EXPLANATORY STATEMENT

Narcotic Drugs Act 1967

Narcotic Drugs Amendment (Cannabis-Related Manufacture Licences and Permits) Regulations 2020

The *Narcotic Drugs Act 1967* (the Act) gives effect to certain of Australia's obligations under the Single Convention on Narcotic Drugs 1961 (the Convention), as in force from time to time. The objective of the Convention is to establish a framework to both prevent abuse and diversion of controlled narcotics and to ensure the availability of such drugs for medicinal and scientific purposes.

Section 27 of the Act provides for the Governor-General to make regulations prescribing matters required or permitted by the Act to be prescribed, or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

The purpose of the *Narcotic Drugs Amendment (Cannabis-Related Manufacture Licences and Permits) Regulations 2020* (the Regulations) is to update fees to complete the implementation of changes to cost-recovery arrangements for the medicinal cannabis scheme (the Scheme) under the Act, administered by the Department of Health.

The Regulations amend the *Narcotic Drugs Regulation 2016* (the Principal Regulation) to complete implementation of the findings from an extensive activity based costing review of fees and charges for the Scheme (the costing review) that was carried out in late 2019 and early 2020.

Specifically, the Regulations:

- apply the fee structure which currently relates to cannabis licences and cannabis permits in the Principal Regulation to cannabis-related manufacture licences and cannabis-related manufacture permits;
- introduce a fee structure for concurrent applications for *three* licences at the same site; and
- extend the concept of commercial and non-commercial licences for undertaking research to cannabis-related manufacture licences.

The findings on charges for cannabis–related manufacture licences are implemented by the *Narcotic Drugs (Licence Charges) Amendment (Cannabis-Related Manufacture Licences) Regulations 2020*, which commence concurrently with the Regulations.

Currently, there are no fees payable in relation to manufacture licences or permits under the Act, although fees are payable in relation to cannabis licences and permits. Following the commencement of the Regulations, fees will be payable for cannabis-related manufacture licences and permits. However they do not introduce any fees for manufacture licences or permits that do not relate to cannabis.

The costing review identified that cost recovery arrangements should be extended to cannabis-related manufacture licences and permits to ensure adequate cost recovery for the work that the Department of Health carries out across tasks such as granting licences and permits, generating invoices and undertaking compliance inspections. The Regulations implement cost recovery arrangements for the Scheme that are consistent with the Australian Government Cost Recovery Guidelines, specifically by removing cross-subsidisation and ensuring that the Department of Health adequately recovers the costs of regulating the Scheme from those participating in it.

The Regulations classify cannabis-related manufacture licences as commercial or non-commercial, similarly to the classification of cannabis research licences as such by the Principal Regulation. This classification provides for a limitation on the amount of charge payable by a non-commercial licence holder under the *Narcotic Drugs (Licence Charges) Regulations 2016* as a means to encourage investment in research related to medicinal cannabis. A cannabis-related manufacture licence will be a non-commercial cannabis-related manufacture licence if the manufacturing to be undertaken will be for research for non-commercial purposes, or primarily for research for non-commercial purposes.

The Department of Finance was consulted and agreed to the cost recovery model, on the basis that it complied with Australian Government Cost Recovery Guidelines, which is reflected in the Regulations. A cost recovery implementation statement was prepared in relation to the applicable licence charges. The Office of Drug Control (ODC) within the Department of Health hosted six engagement sessions with interested parties from November 2019 to early February 2020. The sessions covered findings from the review of the Medicinal Cannabis Cost Recovery Framework and sought feedback on proposed changes to the fees and charges under the Act. Stakeholders, including industry representatives, regulatory consultants and State and Territory government officials attended the public meetings and made submissions to the review. A consultation paper was also published by the ODC in early February 2020, seeking public feedback on the outcomes of the costing review and proposed changes to fees and charges.

The feedback at both the public forums and in written submissions was generally supportive of the changes. Feedback was provided acknowledging that the imposition of fees and charges on non-commercial research licence holders should be carefully considered so as not to unduly burden such entities or have an inhibiting effect on research. This matter has been considered and addressed in the revised cost model. The medicinal cannabis industry sector has acknowledged that a more robust cost recovery framework will provide the appropriate level of resources to regulate the scheme.

Details of the Regulations are set out in the Attachment.

The *Narcotic Drugs Act 1967* specifies no conditions that need to be satisfied before the power to make the Regulations may be exercised.

The Regulations is a legislative instrument for the purposes of the *Legislation Act 2003* and commence on 1 November 2020.

Authority: Subsection 27(1) of the *Narcotic Drugs Act 1967*

ATTACHMENT

Details of the *Narcotic Drugs Amendment (Cannabis-Related Manufacture Licences and Permits) Regulations 2020*

Section 1 – Name
This section provides for the Regulations to be referred to as the *Narcotic Drugs Amendment (Cannabis-Related Manufacture Licences and Permits) Regulations 2020.*

Section 2 – Commencement
This section provides for the commencement of the Regulations on 1 November 2020.

Section 3 – Authority
This section provides that the Regulations are made under the *Narcotic Drugs Act 1967* (the Act).

Section 4 – Schedules
This section provides that each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to the Regulations has effect according to its terms.

Schedule 1 – Amendments

Narcotic Drugs Regulation 2016

Item 1
This item amends section 4 of the *Narcotic Drugs Regulation 2016* (the Principal Regulation) to provide for the addition of four new defined terms to ensure that cannabis-related licences and permits can be subject to fees and charges while excluding licences and permits for manufacturing other narcotics. These terms are:

- cannabis-related licence;
- cannabis-related manufacture licence;
- cannabis-related manufacture permit; and
- cannabis-related permit.

A ***cannabis-related manufacture licence*** is defined as a manufacture licence that will authorise the manufacture of a drug that includes, or is from, any part of the cannabis-plant.

A ***cannabis-related manufacture permit*** is defined as a manufacture permit relating to the manufacture of a drug that includes, or is from, any part of the cannabis plant.

The above two definitions require that the relevant licence or permit is a 'manufacture licence' or 'manufacture permit' as defined by the Act. The definitions do not cover licences or permits that are issued under other Commonwealth, State or Territory laws.

Cannabis-related licence is defined to mean a cannabis licence or a cannabis-related manufacture licence. 'Cannabis licence' is a term defined in the Act, and means a medicinal cannabis licence or a cannabis research licence.

Cannabis-related permit is defined to mean a cannabis permit or a cannabis-related manufacture permit. 'Cannabis permit' is a term defined in the Act, and means a medicinal cannabis permit or a cannabis research permit.

Item 2
This item inserts a new paragraph 35(2)(fa), which facilitates the operation of new section 54AB, which will be inserted by Item 7 below, by prescribing a new information requirement for an application for a cannabis–related manufacture licence where the applicant is seeking a decision of the Secretary as to whether the licence is commercial or non-commercial.

Item 3
This item inserts a new section 36AA which prescribes an application fee for a cannabis-related manufacture licence.

Item 4
This item inserts a new section 38A which prescribes an application fee for a cannabis-related manufacture permit.

Item 5
This item inserts a new section 43A which prescribes an application fee for a variation of a cannabis-related manufacture licence or cannabis-related manufacture permit.

Item 6
This item amends section 52 of the Principal Regulation to provide that decisions made under new sections 54AA and 54AB, to be inserted by Item 7, will be *reviewable decisions* within the meaning of section 15E of the Act.

Item 7
This item inserts new sections 54AA and 54AB, which provide for cannabis-related manufacture licences to be classified as commercial or non-commercial. This classification impacts on the licence charge that will be payable by the licence holder.

New section 54AA deals with licence applications that are made before 1 November 2020 and new section 54AB deals with licence applications that are made on or after 1 November 2020.

New Section 54AA

For licence applications made before 1 November 2020, the avenue for the consideration of a cannabis-related manufacture licence as commercial or non-commercial did not exist. Section 54AA addresses this matter by providing for cannabis-related manufacture licences granted on the basis of an application made before 1 November 2020 to be considered as a commercial licence, unless the Secretary decides otherwise, on application by the licence holder, in accordance with the section.

Subsection 54AA(1) provides that section 54AA applies to licences that are granted on the basis of an application made before 1 November 2020.

Subsection 54AA(2) provides that all cannabis-related manufacture licences that are granted on the basis of an application made before 1 November 2020 are considered to be a commercial licence, unless the Secretary has notified the applicant that it is a non-commercial cannabis-related manufacture licence in accordance with subsection (3).

Subsection 54AA(3) provides that a licence holder may apply to the Secretary for a decision as to whether the cannabis-related manufacture licence granted on the basis of an application made before 1 November 2020 is a non-commercial cannabis-related manufacture licence. The cannabis-

related manufacture licence will be a non-commercial cannabis-related manufacture licence if the Secretary is reasonably satisfied that the relevant manufacturing under the licence will be undertaken for research for non-commercial purposes, or primarily for research for non-commercial purposes, and notifies the applicant in writing accordingly.

Subsection 54AA(4) sets out the information requirements for an application under subsection 54AA(3).

Subsections 54AA (5) and (6) provide that the Secretary, in making a decision under subsection (3), must have regard to the matters in the information requirements under subsection 54AA(4), and may have regard to other matters.

New Section 54AB

For licence applications that are made on or after 1 November 2020, section 54AB will require the Secretary to make a decision on the classification of a cannabis-related manufacture licence as commercial or non-commercial and to notify the applicant in writing at the time of the grant of licence.

Subsection 54AB(1) provides that section 54AB applies to licences that are granted on the basis of an application made on or after 1 November 2020.

Subsection 54AB(2) provides that a cannabis-related manufacture licence is a commercial cannabis-related manufacture licence unless Secretary notifies the applicant, at the time of granting the licence, that it is a non-commercial cannabis-related manufacture licence in accordance with subsection (3).

Subsection 54AB(3) provides that at the time of granting the licence, if the Secretary is reasonably satisfied that the relevant manufacturing under the licence will be undertaken for research for non-commercial purposes, or primarily for research for non-commercial purposes, the Secretary must notify the applicant in writing accordingly.

Subsection 54AB(4) sets out the matters that the Secretary must have regard to in making a decision under subsection (3).

Subsection 54AB(5) provides that the Secretary may also have regard to other matters.

Item 8

Item 8 inserts new section 60 which provides for the application of provisions relating to the Regulations. Subsection 60(1) provides that the new information requirement for an application for a cannabis-related manufacture licence, provided for by Item 2, applies in relation to applications made on or after 1 November 2020.

Subsection (2) provides that application fees are prescribed in relation to applications for a cannabis-related manufacture licence, a cannabis-related manufacture permit, or a variation of a cannabis-related manufacture licence or cannabis-related manufacture permit, made on or after 1 November 2020.

Subsection (3) provides that the amendments to Schedule 1 by the Regulation apply in relation to applications made on or after 1 November 2020.

Item 9
This item amends the note to the heading of Schedule 1 to insert references to the provisions inserted by Items 3, 4 and 5.

Item 10
This item repeals the table in clause 1 of Schedule 1 of the Principal Regulation and replaces it with a new table that sets out application fees relating to cannabis-related licences and cannabis-related permits.

Item 1 provides for an application fee for a cannabis-related licence, except an application covered by item 2 or 3.

Item 2 provides for a fee for two concurrent licence applications relating to the same licenced premises. This fee applies where the application is for any two of the three categories of relevant licences, being medical cannabis licence, cannabis research licence and cannabis-related manufacture licence.

Item 3 provides for a fee for concurrent licence applications relating to the same licenced premises for all three categories of relevant licences, being medical cannabis licence, cannabis research licence and cannabis-related manufacture licence.

Item 4 provides an application fee for a cannabis related permit.

Items 5, 6, 7 and 8 give effect to the fee for an application for variation of a cannabis-related licence or a cannabis-related permit by way of an administrative instrument published on the Department of Health's website, defined in the Principal Regulation as the variation application specification document. This is in accordance with the authority of subsection 28(2) of the Act which authorises the regulations to make provision in relation to a matter by applying, adopting or incorporating, with or without modification, any matter contained in an instrument or other document despite section 14 of the *Legislation Act 2003*. The relevant instrument is freely accessible and free for use.

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*

Narcotic Drugs Amendment (Cannabis-Related Manufacture Licences and Permits) Regulations 2020

The *Narcotic Drugs Amendment (Cannabis-Related Manufacture Licences and Permits) Regulations 2020* (the Regulations) are compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Legislative Instrument

The purpose of the *Narcotic Drugs Amendment (Cannabis-Related Manufacture Licences and Permits) Regulations 2020* (the Regulations) is to update fees to complete the implementation of changes to cost-recovery arrangements for the medicinal cannabis scheme (the Scheme) under the *Narcotic Drugs Act 1967* (the Act), administered by the Department of Health.

The Regulations amend the *Narcotic Drugs Regulation 2016* (the Principal Regulation) to complete implementation of the findings from an extensive activity based costing review of fees and charges for the Scheme (the costing review) that was carried out in late 2019 and early 2020.

Specifically, the Regulations:

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The Regulations classify cannabis-related manufacture licences as commercial or non-commercial, similarly to the classification of cannabis research licences as such by the Principal Regulation. This classification provides for a limitation on the amount of charge payable by a non-commercial licence holder under the *Narcotic Drugs (Licence Charges) Regulations 2016* as a means to encourage investment in research related to medicinal cannabis. A cannabis-related manufacture licence will be a non-commercial cannabis-related manufacture licence if the manufacturing to be undertaken will be for research for non-commercial purposes, or primarily for research for non-commercial purposes.

Human rights implications

As the Regulations do not introduce any changes to the Principal Regulation other than to implement the changes outlined above, they do not engage any of the applicable rights or freedoms.

Conclusion

The Regulations are compatible with human rights as they do not raise any human rights issues.

Greg Hunt, Minister for Health