

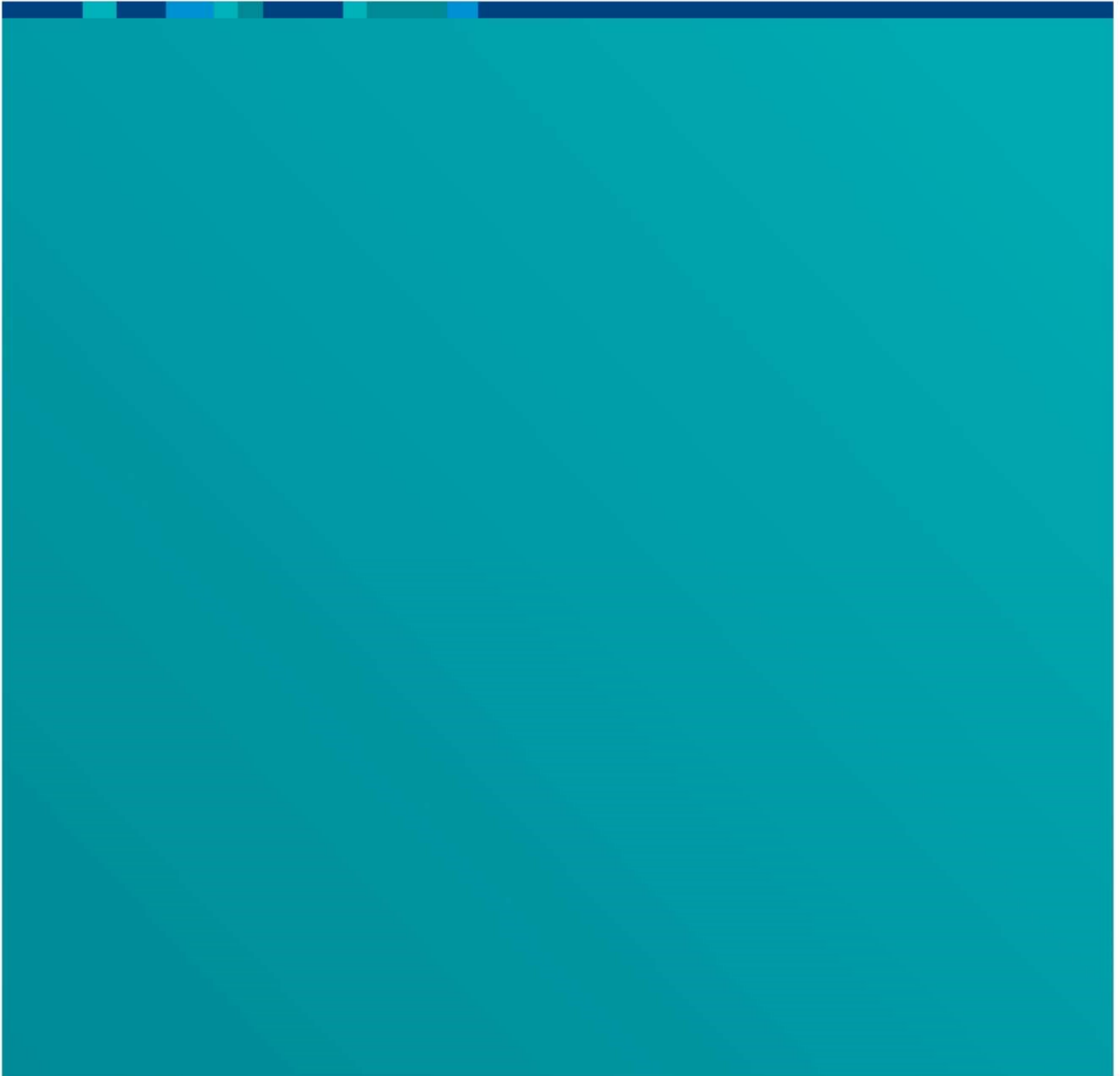


**Australian Government**

**Department of Health**

# **Consultation paper**

## Medicinal Cannabis Permit Reform



**Version control:**

<b>Version</b>	<b>Date Revised</b>	<b>Author</b>	<b>Change Description</b>
1	09/11/2020	Office of Drug Control	Original publication

# Contents

- Contents..... iii
- Purpose..... 4
- Executive Summary ..... 4
- Background ..... 5
- Providing feedback..... 6
- Overview of the current permit arrangements..... 7
  - Legislative Context ..... 7
  - Permits..... 7
- Issues with existing permit arrangements..... 9
- The way forward..... 10
  - Key changes ..... 10
  - Strains and Growing/Production Schedules..... 10
  - Standardised Supply Pathways ..... 12
  - Reporting ..... 14
- Proposed Model..... 15
  - Proposed application information requirements..... 15
  - Proposed matters to be specified in the permit..... 16
  - Benefits and responsibilities under the proposed model ..... 16
  - Proposed legislative changes ..... 17
- Transitional arrangements ..... 18

## Purpose

The Department of Health through the Office of Drug Control (ODC) is conducting a review of medicinal cannabis related permits granted under the *Narcotics Drugs Act 1967* (the Act), including the structure and design, and relevant administrative processes.

In particular, this review considers ways to simplify permit arrangements. It also proposes implementing periodic reporting and compliance monitoring to maintain appropriate regulatory outcomes under the Medicinal Cannabis Scheme (the Scheme).

In conducting this review, the ODC therefore aims to:

- simplify the level of detail in the permits, particularly for cultivation and production
- allow for greater flexibility in business decision-making
- improve the ODC's efficiency, and
- improve industry understanding of regulatory obligations and compliance requirements.

## Executive Summary

The ODC is undertaking a review of the structure, design and administrative processes for medicinal cannabis related permits. This review is part of the broader reforms being implemented as a result of the statutory *Review of the Narcotic Drugs Act*<sup>1</sup> undertaken in 2019 by Professor John McMillan AO (see report tabled in Parliament in September 2019) (Review of the Narcotic Drugs Act).

The current permit arrangements, particularly for cultivation and production related permits, were initially designed to authorise relevant activities and to assist the ODC in managing compliance and reporting functions in the infancy of the Scheme. The process for granting these permits has increased in complexity to encompass the wide variety of cultivation, production and supply activities undertaken by licence holders. This has led to a high level of prescription in such permits, requiring holders to seek variations to change what are often operational matters. This has resulted in an unnecessary regulatory burden on industry and the workload of the ODC.

It is proposed to:

- simplify the information required in an application for a permit authorising cultivation, as detailed information on cultivation and production schedules will not be required
- simplify the contents of permits for cultivation by no longer detailing strains, bespoke supply pathways and cropping schedules in these permits
- simplify the contents of permits by specifying maximum limits on the activities undertaken at the site on the basis of whether the product is low in delta-9 tetrahydrocannabinol (THC) (1% THC or lower) or high THC (>1% THC)
- clarify and simplify supply pathways by specifying standardised categories of entities to/from whom supply can be undertaken

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<sup>1</sup> *Review of the Narcotic Drugs Act 1967* <https://www.odc.gov.au/news-media/news/tabling-report-review-2016-medicinal-cannabis-amendments-narcotic-drugs-act-1967#report>

- clarify obligations in permits by adding maximum quantities for starting materials and waste held onsite to manufacture permits, and
- implement a reporting scheme for permit holders to routinely report on actual and forecasted activities over the permit period.

These changes are expected to have the following benefits:

- permit requirements will be easier for licence holders to understand and comply with
- reduction in the need for permit variations, with variations required mainly only for increasing total quantities specified in a permit, or when seeking permission to cultivate, produce or manufacture high-THC cannabis above existing specified levels.
- fewer variations will reduce the regulatory burden and provide cost savings for industry,
- allow industry to respond quickly to market demands without requiring permit variations, and
- allow ODC to more effectively monitor cultivation and manufacture activities to ensure compliance with Australia's obligations under the Single Convention.

Subject to the outcomes of this permit review, it is anticipated that minimal regulation and legislative changes will be required to give effect to the proposed changes. Any impact on fees and charges will be monitored and adjusted, as necessary, through the annual review of fees and charges for the Scheme. It is a given that any changes to permits under the Act must ensure that Australia continues to be compliant with its international convention obligations.

Feedback is sought on the proposed approach for the reform of medicinal cannabis related permits, particularly any transitional issues to be considered. Details for providing feedback are set out below.

## Background

As a signatory to the *United Nations Single Convention on Narcotic Drugs 1961*, as amended by the 1972 Protocol (Single Convention), Australia has obligations to control the cannabis it cultivates and manufactures, to prevent stockpiling and to report to the International Narcotics Control Board on production and consumption annual estimates.

The Scheme is a licence and permit framework under the Act by which Australia implements its obligations under the Single Convention. The Scheme provides for the cultivation and production of medicinal cannabis for commercial or research purposes and the manufacture of medicinal cannabis products. The Scheme commenced in 2016, as the result of amendments to the Act. Prior to this, the cultivation and production of cannabis within Australia was unlawful.

The Review of the Narcotic Drugs Act made 26 recommendations, two of which (recommendations 8 and 11) referenced making amendments to the *Narcotic Drugs Regulation 2016* (the Regulation) to reduce some complexity and duplication of information required to be supplied with a permit application. These changes were given effect from 1 January 2020 by the Narcotic Drugs Amendment (Review Recommendations) Regulations 2019 during stage 1 of the reform process.

Stage 2 of the reform process, currently underway, involves implementing the remaining recommendations from the Review of the Narcotic Drugs Act, including amending the Act and making further amendments to the Regulations where necessary.

This includes considering recommendation 12, that (broadly) the Act and the Regulation be amended to streamline the permit variation process, including providing greater clarity for licence holders.<sup>2</sup> The ODC is undertaking a review of the arrangements for granting medicinal cannabis related permits in response to this recommendation and in response to feedback received from stakeholders during recent consultations. The underlying issues relating to recommendation 12 have been considered as part of the permit review process, and are proposed to be addressed through the reforming the design and operation of medicinal cannabis related permits as set out in this consultation paper. Accordingly, the department considers amendments to the Act in the terms proposed by that recommendation will not be required.

Detailed discussion related to the recommendations can be found in Chapter 6 of the Report <https://www.odc.gov.au/news-media/news/tabling-report-review-2016-medicinal-cannabis-amendments-narcotic-drugs-act-1967#report>

## Providing feedback

The ODC invites formal feedback on any or all of the matters outlined in this paper. In particular, views are sought on the proposed approach to revising:

- the scope and contents of permits relating to medicinal cannabis
- the permit application process and information requirements
- the approach to specifying supply pathways, and
- information recording and reporting obligations (including frequency of reporting), with increased compliance monitoring.

Observations on issues to be considered and managed in transitioning existing permit holders to the new arrangements are also welcomed.

Submissions in response to this paper close on **Friday 18 December 2020**. All interested stakeholders are encouraged to provide a written submission through the Department of Health's Consultation Hub [at https://consultations.health.gov.au/](https://consultations.health.gov.au/).

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<sup>2</sup> Recommendation 12 is as follows:

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

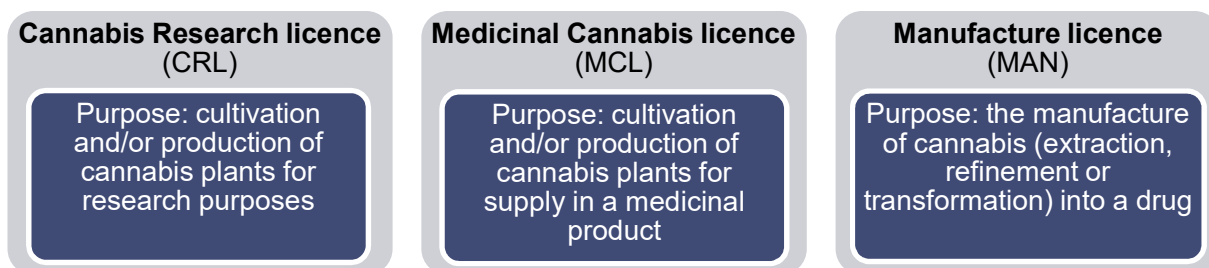
- *that a licence holder must obtain the formal written approval of the Secretary for a variation of a permit, if the variation is of a kind listed in the Regulation*
- *as to any other variation of a permit that is not listed in the Regulation as one that requires the Secretary's written approval -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

# Overview of the current permit arrangements

## Legislative Context

Currently, there are three licence types authorising activities relating to medicinal cannabis that may be granted under the Act:

- Cannabis Research licence (CRL)
- Medicinal Cannabis licence (MCL)
- Manufacture licence (MAN).



Broadly, the purpose of a licence is to allow the Commonwealth to ensure the suitability of:

- entities, and associated persons, proposing to engage in cultivation, production or manufacture activities
- the site, facilities and premises where proposed activities will take place, and
- the controls the entity intends to implement particularly to prevent the diversion of cannabis for illegal purposes.

## Permits

The permit system provides a mechanism to control and monitor the quantity of cannabis cultivated, produced and manufactured in Australia, allowing compliance with obligations under the Single Convention. A holder of a licence under the Act can apply for a relevant permit.<sup>3</sup> The information and document requirements for the application can be found in the Regulations.

The Act allows the Secretary to specify various matters in a permit, including but not limited to maximum quantities and periods of activities. However, for permits authorising cultivation and production, the ODC's current approach is to specify further details, including specific supply pathways and strain information.

### ***Cultivation and Production permits***

#### ***Information Requirements – medicinal cannabis and cannabis research permits***

Medicinal cannabis permits and cannabis research permits authorise cultivation and production activities. The minimum requirements for these permits are substantially similar

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<sup>3</sup> See section 8P for a medicinal cannabis licence holder, 9P for a cannabis research licence holder, and 12 for a manufacture licence holder.

and in addition to some general requirements, impose information requirements depending on whether the relevant licence authorises cultivation and/or production. If the licence authorises both, all of this information is necessary.

An application for a permit relating to a licence which authorises cultivation must include:

- information about the plants and their THC content
- information about the maximum amounts of plants to be cultivated over the period of the permit and to be in the licence holder's possession at any given time
- the period of cultivation (for production or propagation), and
- details of the source of the proposed plants.

An application for a permit relating to a licence which authorises production must include:

- information about the maximum quantities of cannabis or cannabis resin that is proposed to be produced and to be in the licence holder's possession at any given time, and
- the period of production.

#### *Content – medicinal cannabis and cannabis research permits*

Permits for the CRL and MCL licence types currently specify details such as:

- authorised activities
- strain identification details
- THC/cannabidiol CBD ranges
- quantity (both total maximums over the life of the permit and the maximum quantity that may be onsite at any one time) by strain including numbers of seeds, explants, mother plants and cuttings
- cultivation material supplier/source details
- purpose of cultivation
- supply details including; supply pathway (entity receiving material), quantity to be supplied and form supplied in
- anticipated waste produced, and
- planned dates of cultivation and production activities.

#### ***Manufacture permits***

Similar to the permits for cultivation and production, permits for the manufacture of medicinal cannabis products were designed to control quantities, product type and supply pathways.

#### *Information requirements – manufacture permits*

An application for a manufacture permit must include:

- types and quantity of starting material (including source)
- types and quantities of drugs to be manufactured
- proposed end use
- quantities of drugs to be to be possessed at any given time, and
- supply pathways.



## *Content – manufacture permits*

Manufacture permits currently may specify:

- authorised activities
- quantity of starting material required (and stored onsite)
- total quantity of cannabis extract to be manufactured
- maximum amount of cannabis extract to be held at any time on site
- supply activities, and
- supply pathways.

## Issues with existing permit arrangements

The Review of the Narcotic Drugs Act identified a number of issues relating to permits, including:

- submissions to the Review indicated the level of detail required in permit applications was “impractical and constricting”<sup>4</sup>
- some detail was noted in submissions to the Review as being “difficult to estimate prior to cultivation or manufacture occurring”, and
- the level of detail required may also trigger the need for variation applications.

Due to the detailed nature of cultivation and production permits, each permit has a unique structure and layout, which over time has made interpretation of requirements difficult. In particular, cannabis research involving breeding to develop unique strains involves great complexity. The detail currently involved in the permit design process takes time to tailor to individual requirements.

Under the current model, permit variations must be granted prior to any major change in business operations during the permit period for cultivation/production and supply activities.

Consistent previous feedback from industry stakeholders indicate that the current, highly prescriptive permit arrangements inhibits commercial and operational flexibility for individual permit holders, thereby impeding the development of the industry as a whole. Notwithstanding that there are a range of factors and information that must be considered when assessing a permit application, the current approach to the content of permits to be unsustainable.

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<sup>4</sup> Page 66, *Review of the Narcotic Drugs Act 1967*

# The way forward

## Key changes

The ODC proposes the following key changes to the permit arrangements relating to medicinal cannabis:

1. Simplifying and clarifying the information detailed on permits:
  - a. For permits authorising cultivation and production, this will include removing detailed cropping schedules. Rather, the permit will set a limit on the total quantity of material that can be cultivated and produced over the period of the permit and set maximum quantities that can be held on site at any one time. This will result in a reduction in the specificity of any cropping information the ODC may require at the time of application.
  - b. For permits authorising cultivation and production, two broad categories will be introduced and information about specified strains will be removed:
    - low THC, consisting of plants containing less than 1% THC, and
    - high THC, consisting of any plants containing THC that may range above 1%.
  - c. For permits authorising manufacture, clarifying the amount of starting material necessary for the manufacturing activity authorised.
2. Supply pathways will be standardised by referencing categories of entities with which supply can be undertaken. Removing bespoke supply pathways will avoid the need to seek permit variations before supply can be undertaken, as long as the recipient is included within one of the standardised categories included in the permit. Licence holders will need to take reasonable steps to verify that entities to which they intend to supply are legally able to receive the relevant substances. The ODC will monitor compliance with this requirement and take regulatory action where appropriate.
3. Permit holders will periodically report on actual and forecast cultivation, production and manufacture activities, in lieu of detailed information being provided at the application stage and prescribed in the permit.

These key changes are discussed in further detail below, followed by a summary of the proposed model. The paper then sets out the key benefits of the proposed changes, along with the responsibilities of permit holders and the ODC's proposed approach to compliance.

## Strains and Growing/Production Schedules

A key change is to simplify and clarify the content of permits, in particular in relation to strains and growing/production schedules. The intention is to provide in the permit for the maximum amounts that can be cultivated, produced or manufactured over the permit period, and the

maximum amounts of material that can be held on site at any one time, including confirming the quantity of any starting materials.

Information requirements for permit applications will be simplified to remove the need for detailed information relating to cultivation and production schedules. This is in recognition of the fact that this information is often only estimated at the time of the permit application and, if specified in detail in the permit, frequently results in the need for a permit variation.

The content of permits will be simplified so that specific strain information will no longer be included in cultivation and production permits.

#### **EXAMPLE 1**

**Company A holds a Medicinal Cannabis Licence, and wishes to cultivate a single strain of high THC cannabis.**

**After being granted a permit to cultivate, Company A discovers its seed supplier no longer has stock of the high THC strain.**

**Under current arrangements, a permit variation must be granted before an alternative high THC strain can be ordered from the supplier. Under the proposed changes, Company A may source an alternative strain from their supplier without lodging a variation, as long as the strain is within the same high/low THC category authorised in the permit.**

Information on the strains an applicant intends to cultivate is relevant when assessing whether the business is ready to be operational and ought to be granted a permit. As a result, proposed strain information will still be required at the application stage. This approach notes also that businesses should have this information readily available at the time of application. However, the ODC considers it is not necessary for it to prescriptively detail the proposed strain information on the permit, as has previously occurred. The current level of prescription has resulted in an unnecessary regulatory burden, as permit holders must seek a permit variation to change strains for operational reasons. This has been the case even if the proposed change had no impact on the THC levels of the plants to be cultivated under the permit.

Rather, it is proposed the permit will now contain only limits for low and high THC materials, with low THC being classed as containing less than 1% THC. The low or high THC distinction will be used in specifying total authorised amounts in the categories of genetic material, cultivated plants, production activities, manufacture starting material, manufactured drugs and waste.

This proposed approach is a departure from current practice, which involves detailing in cultivation and production permits the particular strains and the number of plants of that strain. This change in approach will provide permit holders greater flexibility to change their growing/production arrangements without having to apply for a formal variation of their permits to grow a particular strain, as long as activities are undertaken in accordance with the maximum levels specified in the permit and within the authorised THC category.

A variation will be required if the permit holder wishes to:

- increase the quantity of high THC material being cultivated or produced (including where the permit holder wishes to move from only conducting activities with low THC material), or
- increase the quantity of low THC material if the total allocation for that activity under both low and High THC under the permit has, or will be, exhausted.

#### SUMMARY

- **Permits will no longer include details of each strain to be cultivated**
- **Instead permits will specify the number of plants, or other cannabis material, in the low THC (<1% THC) or high THC categories (>1% THC)**
- **Cultivation and production schedules will no longer need to be provided at the time of application**

## Standardised Supply Pathways

It is proposed that permits will no longer require information specifying supply pathways to particular entities; instead prescribing that material can be obtained from, and can be supplied to, persons within standardised categories. These categories will be specified in generic terms, and will apply across all permits of the same kind.

As each licence type has particular requirements regarding supply pathways, it is proposed there be a different generic list specifying the authorised supply pathways for each licence type.

This change in approach to specifying supply pathways will:

- remove the need for applicants to supply specific contracts for the entire amount to be cultivated, produced or manufactured under the permit prior to its grant. The requirement for licence holders to have executed contracts in place during the period of the permit will remain and will be subject to compliance monitoring, and
- reduce the need for permit variations during the period of a permit. During the period of a permit, subject to permitted limits relating to authorised amounts, permit holders will have flexibility to change supply arrangements within the standardised categories without the need to apply for a permit variation.

The proposed changes to supply pathways is intended to provide greater flexibility for permit holders to respond quickly to market demands and will minimise the need to apply for permit variations. However, licence holders will bear the responsibility for undertaking due diligence checks, and maintaining records of such, to ensure the entities to whom they supply, or from which they obtain material, fall within the specified standardised categories. If a licence holder has not taken appropriate steps and maintained sufficient records, they may potentially be liable to regulatory action, for example, for breaching licence/permit requirements.

Additionally, a licence holder will also bear responsibility for ensuring that, in entering into any supply arrangement, the total supply arrangements do not exceed the maximum quantity limits set out in the permit.

The ODC considers that maintaining a list on permits of the authorised categories of entities to/from whom cannabis may be supplied is beneficial, as it is transparent and will provide clarity for permit holders when entering supply arrangements, which in turn should assist in minimising the risk of non-compliance.

The ODC will retain the capacity to impose bespoke supply pathways to a particular entity, should this be considered appropriate based on the circumstances of the entity.

#### **EXAMPLE 2**

**Company A holds a Medicinal Cannabis Licence and permit and supplies several entities with dried cannabis flower. A new entity, Company B, holds a Manufacture Licence and permit, and approaches Company A to contract to supply it with dried flower for manufacture.**

**Under current arrangements, Company A must lodge a permit variation application to add Company B as an authorised supply pathway before supply can occur. Under the proposed model, once Company A has undertaken due diligence checks to ensure that Company B is within one of the standardised supply pathways in its permit, it can supply to Company B; a permit variation is not required.**

#### **EXAMPLE 3**

**Company C holds a Cannabis Research Licence and permit and is the sole supplier of genetic material to three companies that each hold a Medicinal Cannabis Licence and permit. Company C suddenly must cease trading due to unforeseen circumstances.**

**Under current arrangements, each company would need to lodge a permit variation application to obtain genetic material from a new contracted supplier. Under the proposed model, no variation would be required. However, each company will need to undertake due diligence checks to ensure the alternative supplier is within one of the standardised supply pathways in their permit.**

### *Supply contracts*

No change is proposed to the statutory condition that the licence holder is required to be a party to certain contracts during the period the permit is force.<sup>5</sup> However, administration of the current requirement to provide relevant contracts at the time of applying for a medicinal cannabis permit will be revised.<sup>6</sup> Instead, licence holders will be required to provide at least one commercial contract for the first permit after the licence has been granted, for a substantial portion of the quantities being applied for (i.e. this would be a commercial contract for supply, not for example for small amounts for testing purposes). While the permit will not specify particular suppliers and recipients (but rather categories of suppliers and

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<sup>5</sup> Section 19 of the *Narcotic Drugs Regulation 2016*.

<sup>6</sup> Section 9 of the *Narcotic Drugs Regulation 2016*.

recipients), the ODC will have the capacity to monitor whether permit holders are party to appropriate contracts during any period a permit is in force.

The contract(s) included with an application will not have to cover the entire quantity of cannabis to which the permit applied for relates. However, the ODC will require at least one supply contract to be provided at the time of applying for a permit. This measure will reduce the risk that a licence holder becomes operational without suitable supply arrangements in place, thereby minimising the risks of stockpiling. It also recognises that often the granting of the permit assists in undertaking commercial negotiations. The proposed approach therefore seeks to an appropriate balance between these two imperatives.

Additionally, a licence holder's permit history will be a relevant consideration in granting future permits. For example, a licence-holder's subsequent permit applications may not result in permits being granted for the total amount applied for, if there is a past history involving a large disparity between the total amount of cannabis applied for under a permit and the amounts actually supplied over the permit period.

#### **SUMMARY**

**The removal of strains, bespoke supply pathways and schedules from permits is expected to benefit industry:**

- **with permit requirements being easier to understand**
- **by limiting the need for permit variations to increase quantities, or permission to cultivate cannabis with higher level of THC, as long as it is below the existing maximums for these as specified in the permit**
- **allowing quick response to market demands without requiring permit variations.**
- **cost savings, with need for seeking permit variations expected to decrease.**

## Reporting

Currently all licence holders are required to maintain records of the activities conducted under licence including information relating to strains, quantities, location and details of suppliers and recipients.

Under the proposed model, all permit holders will be required to periodically provide a report detailing the previous month's actual business operations and planned operations for the coming month. The report, depending on licence type, would include detail such as:

- propagation materials, such as seed or tissue culture (sourced or created)
- plant numbers, including detail of strain and THC range, cultivated
- production (harvest) details, including strain and quantity
- drugs manufactured, including detail such as source of material used in such manufacture, and
- details of any supply, including the name, contact details and authority to receive (such as Narcotic Drugs Act licence holder, state/territory licence, GMP licence etc).

The ODC recognises that some of this information is currently difficult to predict in advance of a permit being granted. Accordingly, the ODC proposes to obtain this information under reporting obligations.

Industry is not expected to be significantly impacted by this change, noting that licence holders are already required to maintain records of activities undertaken under existing licence and permit requirements and to provide information to the ODC when requested. The ODC will engage with industry before settling on reporting requirements.

#### SUMMARY

**In lieu of providing detailed information at the time of application to be included in a permit, licence holders will be required to periodically report on the actual and forecast activities conducted under the permit.**

## Proposed Model

### Proposed application information requirements

Typically, a licence holder will need to supply the following information:

- the site to which the permit relates
- the period for which the permit is sought
- the maximum quantities for both low and high THC materials:
  - for cultivation permits:
    - maximum amounts of genetic material to be obtained or harvested by the applicant over the period of the permit
    - maximum quantity of plants to be grown over the period of the permit
    - maximum quantity of plants to be in the licence holder's control under the permit at any given time
  - for production permits:
    - maximum amount of cannabis or cannabis resin to be produced over the period of the permit
    - maximum amount of cannabis plants, cannabis or cannabis resin to be in the licence holder's control under the permit at any given time
  - for manufacture permits:
    - maximum amount of drugs to be manufactured over the period of the permit
    - maximum amount of starting material and drugs to be in the licence holder's control under the permit at any given time
  - for all permit types, the quantity of waste material that may be held onsite prior to destruction occurring
- proposed strain information will be relevant to include in the application to confirm the intended arrangements and will be readily known by the applicant; although strain information will no longer be prescribed on the permit itself, and
- details of at least one forward supply pathway, including an executed contract.
  - the entire quantity sought in the permit does not have to be proven by supplying contracts but justification for the quantities applied for will need to be provided. Proving that the entire quantity applied for is accounted for by executed arrangements may increase the likelihood that the permit will be granted for the full amount requested.

## Proposed matters to be specified in the permit

In general a permit will specify the following information:

- the relevant licence and site to which the permit pertains
- the maximum quantities in low and high THC categories:
  - for permits allowing cultivation:
    - maximum amounts of genetic material to be obtained or harvested by the applicant over the period of the permit
    - maximum quantity of plants to be grown over the period of the permit
    - maximum quantity of plants to be in the applicant's control at any given time
  - for permits allowing production:
    - maximum amount of cannabis or cannabis resin to be produced over the period of the permit
    - maximum amount of cannabis plants, cannabis or cannabis resin to be in the applicant's control at any given time
  - for manufacture permits:
    - maximum amount of drugs to be manufactured over the period of the permit
    - maximum amount of drugs and starting material to be in the licence holder's control under the permit at any given time, and
  - all permits will also include a maximum quantity of un-processed waste material that can be held onsite at any given time. Records relating to cannabis waste would also need to be kept.

Generally, permits will not specify bespoke supply pathways to particular entities. Rather, categories of authorised entities to/with whom supply may be undertaken will be included on a consistent basis for each kind of permit.

## Benefits and responsibilities under the proposed model

The proposed model reflects a shift in the approach to managing risks arising across the Scheme. Under this approach, the application assessment functions will not seek to manage every potential risk, particularly where monitoring and compliance action could be more appropriate or effective. There will, therefore, be a greater focus on monitoring and compliance activities following the grant of permits, as a consequence of implementing the proposed model. This appropriately recognises that the ODC's permitting function exists within the broader suite of its regulatory functions and powers.

The proposed revised approach will also allow permit holders the flexibility to undertake activities without requiring direct authorising action from the ODC for every matter.

The main changes relate to the matters to be specified in the permit itself. The permit application process will largely not change, as all of the information required will be considered as part of making the decision whether to grant or refuse to grant a permit. However, specific details about particular supply pathways and detailed cultivation/production schedules for particular strains will no longer be specified in the permit itself. This will mean that permit holders will no longer need to seek variations in circumstances where their supply pathways change or where, due to the vagaries of nature, their cultivation or production schedule changes. It is intended that these changes will create



greater flexibility for industry to operate swiftly in accordance with the changing commercial environment, as long as this is within the overall maximum amounts prescribed in the permit.

The ODC will not grant speculative permits (where there are no supply pathways to lawful recipients determined). To this extent the ODC will still require information about the proposed legitimate source of the plants (even if it is not detailed down to the strain level) and will need to be satisfied of the existence of at least one substantial supply pathway. While bespoke supply pathways will generally no longer be specified in permits, relevant information provided in applications must genuinely reflect what the licence holder intends to undertake so it is clear that supply is legitimate. A licence or permit can be suspended or revoked if it was obtained or varied on the basis of information that was false or misleading in a material particular.<sup>7</sup>

Currently, the ODC ensures that the proposed supply pathways are legitimate as part of its assessment and, therefore, a supply pathway specified in the permit can be relied upon as legitimate. As there will be no specification of particular entities with whom supply is authorised in the proposed revised model, licence holders can no longer rely on the ODC to authorise their supply pathways and instead will have the primary responsibility to ensure their integrity.

As part of its monitoring and compliance activities, the ODC may examine whether a change from the original supply pathway can be reasonably explained (for example, if the substantial supply pathway nominated in the application is not utilised at all despite the originally nominated entity still operating).

If a licence holder is found to have failed to undertake due diligence regarding the legitimacy of the suppliers they obtain cannabis plants or cannabis resin from, or the entities they supply cannabis plants, cannabis resin or manufactured drugs to, they may be subject to regulatory compliance actions. Compliance action may be considered appropriate if, for example, the requirements of a permit have been breached because supply to an unauthorised recipient has occurred (being an entity not included in one of the categories of entities to/from whom supply may be undertaken).

#### SUMMARY

- **Permit holders will have greater flexibility to manage operations but must do so within the maximums specified in their permits, or could be subject to compliance action.**
- **ODC will no longer ensure proposed supply pathways are legitimate prior to supply activities being undertaken.**
- **The permit holder will be required to conduct their own due diligence and, if found to be non-compliant, may be subject to compliance action.**

## Proposed legislative changes

It is anticipated that the proposed revised model could be given effect without any legislative changes being required under the current three-licence framework. The Act gives the Secretary a wide discretion as to what matters can be specified in a permit, and to what

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<sup>7</sup> See, eg, s 10P of the Act.

conditions can be imposed on a licence. The proposed changes are largely administrative, with data collection and analysis becoming a record keeping and reporting obligation on which compliance monitoring will be undertaken.

Legislative changes may be required to give effect to the model after the transition to a single licence model. In particular, cannabis research and cannabis-related manufacture may require some considerations currently relevant to licences to be reflected in permits instead. However, the necessary changes will be considered at that time.

In relation to fees, the work effort involved in assessing and granting permits under the revised model will be monitored and applicable fees modified, if warranted, through the annual review of fees and charges for the Scheme. There may, however, be greater costs associated any increase in monitoring or compliance activity.

## Transitional arrangements

### SUMMARY

- **Legislative changes will be limited**
- **Changes will primarily be administrative with data collection and analysis moving from the assessment phase to monitoring and compliance.**

The ODC will need to consider the transitional arrangements once decisions are made in relation to the proposed revised permit model. This could include a staged approach for existing permit holders where their permits are converted to the new model at the expiry of their existing permit or at some other time. Another option is to convert all existing permits to the new model on the same day as the introduction of the new permit arrangement.

The ODC invites comments and observations on issues to be considered and managed in transitioning from current permit arrangements to the proposed new model.

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All information in this publication is correct as at November 2020

