the ND Act is at odds with the spirit of the Single Convention in preventing full use of industrial hemp/low-THC products that are subject to State/Territory regulation. This has implications for the commercial health of that industry, as well as its ability to make non-medicinal cannabidiol products available to Australian consumers. It was said that the need to resolve this overlap will become more pressing if current proposals to reschedule cannabis products in the Single Convention are adopted by the United Nations Commission on Drugs.

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

The submissions noted that the ND Act supports research, and this has been reinforced at the administrative level. Notably, research licence and permit requirements are less onerous, licensing decisions can be made reasonably quickly, and lower licence fees apply. A strong research culture is developing in Australia.

It was felt, nevertheless, that research was being held back by current arrangements. A central problem was said to be that the requirement for a separate cannabis research licence can hamper normal research and development activity under other licences. This is regarded as incongruous, given that stricter security and fitness requirements may have been met to obtain the cultivation or manufacturing licence.

The obligation on license holders to forecast specifically the composition of an end product in production and manufacturing was criticised as constricting and inhibiting innovation and strain development. There has been a reluctance in Australia to accept international trial data to support product development.

Collaboration between licence holders and research institutions can also be hampered by restrictions on the transfer or supply of cannabis product from one licensee to another. These restrictions apply variously to the quantity of cannabis product that can be transferred to a research entity, the permission required to undertake the transfer and the detailed information to be provided to obtain permission.

There is also uncertainty for research licence holders as to what activities are permitted under a licence. Questions have arisen about the scope of authority for activities such as training, analytical testing, validation and combined research projects.

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

The submissions accepted that the Single Convention and the ND Act require a strong regulatory focus on preventing the diversion of controlled narcotics to illegal uses. This focus was understandably paramount when the scheme was being established because of the improbabilities faced in regulating a new industry that is handling a narcotic drug.

A qualifying view was that the diversion risks had been overstated, or at least that a singular emphasis on this issue has been undiminished since the early days of the medicinal cannabis scheme.

Submissions argued that insufficient weight was being given to how diversion risks were lessened by existing Commonwealth, State and Territory legislation relating to cannabis. It was also in the commercial self-interest of the medicinal cannabis industry to guard against illicit diversion and to manage risks effectively, in order to safeguard the integrity of the industry. It was noted too that the diversion risks did not apply to CBD which was non-psychoactive.

The strong focus given to the risk of diversion was felt in other ways. For example, the licensing application questions asked by the ODC included questions relating to commercial risk or judgement that should more appropriately be the concern of the applicant rather than the regulator. It seemed too that the bar had been raised for newer applicants, as ODC requirements became more demanding based on experience gleaned from processing earlier applications.

Another view was that an overemphasis on risk diversion could have the counterproductive effect of stifling the legitimate medicinal cannabis industry and opening an avenue for illegitimate production.

**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 imposed 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?**

The submissions acknowledged that the ODC had not been properly resourced to deal with the unexpectedly large number of licence applications it initially received and that had not abated. Several submissions complimented the ODC for the professional way it grappled with the challenges and consulted constructively with applicants and other stakeholders.

While submissions recognised the challenges facing the ODC, they made similar criticisms of how effectively the medicinal cannabis scheme was operating, including:

- delay in processing licence and permit applications
- uncertainty facing applicants as to the information to be provided in initial applications
- multiple ODC requests under s 14J of the ND Act that appeared to be unnecessary or to duplicate other requests
- inconsistent s 14J requests from two sections within the ODC
- inefficiency arising from different ODC staff dealing with an application at different stages
- more detailed information being required for permit applications than seemed warranted
- lack of visibility by applicants as to the processing stage their application had reached
- having to provide information for a new licence application that had earlier been provided
- existing licence holders not being given priority when lodging permit or licence variation applications.

Similar suggestions were made in many of the submissions to address those issues. The suggestions included:

- giving priority to applications from existing license holders, particularly for permit applications and variations
- allocating a case manager or liaison officer to applicants
- building an online portal through which information can be lodged, stored, retrieved, varied, checked and notified
- providing more extensive published guidance for initial applications
- screening/triaging initial applications for gaps and weaknesses
- cross-referencing s 14J requests to the legislative standards
- introducing indicative timeframes for decision-making.

The sharpest theme across the submissions was that either different or preferential processes should be adopted for existing license holders. It was submitted that if a licence holder has an unblemished regulatory record, greater confidence can be placed on their reliability in subsequent applications and dealings. Appropriately realistic risk management approaches that could be adopted include:

- allowing a licence holder to notify a change rather than seek a permit variation
- imposing more flexible licence and permit conditions that preclude the need for unnecessary variation applications

- allowing licence holders to notify compliance, risk and breach issues in periodic reports rather than contemporaneously
- adopting standard monitoring of the performance of licence holders
- doing occasional spot checks.

Some submissions emphasised those points by drawing a comparison with what was said to be the more streamlined and effective regulatory approaches adopted by the TGA.

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

The submissions on this theme echoed similar points as above. It was acknowledged that a strong compliance focus had been adopted in line with the Single Convention and to ensure that a trusted and respected medicinal cannabis industry would develop in Australia. It was also seen to be important that new licence applicants are required to demonstrate in their initial licence applications that they can meet a high industry standard.

On the other hand, some submissions argued that the administration of the medicinal cannabis scheme was coloured by excessive risk aversion, particularly now that the scheme is established and functioning. This was said to be a contributing factor to the administrative delays that have bedevilled the scheme. It is also said to be inhibiting the development of the industrial hemp/low-THC industry by imposing ND Act requirements on production occurring at the boundary of the regulated industry.

One example (noted above) given of the risk averse focus is that a suitable risk management strategy has not been implemented with respect to existing licence holders who have an unblemished regulatory record. Some felt there was insufficient recognition of an established licence holder's own commitment to and commercial self-interest in strong compliance.

There was also said to be too much attention given during the initial licensing phase to the fine detail of an applicant's proposed operating procedures. This can stifle innovation and continuous improvement, and gives insufficient weight to other processes, such as an applicant's own quality management and reporting obligations and the regulator's audit and inspection powers.

Examples were given of standards or conditions that were thought to be unnecessarily strict. One example was the condition imposed by the ND Regulation that a licence holder not employ a person who has during the previous five years used illicit drugs.<sup>101</sup> This is stricter than the requirement of the ND Act that the criminal record of an applicant or business associate is simply a matter to which the Secretary can have regard at the licensing stage.<sup>102</sup> Another example was the requirement of the ND Act that a licence specify the persons authorised to engage in activities under the licence, which could require a licence variation upon the departure or arrival of a new senior employee.

Finally, it was submitted that the strong focus given to criminal risks of diversion and infiltration had overshadowed competing risks that fall within the objects of the medicinal cannabis scheme. One such risk is that patients will be disadvantaged if the supply pathways for medicinal cannabis are too complicated or rigid, or they may instead opt to source cannabis of untested efficacy from illicit sources.

<sup>101</sup> ND Regulation, regs 18(2)(a) and 39(2)(a).

<sup>102</sup> ND Act, ss 8A(a), 8B(a) and 8H.

**6. Does the ND 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?**

It was noted in submissions that the regulatory framework is complex because of multiple Commonwealth, State and Territory laws and agencies. The submissions acknowledged that this was partly unavoidable because of both the constitutional division of government responsibilities and the overlap in activities that were subject to regulation. Examples given were the overlap between the ND Act and other Commonwealth laws relating to the manufacture of therapeutic goods and the import and export of narcotic drugs, and the overlap between the ND Act and State and Territory laws relating to the hemp industry, access to medicines and regulation of industrial premises.

While accepting this complexity, the submissions proposed that some matters warranted further attention. One is the importance in administering the ND Act of giving appropriate recognition to State and Territory laws that combat criminal risks in relation to manufacture, storage, testing and transport of narcotic drugs. Doing so could reduce the excessive risk aversion that has been criticised in the administration of the medicinal cannabis scheme.

A second is the need for government agencies at all levels to look for ways of reducing the complexity for industry participants, the medical profession and patients. An example that was commended was the introduction in 2018 of a system for online lodgement of single SAS applications to meet relevant Commonwealth, State and Territory requirements.

Contrasting examples were given of areas where jurisdictional integration has been lacking. For example, a person or entity in one jurisdiction who has specialist qualifications or a licensing permission that authorises activities that are cannabis-related, might not have reciprocal recognition in other jurisdictions.

It was felt that more could be done in Australia to monitor the conflict points and uncertainties in the overall regulatory framework and to look for ways of streamlining regulatory requirements. At present it was largely left to industry participants to work their way through the regulatory maze.

## The objects of the ND Act

An objects clause was inserted into the ND Act as part of the 2016 amendments. It reads:

### **2A Object of this Act**

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

The framing of the objects clause in this way is perhaps understandable but it is not informative. It says nothing directly about the policy intention of the new medicinal cannabis scheme that was the purpose of the 2016 amendments. The structure and text of the amended ND Act, viewed alone, convey the sense that the singular concern is industry regulation with an emphasis on strict regulatory compliance.

A contrast can be drawn with government statements that accompanied the introduction of the 2016 amendments. The opening paragraph of the Explanatory Memorandum leads with a reference to patient need:

The Narcotic Drugs Amendment Bill 2016 will provide a legislative framework that will enable cannabis cultivation in Australia and provide Australian patients in need with access to medicinal cannabis for therapeutic purposes. These amendments will also ensure that when cultivation and production of cannabis and manufacture of cannabis for medicinal purposes begin, Australia will remain compliant with its international treaty obligations as defined in the United Nations *Single Convention on Narcotic Drugs, 1961*.<sup>103</sup>

<sup>103</sup> Explanatory Memorandum, Narcotic Drugs Amendment Bill 2016, p 1.

The Regulation Impact Statement that was part of the Explanatory Memorandum also gave prominent attention to patient need, as illustrated by the following:

### **Section 1: The problem to be addressed**

There are community expectations that there should be a licit source of cannabis for medicinal use. The fact that there is illicit cannabis for medicinal purposes is concerning as there are no controls on quality or strength nor is there a prescribing service that is professionally based, nor any system for tracking clinical outcomes, including adverse events. This could expose the community to potentially dangerous substances and outcomes.

... Subject to appropriate safeguards, failure to enable supply of cannabis for medicinal purposes, as well as further scientific study into this treatment option, could deny patients access to new, safe and effective medicines and treatments.<sup>104</sup>

There was a similar message in the Minister's Second Reading Speech when introducing the amending Bill:

The Narcotics Drugs Amendment Bill 2016 provides a clear national licensing scheme allowing the controlled cultivation locally of cannabis for medicinal and scientific purposes.

Importantly this bill provides the critical 'missing piece' for the Commonwealth to enable a sustainable supply of safe medicinal cannabis products to Australian patients in the future.

This government understands that there are some Australians suffering from severe medical conditions for which cannabis may have some application, and we want to enable access to the most effective medical treatments available.<sup>105</sup>

A criticism made in several submissions in response to the Key Themes in this Review is that patient need had been overwhelmed by regulatory concerns in the establishment of the medicinal cannabis scheme since 2016. The submissions suggested that an important first step in rectifying this imbalance was to restate clearly that patient need is a core objective of the medicinal cannabis framework established in the ND Act.

That proposal has much to commend it. A statutory objects clause can be important in signifying how an Act should be understood, administered and construed. The clause will be more valuable if it is an identifiable point of reference for the community.

A revised objects clause in the ND Act should not ignore or overshadow the operation of the ND Act in relation to narcotic drugs generally. The ND Act was enacted in 1967 (nearly fifty years before the medicinal cannabis scheme) and had long applied to controlled drugs such as opiates. A revised objects clause should recognise the broader role and operation of the ND Act.

### **Recommendation 1**

The objects clause (section 2A) in the *Narcotic Drugs Act 1967* be amended to include a statement along the lines that an object of the Act is to enable cannabis cultivation, production, manufacture and research, in order to ensure that medicinal cannabis products are available to Australian patients for therapeutic purposes.

<sup>104</sup> Explanatory Memorandum, Narcotic Drugs Amendment Bill 2016, p 9.

<sup>105</sup> The Hon Ms Ley, Minister for Health, Second Reading, House of Representatives, *Official Hansard*, 10 February 2016, p 1164.

# Chapter 5: Key Terms and Concepts in the ND Act

## Introduction

Several terms used throughout the ND Act serve to delineate its scope and operating principles. Some terms are defined in the ND Act, while others are not. Some definitions adopt or refer to definitions in the Single Convention.

The Discussion Paper invited comment on whether key terms are appropriately defined in the ND Act, having regard to Australia's obligation to adhere to the requirements of the Single Convention. The submissions drew attention to ambiguity or inconvenience in some definitions. Some definitional questions will be answered if the licensing and permit regime is restructured as recommended in Chapter 6, but other issues may warrant amendment of a definition in the ND Act or the publication by the ODC of extended guidance on the meaning of key terms in the ND Act.

## 'Cannabis', 'plant', 'resin', 'extract', 'drug'

The terms 'cannabis', 'cannabis plant' and 'cannabis resin' are used extensively in the ND Act and provide the basis for the medicinal cannabis licensing and permit regime. A medicinal cannabis or cannabis research licence can authorise the cultivation of cannabis plants and the production of cannabis and cannabis resin for medicinal purposes;<sup>106</sup> and a manufacture licence can authorise the manufacture of a 'drug' as listed in the Single Convention or prescribed in the ND Regulation (see below).<sup>107</sup> A related term in the ND Act is 'medicinal cannabis product' that is used in outlining the authorised uses of manufactured drugs.<sup>108</sup>

The terms are also relevant to the offence and civil penalties in the ND Act and other Acts. It is an offence under the ND Act for a licence holder to obtain or cultivate a cannabis plant to produce cannabis or cannabis resin that is not authorised by their medicinal cannabis or cannabis research licence.<sup>109</sup> It is equally an offence to breach a licence condition.<sup>110</sup>

The ND Act adopts the definitions of 'cannabis' and 'cannabis resin' in the Single Convention:<sup>111</sup>

Cannabis means the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted, by whatever name they may be designated.

Cannabis resin means the separated resin, whether crude or purified, obtained from the cannabis plant.

<sup>106</sup> ND Act, ss 8E and 9D.

<sup>107</sup> ND Act, s 11G, and ND Regulation, reg 4A.

<sup>108</sup> ND Act, s 11K(2). As noted in Chapter 4, the term 'medicinal cannabis product' is defined in the ND Act s 4(1).

<sup>109</sup> ND Act, s 11B(1).

<sup>110</sup> ND Act, ss 11C, 11D, 11E.

<sup>111</sup> ND Act, s 4(1); Single Convention, Art 1.1.

The ND Act contains a definition of ‘cannabis plant’ that expands the definition in the Single Convention:<sup>112</sup>

*cannabis plant* means the following:

- (a) any plant of the genus *cannabis*;
- (b) any part of a plant of the genus *cannabis* including, but not limited to, the seeds, stems or leaves of the plant.

Different cannabis expressions are used in other instruments. As noted in Chapter 3, the Single Convention requires State parties to control the use of drugs listed in Schedule I of the Convention, for example, by requiring a licence to manufacture, import or export any such drug.<sup>113</sup> Schedule I includes an entry for ‘cannabis and cannabis resin and extracts and tinctures of cannabis’. Examples given in Chapter 2 of other references in Commonwealth, State and Territory laws to derivatives of the cannabis plant included: Chapter 2 of the Criminal Code, which includes cannabis in the list of controlled drugs that cannot be manufactured, cultivated or possessed, unless authorised by a law such as the ND Act;<sup>114</sup> the Poisons Standard, which lists cannabis, cannabis resin and THC in Schedule 8 and CBD in Schedule 4; and the Customs Export Regulations and the Customs Import Regulations, which list the same products, respectively in Schedule 8 as drugs that require export approval, and in Schedule 4 as drugs that require import approval. There is discussion below of another reference to cannabis products in reg 4A of the ND Regulation.

Three aspects of the cannabis definitions in the ND Act have attracted both comments and controversy:

- the contemporary suitability of the definitions, including the expansive effect of including ‘extracts’
- the alignment between the definitions in the ND Act and the terms of the Single Convention
- the difficulty posed by the definitions for hemp cultivation and sale in accordance with State and Territory laws.

### **Contemporary suitability of cannabis terminology**

It is often observed that the Single Convention was formulated in 1961 and contains terminology that reflects the thinking of that time. Now, it is said, over fifty years later, there is a different understanding of the nature, composition and therapeutic uses and psychoactive effects of cannabis.

There is little that can be drawn from that observation so far as this Review is concerned. The observation is usually a forerunner to a different point about how the law should apply to cannabis. A common criticism is that cannabis as defined in Australian legislation is classified as an illegal narcotic drug that is tightly controlled by legislation such as the ND Act, the TG Act and the Criminal Code.

As already noted, the object of the ND Act is to give effect to Australia’s obligations under the Single Convention.<sup>115</sup> That can only be done by adopting at least the substance of the definitions in the Single Convention. The ND Act does that, subject to two points below about CBD and the seeds of the cannabis plant.

<sup>112</sup> Ibid.

<sup>113</sup> Single Convention, Articles 2.1, 29 and 31.

<sup>114</sup> *Criminal Code Regulation 2019*; the expression used in Schedule 1, Item 50 of the Regulation is ‘Cannabis (in any form, including flowering or fruiting tops, leaves, seeds or stalks, but not including Cannabis resin or Cannabis fibre)’.

<sup>115</sup> ND Act, s 2A.

There are proposals under consideration at the international level, as discussed in Chapter 3, to reschedule cannabis products in the Single Convention. Those proposals have not reached a definitive stage, which again means that little can be drawn from that development for the purposes of this Review. There is no certainty that the rescheduling will be adopted, and if it is, this will not occur until after this report is tabled in the Parliament, and possibly no earlier than 2020.

It is relevant nonetheless that the WHO has not recommended that ‘cannabis’ and ‘cannabis resin’ be removed from the schedules in the Single Convention, or that the definitions of those terms be changed. The central proposals are to delete references to cannabidiol and extracts and tinctures of cannabis, from Schedule I of the Convention; and to list THC only in Schedule I (and not Schedule IV). This rescheduling would differentiate between cannabis components that are psychoactive and those that are not (respectively, THC and CBD).

## Alignment between the ND Act and the Single Convention

There are two important differences between the provisions of the ND Act and ND Regulation and the terms of the Single Convention.

First, the term ‘drug’ is defined in reg 4A of the ND Regulation as including cannabidiol (or CBD), as follows:

### 4A Prescription of substances

For the purposes of ... the definition of *drug* in subsection 4(1) of the [ND] Act, the following substances are prescribed:

- (a) tetrahydrocannabinol (including all isomers, salts and acids);
- (b) cannabidiol (including all isomers and salts);
- (c) dronabinol.

The manufacture licence provisions in the ND Act apply to the substances prescribed in reg 4A. In effect, those substances are treated as narcotics to be controlled in the manner required by international conventions to which Australia is a party. THC and dronabinol are appropriately prescribed as they are listed in the *Convention on Psychotropic Substances, 1971*, which has been given force in Australia by the *Psychotropic Substances Act 1976* (Cth).

Cannabidiol, in a pure form, is not listed (or scheduled) as a narcotic drug in the international drug control conventions to which Australia is a party. Further, the Expert Committee on Drug Dependence of the WHO recommended after a review of cannabis scheduling in June 2018 that ‘preparations considered to be pure CBD should not be scheduled within the International Drug Control Conventions’.<sup>116</sup>

In summary, CBD should not be separately prescribed as a drug to which the manufacture licence provisions of the ND Act apply. The inclusion of CBD in reg 4A imposes controls on its manufacture that are unnecessary and can impede the development of synthetic cannabinoid medicines. The ND Act would continue to apply (in accordance with the Single Convention) to cannabis extracts (such as resins) that include both THC and CBD.

Recommendation 2 (below) is that CBD is deleted from the definition of ‘drug’ in reg 4A of the ND Regulation. This would be consistent with other Australian practice. For example, as noted in Chapter 3, the TGA re-classified CBD in July 2015 from being a ‘prohibited substance’ in Schedule 9 of the Poisons Standard to being a ‘prescription medicine’ in Schedule 4 of the Standard.<sup>117</sup> Second, the ND

<sup>116</sup> Letter (and Annexure) from the Director-General of the WHO to the Secretary-General of the United Nations, 23 July 2018, available at: [https://www.who.int/medicines/access/controlled-substances/UNSG\\_SignedDGletter.pdf?ua=1](https://www.who.int/medicines/access/controlled-substances/UNSG_SignedDGletter.pdf?ua=1).

<sup>117</sup> The description of cannabidiol in Schedule 4 of the Poisons Standard is given in Chapter 2 under ‘Scheduling’.

Act requires a licence (among other things) for ‘the cultivation of cannabis plants’.<sup>118</sup> As noted above, ‘cannabis plant’ is defined in the ND Act s 4(1) to mean:

1. any plant of the genus cannabis;
2. any part of a plant of the genus cannabis including, but not limited to, the seeds, stems or leaves of the plant.

The definition of ‘cannabis plant’ in the Single Convention refers only to paragraph (a) of that definition and not paragraph (b).<sup>119</sup>

A consequence is that a medicinal cannabis licence or cannabis research licence may extend to and impose controls on the seeds of the cannabis plant, in a manner not required by the Single Convention. This can introduce an unnecessary administrative burden or complexity in the administration of the ND Act.

### **Recommendation 2**

The *Narcotic Drugs Regulation 2016* be amended by deleting paragraph 4A(b) (specifically, ‘cannabidiol (including all isomers and salts)’).

### **Recommendation 3**

The *Narcotic Drugs Act 1967* be amended by deleting paragraph (b) from the definition of ‘cannabis plant’ in section 4(1) of the *Narcotic Drugs Act 1967* (specifically, ‘(b) any part of a plant of the genus cannabis including, but not limited to, the seeds, stems or leaves of the plant’).

## **Hemp cultivation and supply**

A vexing issue in Australia has been the possible application of Commonwealth laws, including the ND Act, to the cultivation and commercial sale of low-THC hemp.

As noted in Chapter 2, low-THC hemp is an extract from the cannabis plant, but is not a psychotropic substance. It is increasingly cultivated in Australia, in accordance with State and Territory laws, for industrial and horticultural purposes and as a food ingredient.<sup>120</sup> Hemp is generally grown outdoors and is not subject to the strict security requirements that apply under the ND Act to cannabis products that are narcotics.

The Single Convention differentiates between narcotic drugs to which the Convention applies and non-narcotic substances of a related kind that may fall outside the Convention when certain conditions are met. This intention is expressed in two articles of the Convention that were referred to in Chapter 3:

- Art 2.9 provides that Parties are not required to apply the provisions of the Convention to drugs commonly used in industry for other than medical or scientific purposes, if appropriate steps are taken to ensure that any such drugs are not liable to be abused or have ill effects or yield harmful substances.
- Art 28.2 declares that the Convention does not apply to the cultivation of the cannabis plant exclusively for industrial or horticultural purposes.

The distinction drawn in those Articles of the Convention is indirectly affirmed in ss 7 and 7A(1) of the ND Act. Those sections purport to save the operation of State and Territory laws that are not

<sup>118</sup> ND Act, ss 8E(1)(a), 9D(1)(a).

<sup>119</sup> Single Convention, Art 1.1(c). The definition of ‘Cannabis’ in the Convention excludes ‘the seeds ... when not accompanied by the tops’: Art 1.1(b).

<sup>120</sup> *Industrial Hemp Act 2015* (Tas), *Hemp Industry Act 2008* (NSW), *Industrial Hemp Act 2017* (SA), *Industrial Hemp Act 2004* (WA) and *Hemp Fibre Industry Facilitation Act 2004* (ACT).

inconsistent with the ND Act and do not authorise the cultivation or production of cannabis products ‘for medicinal or related scientific purposes’.<sup>121</sup>

A complaint aired during this Review in submissions and consultations is that Commonwealth law including the ND Act can have an overlapping and inhibiting effect on the cultivation and commercial sale of low-THC hemp. Three examples were given.

The first was that the manufacture licence provisions of the ND Act can apply to pure cannabidiol as a result of it being included in the definition of ‘drug’ in the ND Regulation, reg 4A. Recommendation 2 (above) was that reg 4A be amended to remove the reference to cannabidiol.

The second example concerned the operation of the *Customs (Prohibited Export) Regulations 1958*, which can prevent the grant of a licence to export a product that has been produced or manufactured from low-THC hemp in accordance with State or Territory law but not under an ND Act licence. The customs laws are beyond the scope of this Review, but their interaction with the Single Convention raises a common issue. Regulations 10, 10A and 10C of the *Customs (Prohibited Export) Regulations 1958* have the combined effect that a drug listed in Schedule 8 of the Regulations cannot be exported from Australia unless export permission would be consistent with the requirements of the Single Convention. This applies to cannabis, cannabis resin and extracts and tinctures of cannabis, to which the Single Convention applies. A low-THC hemp substance can be a cannabis extract that falls within that description, even though it may be an ingredient of a product that is for a non-therapeutic use such as a cosmetic product. The licensing controls envisaged by the Single Convention and implemented by the ND Act may have to be satisfied before an export licence can be granted.

A third example was that an entity licensed under State and Territory laws to cultivate low-THC hemp cannot harvest and sell the cannabis flower tops to an ND Act licence holder without also holding an ND Act licence. The flower tops must be destroyed – and a potential commercial benefit squandered.

It is not possible to take that example further in this Review as the issues it raises are not straightforward. The impediment to sale may originate both in Commonwealth and State and Territory laws – in Commonwealth law, because flower tops fall within the definition of ‘cannabis’ in both the Single Convention and the ND Act; and in State and Territory laws, because the authority to cultivate and process low-THC cannabis may relate only to non-therapeutic use and apply only to a plant that is substantially free of leaves and flowering heads.<sup>122</sup> As a practical matter it may also be the case that a particular variety of low-THC cannabis may have little medicinal or scientific value for an ND Act licence holder.

## Comment

Australian law and the Single Convention are framed on the understanding that the rigorous requirements of the Convention do not apply to non-narcotic substances that are derived from the cannabis plant if used for industrial and horticultural purposes and not for medicinal or scientific purposes. That understanding is broadly reflected in Australian laws that differentiate between cultivation and manufacture of cannabis products to which the ND Act applies, and low-THC hemp production that is regulated by State and Territory laws.

It is important that those distinctions are not blurred. While this Review is concerned only with the ND Act, the terms and operation of the Act are centrally important to a faithful implementation of the Single Convention in Australia. This broad issue was under consideration within the department during the course of this Review, and it is important that consideration of the issue continue.

### Recommendation 4

The Australian Government Department of Health continue to monitor and advise Government on options (if any) for altering the operation of the *Narcotic Drugs Act 1967*, consistently with the provisions of the Single Convention, to remove any unintended obstacles to the cultivation and commercial sale of low-THC hemp under State and Territory law.

<sup>121</sup> ND Act, s 7A(1)(a) and (b)

<sup>122</sup> Eg, the *Drugs, Poisons and Controlled Substances Act 1981* (Vic) s 62(1).

## ‘Cultivation’, ‘production’, ‘manufacture’

Different procedures in the ND Act apply to the licensing of ‘cultivation’ and ‘production’ (jointly), ‘research’ and ‘manufacture’.<sup>123</sup> The meaning of those terms is therefore an important element of the medicinal cannabis scheme. The term ‘research’ is discussed in the next section of this chapter; the other three terms are discussed in this section.

The terms ‘cultivate’ and ‘production’ are defined in the ND Act. In summary form, cultivation refers to the growing of a cannabis plant, while production refers to harvesting the cannabis flower or plant resin. The specific definitions in the Act are as follows:

*cultivate a cannabis plant* includes the following:

- (a) sow a seed of a cannabis plant;
- (b) plant, grow, tend, nurture or harvest a cannabis plant;
- (c) graft, divide or transplant a cannabis plant;

but does not include the separation of cannabis or cannabis resin from a cannabis plant<sup>124</sup>

*production* has the same meaning as in the Convention<sup>125</sup> [as follows:]

“Production” means the separation of opium, coca leaves and cannabis and cannabis resin from the plants from which they are obtained.<sup>126</sup>

Little turns, in a practical legal sense, on the difference between cultivation and production. A medicinal cannabis licence can authorise either or both, as well as associated activities such as obtaining a cannabis plant, storage, packaging, transport and disposal of cannabis product.<sup>127</sup> The definitions are relatively broad in nature; the definition of cultivation is not exhaustive; and the list of associated activities that can be authorised by a medicinal cannabis licence is not exhaustive.

The scope of ‘manufacture’ is important both individually and in contrast with other terms in the Act. Section 4(2) of the ND Act provides the following explanation of the meaning of ‘manufacture’:

For the purposes of this Act, the manufacturing of a drug consists of the carrying out of any process by which the drug may be obtained, and includes the refining of a drug and the transformation of one drug into another drug, but does not include the separation of opium, coca leaves, cannabis or cannabis resin from the plants from which it is or they are obtained.

That provision has to be read with reg 4A (quoted above) which lists THC, CBD and dronabinol as being ‘drugs’ for the purposes of the ND Act and for which a manufacture licence can be granted under the ND Act. The ND Act also provides a non-exclusive list of activities that can be authorised by a manufacture licence – including the supply, packaging, transport, storage, possession, control, disposal and destruction of a drug.<sup>128</sup> The ND Act provisions can also be read alongside the definition in the Single Convention:

“Manufacture” means all processes, other than production, by which drugs may be obtained and includes refining, as well as the transformation of drugs into other drugs.<sup>129</sup>

<sup>123</sup> Cultivation and production in the ND Act are licensed under Chapter 2, Part 2, Division 1; research under Chapter 2, Part 2, Division 2; and manufacturing under Chapter 3, Part 2, Division 1.

<sup>124</sup> ND Act, s 4(1).

<sup>125</sup> ND Act, s 4(1).

<sup>126</sup> Single Convention, Art 1(t).

<sup>127</sup> ND Act, s 8E(1).

<sup>128</sup> ND Act, s 11G(1)(b).

<sup>129</sup> Single Convention, Art 1(n).

There was a view aired in the submissions to this Review that the definitions in the ND Act are unclear and in practice can lead to confusion in the licensing process. Issues that were noted included the meaning of ‘transformation’ of a drug, whether the ordinary meaning of ‘manufacture’ includes analytical and research activities, and whether extraction processes fit within production or manufacture.

A possible difficulty in delineating the scope of manufacture for the purposes of the ND Act is that the term is differently defined in the TG Act:

*manufacture*, in relation to therapeutic goods that are not medical devices, means:

- (a) to produce the goods; or
- (b) to engage in any part of the process of producing the goods or of bringing the goods to their final state, including engaging in the processing, assembling, packaging, labelling, storage, sterilising, testing or releasing for supply of the goods or of any component or ingredient of the goods as part of that process.<sup>130</sup>

That definition is framed to deal with the activities regulated by the TG Act, which are different in some respects to those regulated by the ND Act. There are nevertheless potential points of confusion, for example, in that the TG Act definition includes the term ‘produce’ whereas ‘production’ is excluded from the Single Convention definition.

A related concern expressed in some submissions is that manufacture of medicinal cannabis products can require separate licences under both the ND Act and the TG Act if the product is for human use.

## Comment

The application of the ND Act to the manufacture of cannabis derivatives gives rise to several issues.

One is that the definition of ‘drug’ for which a manufacture licence can be granted under the ND Act includes THC, CBD and dronabinol. Recommendation 2 (above) is that CBD should be deleted from this definition.

A second issue is that there is overlap (and potential duplication) between the ND Act manufacture licence provisions and other laws applying to the manufacture of drugs, specifically the TG Act and State and Territory laws. A manufacture licence holder under the ND Act may have similar compliance obligations under several laws.

There is scope for rationalising the licensing structure in the ND Act, as discussed in Chapter 6. One option is to narrow the scope of the ND Act manufacture provisions applying to cannabis and to place greater reliance on the operation of State and Territory laws in meeting Australia’s obligations under the Single Convention.<sup>131</sup> Another option is to replace the present structure of three separate licences with a new structure under which a single licence could authorise all or some of cultivation, production, research and manufacture. Fewer interpretive issues would then arise regarding the distinction between manufacture and other processes.

A third issue, that squarely arises under the present requirements of the ND Act, is that an application for a manufacture licence must provide details of the activities the applicant proposes to take under the licence.<sup>132</sup> This can present a threshold difficulty if the applicant is uncertain as to the range of activities that fall within the scope of manufacture or that require an ND Act licence. It is not clear whether the quandaries about the meaning of ‘manufacture’ that were raised in some submissions are shared widely by other licence applicants or holders, but they nevertheless point to some gaps in understanding.

<sup>130</sup> TG Act, s 3(1).

<sup>131</sup> See Single Convention, Arts 12, 20, 29.

<sup>132</sup> ND Regs, reg 35(2)(f).

This issue should be addressed through elaboration of the current guidance on the meaning of manufacture published by the ODC in November 2016.<sup>133</sup> That guidance, published when the medicinal cannabis amendments to the ND Act were commencing, contains minimal practical examples, and does not deal with the comparison (and interaction) between the ND Act requirements, TG Act requirements and relevant State and Territory laws. The development and republication of this guidance should include consultation with current licence holders and industry associations to ensure the guidance addresses relevant issue of concern to them.

### **Recommendation 5**

The Office of Drug Control publish more extensive guidance than is currently published on:

- the meaning of ‘manufacture’ in the *Narcotic Drugs Act 1967*
- the relationship of that term to other relevant terms in the *Narcotic Drugs Act 1967* (such as ‘cultivation’, ‘production’ and ‘research’)
- the comparison between the manufacture licence provisions in the Act and manufacture requirements in the *Therapeutic Goods Act 1989* and State and Territory laws.

## **‘Research’**

The term ‘research’ is not defined in either the ND Act or the Single Convention. The most that is said in the ND Act is that a cannabis research licence can authorise activities such as cultivation and production of cannabis plants to produce cannabis or cannabis resin for research relating to medicinal cannabis, and associated activities such as packaging, transport and storage of cannabis product.<sup>134</sup> Further, a Note to reg 11 of the ND Regulation (which specifies the form an application for a cannabis research licence must take) comments that a research licence can authorise activities related to cultivation or production, such as testing cannabis to determine the concentration of THC in the leaves and flowering heads of a plant.<sup>135</sup>

The main comment regarding the definition of research that was made in the submissions and consultations is that it can be artificial to attempt to draw a sharp distinction between research, on the one hand, and cultivation, production and manufacture on the other. It was said that activities commonly regarded as research can incidentally arise during production and manufacture, which do not necessarily conform to a pre-determined pattern.

The normal understanding of research is that it can involve elements of investigation, experimentation, evaluation, analysis and generation of new knowledge. Those processes can form part of a quality control and improvement strategy in production and manufacture. As the familiar cognate term ‘research and development’ suggests, research can be an integral part of production and manufacture in a commercial setting.

A related point raised in the submissions and consultation is that the ND Act distinction between research and other activities potentially precludes separate attention being given during cultivation and production to processes such as plant strain development and improvement of growing conditions. That point is taken up in Chapter 6 in the discussion of whether the ND Act should maintain the present distinction between medicinal cannabis licences, cannabis research licences and manufacture licences.

<sup>133</sup> Office of Drug Control, *Medicinal Cannabis Manufacture Licences and Permits*, 2 November 2016 (version 1.0), available at: <https://www.odc.gov.au/publications/medicinal-cannabis-manufacture-licences-and-permits>

<sup>134</sup> ND Act, s 9D(1).

<sup>135</sup> ND Regs, Note to reg 11(2)(f).

## Comment

The absence of a definition of ‘research’ in the ND Act will be less an issue if a new licensing framework is adopted by which a single licence can authorise all of some of cultivation, production, manufacture and research. That approach would make it unnecessary to spell out what is meant by research. A licence would specify the authorised activities; and any use of the term ‘research’ in the licence could rely on the ordinary understanding of the term.

Different considerations arise if research licences are retained as a separate licence category in the ND Act. It is then necessary to decide what activities can be applied for and authorised under a research licence – bearing in mind too that lower charges and fees apply to research licences and permits. While it could be helpful for that purpose to amend the ND Act to include a definition of ‘research’, it does not appear that the absence of such a definition has been a matter of concern for research licence applicants and holders. No submission along those lines was made to this Review.

The counterpart concern raised in this Review – uncertainty as to the research-type activities that can be authorised by a medicinal cannabis licence or manufacture licence – could also be addressed in the first instance at an administrative level without the need for legislative amendment of the ND Act or ND Regulation.

The ND Act does not spell out explicitly the matters that can be authorised by a medicinal cannabis or manufacture licence. Instead, the ND Regulation requires an application for such a licence to provide ‘details of the activities the applicant proposes to undertake under the licence, being activities mentioned in’ s 8E(1) of the ND Act (as to a medicinal cannabis licence application) or s 11G(1) (as to a manufacture licence application).<sup>136</sup> As noted above, those sections provide a non-exhaustive list of the activities that may be authorised by a licence. The sections also include expansive language as to the activities that can be listed in an application – ‘activities relating to such obtaining, cultivation or production’ and ‘activities relating to such manufacture’.<sup>137</sup> Consistently with this, a note to reg 5(2)(f) in the ND Regulation emphasises the non-exhaustive nature of the licence application requirements:

Note: Under subsection 8E(1) of the Act, an applicant is not restricted to applying for a licence authorising activities expressly mentioned in that subsection and may, in accordance with paragraph 8E(1)(c) of the Act, apply for a licence authorising activities related to cultivation or production. Such activities could include, for example, testing cannabis to determine the concentration of tetrahydrocannabinol in the leaves and flowering heads of cannabis plants, or the transport of such plants to persons carrying out testing of the plants for the purposes of supply.

In summary, action can presently be taken by the ODC to clarify the scope of ‘research’ and the activities of a research or product development nature that can be authorised by a medicinal cannabis licence or a manufacture licence. This could appropriately result in more extensive guidance being published by the ODC, building on the information circulars concerning research earlier published by the Office.<sup>138</sup> The need for more extensive guidance may, however, be overtaken by the implementation of other recommendations in this report for legislative amendment of the ND Act and the ND Regulation relating to licence categories.

<sup>136</sup> ND Regulation, reg 5(2)(f) (medicinal cannabis licence application), and reg 35(2)(f) (manufacture licence application)

<sup>137</sup> ND Act, ss 8E(1)(c), 11G(1)(b).

<sup>138</sup> Office of Drug Control, Policy Circular #02/17, *Cannabis Research - Using cannabis for medicinal cannabis research and medical research* (October 2017), available at: <https://www.odc.gov.au/publications/cannabis-research-using-cannabis-medicinal-cannabis-research-and-medical-research>; Office of Drug Control, Policy Circular #01/17, *Medicinal Cannabis Cultivation and Production Licences – Testing of Cannabis and Cannabis Resin* (August, 2017), available at: <https://www.odc.gov.au/publications/medicinal-cannabis-cultivation-and-production-licences-testing-cannabis-and-cannabis>.

**Recommendation 6**

The Office of Drug Control consider publishing more extensive guidance than is currently published on:

- the meaning of the term ‘research’ in the *Narcotic Drugs Act 1967*
- the activities of a research or product development nature that can be authorised by a medicinal cannabis licence or manufacture licence in the absence of a separate cannabis research licence.

**‘Fit and proper’, ‘business associate’, ‘serious criminal offence’**

These three terms play a part in the licensing requirements for a licence or permit under the ND Act. Briefly, an applicant must be a fit and proper person to hold a licence or permit; the applicant’s business associates must be fit and proper persons to be associated with the applicant for the licence or permit; and the applicant must not have engaged in conduct that constitutes a serious criminal offence in the previous ten years. Each of those terms will now be separately considered.

The ND Act spells out matters that can be considered in deciding whether an applicant or a business associate is a fit and proper person.<sup>139</sup> These 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.

There has been no direct criticism of either a fit and proper person test being a licensing criterion or the factors that are to be considered in applying that test. There has been commentary on three associated matters that are taken up in other chapters, but which warrant summary mention at this stage:

- The ND Regulation is highly prescriptive as to the information and documents an applicant must submit in support of a licence application. Many of the requirements are directed at whether the applicant is fit and proper to hold the licence. Recommendation 8 (below) is that the ND Regulation should be revised with a view to reducing the number of separate requirements that an applicant is required to meet.
- An applicant who is applying for multiple licences (either simultaneously or consecutively) is required to submit separate applications that each contain the information and documents required by the ND Regulation. Recommendation 8 also proposes a consolidation of the separate requirements so that an applicant is not required to submit the same information in duplicate.
- A licence holder must notify the Secretary (or the ODC as delegate) of any matter that may affect whether the licence holder or a business associate still meets the fit and proper person test.<sup>140</sup> The ND Act does not directly address how the ODC is to respond to or deal with that notification. Recommendation 20 is that the ODC, as part of a proposed regulatory guidance document, explain how notifications are dealt with.

<sup>139</sup> ND Act, s 8A and s 8B (whether a body corporate is a fit and proper person).

<sup>140</sup> ND Act, ss 10K(1)(a), 12N(1)(a).

The ND Act provides that two or more persons are ‘business associates’ for the purposes of the Act 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.<sup>141</sup>

There has been no direct criticism either of the definition of business associate or of this connection being relevant to a licence applicant’s eligibility for a licence. One associated matter is taken up in Chapter 7. Recommendation 19 is that the relationship between a business associate and a licence holder should be a discretionary rather than a mandatory ground for revocation of a licence. One reason for that recommendation is that there is an element of imprecision as to who is a ‘business associate’, for example, a person with a financial interest in the business who can exercise a ‘significant interest’ over the business, or a person who holds an ‘executive position’ in the business.

The term ‘serious criminal offence’ is defined in the ND Act as including offences involving dishonesty, fraud, drug cultivation or trafficking or that are punishable by imprisonment for five years or more.<sup>142</sup> 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.<sup>143</sup>

No change to that definition is recommended.

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<sup>141</sup> ND Act, s 4(1).

<sup>142</sup> ND Act, s 4(1).

<sup>143</sup> ND Act, ss 8H, 9G.

# Chapter 6: Medicinal cannabis licences and permits

## Introduction

The central feature of the medicinal cannabis scheme introduced into the ND Act in 2016 was a licensing and permit framework to regulate cannabis cultivation, production and manufacture for medicinal and scientific purposes. The framework is explained in Chapter 4.

The Discussion Paper for this Review invited submissions on specific aspects of the licensing and permit scheme, among them:

- Is it an appropriate structure in the ND Act to have three categories of licences and permits – for cultivation/production, research and manufacture?
- Should there be greater flexibility as to the activities that can be conducted under a licence?
- Are the criteria for the grant of licences appropriate?
- Is change needed as to the term, renewal or variation of licences?
- Are the conditions imposed on licences appropriate?
- Are the special licensing requirements in the ND Act appropriate, such as that in s 11K applying to manufacturing licences?

For the most part those questions relate to the terms of the ND Act and the ND Regulation. Other questions asked in the Discussion Paper about the administration of the licensing and permit provisions are examined in Chapter 9.

Many submissions to the Review addressed those questions, particularly the submissions from existing licence holders and industry associations.

There was an underlying acceptance in most submissions that a medicinal cannabis cultivation scheme will necessarily be framed around a licensing and permit system – though some submissions contended that an entirely different approach was required, without spelling out what it would be.<sup>144</sup> The Single Convention requires a Party that permits the cultivation of cannabis plants and the manufacture of narcotic drugs to do so through a licensing scheme.<sup>145</sup>

Another underlying theme in submissions was that the licensing scheme could be improved and could work better, through both legislative and administrative reform. There was a call generally for greater flexibility in licence categories and licensing requirements.

This chapter considers six aspects of the licensing and permit framework in the ND Act:

- the existing framework of three separate licences and related permits: this Review recommends that the existing licence categories applying to cannabis be replaced with a single licence category that could authorise all or some of cultivation, production, manufacture and research
- the licensing requirements, including the information and documents an applicant must submit in support of a licence application: the Review notes some licensing requirements in the ND Regulation that may no longer be necessary, are inappropriately phrased or are too prescriptive. Reform options that are considered are to delete, simplify and consolidate the requirements, supplemented in some instances by explanatory guidelines issued by the Minister under the ND Act

<sup>144</sup> Some submissions referred as an alternative approach to the Regulator of Cannabis Bill 2014 (see Chapter 2), that provided for the Regulator to administer a medicinal cannabis licensing scheme.

<sup>145</sup> Single Convention, Articles 23, 28, 29.

- the term of a licence, and the absence of a power in the ND Act to renew a licence: the report recommends that licences ordinarily be granted for a period of three years, and that a renewal power be inserted in the ND Act
- the procedure for applying for a permit and a variation of a permit: the report recommends that a plainer procedure be adopted for both
- the scale of fees and charges imposed on licence applicants and holders, as part of a partial cost recovery scheme in the ND Regulation: the report does not recommend change to the current scale of fees and charges, which are annually reviewed
- the review and appeal mechanisms in the ND Act that are available to aggrieved licence applicants and holders: the report does not recommend any change to current arrangements.

## Separate licence categories

The scheme in the ND Act for three categories of licence has been vexing for licence applicants and holders, as illustrated in the following points:

- A licence applicant may have to submit three separate applications for a medicinal cannabis licence, cannabis research licence and manufacture licence. It can be time-consuming to prepare multiple applications and there can be duplication in the information provided in each application.
- Each licence application may be the subject of separate liaison with different ODC staff. Multiple requests may be received under s 14J of the ND Act for further information relating to each application. There can be added complication if there is duplication or overlap in those information requests. The chance of this occurring may be greater if the licence applications are submitted at different points in time.
- It can be unclear as to what activities fall within each licence category. Much will depend on the terms of a licence, and whether the licence holder has only one type of licence. Questions have been raised, for example, as to the research (including product development and testing) that can be undertaken under medicinal cannabis and manufacture licences, and as to the training and analytic testing that can be undertaken under a cannabis research licence.
- An applicant for a medicinal cannabis licence must demonstrate a supply arrangement with a licensed manufacturer, and an applicant for a manufacture licence must demonstrate a supply chain to a patient consistent with the requirements of the TG Act. The separate licence categories can make it more complex to comply with those licensing requirements.
- Licence and permit conditions commonly restrict the uses that can be made of cannabis product during production, research and manufacture, and the transfer or supply of that product from one licence or permit to another. The system of separate licences and permits may make it more complex for licence holders to navigate the conditions that apply in a particular instance.
- The system of separate licences and permits may also accentuate the complexity that a licence holder faces in applying for variation of a licence or permit condition and, in turn, the delay for the licence holder in obtaining approval of the variation.
- The holder of a manufacture licence under the ND Act may also need a manufacturing licence under the TG Act. Some licence holders claim to have been burdened and unsure as to the separate but overlapping licence requirements.
- A research licence does not authorise medicinal cannabis to be supplied for human use, such as the use of a medicine in a clinical trial.
- The three licence structure adds to the number of separate applications (and associated queries and administrative steps) that the ODC must handle. Administrative delay, which has been a chief complaint about the administration of the medicinal cannabis scheme, could be lessened if the application framework and procedure was less complex.

Those complications could be lessened – though not removed altogether – if a different licensing framework was adopted in the ND Act. There are four broad options to consider (the options are not mutually exclusive):

- Abolish the separate licence categories in the ND Act and replace them with a single licence category that authorises some or all of cultivation, production, manufacture and research. Different licensing criteria and requirements would apply depending on the range of activities that an applicant sought authority to undertake. Application fees and licence charges would also vary according to the nature of the application being lodged and the activities authorised in any licence that was granted.
- Retain the existing licence categories but add a fourth category that could authorise some or all of cultivation, production, manufacture and research. The purpose behind this proposal is to retain the greater simplicity for an applicant for a single category licence (particularly a research licence).
- Broaden the scope of medicinal cannabis and manufacture licences to permit research under those licences. This proposal addresses a limitation that was commonly criticised in submissions and consultations. The possibility of implementing this option by administrative rather than legislative change was raised in Chapter 5 of this report.
- Leave the manufacture of medicinal cannabis products to be regulated by existing State and Territory laws and the TG Act. Appropriate arrangements would have to be put in place to ensure the Commonwealth met its obligations under the Single Convention to control and supervise aspects of manufacturing that were not controlled by other laws (for example, national stock and manufacturing levels) and to the report to the INCB.

The most appealing of those options is the first option to adopt a single licence structure. It is admittedly the most far-reaching option and would require substantial revision of Chapter 2 of the ND Act to set out an integrated framework applying to cannabis cultivation, production, research and drug manufacturing. Chapter 3 of the ND Act would continue as at present to apply to the manufacture of drugs within the meaning of the Single Convention, but not the manufacture of cannabis, cannabis resin and extracts and tinctures of cannabis or medicinal cannabis products, which would fall within the revised Chapter 2. Chapter 4 of the ND Act, relating to monitoring and enforcement, would continue to apply to all licensing under Chapters 2 and 3.

There would be an associated need in adopting a single licence structure to revise related provisions of the ND Regulation as well as administrative procedures and forms. A review may also be necessary of the provisions of the ND Act and ND Regulation relating to permits, and in particular whether conditions and requirements that are currently specified in permits should instead be specified in licences or dealt with at an administrative level.

A single licence structure would have numerous potential benefits:

- The licence application process could be simplified and streamlined. Only a single licence application would ordinarily be required that spelt out the range of activities the applicant sought authority to undertake, either immediately or on an incremental basis.
- It would be more straightforward for the ODC to handle a single licence application rather than multiple applications from the same applicant. This would potentially address some administrative concerns that applicants have raised, such as delay, duplication and dealing with multiple ODC staff in the licence application process.
- The current uncertainties about which activities can be licensed under each of the three licence categories would be answered. An applicant could seek a licence that authorised all or any of cultivation, production, research or manufacture.
- There could be more flexibility for a licence holder to manage cannabis product under the single licence, and to notify licensing activity and changes to the ODC, rather than applying for a licence variation or a new licence in response to unanticipated developments.

- Individual licences could be tailored to an applicant’s plan of developing a business in stages. A single licence that underpinned planned future growth or adaptation would provide greater commercial certainty for a licence applicant.
- It would be potentially more straightforward for an applicant to substantiate that an acceptable supply chain arrangement was in place to link production, manufacture and patient supply.
- A licence holder would be better placed to decide if its licence should extend to manufacture, or whether a separate TG Act licence would adequately provide authority for the licence holder’s planned manufacturing activities.
- A single licence structure would enable fresh consideration of regulatory options for ensuring effective alignment and integration of ND Act licensing and State and Territory regulation, particularly of industrial/low-THC hemp.

The other three licence restructure options also have merit, but with qualifications. The principal merit of the second option (a fourth licence category) is that it is a more cautious and qualified response to the concerns that have been raised in this Review. On the other hand, it could complicate the existing structure to have four licence categories.

The principal merit of the third option (permitting research in all three licence categories) is that it retains a simpler structure for applicants that intend only to undertake research. However, there is no reason in principle why that simplicity could not be retained as a separate stream of a single licence structure. This option also fails to address some non-research concerns that were raised about the existing licensing structure.

The fourth option (dispensing with ND Act licensing for manufacture of drugs derived from the cannabis plant) does not take full account of the different criteria and additional requirements that can apply to an application for a manufacturing licence under the TG Act.<sup>146</sup> The differences may not directly concern a manufacturer who already has a GMP licence, but are squarely relevant to other applicants who may be better suited to applying only for an ND Act manufacture licence.

A final issue to consider is whether a single licence structure for cannabis products would be consistent with Australia’s obligations under the Single Convention. The current three licence structure is not a requirement of the Single Convention. It requires only that cultivators be licensed by an Australian Government agency and that the parties to the Convention control under licence the establishments and premises in which the manufacture of drugs takes place.<sup>147</sup>

No official explanation was given at the time the medicinal cannabis scheme was before the Parliament in 2016 as to why a system of three separate licences was chosen. The most likely explanation is historical and practical: that a three licence structure built on the separate provisions in the Single Convention relating to cultivation and manufacture, and on the existing provisions in the ND Act relating to manufacturing; and a new category of research licence would be simpler for research organisations and could authorise cultivation for research without the need for a separate medicinal cannabis licence. Those are not compelling reasons to retain the present three licence structure.

### **Recommendation 7**

The *Narcotic Drugs Act 1967* be amended to establish a new licence structure applying to medicinal cannabis products. The *Narcotic Drugs Act 1967* should provide for the issue of a single licence to authorise all or some of cultivation, production, manufacture and research of such products.

<sup>146</sup> These are explained in a Therapeutic Goods Administration publication, *Australian manufacturing licences and overseas GMP certification: A step-by-step guide* (March 2019).

<sup>147</sup> Single Convention, respectively Art 28.1 (read with Art 23.2(b)) and Art 29.2(b).

## Licensing requirements

The ND Act and the ND Regulation impose many licensing requirements that reflect an underlying premise of the medicinal cannabis scheme – that it must neutralise a major risk of diversion and criminal infiltration inherent in a scheme that permits cultivation, research and manufacture of cannabis products. Many licensing requirements are directed at whether an applicant is fit and proper to hold a licence or has implemented effective measures to minimise risks of diversion and criminal infiltration in undertaking activities authorised by a licence or permit.

The licensing requirements in the ND Regulation in particular are highly prescriptive. Many of the submissions to this Review were critical of the level of prescription, the administrative burdens it imposes on applicants and the uncertainties it gives rise to in the licence and permit application process. Examples that were given in submissions of issues relating to the licensing requirements include the following:

- An application for a manufacture licence under the ND Act relating to cannabis must provide details of the drugs to be manufactured and their proposed end use; depending on the level of detail required, it is said that this can constrain the industry from undertaking pharmaceutical development activity, contrary to accepted international practice which aims to ensure that a manufacturing process is underpinned by quantitative and qualitative data about the process and the product.
- The manufacture licensing provisions in the ND Act apply to cannabidiol in a pure form. This is not directly a requirement of the Single Convention and can impose ND Act controls unnecessarily on the manufacture of cannabidiol.
- The supply chain requirements are complex and difficult to satisfy because of the detailed agreements that are required to have been entered into with manufacturers or prescribers in advance of any activity occurring. The supply chain requirements are not a requirement of the Single Convention in the form adopted in the ND Act and ND Regulation. One effect is that a licence holder may find the easier path is to produce and manufacture medicinal cannabis products for the export market.
- It can be unclear as to the matters that must be covered by licensing, for example, molecules prior to creation, or the application of analytic method to a product sourced from a third party.
- Over time more detailed and comprehensive information has been required in licence applications.
- It is unclear what information must be provided in licence applications, as illustrated by the range of questions that are raised in requests under s 14J of the ND Act to provide additional information; this can lead to substantial delay in the licence approval process.
- Duplicate information can be required when multiple licence applications are lodged by the same applicant, including as to police checks.
- Some conditions that are imposed on licences can be onerous. For example, the requirement in s 8M(e) of the ND Act to specify in a medicinal cannabis licence ‘the persons authorised by the licence to engage in activities authorised by the licence’ has meant that physical rather than supervisory presence of an authorised person has been required when licensed activities are being undertaken.<sup>148</sup>
- The ND Act requirement that regard be had during the licensing approval process to whether an applicant ‘has a sound and stable financial background’ and is able to comply with licence obligations<sup>149</sup> has given rise to complaints that the approval process can delve further into an applicant’s commercial business model than is necessary to address security or risk management concerns.

<sup>148</sup> See also ND Regulation, regs 7A(b), 13A(b).

<sup>149</sup> ND Act, s 8A(g).

- Restrictions have been imposed on the employment and monitoring of staff that are also said to go further than the ND Act requires and that can be impracticable.

The ODC has acknowledged those concerns, in consulting with applicants and industry representatives to explain the nature and purpose of the licensing requirements and to examine options for simpler compliance. Generally, there is an acceptance within the department that the risk of criminal infiltration and diversion within the medicinal cannabis scheme has been controlled through current measures and that licence holders have (and can be expected to play) an effective role in managing those risks.

The purpose of the licensing requirements is both understandable and generally apparent from their face. On the other hand, many requirements go further than may be necessary. The reform options include deleting, simplifying and consolidating some of the requirements, possibly supplemented with information requirements specified by the Secretary, guidelines issued by the Minister or administrative guidance published by the ODC. To explain:

- The ND Act requires an application for a licence to be made in the form or manner approved in writing by the Secretary and to include the information or documents required by the ND Regulation or ‘specified in writing by the Secretary’.<sup>150</sup> If the detailed requirements that are currently in the ND Regulation are scaled back, greater reliance could be placed on the Secretary’s power to specify information and document requirements either in a template licence application form or in supplementary guidance.
- The ND Act confers powers on the Minister to issue guidelines for the purposes of the Act.<sup>151</sup> The guidelines are not a legislative instrument, though a decision maker under the ND Act is required to have regard to any such guidelines.<sup>152</sup> Guidelines provide a model for industry regulation that is frequently adopted as they lay down a regulatory framework that is both formal but flexible and readily adjustable as circumstances or objectives change.
- The ODC currently publishes informative guidance on the operation of the licensing and permit provisions in the ND Act, including on the meaning of key terms in the ND Act and ND Regulation. Several recommendations in this report are for the ODC to supplement and develop that written guidance. This role can be expanded and tailored to the structure and detail of a revised ND Act and ND Regulation.

Following are prime examples of features of the ND Regulation that warrant amendment or revision by one or more of the preceding options.

- ***Consolidating information and document requirements:*** The ND Regulation deals separately with applications for medicinal cannabis licences and permits,<sup>153</sup> cannabis research licences and permits<sup>154</sup> and manufacture licences and permits.<sup>155</sup> While there are different criteria to be satisfied for each licence, there are also many common criteria and standard conditions to be met (for example, the fit and proper person requirement). The consequence is that an applicant for multiple licences or permits may have to separately submit similar or identical information and documents for each application.
- The information and document requirements for all licences and permits could be combined in a single set of provisions that apply to all applications, with sub-categories for requirements that are specific to only one type of licence or permit activity. These regulations could, as explained above, be supplemented by instructions issued by the Secretary, guidelines issued by the Minister or informal guidance published by the ODC.

<sup>150</sup> ND Act, s 8E(2) (medicinal cannabis licence application), s 9D(2) (cannabis research licence application), s 11G(2) (manufacture licence application). Cf the TG Act s 22C(2) which similarly provides that an application is to be made in a form approved by the Secretary.

<sup>151</sup> ND Act, s 26C.

<sup>152</sup> ND Act, s 26C(2),(3).

<sup>153</sup> ND Regulation, regs 5, 6, 8.

<sup>154</sup> ND Regulation, regs 11, 12, 14.

<sup>155</sup> ND Regulation, regs 11, 12, 14.

- The adoption of a single licence structure in the ND Act (see Recommendation 7) would require consequential changes to the licence application process, and the information and documents to be provided. So, too, would adoption of the following proposal for deletion or simplification of some information requirements.
- ***Simplifying information and document requirements:*** The ND Regulation contains a highly detailed list of the information and documents that must be provided in support of a licence or permit application. For example, the list of items in regs 5, 6 and 8 relating to medicinal cannabis licences and permits is approximately nine pages long. As a legislative requirement, strict compliance with the items in that long list is required before a licence or permit can be granted. It appears this is a contributory factor to both the volume of s 14 J information requests made by the ODC to applicants and delays in processing licence and permit applications.
- The information requirements may individually be relevant to some but not all licence and permit applications. As part of the revision and consolidation of the information submission requirements, each individual requirement to provide information and documents should be reviewed to assess if it should remain a mandatory requirement or could instead be cast as a discretionary requirement that can be imposed in appropriate circumstances by the ODC, and supplemented by instructions issued by the Secretary, guidelines issued by the Minister or informal guidance published by the ODC.
- Another similar example of a regulation that appears to be unnecessarily prescriptive is reg 5(5) which requires a licence application to provide specific details regarding the cannabis plants, cannabis and cannabis resin that the applicant will deal with under the licence. It would be appropriate and less onerous to require an applicant to outline the arrangements that will be in place to record the amount of cannabis plants, cannabis and cannabis resin the applicant will deal with.
- ***Lessening requirements that go further than the ND Act requires:*** The ND Regulation elaborates on the licence application requirements in the ND Act, but in doing so may go further in some instances than the ND Act requires. An example is the regulation that gives effect to the requirement in s 8G(d) of the ND Act that the Secretary in granting a licence be satisfied that the applicant will take all reasonable measures to ensure the physical security of cannabis plants, cannabis or cannabis resin that is in the applicant's possession or control and was obtained, cultivated or produced under the licence. Regulation 5(2)(h)-(i) requires an applicant to provide 'details of the arrangements that will be in place', variously, to ensure the physical security of cannabis products that are cultivated, obtained or produced under the licence, to ensure that loss or theft is detected immediately and reported, to ensure safe and secure disposal, of transport security arrangements, and of arrangements with emergency services agencies.
- The ND Regulation would better align with s 8G(d) of the ND Act if the specific requirements were replaced with a more general requirement that used similar wording to the Act, for example, that an application provide details of the security measures (rather than arrangements) that will be in place in relation to substances that are in the applicant's possession or control in pursuance of the licence. This general licensing requirement could be supplemented by instructions issued by the Secretary, guidelines issued by the Minister or informal guidance published by the ODC. The supplementary guidance could explain that the security measures can be tailored to relevant circumstances such as the number of cannabis plants covered by the licence and the THC content of the plants.
- ***Regulation 4A:*** Recommendation 2 in Chapter 5 is that the reference to cannabidiol be deleted from this regulation, with the consequence that the manufacture licence provisions in the ND Act would not apply to cannabidiol in a pure form. This would have a consequential and simplifying effect on manufacture licence applications and licence conditions.

- **Regulation 19:** Section 10J of the ND Act makes it a condition of medicinal cannabis licences that cultivation or production under the licence is covered by a contract with, respectively, an authorised producer or manufacturer. Regulation 19 prescribes the content that a contract must have. Roughly 25 elements are prescribed to do with the number and composition of plants, concentration of elements, security arrangements and disposal. Experience has shown that it is not possible to meet those requirements prospectively, except perhaps by scaling back the contract to a commercially basic level.
- Regulation 19 should be repealed in its current form and replaced by a regulation that places an obligation on a licence holder to demonstrate that the next step in the supply chain is covered by a contract that deals with matters that are listed in the ND Regulation but at a higher level of generality. A revised r 19 must still comply with s 10J of the ND Act, though it requires only that ‘a contract that deals with matters prescribed by the regulations is in existence’. It would be consistent with that requirement for r 19 to provide that contract details necessary to support compliance oversight shall be included in a permit to undertake cultivation or production.
- **Regulations 18 and 39:** Regulations 18 and 39 supplement 10F of the ND Act by specifying categories of persons who are regarded as unsuitable to be employed or engaged by a licence holder to carry out activities authorised by the licence. Recommendation 14 in Chapter 7 is that the restrictions imposed by rr 18 and 39 be scaled back. This would have a consequential and simplifying effect on the obligations of a licence holder, and in particular as to the information or notifications that must currently be provided to the ODC.
- **Inexact and demanding decision making criteria:** Some regulations require an applicant to provide information and for the ODC to form a view, according to criteria that are inexact, elastic or demanding. This can be challenging for both the applicant and the regulator. Examples include the following statutory phrases:
  - regulation 11(2)(fa): ‘the primary purpose of the research’
  - regulation 5(2)(g)(iii): ‘the total area, and geographic coordinates, of the land at the location’ – as opposed, for example, to ‘the total area under cultivation’
  - regulation 5(2)(l): ‘details of the arrangements that will be in place with emergency services, police and local government authorities’ to deal with a specific list of possibilities in relation to specific items
  - regulation 5(3)(b): ‘details of any civil penalty (however described) imposed, at any time, upon the applicant under a law of the Commonwealth, a State or a Territory’
  - regulation 5(3)(h): ‘details of the applicant’s previous business experience’
  - regulation 5(3)(j): ‘whether the applicant is affected by bankruptcy’
  - regulation 5(3)(k): ‘details of the applicant’s current financial circumstances’
  - regulation 5(4)(h): ‘details of the previous business experience ... of the shareholders of the body corporate who are in a position to influence the management of the body corporate’
  - regulation 5(6): ‘details of the procedures (including recruitment procedures) that will be used by the applicant’ to ensure employment of suitable persons

A unifying theme in those examples is the expansive obligation they cast on applicants to provide a potentially extensive range of information that may be relevant to whether the applicant is fit and proper to hold a licence under the ND Act. While information falling within each category could have a bearing on that issue, conversely each category could draw in many items of information that will have no practical relevance.

These (and similar) examples in the ND Regulation should form part of a revision and consolidation of the application requirements in the Regulation. The revision options that should be canvassed include deletion of unnecessary requirements, consolidation/merger of similar requirements, scaling back the number and breadth of the mandatory requirements, and elaboration of more generally-framed requirements in Ministerial guidelines under s 26C of the ND Act or in informal guidance published by the ODC.

### **Recommendation 8**

The requirements imposed by the *Narcotic Drugs Regulation 2016* on licence and permit applicants to provide information and documents in support of applications be revised, with the following objectives:

- to delete requirements that are no longer necessary to attaining the objectives of the licensing or permit decision
- to merge or consolidate requirements that are similar in nature, so as to reduce the number of separate requirements that applicants are required to meet
- to reduce the number and breadth of mandatory requirements imposed on applicants, and
- to frame the requirements in more general terms that can, in appropriate circumstances, be elaborated in guidelines issued by the Minister under section 26C(1) of the *Narcotic Drugs Act 1967* or in informal guidance published by the Office of Drug Control.

## **Section 11K of the ND Act**

Section 11K of the ND Act provides that a licence cannot be granted for the manufacture of a drug derived from any part of the cannabis plant unless the Secretary is satisfied that the intended use of the drug is for one of a number of applications that are specified in s 11K or in the ND Regulation. The present list of permitted uses (that are set out fully in Chapter 4) includes certified research, in a certified clinical trial, to be supplied as a medicinal cannabis product in accordance with the TG Act or for approved export.

This limitation on the grant of manufacture licences was inserted in the ND Act in 2016 as part of the new medicinal cannabis scheme. The apparent purpose was to combat any risk of a cannabis product being diverted to an illicit, inappropriate or unapproved purpose, for example, to an unqualified research body or without adequate TGA oversight. No similar requirement (either prior to 2016 or subsequently) applies to the manufacture of other narcotic drugs in Australia.

While the list of permitted uses can always be extended by regulation, the situation at present is that a number of potential applications for medicinal cannabis products are not permitted, for example:

- medical research outside a clinical trial, including product formulation
- testing a manufactured medicinal cannabis product for compliance with GMP licensing requirements
- the development of reference standards for medicinal cannabis
- the use of medicinal cannabis products in veterinary treatment.

It is not strongly apparent why this tighter control should be imposed on medicinal cannabis and not on other therapeutic drugs. Nor is clear that s 11K is necessary to achieve an outcome that other Commonwealth, State and Territory laws could not achieve. A substantial number of other laws that are carefully administered (including the TG Act) control the supply and use of medicinal cannabis products, and for s 11K to restate that purpose adds little. Equally, research and clinical trials are closely controlled by other regulatory rules and protocols. If reassurance was needed that those other laws and processes will be observed, this could be achieved through a condition imposed on a manufacture licence on a case-by-case basis.

Section 11K also produces an uneven effect for imported and locally manufactured drugs. The potential applications outlined above can currently be serviced through imported medicinal cannabis products, but not by medicinal cannabis products that are manufactured under an ND Act licence. This gives a competitive advantage to international products over locally manufactured products, and potentially limits the development of Australian industry.

There is also a current anomaly in the operation of s 11K as regards patient supply, though this is principally a consequence of other legislative developments. A locally manufactured medicinal cannabis drug can be made available to patients through the Authorised Prescriber, Special Access Scheme B and clinical trial pathways, as those pathways fall within the list of permitted uses under s 11K. Special Access Scheme A is not a permitted pathway, as it is a notification rather than approval pathway that does not involve TGA oversight and can be used for unapproved therapeutic goods. However, an imported medicinal cannabis product can be made available under SAS A. A proposed regulation under the TG Act in 2016 would have closed that importation pathway, but the proposed regulation was disallowed in the Senate under the *Legislation Act 2003* (Cth).<sup>156</sup>

It is recommended below that s 11K be repealed. There is no reason in principle why medicinal cannabis drugs that are manufactured pursuant to a licence under the ND Act should be treated differently to other therapeutic drugs manufactured pursuant to an ND Act licence. Section 11K also has an anomalous effect in treating locally manufactured products less favourably than imported products. If it is thought desirable to impose limitations on the permitted uses of locally manufactured products, this would be better done in other ways rather than through s 11K.

### Recommendation 9

The *Narcotic Drugs Act 1967* be amended by repealing section 11K, on the basis that it imposes an unnecessary and counterproductive constraint on the permitted uses of medicinal cannabis products that are manufactured pursuant to licences under the *Narcotic Drugs Act 1967*.

## Licence term and renewals

The ND Act requires that licences and permits specify the period in which they are in force.<sup>157</sup> The Act does not specify the maximum allowable licence or permit period. There is no procedure in the Act to renew an existing licence or permit – 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.<sup>158</sup>

The early practice of the ODC was to grant medicinal cannabis licences for a period of one year. They are currently granted for up to three years. Research licences are typically granted for a period of three years.

In 2018 the power to vary a licence at the Secretary's initiative<sup>159</sup> was used to extend the term of all existing licences for one year. That practice has been continued in 2019 for licences that were initially issued for a short term. A sensible rationale for that practice is that it can take longer to consider and finalise a licence application.

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.

<sup>156</sup> The *Therapeutic and Other Legislation Amendment (Narcotic Drugs) Regulation 2016*, reg 12A(1), Items 1 and 4, disallowed under the *Legislation Act 2003* (Cth) s 42. See

[https://www.aph.gov.au/Parliamentary\\_Business/Statistics/Senate\\_StatsNet/statements/disallowance/2017](https://www.aph.gov.au/Parliamentary_Business/Statistics/Senate_StatsNet/statements/disallowance/2017)

<sup>157</sup> 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).

<sup>158</sup> ND Act, s 24C.

<sup>159</sup> ND Act, s 10M (cannabis licences and permits); s 13 (manufacture licences and permits).

There was understandably a view expressed strongly in the submissions from industry participants that a licence should be granted for a term of more than one year – some suggested five years. The practice adopted in 2018 and 2019 to extend the short term of existing licences affirms that view.

Several considerations support a licence term that is ordinarily more than one year. These include: the existing practice in the ODC; the considerable commercial investment that an entity will have made in applying for a licence and establishing a commercial operation; the need for relative certainty in conducting a business and planning for the future; and the common practice in other areas of commerce of granting licences that are automatically or presumptively renewed on a periodic basis.

Another relevant consideration, pointing in the opposite direction, is that a regulator of medicinal cannabis licences must be satisfied that the licensee meets the high standards required by the ND Act to mitigate the risks of criminal diversion and infiltration. A re-licensing or renewal process can automatically trigger an ample reassessment of whether a licensee is fit and proper to hold a licence. The renewal process will likewise focus the licence holder's attention on the need to demonstrate their compliance capability at all stages during the licence period.

That does not mean that a licence renewal process should be treated as no different to an initial grant process. Unless there are special circumstances, a licence holder should not have to submit the same range of information and documents required for the initial licence grant. The renewal process can be more akin to an accreditation process, though rigorous nonetheless.

It also seems appropriate that the grounds for refusal of a licence renewal should be similar to those for revocation of a licence. These are discussed in Chapter 7. In summary they include that a licence holder is no longer a fit and proper person to hold the licence, a condition of the licence has been broken, the licence holder has engaged in conduct that is an offence under the ND Act, a licence charge has not been paid, the premises or security arrangements applying to the licence or cannabis product are not suitable, or the licence holder has not provided information as required.

A workable model to balance those considerations would be as follows:

- the ND Act should provide that a licence can be granted for a maximum term of five years
- the present administrative practice of ordinarily granting licences for a term of three years should continue – that practice could, when settled, be explained in guidance issued either informally by the ODC or more formally in ministerial guidelines under s 26C of the ND Act
- the ND Act should provide (adopting the language of s 8E) that an application for renewal is to be made in the form or manner approved by the Secretary in accordance with the ND Regulation
- the ND Act should spell out the grounds for refusing the renewal of a licence, which should be based on the grounds for revocation of a licence
- the ODC should continue to discharge at all times its monitoring and enforcement functions to ensure compliance by licence holders with the terms of the ND Act and the conditions of their licences
- the scale of licence fees and charges be adjusted to take account of a new licensing framework.

### **Recommendation 10**

The *Narcotic Drugs Act 1967* be amended to provide:

- a medicinal cannabis licence, cannabis research licence or manufacture licence applying to cannabis products shall be granted for a term of maximum term of five years
- a licence holder may apply for renewal of the licence at the expiration of the licence term, in accordance with the *Narcotic Drugs Regulation 2016*
- the renewal of the licence may be refused on a ground on which the Secretary must or may revoke a licence.

## Permits

Permits to accompany a licence are an accepted element of the medicinal cannabis scheme in the ND Act. It is also a requirement of the Single Convention that the manufacture of drugs will be authorised by both a licence and ‘periodical permits specifying the kinds and amounts of drugs which [the licence holder] shall be entitled to manufacture’.<sup>160</sup>

The permit requirements are spelt out in the ND Regulation.<sup>161</sup> For example, the information requirements for a medicinal cannabis permit that authorises cultivation are that the licence applicant must provide information on matters such as the types and strains of cannabis plants to be cultivated, the THC, CBD and other cannabinoids in the plants, the size of the cannabis crop, the number of plants to be cultivated, the period of cultivation, and the source of the plants.<sup>162</sup>

The rules and practices surrounding permits give rise to three issues in this Review:

- the level of detail currently required in permit applications
- whether a more streamlined procedure for varying permits is needed
- the role of permits in the medicinal cannabis licensing scheme.

As to the first point, several submissions criticised the level of detail required in permit applications as being impractical and constricting. Examples given were the finished product specification, the number of seeds and tissue culture samples, the name and source of each cannabis strain, and precise details of the supply chain arrangements with manufacturers and prescribers. The submissions explained that it was difficult to estimate those exact details prior to cultivation or manufacturing commencing, and in any case this detail could be recorded at the end of the process or could be checked through auditing. The level of detail required could also trigger the need for an application to vary a permit, which could introduce further delay and administrative complexity into the process.

It is not practicable in this Review to examine the merits of any individual complaints about permit specifications. However, two observations can be made. One is that the information required in a permit application should not go further than what the ND Regulation requires. A licence holder who feels that the ODC has required information additional to that specified in the ND Regulation can request the ODC to point to the provision in the Regulation that supports the information request.

The other observation is that the ND Regulation should itself be reviewed in the course of the simplification and consolidation process recommended earlier in this chapter. The aim of the review would be to better align the Regulation with the requirements of the Single Convention and the regulatory objectives of the medicinal cannabis scheme.

There is room for considerable flexibility consistently with the Single Convention to choose the detail to be included in a permit application. For example, as to manufacture licences the Convention requires only that periodical permits specify ‘the kinds and amounts of drugs’ which shall be manufactured. There is no comparable requirement in the Convention spelling out the detail to be recorded in permits authorising cultivation, production or research – or, indeed, any requirement that permits be issued for those activities.

Other considerations will also be relevant in deciding the details that should appropriately be specified in permits. Parties to the Convention have reporting obligations which can only be met if sufficient information is collected. Compliance and monitoring activities undertaken by the ODC will also be structured around a licence holder’s compliance with licence and permit conditions.

<sup>160</sup> Single Convention, Art 29(2)(c).

<sup>161</sup> As required by the ND Act, ss 8P, 9N and 12.

<sup>162</sup> ND Regulation, reg 8(3)

That said, it appears that the level of detail required in permit applications goes further than what is required to meet Convention requirements and the need to minimise the criminal risks of diversion and infiltration.

As to permit variations, experience suggests that a more flexible procedure is required – even if permits in future contain less detailed conditions and stipulations. It is sound in principle to require a licence or permit holder to apply for a variation if applicable conditions or stipulations can no longer be complied with. But that will not be a sound procedure in practice if the licence or permit holder is stalled by a long decision making delay. Two examples given in submissions were of delay in awaiting decisions on applications to transfer cannabis plants from one permit to another, and to vary the number of plants in cultivation.

A workable model to balance those considerations would be as follows:

- A licence holder is required to notify any proposed variation of a condition or term of a permit to the Secretary (or ODC as delegate).
- If the variation is of a kind listed in the ND Regulation as one that requires the approval of the Secretary, the licence holder must await formal written approval before acting on that basis. Variations that required formal approval could be confined to those that were substantive in nature or posed a material risk to the security of a licensed activity. Those broad concepts could be further explained in guidance issued either informally by the ODC or more formally in ministerial guidelines under s 26C of the ND Act.
- The licence holder may otherwise act on the basis that the permit has been varied following notification to the Secretary.
- It would be open to the Secretary at any time to exercise the standard compliance and enforcement powers in the ND Act, such as the power at the Secretary's own initiative to vary a cannabis licence or permit,<sup>163</sup> or to require a licence holder to provide any information or documents.<sup>164</sup>

The third issue – the role of permits – has largely been assumed rather than examined in the operation of the medicinal cannabis licensing scheme. As noted above, permits are a Single Convention requirement for manufacturing but not for other processes – and the Convention requirement for manufacture permits is limited to the kinds and amounts of drugs to be manufactured.

It will be necessary to review the current permit requirements in the ND Act and ND Regulation if other recommendations in this report are implemented – such as Recommendation 7, proposing a single licence structure in the ND Act; and Recommendation 8, proposing a reduction and simplification of the information and document requirements for licence and permit applications.

Adoption of those recommendations would, in principle, provide an opportunity to explore larger questions to do with the role of permits in the medicinal cannabis licensing scheme. While permits achieve a number of objectives in the scheme, the core objectives are the reporting and monitoring obligations that the ODC discharges. In theory, reporting and monitoring could probably be fulfilled by other measures, though perhaps less effectively.

This report does not include a recommendation for either a wholesale review of the role of permits, or a departure from the permit system for medicinal cannabis and cannabis research licences. The purpose in raising this topic is merely to underline that it is a larger background issue that intersects with any other (and more limited) review that is undertaken of the current permit requirements in the ND Act and ND Regulation.

<sup>163</sup> ND Act, s 10M.

<sup>164</sup> ND Act, s 14J.

**Recommendation 11**

The information and document requirements in the *Narcotic Drugs Regulation 2016* applying to an application for a medicinal cannabis permit, cannabis research permit or manufacture permit be reviewed to reduce the level of detail and specificity required in applications, as part of the review proposed in Recommendation 8 to reduce the detailed prescriptive requirements in the *Narcotic Drugs Regulation 2016*.

**Recommendation 12**

The *Narcotic Drugs Act 1967* (sections 10M, 10N, 13, 13A) and the *Narcotic Drugs Regulation 2016* be amended to provide:

- that a licence holder must obtain the formal written approval of the Secretary for a variation of a permit, if the variation is of a kind listed in the *Narcotic Drugs Regulation 2016*
- as to any other variation of a permit that is not listed in the *Narcotic Drugs Regulation 2016* as one that requires the Secretary's written approval – the licence holder shall notify the variation to the Secretary before acting on the basis of the variation.

## Licence fees and charges

The medicinal cannabis scheme implements a partial cost recovery scheme, in line with the *Australian Government Charging Framework* (July 2015). 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 the 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 Regulation, made under the ND Act,<sup>165</sup> imposes licence and permit application fees and inspection fees (as listed below).<sup>166</sup> These fees commenced on 30 October 2016. Lower 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), impose 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.<sup>167</sup> The charge commenced on 10 December 2016.

<sup>165</sup> ND Act, s 28(1)(c).

<sup>166</sup> ND Act, s 54 (inspection fees), Schedule 1 (application fees).

<sup>167</sup> *Commonwealth Constitution*, s 55.

The scale of fees and charges is as follows:

<b>Application fees</b>	<b>Fee (\$)</b>
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.<sup>168</sup>

<b>Licence charges</b>	<b>Charge (\$)</b>
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.

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
- meeting Australia’s commitments under the Single Convention.

<sup>168</sup> ND Regulation, s 53.

The scale of fees and charges has not changed since they were set in 2016. A periodical review is undertaken and published on the ODC website.<sup>169</sup> The latest review published in November 2018 observed:

The ODC is aware, based on internal and external reviews, that significantly more time is spent on assessing applications than the original assumptions that form the basis of this [Cost Recovery Implementation Statement]. In order to revise the cost recovery framework, in 2019 the ODC will conduct a more comprehensive review of the cost recovery model with a view to amending fees and charges as necessary. ...

Where changes to fees and/or the levy are proposed (other than annual indexation), stakeholders will be asked to provide their feedback on the cost recovery arrangement through the ODC website.<sup>170</sup>

The Discussion Paper for this Review invited submissions on whether the scale of fees and charges was appropriate. There was no consistent theme in the responses.

A few submissions commented that the current scale of fees was appropriate, while an equal number suggested that the scale be increased either to deter ill-prepared applications or to ensure that the ODC would be adequately funded to undertake its functions. A couple of submissions suggested that manufacture licence and permit fees be introduced, principally to ensure consistency in the treatment of licences and permits.

Another issue on which some submissions commented was the date on which the first annual licence fee is payable. One submission asked for greater clarity on this issue; while a couple asked that payment be postponed until the licence holder was ready to commence commercial operation.

## Comment

It is premature in this Review to recommend any change to the current scale of fees and charges. There is no evidence to suggest that the scale is too high. The ODC has foreshadowed that a comprehensive review will be undertaken in the next year, and that stakeholders will be consulted.

A variation of the scale will also be required if some of the recommendations in this Review are accepted. For example, if the current structure of three separate licences is replaced by a new structure in which an applicant may apply for a single licence to undertake all of some of cultivation, production, research and manufacture, the scale of fees and charges would need to be tailored to the range of activities encompassed by a particular application and licence.

Similarly, any change to the permit provisions in the ND Act or ND Regulation may require a review or relevant charges. In particular, it would be inappropriate to maintain the current fee of \$1,730 to apply to vary a medicinal cannabis or cannabis research permit if the ND Regulation is changed to allow notification of minor variations that do not require formal approval. A couple of submissions were already critical of the high cost applying to a minor variation application.

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<sup>169</sup> See Department of Health, '[Cost Recovery Implementation Statement: Regulation of Medicinal cannabis](#)' (Version 1.3, November 2018).

<sup>170</sup> Cost Recovery Implementation Statement (2018), pp 5, 16.

## 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.<sup>171</sup>

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.<sup>172</sup> The person may firstly seek internal review of the decision by applying to the Minister.<sup>173</sup> 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.<sup>174</sup> 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.<sup>175</sup>

An application may be made to the Administrative Appeals Tribunal (AAT or 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 review 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.<sup>176</sup> Recommendation 18 below is that the ODC should initiate discussion with Commonwealth, State and Territory law enforcement agencies about those provisions to ensure they are understood and work effectively.

### Comment

No change is recommended to these provisions in the ND Act. They provide an appropriate framework for internal and external review of decisions that directly affect the interests of applicants and licence holders. The review framework is consistent with best-practice administrative law principles.

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<sup>171</sup> ND Act, s 15D; ND Regulation, s 52.

<sup>172</sup> ND Act, s 15G.

<sup>173</sup> ND Act, s 15G.

<sup>174</sup> ND Act, s 15H.

<sup>175</sup> ND Act, s 15J(2).

<sup>176</sup> ND Act, ss 15F(2A), 15M(2), 15N.

# Chapter 7: Compliance and enforcement

## Introduction

One dimension of the ND Act is that it establishes a regulatory framework for medicinal cannabis. The ODC can be viewed in that setting as an Australian Government regulatory body. The ND Act contains a familiar range of regulatory functions and powers that are exercisable by the ODC under delegation from the Secretary of the department. They include powers to impose conditions on licences, investigate compliance by licence holders with those conditions and the requirements of the ND Act, enter premises, question people, gather information, issue directions, and vary and revoke licences. Those controls are reinforced by civil penalty and offence provisions in the ND Act.

There was little comment during this Review in submissions and consultations on the nature and breadth of those powers and how they are being exercised. There was general acceptance that the regulatory focus is important in the medicinal cannabis scheme, given Australia's overriding obligation to comply with the Single Convention. The Convention emphasises the need for tight government control on the cultivation and manufacture of cannabis as a narcotic drug that is susceptible to misuse and criminal enterprise.

There was frequent acknowledgement too in this Review that both the ODC and industry have worked constructively – separately and in collaboration – to ensure voluntary compliance with licence obligations and regulatory standards. That is typically branded as the central goal of effective regulation.

The regulatory framework is nevertheless a fundamental and lasting feature of the ND Act. At this early stage of the medicinal cannabis scheme, the primary emphasis has been on implementation and the grant of licences and permits. Circumstances may later require more assertive compliance enforcement activity and the exercise of regulatory powers that have been little used to date.

This chapter describes the regulatory framework in the ND Act, with some observations and recommendations. This is done to highlight the central place of the regulatory framework in the medicinal cannabis scheme. The principal recommendation at the end of the chapter is that the ODC develop and publish more extensive guidance than has been published to date on the ODC's regulatory approach and priorities.

## Regulatory functions and powers in the ND Act

### Licence and permit conditions

The ND Act imposes several standard conditions on all licences granted under the ND Act. There is elaboration of some conditions in the ND Regulation.<sup>177</sup> Additional conditions can also be imposed individually on licences. Breach of a licence condition is a ground for revocation of the licence.<sup>178</sup>

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<sup>179</sup>

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<sup>177</sup> Eg, ND Regulation, ss 18, 19, 20.

<sup>178</sup> ND Act, s 10P(2)(a).

<sup>179</sup> ND Act, ss 10E, 12G.

- 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<sup>180</sup>
- activities undertaken under the licence must be authorised by a permit<sup>181</sup>
- an authorised inspector can inspect the premises in which cultivation, production or manufacture is undertaken, and take samples<sup>182</sup>
- the licence holder must notify the Secretary, firstly, 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, secondly, of any breach of the licence, and thirdly, of any matter that is a ground for revocation of the licence.<sup>183</sup>

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.<sup>184</sup>

Special conditions are also imposed on manufacture licences to reinforce the special licensing requirement in s 11K of the ND Act 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.<sup>185</sup>

One other regulatory requirement, though not expressed in the ND Act as a condition, operates in the same way. The Act requires that a licence specify matters such as the term of the licence, the name of the licence holder, the authorised activities, the premises at which they will be carried out, and ‘the persons authorised by the licence to engage in activities authorised by the licence’.<sup>186</sup> The effect of that last stipulation is that a licence may contain as an annex a list of senior employees, and that any departure or arrival of a new senior employee will require a variation of the licence.

This Review examined the standard conditions that are imposed on medicinal cannabis and manufacture licences. The following observations can be made:

- There were 51 standard conditions – 24 in medicinal cannabis licences and 24 in manufacture licences.
- Roughly one-third (18) of those conditions are required by the ND Act to be imposed on licences; the other two-thirds are imposed on a discretionary basis.<sup>187</sup>
- As many as 22 of the standard conditions that are imposed in medicinal cannabis licences and in manufacture licence are framed in similar terms (14 are statutory conditions, and 8 imposed conditions). The result is that an entity that holds both types of licences may have duplicate obligations under both licences.
- Some conditions merely restate the overriding legal obligation of the licence holder to act in accordance with the ND Act, ND Regulation and licence and permit conditions.

<sup>180</sup> ND Act, s 10F; ND Regulation reg 18(2); s 12H.

<sup>181</sup> ND Act, ss 10G, 12J.

<sup>182</sup> ND Act, ss 10H, 12K.

<sup>183</sup> ND Act, ss 10K, 12N.

<sup>184</sup> ND Act, ss 10D, 12F.

<sup>185</sup> ND Act, ss 12L, 12M.

<sup>186</sup> ND Act, ss 8M(e), 9L(e), 11N(e),

<sup>187</sup> ND Act, ss 8K, 11L.

## Comment

Four recommendations are made below concerning licence conditions and their administration. The following can be said to explain those recommendations.

First, a relatively large number of conditions are currently imposed on licences. These are in addition to the numerous and specific requirements in the ND Act and ND Regulation that a licence holder is required to observe. The number and breadth of conditions can add to the compliance burden facing a licence holder, not least because a breach of a licence condition must be notified to the ODC and is a ground for suspension or revocation of the licence.

It is important, accordingly, that conditions are appropriately framed and imposed. The ODC should review the standard licence and permit conditions, with a view to imposing licence conditions only as required and that the conditions are appropriately framed. The imposition of conditions can be further streamlined if Recommendation 7 in Chapter 6 is implemented to establish a single licence structure.

Second, the ND Act provides that it is a condition of a licence that the licence holder takes reasonable steps not to employ or engage a person to carry out activities authorised by the licence if the person is in a class of persons prescribed in the ND Regulation.<sup>188</sup> Regulations 18 and 39 prescribe the following two classes of person who will not be regarded as suitable staff:

- ‘persons who are undertaking, or who have undertaken, treatment for drug addiction’<sup>189</sup>
- ‘the person has, during the [previous] 5 years ... used illicit drugs’.<sup>190</sup>

Both conditions are more restrictive than the ND Act, which provides that a licence holder shall take reasonable steps not to employ a person *convicted* of a *serious* offence in the previous five years.<sup>191</sup> It is relevant too that the Secretary, in deciding whether a person is fit and proper to hold a licence under the Act, can decide to excuse the fact that the person has been convicted of a serious offence during the previous ten years.<sup>192</sup>

An additional difficulty with the first condition is that it operates as a permanent bar against employment and could be read as a deterrent to seeking treatment. This restriction could be deleted from regs 18 and 39 as those regulations already constrain the employment of those who have a drug addiction or have been convicted of a drug-related offence in the previous five years.

Third, the requirement in the ND Act (listed above) that a licence must contain the names of all authorised persons goes further than necessary. The requirement is ambiguous: one interpretation (which is less demanding) is that a licence must list senior staff of a licence holder who are responsible for supervising all activities authorised by the licence; but another interpretation (which is more far-reaching) is that *all* authorised persons in a facility be listed on a licence, with the added consequence that any change to the list be the subject of a licence variation application. The Act could be amended to include a more flexible requirement, for example, that the authorised persons to be listed in a licence will be specified in the ND Regulation.

Fourth, the notification requirement that is imposed as a standard condition on all licences can potentially operate in an unfairly prejudicial way to licence holders. Failure to comply with this condition is a ground for revocation.<sup>193</sup> Yet the circumstances in which notification is required may not be clear-cut – ‘a matter that may affect whether the licence holder is a fit and proper person to hold the licence’, ‘a matter that may affect whether ... a business associate ... is a fit and proper person to be associated with the licence holder’ and ‘any other matter that may require or permit the Secretary to revoke the licence’.<sup>194</sup>

<sup>188</sup> ND Act, ss 10F, 12H.

<sup>189</sup> ND Regulation, reg 18(1)(a), 39(1)(a).

<sup>190</sup> ND Regulation, reg 18(2)(a), 39(2)(a).

<sup>191</sup> ND Act, ss 10F(1)(b), 12H(1)(d).

<sup>192</sup> ND Act, ss 8G(8G(1)(b), 8H, 9F(1)(b), 9G.

<sup>193</sup> ND Act, ss 10P(2)(a), 13B(2)(a).

<sup>194</sup> ND Act, ss 10K(1)(a),(b), 12N(1)(a),(b).

As a practical matter it would be in the interest of a licence holder to be diligently proactive in notifying matters of potential relevance to the ODC. In part, that is what the ND Act intends to bring about.

However, the ND Act does not directly address how the ODC is to respond to or deal with any notification. By implication, a notification may trigger the exercise by the ODC of its compliance and enforcement powers, such as the power to vary or revoke a licence, issue a direction to the licence holder, require information to be provided or to conduct an inspection.

The range of options available to the ODC – that can involve quite serious enforcement action – mean that it would be inappropriate to prescribe how and when the ODC is to respond following a notification. On the other hand, silence on the part of the ODC can place the licence holder in an uncertain position that is unfairly prejudicial. Questions that may go (unanswered) through the mind of the licence holder include whether the notification was adequate or unnecessary, whether other action is required regarding the matter that was notified, and whether there are similar matters that require notification.

An appropriate balance could be struck through the publication by the ODC of guidance on how notifications are dealt with and the procedure to be followed by a licence holder to gain clarity following a notification. The guidance should form part of the proposed regulatory guidance that is the subject of Recommendation 20 below.

**Recommendation 13**

The Office of Drug Control review the standard licence conditions that are imposed on medicinal cannabis, cannabis research and manufacture licences, to ensure that conditions are not imposed unnecessarily and that conditions are appropriately framed.

**Recommendation 14**

The *Narcotic Drugs Regulation 2016*, regulations 18 and 39 be amended:

- to delete the condition that a licence holder take reasonable steps not to employ a person who has sought treatment for drug addiction
- to amend the condition that a licence holder take reasonable steps not to employ a person who has used illicit drugs during the previous five years, by providing instead (in terms similar to sections 8H and 9G of the *Narcotic Drugs Act 1967*) that the Secretary may excuse reliance on that condition if the licence holder has taken reasonable steps to ascertain drug usage by employees and has disclosed any relevant knowledge to the Office of Drug Control.

**Recommendation 15**

Sections 8M(e), 9L(e) and 11N(e) of the *Narcotic Drugs Act 1967* be amended to require that a licence specify the persons who are required by the *Narcotic Drugs Regulation 2016* to be specified as persons who can engage in activities authorised by the licence.

**Recommendation 16**

The Office of Drug Control include guidance on the operation of the notification requirements in sections 10K and 12N of the *Narcotic Drugs Act 1967*, when undertaking a review of the ODC publication, *Guidance: Compliance, Enforcement and Inspections*, as proposed in Recommendation 20.

## Inspection powers

The ND Act provides for the appointment of authorised inspectors to exercise the extensive range of regulatory enforcement powers listed in the *Regulatory Powers (Standard Provisions) Act 2014* (Cth) (Regulatory Powers Act).<sup>195</sup> 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 ND Act.<sup>196</sup> 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.<sup>197</sup>

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 month period. Inspections may also be undertaken for other purposes, such as monitoring site remediation and crop destruction. Twelve inspections were undertaken in 2018 (both announced and unannounced), and it is expected that more will be taken as more licences and permits are granted.

### Comment

The ND Act appropriately provides for the exercise of the regulatory powers listed in the Regulatory Powers Act and the ND Act. The Regulatory Powers Act sets out the criteria and limitations on the exercise of the powers conferred by that Act. The exercise of these powers is subject to judicial scrutiny under the *Administrative Decisions (Judicial Review) Act 1977* (Cth) (ADJR Act) and s 39B of the *Judiciary Act 1904* (Cth).<sup>198</sup>

### Information gathering powers

The ND Act confers information gathering powers that are exercisable in the consideration of licence and permit applications, and more generally in the administration of the ND Act. The powers include:

- requiring a licence applicant to allow inspection of the land or premises to which a licence application relates<sup>199</sup>
- requiring an applicant or licence holder to provide information or documents that are reasonably required for the administration of the ND Act<sup>200</sup>
- requesting information or documents relevant to a licence or permit from any source<sup>201</sup>
- requiring a State or Territory agency to provide relevant information or documents (subject to special restrictions applying to sensitive law enforcement information).<sup>202</sup>

<sup>195</sup> ND Act, Chapter 4.

<sup>196</sup> ND Act, s 14C.

<sup>197</sup> ND Act, ss 10H, 12K.

<sup>198</sup> As to overlapping nature of those administrative law review mechanisms, see Administrative Review Council, *Federal Judicial Review in Australia*, Report No 50 (2012).

<sup>199</sup> ND Act, ss 8F(3), 9E(3), 11H(3).

<sup>200</sup> ND Act, s 14J.

<sup>201</sup> ND Act, s 14K.

<sup>202</sup> ND Act, s 14L.

## Comment

It is appropriate that the ND Act includes those information gathering powers. They are an essential regulatory tool to ensure that officers administering the ND Act are fully and properly informed of all relevant matters, especially in deciding if licence applicants or holders are fit and proper to engage in cultivation, research or manufacture of cannabis products. It is equally important that the powers are exercised lawfully and reasonably having regard to the rights of those from whom information is being collected, often by compulsory direction.

To ensure that interests of that nature are properly balanced, the Administrative Review Council (ARC) adopted a set of twenty best-practice principles, described as ‘a guide to government agencies, to ensure fair, efficient and effective use of coercive information-gathering powers’.<sup>203</sup> Matters covered in the principles include the ‘trigger’ threshold for the exercise of a coercive power, delegation of powers, training, notices, examinations, privilege and exchange of information with other agencies.

The ARC best-principles can provide appropriate guidance for the ODC in relation to the information gathering powers that are exercisable under the ND Act. The principles should be consulted and possibly referred to in the regulatory guidelines that are recommended later in this chapter.

Two specific issues regarding the information gathering powers also require noting. One issue concerns the way that s 14J of the ND Act has been used to request information from applicants during consideration of licence applications. This goes to the administration of the ND Act and is discussed in Chapter 9.

The other issue relates to the protection of information held by the Secretary (or regulator) that is ‘sensitive law enforcement information’. The information gathering powers that are summarised above can be used by the regulator to require a Commonwealth, State or Territory law enforcement agency to provide information that may require special protection against disclosure. Disclosure may pose a risk of prejudicing Australia’s law enforcement interests by, for example, disrupting law enforcement efforts, revealing law enforcement methods, endangering informants or witnesses or discouraging law enforcement agencies from sharing information with other agencies.

Disclosure that could pose those risks is defined by the ND Act as ‘sensitive law enforcement information’.<sup>204</sup> It is protected in several ways: the information is not to be disclosed in the reasons explaining a decision that is reviewable (such as revocation of a licence);<sup>205</sup> if the information is to be relied upon in making a reviewable decision the giver of that information must first be consulted;<sup>206</sup> the natural justice hearing rule is displaced to the extent that it would otherwise require the disclosure of sensitive law enforcement information to a person;<sup>207</sup> it is an offence (subject to exceptions) to disclose sensitive law enforcement information that a person has obtained under the ND Act;<sup>208</sup> if a party commences proceedings in the AAT to review a decision made under the ND Act, the Secretary may apply to the Tribunal for an order to protect sensitive law enforcement information from being disclosed during the course of the proceedings.<sup>209</sup>

<sup>203</sup> Administrative Review Council, *The Coercive Information-gathering Powers of Government Agencies*, Report No 48 (2008), p xi.

<sup>204</sup> ND Act, s 4(1).

<sup>205</sup> ND Act, ss 11(2)(aa) and (5); 13C(2)(aa) and (5); 15F(1)(b), (2)(e) and (2A); 15J(1)(b) and (4). See also s15N relating to the reasons required to be given if an application for review of a decision is made to the AAT.

<sup>206</sup> ND Act, ss 15F(2A)(b), 15J(4)(b).

<sup>207</sup> ND Act, s 21A.

<sup>208</sup> ND Act, s 14MA.

<sup>209</sup> The Tribunal can make a range of orders under the AAT Act, s 35, including an order that a private hearing be held, as to the persons who may be present during a private hearing, or restricting the publication of disclosure of evidence either generally or to a party.

There is a question as to whether the provisions in the ND Act relating to the protection of sensitive law enforcement information in the course of AAT proceedings go far enough to ensure adequate protection. The extent of any protection may depend on the Secretary applying to the Tribunal to make an order and on the terms of an order the Tribunal is prepared to make. In deciding whether to make an order the Tribunal is required ‘to take as the basis of its consideration the principle that it is desirable’ that proceedings be held in public and that all evidence before the Tribunal is made available to the parties, and also to consider ‘the confidential nature ... of the information’ to which an order may relate.<sup>210</sup>

It is a contested issue from time to time in court or tribunal proceedings as to whether an item of information that one party wishes to remain confidential should be disclosed in the proceedings. It is ultimately for the court or tribunal to rule on that matter. That is not to say that a law enforcement agency will not harbour a concern either that an item of information should not be disclosed in tribunal proceedings or that the AAT should be properly informed by a non-disclosure application and submissions before that can occur. There is a risk, arising from those possibilities, that a law enforcement agency will be disinclined to provide the ODC with information that would assist it in conducting extensive background checks on individuals involved in the medicinal cannabis industry.

The ND Act recognises and seeks to give effect to those considerations. In addition to the protection measures already mentioned, two other protections are that the head of a State or Territory law enforcement agency can decline to provide sensitive law enforcement information when required to do so;<sup>211</sup> and information that is known by the Secretary (or regulator) to be sensitive law enforcement information is to be identified as such.<sup>212</sup>

The current provisions were inserted into the ND Act in late 2016, in recognition of the special protection required for sensitive law enforcement information.<sup>213</sup> The Statement of Compatibility with Human Rights that accompanied the Narcotic Drugs Amendment Bill 2016 explained: ‘These amendments to the ND Act are proposed to give law enforcement agencies confidence that they can share pertinent information and that it won’t be released to the applicant or to third parties, thus protecting ongoing criminal investigations and investigation techniques’.<sup>214</sup> The Explanatory Memorandum for the amending Bill also noted: ‘the amendments are designed to strike an appropriate balance between protecting law enforcement operations and intelligence and upholding administrative law principles and requirements’.<sup>215</sup> The same issue, of striking that balance, arises in many other regulatory schemes and the balance is generally struck in the same way.<sup>216</sup>

Any lingering concerns about the protection of sensitive law enforcement information are best taken up in consultation between the ODC and Commonwealth, State and Territory law enforcement agencies. A desirable option may be an administrative protocol requiring that law enforcement agencies are properly informed in advance of any relevant AAT proceedings so they can be consulted about a potential application or submission to the Tribunal. Equally, an administrative protocol can spell out the arrangements put in place to implement the requirement of the ND Act to identify sensitive law enforcement information that is held by the ODC.

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<sup>210</sup> AAT Act, s 35(5).

<sup>211</sup> ND Act, s 14L(3A).

<sup>212</sup> ND Act, s 14LA.

<sup>213</sup> *Narcotic Drugs Legislation Amendment Act 2016* (Cth).

<sup>214</sup> Statement of Compatibility with Human Rights, *Narcotic Drugs Legislation Amendment Bill 2016* (2016).

The Statement also observed: ‘The proposed amendments are designed to strike an appropriate balance between ensuring procedural fairness is accorded to the applicant and protecting sensitive law information from disclosure’.

<sup>215</sup> Explanatory Memorandum, *Narcotic Drugs Legislation Amendment Bill 2016* (2016), p 2-3.

<sup>216</sup> See also *Graham v Minister for Immigration and Border Protection* [2017] HCA 33, in which the High Court held, for constitutional reasons, that a provision in the *Migration Act 1958* (Cth) could not prevent disclosure of law enforcement information to a federal court for the purpose of reviewing a decision under that Act.

**Recommendation 17**

The Office of Drug Control take account of the best practice principles on coercive information gathering powers published by the Administrative Review Council, when undertaking a review of the ODC publication, *Guidance: Compliance, Enforcement and Inspections*, as proposed in Recommendation 20.

**Recommendation 18**

The Office of Drug Control initiate discussion with Commonwealth, State and Territory law enforcement agencies:

- to ensure there is a shared understanding of the protections in the *Narcotic Drugs Act 1967* for sensitive law enforcement information, and
- to ascertain if there is a need for an administrative protocol regarding the operation of those protections, especially as they apply to sensitive law enforcement information that may be provided to the Administrative Appeals Tribunal in proceedings before the Tribunal for the review of a decision under the *Narcotic Drugs Act 1967*.

**Directions**

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.<sup>217</sup> Directions may:

- require a licence holder 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.<sup>218</sup>

**Comment**

It was noted above that the power to issue a direction relating to the destruction of cannabis products could be used to ensure consistency with destruction requirements applying under some State and Territory legislation.

<sup>217</sup> ND Act, s 15C.

<sup>218</sup> ND Act, ss 14P, 15, 15A.

## Licence revocation and suspension

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.<sup>219</sup>

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.<sup>220</sup>

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.<sup>221</sup>

No revocation of a licence or permit has yet occurred.

The discretionary grounds for revocation can alternately be used as discretionary grounds for suspension of a licence or permit.<sup>222</sup> The procedure for suspension is spelt out in the ND Regulation. In summary:

- a licence holder shall ordinarily be given 20 business days' notice of a suspension decision, except that suspension can take place on the date of notification if the Secretary is satisfied on reasonable grounds that there is a risk that cannabis plants, cannabis or cannabis resin may be lost, diverted or stolen if the suspension does not take place immediately<sup>223</sup>
- the period of suspension must not be more than six months, but a lesser period can be specified<sup>224</sup>
- the notice of suspension can allow specified production to occur under the licence during the suspension<sup>225</sup>
- written notice of a proposed suspension must be given to a licence holder, and procedural fairness steps followed, unless the suspension is to operate immediately.<sup>226</sup>

<sup>219</sup> ND Act, ss 10P(1), 13B(1).

<sup>220</sup> ND Act, ss 10P(2), 13B(2).

<sup>221</sup> ND Act, ss 11, 13C.

<sup>222</sup> The ND Act ss 11A and 13D provide that the regulations may make provision for suspension of licences or permits.

<sup>223</sup> ND Regulation, reg 26(3).

<sup>224</sup> ND Regulation, reg 26(4),(5)

<sup>225</sup> ND Regulation, reg 27.

<sup>226</sup> ND Regulation, reg 28.

## Comment

The ND Act necessarily confers power to revoke and suspend licences and permits. The grounds for doing so are appropriately tied to the obligations the ND Act imposes on licence holders, as well as the regulatory risks the ND Act is directed at. There is a guarantee of procedural fairness as to the procedure to be followed if revocation or suspension action is initiated. That guarantee is legally enforceable, including by internal review under the ND Act and by judicial review under the ADJR Act and the *Judiciary Act 1903* (Cth).

The revocation grounds could have greater practical relevance if two recommendations in Chapter 6 are accepted – that a procedure be included in the ND Act to enable a licence holder to apply for renewal of a licence; and renewal may be refused on a ground on which the Secretary must or may revoke a licence.

Only one change is recommended to the current revocation provisions in the ND Act. The third ground for mandatory revocation listed above – that a business associate is no longer fit and proper to be associated with a licence holder – should be made a discretionary ground of revocation. This ground, unlike the other two mandatory revocation grounds, does not relate to the conduct or integrity of the licence holder but to that of a third party, a business associate. There is also an element of imprecision in who is a ‘business associate’ – the term is defined as including both a person with a financial interest in the business who can exercise a ‘significant interest’ over the business, and a person who holds an ‘executive position’ in the business.<sup>227</sup>

It is more appropriate that the relationship of a business associate to a licence holder should be a discretionary factor in relation to the revocation of a licence.

### Recommendation 19

Sections 10P and 13B of the *Narcotic Drugs Act 1967* be amended to provide that the relationship between a business associate and a licence holder is a discretionary ground for the revocation of a licence (subsections 10P(2) and 13B(2)) and not a mandatory ground for revocation (subsections 10P(1) and 13B(1)).

## Offences and civil penalties

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

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<sup>228</sup>
- breaching a condition of a medicinal cannabis licence that authorises cultivation<sup>229</sup> and/or
- breaching a condition of a medicinal cannabis licence that authorises production.<sup>230</sup>

The Regulatory Powers Act also creates offences and imposes civil penalties upon people to whom regulatory action has been directed for failing to comply with some of the obligations imposed by that Act.<sup>231</sup>

## Comment

No change is recommended to these provisions in the ND Act.

<sup>227</sup> ND Act, s 4(1).

<sup>228</sup> ND Act, ss 11B, 11D.

<sup>229</sup> ND Act, s 11C.

<sup>230</sup> ND Act, s 11E.

<sup>231</sup> See also ND Act, s 13N relating to civil penalties under the Regulatory Powers Act.

## Development of comprehensive regulatory guidance

The compliance, enforcement and regulatory functions and powers in the ND Act are vitally important from several angles.

They underpin the central objective of the ND Act to ensure that Australia complies with its obligations under the Single Convention. Information gathered under the Act is needed to enable the Australian Government to report to the INCB. The effective administration of the regulatory functions provides a reassurance to the Australian Government and the community that the medicinal cannabis scheme is operating as intended.

The exercise of the compliance and enforcement powers can impose significant legal and commercial obligations on licence applicants and holders. Certainty and clarity about how the medicinal cannabis scheme will be administered is a shared expectation of all stakeholders.

Considerations of that kind lie behind the practice of some regulatory bodies of publishing comprehensive regulatory guidance on matters such as:

- the regulatory powers that can be exercised by the body
- the circumstances in which those powers may be exercised
- its approach to using those powers, especially the body's attitude to voluntary compliance, risk management and coercive action
- the regulatory goals and priorities of the body
- the procedural fairness principles that are followed when potentially adverse regulatory action is taken against a person
- that person's rights to question or challenge the regulatory action
- the mechanisms available for industry and stakeholder consultation as regards the body's regulatory approach and priorities.

Two examples of regulatory action guidance that exhibit those features are the *TGA Regulatory Compliance Framework* and the Office of the Australian Information Commissioner's *Privacy Regulatory Action Policy*.

The ODC took an early step in publishing a document, *Guidance: Compliance, Enforcement and Inspections* (October 2016). The document is largely descriptive of the ODC's regulatory enforcement powers.

Since publication of that guide, the ODC has gained significantly greater experience in regulatory strategy issues and when to exercise formal powers under the ND Act. There is also now a more established medicinal cannabis industry that has both a strong interest in the ODC's regulatory stance as well as experience to contribute in shaping a more comprehensive framework. This is evident from the submission to this Review from MCIA, which discusses regulatory issues.<sup>232</sup> There is also a need, as discussed in Chapter 9, to articulate the ODC's risk management approach.

Overall, it is an appropriate time for the ODC to develop and publish more comprehensive regulatory guidance.

### Recommendation 20

The Office of Drug Control review its publication, *Guidance: Compliance, Enforcement and Inspections*, with a view to developing and publishing more comprehensive and contemporary regulatory guidance. Public consultation be a part of this review.

<sup>232</sup> Submission from MCIA

# Chapter 8: Interaction of the ND Act with other laws

## Introduction

The interaction between the ND Act and other Commonwealth and State and Territory laws was designated as a Key Theme of this Review, as explained in Chapters 1 and 5. The ND Act is one of many Australian laws relating to cannabis, and it has an overlapping operation with other laws dealing with cannabis cultivation, manufacture, research, possession and supply.

Some overlap issues have been discussed in other chapters. This chapter draws that discussion together to highlight that the interaction of the ND Act with other laws is a distinct and important issue and that it warrants active monitoring.

Three dimensions of the topic are covered in this chapter:

- the adequacy of published guidance on the interaction of the ND Act and other laws
- identifying interaction issues that may warrant consideration and action
- ND Act provisions to preserve the operation of State and Territory laws.

The theme of this chapter can be captured in two contrasting observations. One is that participants at all points on the compass – regulators, growers, manufacturers, prescribers, pharmacists and patients – accept that in a complex federal legal setting there will be numerous issues arising as to how different laws interact.

The other observation is that there are common goals in many of the laws; ensuring the laws work well together is therefore important. A goal that has become steadily more prominent in recent years is to ensure that a safe, legal and sustainable supply of cannabis is available within Australia for therapeutic and research purposes. That goal must be balanced with others, notably the goal of protecting the Australian community by ensuring that locally cultivated and manufactured cannabis products are not diverted to illegal purposes.

## Guidance on the interaction of the ND Act and other laws

The community looks to government agencies to provide clear and helpful advice on the laws they administer and their interaction with other laws. People typically turn to an agency's website to find that advice.

The ODC website provides a valuable collection of clear and accessible advice that is earmarked for different groups – cultivators, manufacturers, importers, exporters, travellers, prescribers and patients. The ODC website contains downloadable forms for different licence and import/export processes, a comprehensive and helpful Frequently Asked Questions, operational statistics, the minutes of meetings of the Australian Advisory Council on the Medicinal Use of Cannabis, and links to the advice provided on the websites of other Commonwealth, State and Territory agencies.

There is little said on the ODC website about the operation of relevant State and Territory laws. These are mostly noted in general terms – for example, that a manufacture licence 'is in addition to any licence issued by State or Territory Governments', or that a licence holder's purchase of stock in Australia 'must be consistent with their state/territory licence'.

Links are provided to the health department websites of all States and Territories – though not to specific information pages on three of those websites<sup>233</sup> and two specific advice links were no longer operative.<sup>234</sup> The information pages on some State and Territory websites give a helpful explanation of the concurrent operation of both State and Commonwealth laws.<sup>235</sup>

It is well understood that websites play a vital and central role in the effective administration of any statutory scheme. Websites, however, are not static. The content and presentation will exhibit strengths and weaknesses that are likely to change over time.

On first appearance there is scope to enhance the quality of the ODC website as to the advice it gives about the interaction of the medicinal cannabis scheme in the ND Act with State and Territory laws. Whether specific content changes are required that would fit appropriately with the existing website content and objectives is ultimately a judgement for the ODC to make. The most that need be said in this report is that the ODC should review this issue periodically in consultation with the Australian Advisory Council on the Medicinal Use of Cannabis and the three intergovernmental working groups (Medicinal Cannabis Access Working Group, Cultivation and Production Working Group and Law Enforcement Working Group).

### **Recommendation 21**

The Office of Drug Control review the information presented on its website to evaluate if further helpful information or links can suitably be provided on the interaction of the medicinal cannabis scheme in the *Narcotic Drugs Act 1967* with relevant Commonwealth, State and Territory laws. This review be undertaken in consultation with the Australian Advisory Council on the Medicinal Use of Cannabis and the three intergovernmental Working Groups.

## **Monitoring the interaction of the ND Act with other laws**

The submissions to this Review gave examples of poor or inefficient interaction of Commonwealth, State and Territory laws relating to cannabis. Some of the examples fall outside the scope of this Review as they do not relate to the operation of the ND Act. A few other examples raise issues larger than the examples themselves and would require more extended consultation and analysis than was appropriate in this Review. A couple of examples are partially addressed by recommendations in other chapters of this report.

The examples raised with this Review are listed below to illustrate that the interaction of the laws in each jurisdiction relating to medicinal cannabis is a lively topic. This underscores the need to ensure there is a proper process in place to maintain a steady focus on the interaction of the ND Act and other laws. A recommendation to that effect is made below after the following summary of examples.

- Manufacture licence holders under the ND Act may be subject to other laws relating to manufacturing. One is the TG Act, which requires a licence to manufacture therapeutic goods if the product is intended to be supplied for human use (also called a GMP licence, or good manufacturing process licence).<sup>236</sup> State medicines and poisons laws relating to matters such as site security, storage and transport may also apply.

A view propounded by some commentators is that the ND Act manufacture licence provisions should not apply to cannabis in light of these other laws as those laws have effectively regulated the manufacture of opiates and controlled drugs over many years. A different approach adopted in this report is that the licensing of manufacturing in relation to cannabis should be merged into a new single licence structure (see Recommendation 7).

<sup>233</sup> Australian Capital Territory, Northern Territory and South Australia (June 2019).

<sup>234</sup> Queensland and Tasmania (June 2019)

<sup>235</sup> For example, Victoria: [www2.health.vic.gov.au/public-health/drugs-and-poisons/medicinal-cannabis/business-industry](http://www2.health.vic.gov.au/public-health/drugs-and-poisons/medicinal-cannabis/business-industry)

<sup>236</sup> *Therapeutic Goods (Manufacturing Principles) Determination 2018*, made under the TG Act s 36.

For the moment, however, it is desirable that more extensive guidance is published by the ODC as to the interaction of the different manufacturing requirements (see Recommendation 5). An added consideration is that there is potential for misunderstanding as to the scope of the ND Act manufacture requirements as they go further than required by Article 29 of the Single Convention.

- A related example was that there is overlap between Commonwealth requirements and State/Territory poisons legislation on matters such as product assays, dissolution tests and stability trials, and the personnel who are qualified to undertake those tasks. Regulation of those processes has been long-established in Australia, and the recent imposition of ND Act requirements applying to cannabis is said to be a source of confusion and conflict.
- A similar suggestion for reducing the rigour and administrative burden of ND Act licensing processes is for more recognition to be accorded to State and Territory laws and regulatory processes relating to matters such as storage, testing, transport and site security.
- As noted in Chapters 5 and 6, there have been complaints about the application of manufacture licence provisions in the ND Act to low-THC hemp production and export. Recommendation 2 to delete cannabidiol from the definition of ‘drug’ in the ND Regulation will partly address that complaint.
- The licensing requirements in the ND Act and in State and Territory legislation relating to cultivation and manufacture are similar though differently expressed. The result can be that staff of an entity that meet one licensing requirement (for example, the ‘fit and proper person’ test in the ND Act) may not be recognised as meeting a similar licensing requirement in another jurisdiction (for example, to be ‘suitably qualified’ for a particular function). The suggestion is that procedures for reciprocal recognition should be developed.
- There have been calls for regulatory changes that will enable better commercial integration within the Australian cannabis and hemp industries. For example, an entity that is licensed under State/Territory law to cultivate hemp cannot harvest and sell the cannabis flower tops to an ND Act licence holder, without the State licence holder also obtaining an ND Act licence. This is discussed in Chapter 5.
- Recommendation 18 is for the ODC to initiate discussion with Commonwealth, State and Territory law enforcement agencies regarding the legal and administrative protocols applying to the provision of sensitive law information to the ODC.
- A final and specific suggestion was that Commonwealth practice regarding destruction of cannabis substances should align with the requirement in some States and Territories for supervised destruction of Schedule 8 and Schedule 9 substances.<sup>237</sup>

As those examples illustrate, numerous issues will arise as to the interaction of the ND Act with other laws relating to cannabis. There are likely to be as many different perspectives on whether a problem exists and how it should be tackled. The medicinal cannabis scheme can operate more efficiently and effectively if there are semi-formal processes in place to enable those issues to be raised and discussed.

Consultative processes evolve and adapt. Existing consultative mechanisms relating to medicinal cannabis include the Australian Advisory Council on the Medicinal Use of Cannabis, three intergovernmental working groups (Medicinal Cannabis Access Working Group, Cultivation and Production Working Group and Law Enforcement Working Group), and occasional consultation between the department and two non-government bodies (Medicinal Cannabis Industry Australia and Medicinal Cannabis Council Inc.).

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<sup>237</sup> Eg, *Poisons Regulations 2008* (Tas), reg 38(2)(a); *Poisons and Therapeutic Goods Regulation 2008* (NSW), reg 125(2)(a).

Those consultative mechanisms are active and supported by the people, entities and agencies that are involved. The only additional measure that could usefully be added at this stage is to make the interaction of the ND Act with other Australian laws a standing agenda item at meetings of the Advisory Council and the Working Groups. While interaction issues are currently discussed in those forums, a standing agenda item is a common protocol to highlight the importance of a topic and to ensure that it receives separate attention. It can later be removed as a standing agenda item if this status seems unnecessary.

### **Recommendation 22**

The Australian Government Department of Health arrange for the interaction of the *Narcotic Drugs Act 1967* and other relevant Commonwealth, State and Territory laws relating to cannabis to be a standing agenda item in the meetings of the Australian Advisory Council on the Medicinal Use of Cannabis and the three intergovernmental Working Groups.

## **ND Act provisions that preserve the operation of State and Territory laws**

The ND Act declares an intention not to override State and Territory laws except to the extent of any inconsistency.<sup>238</sup> The intention is that the types of State and Territory law referred to in Chapter 2 relating to matters such as medicines, poisons, controlled substances and criminal activity will continue to operate alongside the ND Act.

The main qualification is that 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 licence holder from taking action under their licence or permit.<sup>239</sup> The intent is that the ND Act establishes a consistent national scheme in line with Australia's Single Convention obligations. However, the operation of a State or Territory law that would be overridden by the ND Act can be preserved by a regulation under the ND Act.<sup>240</sup>

A special feature of the ND Act to preserve State and Territory laws relating to medicinal cannabis is s 25A. It authorises the Secretary 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.<sup>241</sup> Specifically, a State or Territory agency to which a s 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.<sup>242</sup>

A s 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 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
- appropriate reporting arrangements are in place consistently with Australia's Single Convention reporting obligations.<sup>243</sup>

<sup>238</sup> ND Act, s 7.

<sup>239</sup> ND Act, s 7A(1).

<sup>240</sup> ND Act, s 7A(2).

<sup>241</sup> ND Act, s 25A.

<sup>242</sup> ND Act, s 7A(1).

<sup>243</sup> ND Act, s 25A(1).

The s 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 under the new Commonwealth licensing system. The Explanatory Memorandum to the Narcotic Drugs Amendment Bill 2016 explained that the intent of s 25A was ‘to allow the earliest possible patient access’, but ‘is not intended to be used on a permanent basis’.<sup>244</sup> Authorisations were granted to both Victoria and NSW to cultivate cannabis plants and produce cannabis or cannabis resin – in Victoria for medicinal purposes, and in NSW for the purposes of research relating to medicinal cannabis. Victoria was granted a subsequent authorisation to manufacture cannabis extracts for medicinal purposes. The Victorian approval expires in October 2019 and the NSW approval in July 2019 (NSW has applied for a 12 month extension).

It seems likely that s 25A will soon be a spent provision, on the expiration of the current approvals. There is broad acceptance of the ND Act framework for licensing cultivation, research and manufacture. There is also a strong intergovernmental focus upon the effective operation of the patient access pathways described in Chapter 2. It is notable too that Queensland recently repealed the *Public Health (Medicinal Cannabis) Act 2016* (Qld) that provided a comprehensive framework for access to medicinal cannabis.

Although s 25A does not have any untoward or obstructive impact on the operation of the medicinal cannabis scheme, it seems appropriate that it be repealed if it becomes a spent provision.

**Recommendation 23**

Section 25A of the *Narcotic Drugs Act 1967* be repealed if, at the expiration of current approvals under the section, it becomes a spent provision that is no longer required.

<sup>244</sup> Narcotic Drugs Amendment Bill 2016, ‘Explanatory Memorandum’, p 97.

# Chapter 9: Implementation and administration of the medicinal cannabis scheme

## Introduction

The Office of Drug Control in the Health Products Regulation Group of the department has played a central role in implementing and administering the medicinal cannabis scheme since 2016. The ODC is at the front line of the scheme – receiving and making decisions on licence, permit, import and export applications; handling administrative queries and variation requests; providing guidance and advice through the ODC website and in response to individual enquiries; and conducting regulatory monitoring, compliance and enforcement activities.

Not surprisingly, much of the commentary in this Review on the operation of the medicinal cannabis scheme included commentary on the work of the ODC. Many comments did not differentiate between the legislative rules the ODC was administering and how the ODC went about that task. There may, for example, be a dual element in a complaint that an applicant was required to submit more detailed information than seemed warranted, or to re-submit the same information in a fresh application.

The main lines of criticism of the administration of the medicinal cannabis scheme were summarised in Chapter 5 in relation to Key Theme 4.<sup>245</sup> This chapter elaborates on five aspects of the ODC's work:

- its work overall in administering the medicinal cannabis scheme
- its regulatory focus on risk minimisation
- the service provided to existing licence holders
- requests for information and documents under s 14J of the ND Act
- other issues and suggestions for administrative improvement.

A couple of points from the earlier discussion should be restated. The first is that the department received additional funding in 2018 to support the medicinal cannabis scheme. The administrative demands of the scheme were higher than initially anticipated – due principally to the large number of licence applications received. The additional funding will support a marked increase in the number of ODC staff, possibly up to thirty staff.

The funding is also being used for an independent business review of ODC processes, due to be completed in mid-2019. The business review may cover some of the same ground as this Review and may prompt administrative changes that are implemented before this report is published. This chapter is framed on that basis and deals with only a few key issues and makes only three recommendations.

A second point is that recommendations in other chapters of this report would – if implemented – resolve many of the concerns that licence holders and applicants raised with this Review. An example would be the amendment of the ND Regulation to consolidate and reduce the separate number of information and document requirements that a licence applicant is currently required to meet.

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<sup>245</sup> 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 administrative burden imposed 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 permit?

## The work of the Office of Drug Control

The focus of this Review has been the structure and operation of the ND Act. The ODC's regulatory approach is integral to the operation of the Act but has not itself been a free-standing topic of inquiry. The comments that are made about the ODC's work should be approached with that limitation in mind.

There has been general acknowledgement by those participating in this inquiry that the ODC has done well in implementing a complex scheme that has imposed considerably higher administrative and resource demands than was anticipated. Many commentators, in submissions and consultation forums, wished to record their complimentary assessment of the professional way the ODC had implemented the scheme and engaged constructively with applicants over more than two years.

Numerous strengths in the ODC's performance can be noted:

- The medicinal cannabis scheme in the ND Act has been successfully established. The licensing and permit framework is operating in accordance with the ND Act and ND Regulation and 63 licences have been issued and at least twice as many applications are being processed.
- Research into medicinal cannabis is underway at a number of institutions.
- The objective of the Single Convention of ensuring that the community is protected against the diversion of locally cultivated and manufactured cannabis products has been met.
- The ODC has displayed both technical and administrative competence in cannabis regulation.
- The ODC is working well with a diverse range of stakeholders – other government agencies, licence applicants and holders, researchers, exporters and importers, and industry associations.
- Practical guidance and information updates are provided through the ODC website.
- The ODC has been open-minded and responsive to complaints and suggested changes about its administration of the ND Act. Procedural changes have already been implemented and will continue through a business review program that is currently underway.

## The ODC's regulatory focus on risk minimisation

The first couple of years of the medicinal cannabis scheme have been marked by a strong focus on minimising the risk of criminal incursion in the scheme. Commentators acknowledge why this occurred – to meet the requirements of the Single Convention in establishing a new industry handling a potentially harmful narcotic drug.

However, there is broad acceptance in and outside government that the risk minimisation focus can be reassessed. The risks have been successfully contained to date. Licence applicants and holders have been proactive in demonstrating their preparedness to ensure that criminal risks do not materialise. A closely regulated industry has been established in which the risks may not in practice be as high as once feared.

The rationale for lessening the risk minimisation focus is to reduce the administrative complexity and burden for licence applicants and holders and the ODC. A common theme in many complaints is that there is excessive risk aversion that is displayed in many ways – the extensive range of information required in applications, multiple requests to provide further information, numerous and highly prescriptive conditions imposed on licences and permits, onerous notification and reporting obligations, restrictions on the transfer and use of cannabis products, and time-consuming variation procedures.

The risk minimisation emphasis runs through the ND Act, the ND Regulation and the regulatory method of the ODC. It is not a simple matter of the ODC changing direction and adopting a different risk management strategy. It will necessarily be guided by its responsibility to administer the Act and the Regulation in the form they appear from time to time. Much will therefore depend on whether legislative changes are made along the lines recommended elsewhere in this report.

There is nevertheless scope for the ODC to adjust its work methods, after first articulating its regularity approach and priorities. While the ND Regulation establishes a highly prescriptive framework that the ODC must administer, some of the licensing, permit, monitoring and compliance requirements have a discretionary element. For example, it is open to the ODC to make discretionary decisions on the information that applicants are required to provide, the conditions that will be imposed on licences and permits, the approach to be taken in receiving and approving variation applications, the frequency and scope of inspections and compliance monitoring generally, and the limits set on cannabis product that can be supplied to and held by a testing body.

There is also an overriding strategic regulatory choice – whether to give priority (and dedication of administrative resources) to ‘back end’ compliance measures such as inspections and monitoring, rather than ‘front end’ compliance through detailed licence assessment. Adoption of a ‘back end’ priority may ease the current burden the ODC faces in dealing with a growing backlog of licence applications.

The necessary next step is for the ODC to develop and publish a risk management framework. Two excellent guides for doing so are the *Commonwealth Risk Management Policy*, published by the Department of Finance in 2014, and the Australian Standard, *Risk Management – Guidelines* (AS/NZS ISO31000-2018). Although those policies are partly directed to internal risk management and audit in organisations, they are also outward facing.

The goal of the Commonwealth Policy (which draws from the Australian Standard) is stated as follows: ‘to embed risk management as part of the culture of Commonwealth entities where the shared understanding of risk leads to well informed decision making’.

The Policy incorporates nine elements that agencies are required to comply with in order to establish an appropriate system of risk oversight and management. The first two elements require agencies to establish a risk management policy and a risk management framework. Following are some excerpts from the Commonwealth Policy to illustrate its relevance to the challenge now facing the ODC of reassessing its risk management focus:

- ‘A risk management policy links the entity’s risk management framework to its strategic objective(s). Communicating the accountabilities, responsibilities and expectations within an entity’s risk management policy is important to ensure a common understanding of risk across the entity. ... An entity *must* establish and maintain an entity specific risk management policy that: *a.* defines the entity’s approach to the management of risk and how this approach supports its strategic plans and objectives; *b.* defines the entity’s risk appetite and risk tolerance ...’ (*Element 1*)
- ‘An entity *must* establish a risk management framework which includes: ... *b.* an overview of the entity’s approach to managing risk; *c.* how the entity will report risks to both internal and external stakeholders; ... *e.* an overview of the entity’s approach to embedding risk management into its existing business processes; *f.* how the entity contributes to managing any shared or cross-jurisdictional risks ...’ (*Element 2*)
- ‘A positive risk culture promotes an open and proactive approach to managing risk that considers both threat and opportunity.’ (*Element 5*)
- ‘Communicating and consulting about risk underpins the successful management of risk. Effective communication requires consultation with relevant stakeholders and the transparent, complete and timely flow of information between decision makers.’ (*Element 6*)

- ‘Accountability and responsibility for the management of shared risks must include any risks that extend across entities and may involve other sectors, community, industry or other jurisdictions.’ (*Element 7*)
- ‘The effective management of risk is a process of continuous improvement, requiring regular review and evaluation mechanisms.’ (*Elements 9*)

#### **Recommendation 24**

The Office of Drug Control develop a risk management framework dealing with the exercise of its regulatory functions, drawing from the *Commonwealth Risk Management Policy* and the Australian Standard, *Risk Management – Guidelines*.

## **Service provided to existing licence holders**

The ODC understandably adopted a ‘queuing’ system for licence and permit applications. All applications would be queued at the date of receipt and dealt with in that order. This arrangement could be expected to work fairly and efficiently based on the predicted number of licence applications.

Unforeseen developments undermined the sustainability of this arrangement. Up to three times more applications were received than expected. The rate of new applications has not slowed. More time than anticipated has been spent on processing some applications because of inadequate information provided by applicants. Numerous applications have been received to vary the precise details recorded on licences and permits. There have been suggestions too that some new applicants ‘game the system’ by prematurely lodging inadequate applications either to gain a place in the queue or to obtain ODC advice on necessary steps to improve an application.

The ODC has acknowledged those problems and turned its mind to developing arrangements that are more tailored to client needs and the different categories of ODC work. For example, a guidance statement the ODC issued in October 2018 advised that a new screening assessment process was being introduced to ensure that deficiencies in applications could be addressed shortly after the applications were received.<sup>246</sup> Another change being introduced on a trial basis with a couple of established licence holders is a fast-track procedure for notifying and accepting licence and permit variations. The business review that is underway is also expected to bring forward proposals for improved case management.

It will be important, going forward, that ODC processes can differentiate the special needs of existing licence holders. They can rightly expect a level of client service that recognises the stage they have reached in preparing an application that has been approved through a demanding and rigorous licencing process. Licence accreditation should be thorough to meet risk objectives, but licence holders have passed that initial threshold. Their commercial investment in applying for a licence and building capacity to undertake cultivation or manufacture has added weight.

Several measures were suggested in submissions for the ODC to provide a better level of service to existing licence holders. These include the appointment of ODC case managers or liaison officers to those licensees; allowing minor licence and permit variations to be approved upon notification; imposing less frequent reporting obligations; granting licences for extended terms; having less prescriptive permit conditions; having a fast-track procedure for manufacture licence applicants who already hold a medicinal cannabis licence; and holding regular industry consultation forums.

<sup>246</sup> Office of Drug Control, ‘Application processes for licences and permits under the Narcotic Drugs Act 1967’ (19 October 2018).

Some of those suggestions are picked up in recommendations in this report. Others are likely to be considered in the business review that is underway. With that in mind the following recommendation does not go further than urging the ODC to differentiate the special needs of existing licence holders.

### **Recommendation 25**

The Office of Drug Control review its administrative procedures to identify changes that can be implemented to provide an enhanced level of client service to existing licence holders.

## **Requests for information and documents under section 14J of the ND Act**

Under s 14J of the ND Act an applicant or licence holder can be required to provide information or documents that are reasonably required for the administration of the Act. As noted in Chapter 7, this and associated regulatory powers enable officers administering the ND Act to be properly informed of all relevant matters.

Several criticisms were made during this Review about s 14J requests, mostly about requests made when licence applications were being assessed:

- Applicants will commonly receive s 14J requests after lodging applications. This raises the question of whether the ODC has provided adequate guidance to prospective applicants as to the information required in applications.
- Section 14J requests may require information that has already been provided in an application or in response to another s 14J request. This suggests that licence applications may not be properly scrutinised or that s. 14J requests work from a standard template or procedure.
- An applicant for multiple licences may receive similar s 14J requests in respect of each application.
- Different applicants will receive similar s 14J requests that do not seem separately tailored to their individual applications.
- The s 14J requests can be extensive and burdensome to comply with. It can be difficult to see why particular information was requested and how it will be relevant to the licensing criteria. This can delay an application being processed.
- Section 14J requests may be poorly framed, which can generate either an inadequate response or a further s 14J request, leading to further delay.
- Section 14J requests that are received separately from the two sections in the ODC (Drug Control Section and Medicinal Cannabis Section) may be duplicative or inconsistent.

It was not practicable in this Review to undertake an authoritative review of s 14J requests. Whether a particular s 14J request was appropriate and well-framed would require referral back to the application to which it related, as well as analysis of how any information provided was subsequently used by the ODC. Some s 14J requests can include more than thirty questions.

However, the review did examine 25 s 14J requests that were a reasonable cross-section of the requests sent to different types of applicants, including some that had made public submissions to this Review. The following general observations can be made:

- Most of the questions raised in s 14J requests appear to have a legitimate purpose – for example, requesting clarification about the design of premises, the fit and proper requirement, business relationships, record keeping arrangements and how security and IT systems will function.

- Some other questions are more open-ended and may be difficult to answer in a reliable manner – for example, who will be responsible for undertaking a future review of a particular document, or how the applicant will respond to natural disasters. It is clear too that some requests would require considerable time and effort to respond to.
- It may be hard to comply with some s 14J questions in advance of a business operation being established – for example, to provide a list of the standard operating procedures that will be in place, or the method of disposal to be used by a third party waste disposal entity.
- A tight timeframe is imposed on some requests that is at odds with the ODC’s own processing times – for example, a response within 4-6 weeks ‘or the application will be cancelled’, when submissions noted that ODC licence processing can take more than a year.

Two things are clear. One is that the ODC makes regular and probing use of the s 14J power. The second is that the ODC’s heavy reliance on the power is a source of considerable grievance among many applicants and licence holders. Their complaints echo other themes that have emerged in this Review about the intense risk aversion focus that has been apparent in the first couple years of the medicinal cannabis scheme.

The ODC is currently reviewing its s 14J requests, in conjunction with the business review that is underway. There would be benefit in continuing this review on a periodic and more structured basis. This can be done internally within ODC, with participation of both DCS and MCS staff and independent participation from elsewhere in the department or another agency. What is required, for example, is that the internal audit/review team scrutinise about 5-10 s 14J notices from the previous six months according to the following criteria:

- Were all questions in the s 14J request necessary, properly framed and tied to the licensing criteria in the ND Act and ND Regulation?
- Was the information provided in response to the s 14J requests used in licence processing?
- Were the obligations placed on the applicant or licence holder by the s 14J notice reasonable?
- Was a s 14J request the better option for obtaining the information the ODC required?
- Would better ODC guidance or a better licence or permit application form obviate the need for any of the questions in the s 14J notice?

#### **Recommendation 26**

The Office of Drug Control undertake a review, every six months, of a sample of notices issued during the previous six months under section 14J of the *Narcotic Drugs Act 1967* requiring the provision of specified information, to evaluate the ODC’s reliance on section 14J and the quality of section 14J notices. The review include participation of at least one independent representative from elsewhere in the Australian Government Department of Health or another Commonwealth agency.

## Other suggested administrative improvements

This section summarises other comments and suggestions about the ODC's work that were made during this Review in submissions and consultations. The ODC is aware of these points through its own consultations and may consider them as part of the independent business review that is underway.

This Review has not undertaken an independent assessment of these comments and suggested reforms: no endorsement is intended by providing this summary list. The purpose in doing so is to place on the record for present consideration and future reference the thoughtful suggestions that many commentators made.

- Administrative delay in licence and permit applications being finalised was frequently commented upon. It was wryly observed that licences were initially granted for 12 months yet it can take more than 18 months for an application to be approved. The delay can be self-perpetuating, as the licence application may need to be updated and varied during that time. There was support for the introduction of decision making timeframes – either administratively or in the ND Act or ND Regulation. The ODC in fact published its processing timeframes in October 2018.<sup>247</sup> initial receipt and notification (5 working days); screening and requests for further information (10 working days); evaluation and decision (195 working days, plus extra days if the application is varied during evaluation, or while waiting for additional information to be provided).
- A related suggestion was that the dates for payment of application fees and licence charges should be adjusted to better align with the processing timeframes and the commencement of activity under a licence.
- Applicants and licence holders would benefit greatly by the introduction of a web portal or online system for licence administration. This could facilitate lodgement of applications and documents, cross-referral to or attachment of documents already in the system, visibility and tracking of licensing progress, management of variation applications and notifications, information queries being dealt with, and communication generally with the ODC.
- Established licence holders with an unblemished compliance record should be moved to quarterly rather than monthly reporting.
- Coordination and information sharing between the DCS and MCS sections within the ODC could be improved.
- It is not always clear how ODC requests and decisions align with the legislation. Equally, some ODC interpretations of the ND Act and ND Regulation are questionable. These disagreements could more easily be resolved if comprehensive information was published by the ODC, and if that guidance was linked to the relevant legislative provisions. The ODC could also consider, in time, adopting the practice of the Australian Taxation Office of publishing advisory rulings.
- It is important that within the ODC there is appropriate technical and expert knowledge to deal with specialist issues that arise, for example, relating to pharmaceutical, research, manufacturing and industry matters. The ODC should review its staffing profile to ensure that it holds this expertise.
- The criminal history checks that are undertaken during licence assessment should be reviewed to ensure greater efficiency. Checks undertaken through the Australian Federal Police can take longer than those through Crim Trac and should only be used for senior officers in a licensed entity.
- The 200g limit that is placed on the amount of cannabis product that can be held at any time by a testing body is arbitrary and artificial. This limit impedes the small number of testing bodies from receiving batches simultaneously from several licence holders. There is no legal requirement for this limit, and it is odds with long-established practice in other areas where cannabis testing is undertaken (for example, in policing).

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<sup>247</sup> Office of Drug Control, 'Application processes for licences and permits under the Narcotic Drugs Act 1967' (19 October 2018).

## Appendix A—Terms of Reference

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.

# Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Professor John McMillan AO	10 July 2019