

EXPLANATORY STATEMENT

Narcotic Drugs Act 1967

Narcotic Drugs (Licence Charges) Amendment (Charge Amounts and Other Measures) Regulations 2021

The instrument increases charges for licences for medicinal cannabis related activities to support the recovery of the costs of administering the medicinal cannabis scheme.

The *Narcotic Drugs (Licence Charges) Act 2016* (the Charges Act) imposes annual charges on licences granted under the *Narcotic Drugs Act 1967* which relate to cannabis. The Office of Drug Control (ODC), which is part of the Department of Health (the Department), is responsible for administering the Act.

Section 9 of the Charges Act provides that the Governor-General may make regulations prescribing matters required or permitted by the Act to be prescribed. Subsection 8(1) of the Charges Act provides that the amount of the charge for a period is such amount as is prescribed by the regulations.

The main purpose of the *Narcotic Drugs (Licence Charges) Amendment (Charge Amounts and Other Measures) Regulations 2021* (the proposed Regulations) is to amend the *Narcotic Drugs (Licence Charges) Regulation 2016* (the Charges Regulation) to increase the annual charge set out in those regulations, for the financial year 2021-22. The Regulations complement the *Narcotic Drugs Amendment (Fees) Regulations 2021* which increase fees for medicinal cannabis related applications for the 2021-22 financial year.

The increase applies to the annual charges applying to medicinal cannabis licences, cannabis research licences and cannabis-related manufacture licences.

The increase is based on an indexation formula used to calculate adjustments to fees and charges based on the relevant work effort, and average salary rates for the Department of Health.

In applying this increase, the rounding policy is, for all amounts, to round to the nearest \$10.

In relation to consultation, the ODC undertook extensive stakeholder consultation during the review of the ODC's fees and charges, which led to the introduction of a new activities based costing model for ODC in 2020, and this included indicating to industry the new framework would include annual indexation of fees and charges. Further consultation with industry continues as part of ongoing industry stakeholder events relating to the ODC's reforms process.

Details of the proposed Regulations are set out in the [Attachment](#).

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

The Regulations are a legislative instrument for the purposes of the *Legislation Act 2003*.

The Regulations commence on 1 July 2021.

Authority: Section 9 of the *Narcotic Drugs
(Licence Charges) Act 2016*

Details of the Narcotic Drugs (Licence Charges) Amendment (Charge Amounts and Other Measures) Regulations 2021

Section 1 – Name

This section provides for the Regulations to be referred to as the *Narcotic Drugs (Licence Charges) Amendment (Charge Amounts and Other Measures) Regulations 2021*.

Section 2 – Commencement

This section provides for the commencement of the Regulations on 1 July 2021.

Section 3 – Authority

This section provides that the Regulations are made under the *Narcotic Drugs (Licence Charges) Act 2016*.

Section 4 – Schedules

This section provides that each instrument that is specified in a Schedule to the 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

Items 1, 2 and 6

These items divide the *Narcotic Drugs (Licence Charges) Regulation 2016* (the Charges Regulation) into Parts. This would be for the purpose of improving readability.

Items 3 to 5 – Paragraphs 6(2)(a) and (b), subparagraph 6(2)(c)(i)

These items amend the amount of each component of the charge in the Charges Regulations, from 1 July 2021, subject to the rounding policy.

Item 7– Section 10

This application item provides for the amended amounts to apply from 1 July 2021.

In terms of the components at paragraphs 6(2)(a) and 6(2)(b), these amendments have effect only in relation to charge for licence years that start on or after 1 July 2021.

The amendment to the component at paragraph 6(2)(c), which involves a charge relating to the undertaking of various listed activities, potentially affect the charge on a licence which licence year started prior to 1 July 2021. However, the amended amount only has effect in relation to activities carried out on or after 1 July 2021.

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 (2021 Measures No.1) Regulations 2021

The *Narcotic Drugs (Licence Charges) Amendment (2021 Measures No. 1) Regulations 2021* (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 Regulations

The Regulations are made under section 9 of the *Narcotic Drugs (Licence Charges) Act 2016*.

The purpose of the Regulations is to amend the *Narcotic Drugs (Licence Charges) Regulation 2016* (the Charges Regulation) to increase the annual charge set out in those regulations, for the financial year 2021-22.

The increase applies to the annual charges applying to medicinal cannabis licences, cannabis research licences and cannabis-related manufacture licences. This encompasses registered goods (including provisionally registered medicines), listed goods, biologicals and medical devices.

The increase is based on an indexation formula used to calculate adjustments to fees and charges based on the relevant work effort, and average salary rates for the Department of Health.

In applying this increase, the rounding policy was, for all amounts, to round to the nearest \$10.

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 and Aged Care