EXPLANATORY STATEMENT

Narcotic Drugs Act 1967

Narcotic Drugs Amendment (Licence Charges) Regulation 2016

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 medical and scientific purposes.

The Act regulates the cultivation of cannabis plants for the production of cannabis and cannabis resins for medicinal and scientific purposes and the manufacture of drugs, such as morphine, of which Australia is the world's leading supplier for raw materials, as well as medicinal cannabis products. The medicinal cannabis framework in Australia has recently commenced operation. The framework authorises the lawful cultivation of cannabis plants and production of cannabis and cannabis resins in Australia in order to provide Australian patients with access to medicinal cannabis for therapeutic purposes. Australia's other obligations under the Convention are implemented in other Commonwealth legislation such as the *Criminal Code Act 1995*, the *Customs (Prohibited Imports) Regulations 1956* and the *Customs (Prohibited Exports) Regulations 1958*, as they relate to trafficking of drugs and import/export of drugs.

Subsection 27(1) 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. Paragraph 28(1)(e) of the Act authorises the regulations to provide for matters relating to the payment of charge, including the time and manner of payment, pro-rating, refunds, reduction, remission and waiving.

The purpose of the *Narcotic Drugs Amendment (Licence Charges) Regulation 2016* (the Regulation) is to provide for matters relating to the payment of licence charges in relation to cannabis licences granted under the Act. The Regulation specifies when a charge is due and payable in respect of a licence, who it is payable to, the recovery of licence charge that is due and payable, provides for the classes of cannabis research licences (commercial and non-commercial cannabis research licences) and the matters to which the Secretary of the Department of Health (the Secretary) must have regard in determining the cannabis research licence is for non-commercial purposes. Non-commercial cannabis research licence holders will only be required to pay one licence charge for the period for which the licence is in force, instead of for each period of 12 months that the licence is in force.

The imposition of licence charges forms part of the cost recovery arrangement in relation to the administration of medicinal cannabis framework. The Minister for Finance was consulted and agreed to the cost recovery model. A cost recovery implementation statement was prepared in relation to the applicable fees and licence charges. The Department of Health has consulted the public and stakeholders at a series of public meetings held in each state capital about the medicinal cannabis regulatory framework, applicable requirements and costs in the form of fees and charges. The Attorney-General's Department was consulted in relation to

the new reviewable decisions, and agreed with the inclusion of those new provisions in the list of decisions that are reviewable under the Regulation.

Details of the Regulation are set out in the Attachment.

The Act specifies no conditions that need to be satisfied before the power to make the Regulation may be exercised.

The Regulation would be a legislative instrument for the purposes of the *Legislation Act 2003* and would commence at the same time as *the Narcotic Drugs (Licence Charges) Regulation 2016*.

The *Narcotic Drugs (Licence Charges) Regulation 2016* commence on the day after it is registered.

The Minute recommends that the Regulation be made in the form proposed.

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

ATTACHMENT

Details of the *Narcotic Drugs Amendment (Licence Charges) Regulation 2016*

Section 1 – Name

This section would provide for the Regulation to be referred to as the *Narcotic Drugs Amendment (Licence Charges) Regulation 2016*.

Section 2 – Commencement

This section would provide for the Regulation to commence at the same time as the *Narcotic Drugs (Licence Charges) Regulation 2016* commences. *The Narcotic Drugs (Licence Charges)* Regulation commences on the day after it is registered. However, the provisions of the Regulation do not commence at all if the *Narcotic Drugs (Licence Charges) Regulation* does not commence.

Section 3 – Authority

This section would provide that the Regulation is made under the *Narcotic Drugs Act 1967* (the Act).

Section 4 – Schedules

This section would provide 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, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1 – Amendments

Narcotic Drugs Regulation 2016

Item 1 - After paragraph 11(2)(f)

Item 1 would insert a new paragraph 11(2)(fa) detailing the information required to be provided by an applicant for a non-commercial cannabis research licence in relation to the research that the applicant proposes to undertake under that licence.

Section 11 of the *Narcotic Drugs Regulation 2016* (the Principal Regulation) specifies the information that an applicant is required to provide with the application for a cannabis research licence. New paragraph 11(2)(f) requires additional details about the research that the applicant proposes to undertake under the licence, but only if the applicant seeks a decision from the Secretary under subsection 54A(2) of the Regulation (Item 3 refers) that the cannabis research licence is a non-commercial cannabis research licence. The information required relates to details with regard to the primary purpose of the research, who benefits from the research, how any products that may be developed as a result of the research will be used, the source of the funds for the research (such as government research grants) and who owns or operates the research facilities in which the research will be undertaken (such as a government research facility or a facility owned by the applicant for the licence).

Item 2 – At the end of section 52

Item 2 inserts new paragraph (h) in the list of reviewable decisions under section 52 of the Principal Regulation.

New paragraph (h) provides that a decision made by the Secretary under subsection 54A(2) that the research an applicant proposes to undertake will be for non-commercial purposes or primarily for non-commercial purposes is a reviewable decision under 15E of the Act. Thus sections 15F-15L relating to internal review by the Minister or internal reviewer, review by the Administrative Appeal Tribunal and procedures in relation to the review of decisions, apply to a decision about whether a research that an applicant proposes under a cannabis research licence will be undertaken for non-commercial purposes or primarily for non-commercial purposes.

Item 3 - After Division 1 of Part 5

Item 3 inserts a new Division 1A – Charges, in the Regulation consisting of new sections 54A, 54B, and 54C.

New section 54A

Subsection 54A(1) of the Regulation provides that a cannabis research licence is a commercial cannabis research licence, if when granting the licence, no decision is required to be made and be notified to the applicant under subsection 54A(2) of the Regulation.

Subsection 54A(2) of the Regulation requires the Secretary, when granting a cannabis research licence to notify the applicant in writing that the Secretary is reasonably satisfied that the research the applicant proposes to undertake will be undertaken for non- commercial purposes, or primarily for non-commercial purposes. This determination is primarily for the purposes of assessing the amount of charge to be imposed on the licence under section 6 of the *Narcotic Drugs (Licence Charges) Regulation 2016*.

Subsection 54A(3) provides that in making a decision under subsection 54A (2) about research that an applicant proposes to undertake, the Secretary is required to have regard to the following matters:

(a) the primary purpose of the research;
(b) who will benefit from the research;
(c) how any products that may be developed as a result of the research will be used;
(d) the source of funds for the research;
(e) who owns or operates the research facilities in which the research will be undertaken.

The Secretary may be inclined to decide that the proposed research by the applicant for a cannabis research licence is a non-commercial cannabis research licence if the research is a government funded research, it is proposed to be carried out in a government research facility, the research is proposed to be undertaken for the benefit of Australian patients in assessing efficacy of particular medicinal cannabis products **and** the applicant proposes to produce cannabis for the manufacture of medicinal cannabis products for clinical trials in order to further knowledge in relation to the efficacy of the product.

Subsection 54A (4) provides that subsection (3) does not limit the matters to which the Secretary may have regard in making a decision under subsection (2).

Section 54B

Paragraph 28(1)(e) of the Act authorises the regulations to provide for matters relating to the payment of charge, including the time and manner of payment, pro-rating, refunds, reduction, remission and waiving.

New section 54B provides that for the purposes of paragraph 28(1)(e) of the Act, the licence charge payable in respect of a licence is payable to the Secretary on behalf of the Commonwealth and is due to be paid by the licence holder on the day specified in an invoice given to the holder of the licence by the Secretary.

Section 54C

New section 54C provides that for the purposes of paragraph 28(1)(e) of the Act the charge that is due and payable by the licence holder is a debt due to the Commonwealth and may be recovered by the Secretary on behalf of the Commonwealth by action in court. Thus, where a licence is revoked prior to the end of the period stated in the copy of the licence given to the licence holder, the licence holder is still required to pay the licence charge. If in this particular example, the charge is not paid, that unpaid charge is a debt due to the Commonwealth and may be recovered by the Secretary on behalf of the Commonwealth.

Statement of Compatibility with Human Rights

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

Narcotic Drugs Amendment (Licence Charges) Regulation 2016

The *Narcotic Drugs Amendment (Licence Charges) Regulation 2016* is 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 (Licence Charges) Regulation 2016* (the Regulation) is to provide for matters relating to the payment of licence charges in relation to cannabis licences granted under the *Narcotic Drugs Act 1967*. The Regulation amends the Narcotic Drugs Regulation 2016. The Regulation specifies when a charge is due and payable in respect of a licence, who it is payable to, the recovery of licence charge that is due and payable, provides for the classes of cannabis research licences (commercial and non-commercial cannabis research licences) and the matters to which the Secretary of the Department of Health (the Secretary) must have regard in determining the cannabis research licence is for non-commercial purposes. Non-commercial cannabis research licence holders will only be required to pay one licence charge for the period for which the licence is in force, instead of for each period of 12 months, or part of that period, that the licence is in force.

Human rights implications

The Regulation only relates to the administrative arrangements relating to the payment and recovery of licence charges imposed in relation to cannabis licences granted under the Act and does not engage any of the applicable rights or freedom.

Conclusion

This legislative instrument is compatible with human rights as it does not raise any human rights issues.

Sussan Ley, Minister for Health and Aged Care