

EXPLANATORY STATEMENT

Narcotic Drugs (Licence Charges) Act 2016

Narcotic Drugs (Licence Charges) Amendment (Cannabis-Related Manufacture Licences) Regulations 2020

The *Narcotic Drugs (Licence Charges) Act 2016* (the Act) enables the Commonwealth to impose a charge on a licence granted under the *Narcotic Drugs Act 1967* (the ND Act) and that is in force within a specified period.

Section 9 of the Act provides that the Governor-General may make regulations prescribing all matters that are required or permitted to be prescribed, or which are necessary or convenient to be prescribed to give effect to the Act.

The purpose of the *Narcotic Drugs (Licence Charges) Amendment (Cannabis-related Manufacture Licences) Regulations 2020* (the Regulations) is to update licence charges to complete the implementation of changes to cost-recovery arrangements for the medicinal cannabis scheme (the Scheme) under the ND Act, administered by the Department of Health.

The Regulations amend the *Narcotic Drugs (Licence Charges) 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 charging structure which currently relates to cannabis licences and cannabis permits in the Principal Regulation to cannabis related-manufacture licences
- extend the concept of commercial and non-commercial licences to cannabis-related manufacture licences to limit the charge on non-commercial licence holders.

The findings on fees for cannabis-related manufacture licences and permits are implemented by the *Narcotic Drugs Amendment (Cannabis-Related Manufacture Licences and Permits) Regulations 2020*, which commence concurrently with the Regulations.

Currently, there are no licence charges payable by the holder of a manufacture licence granted under the ND Act, although charges are payable by other kinds of medicinal cannabis licence holders. Following commencement of the Regulations, holders of a cannabis-related manufacture licence will pay an annual charge. However, there will be no implications for licences granted for the manufacture of other narcotics.

The Regulations provide for licences classified as non-commercial cannabis-related manufacture licences under the *Narcotic Drugs Amendment (Cannabis-Related Manufacture Licences and Permits) Regulations 2020* to have a limit imposed on the annual charges payable as a means to encourage investment in research related to medicinal cannabis. Non-commercial cannabis licence holders will be subject to both a licence charge incurred following the grant of a licence and a site charge incurred following grant of a permit. However, non-commercial cannabis licence holders will only be subject to each of these charges once during the period of the licence, compared with the requirement for commercial licence holders to pay such charges annually.

The costing review identified that cost recovery arrangements should be extended to cannabis-related manufacture licences and permits to ensure the adequate recovery of the costs 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 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 ND 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 cost recovery 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 Act 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: Section 9 of the *Narcotic Drugs (Licence Charges) Act 2016*

Details of the Narcotic Drugs (Licence Charges) Amendment (Cannabis-Related Manufacture Licences) Regulations 2020

Section 1 – Name

This section provides for the Regulations to be referred to as the *Narcotic Drugs (Licence Charges) Amendment (Cannabis-Related Manufacture Licences) 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 (Licence Charges) Act 2016* (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 (Licence Charges) Regulation 2016

Item 1

This item inserts new definitions of:

- cannabis-related manufacture licence;
- commercial cannabis-related manufacture licence; and
- non-commercial cannabis-related manufacture licence.

These terms are defined by incorporating the definition of these terms in the *Narcotic Drugs Regulation 2016*, for consistency with the identification of the item in relation to the imposition of fees under that Regulation. These definitions are incorporated as in force from time to time, as permitted by section 14 of the *Legislation Act 2003*.

Items 2 and 3

These items each insert a new paragraph (d) and (e) at the end of subsections 5(1) and 6(1) respectively of the *Narcotic Drugs (Licence Charges) Regulation 2016* (the Principal Regulation). The new paragraph references cannabis-related manufacture licences as being a class of licence to which section 5 (Periods for imposition of charge on licences) and section 6 (Amount of charge for licences) relates.

Items 4 and 5

These items amend paragraph 6(4)(c) of the Principal Regulation, which relates to the testing of samples, to also include samples taken in the exercise of a power under section 24 of the *Narcotic Drugs Act 1967* in relation to a licence.

Item 6

This item incorporates non-commercial cannabis-related manufacture licences in subsections 6(5) and 6(6) of the Principal Regulation, which currently provide for limits on charge for non-commercial cannabis research licences. This is done by repealing the subsections and substituting provisions that list both non-commercial cannabis research licences and non-commercial cannabis-related manufacture licences as kinds of licences on which charge is limited.

Item 7

This item sets out application provisions relating to the Regulations.

Subsection 9(1) confirms the section provides for the application of the Principal Regulation as amended by the Regulations.

Subsection 9(2) provides that the definition of ‘licence year’ in subsection 5(2) applies to cannabis-related manufacture licences, regardless of when they came into force.

Subsection 9(3) and (4) provide that the licence charge under paragraph 6(2)(a) applies to licence years that start before 1 November and end on or after 1 November on a *pro rata* basis.

Subsections 9(5) and (6) provide that paragraph 6(2)(b), which applies where a permit is in force, applies to a charge on a cannabis-related manufacture licence for a licence year that starts before 1 November 2020 and ends on or after 1 November on a *pro rata* basis. The relevant formula for determining the amount depends on whether any of the permits are in force on 1 November 2020, but each formula has the effect of only counting the days in the licence year which are after 1 November 2020 and during which the permits are in force.

Subsection 9(7) provides that paragraph 6(2)(c) (such as monitoring, investigations, testing) (such as monitoring, investigations, testing), which provides for charge for activities covered by subsection 6(4), applies to charge on a cannabis-related manufacture licence for licence years that end on or after 1 November 2020 for activities that are carried out after 1 November 2020.

Statement of Compatibility with Human Rights

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

Narcotic Drugs (Licence Charges) Amendment (Cannabis-Related Manufacture Licences) Regulations 2020

The *Narcotic Drugs (Licence Charges) Amendment (Cannabis-Related Manufacture Licences) 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 Regulations are made under section 9 of the *Narcotic Drugs (Charges) Act 2016* (the Act).

The purpose of the *Narcotic Drugs (Licence Charges) Amendment (Cannabis-related Manufacture Licences) Regulations 2020* (the Regulations) is to update licence charges to complete the implementation of changes to cost-recovery arrangements for the medicinal cannabis scheme (the Scheme) under the *Narcotic Drugs Act 1967* (the ND Act), administered by the Department of Health.

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The Regulations provide for licences classified as non-commercial cannabis-related manufacture licences under the *Narcotic Drugs Amendment (Cannabis-Related Manufacture Licences and Permits) Regulations 2020* to have a limit imposed on the annual charges payable as a means to encourage investment in research related to medicinal cannabis. Non-commercial cannabis licence holders will be subject to both a licence charge incurred following the grant of a licence and a site charge incurred following grant of a permit. However, non-commercial cannabis licence holders will only be subject to such charges once during the period of the licence, compared with the requirement for commercial licence holders to pay such charges annually.

Human rights implications

As the Regulations do not introduce any changes to the Charges 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