

EXPLANATORY STATEMENT

Narcotic Drugs Act 1967

Narcotic Drugs 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. 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. The *Narcotic Drugs Amendment Act 2016* recently amended the Act to implement a medicinal cannabis framework in Australia that 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.

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.

The primary purpose of the *Narcotic Drugs Regulation 2016* (the Regulation) is to make regulations necessary for carrying out, or to give effect to, the regulatory framework for the licensing of the cultivation of cannabis and the production of cannabis and cannabis resins for medicinal and scientific purposes, as well as in relation to the manufacture of drugs as provided for under the Act.

The key features of the medicinal cannabis framework under the Act include:

- two cannabis licences, one that authorises the cultivation of cannabis for the production of cannabis or cannabis resins for manufacture into medicinal cannabis products; the second that authorises research into the cannabis plant that is to be used for medicinal purposes. The latter could include research into growing conditions, cannabinoid yields from different strains, ensuring consistency in yields and other matters related to ensuring a safe, predictable raw material
- a strict 'fit and proper person' test that will be applied to licence applicants and their relevant business associates and that involves the consideration of a range of matters including criminal history, relevant business associates and family, financial status, business history and capacity to comply with licence conditions. Licence holders will also be expected to remain 'fit and proper' persons while they hold their licence. This test is explicitly designed to enable the exclusion of criminal elements, including persons involved or associated with persons involved in organised crime that may be

- tempted to use the licence scheme as cover for illegal activities. The fit and proper person requirements also apply to applicants for, and holders of, manufacture licences
- a need to demonstrate that a supply arrangement exists between a person cultivating or producing cannabis and a licensed manufacturer, in order to get a licence
 - a permit system for controlling how much cannabis can be produced. This will assist in meeting a key obligation of the Single Convention to prevent over-production. Other than in the case of research, a permit will not be granted for production unless a contract exists between the licence holder and a licensed manufacturer
 - conditions applying to the licence that ensures security of the crop so that it will not be diverted to illicit uses
 - substantial penalties for offences for breaches of conditions and for undertaking unauthorised activities
 - a comprehensive suite of regulatory controls, including: powers to give directions to licence holders, including the destruction of crops; inspection, monitoring and investigation powers; powers to issue infringement notices and seek civil penalties; and the capacity for the Secretary to accept enforceable undertakings and to seek injunctions – these are all designed to assist in ensuring the overall integrity of the system.

The Regulation also specifies the information and documentation that must be provided by an applicant at various key points – e.g. for an application for a licence and for a permit associated with a licence under the Act, for any variation of a licence or permit. The Regulation also sets out the arrangements relating to the suspension and revocation of licences and permits, the surrender of a licence, applicable fees and when fees may be reduced or waived.

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 is a legislative instrument for the purposes of the *Legislation Act 2003* and commences on 30 October 2016.

Commonwealth, State and Territory law enforcement and other agencies, the public and industry representatives were consulted in relation to the details of the Regulation. The Department of Health has consulted 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.

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

Details of the Narcotic Drugs Regulation 2016**Part 1 – Preliminary***Section 1 – Name*

This section provides for the Regulation to be referred to as the Narcotic Drugs Regulation 2016.

Section 2 – Commencement

This section provides that the Regulation commences at the same time as Schedule 1 of the *Narcotic Drugs Amendment Act 2016* commences (under section 2 of that Act, Schedule 1 of that Act will commence either on a day to be fixed by Proclamation or, if there is no proclamation, on 30 October 2016 (which is the day after the eighth month after receiving Royal Assent)).

Section 3 – Authority

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

Section 4 – Definitions

Section 4 of the Regulation sets out a number of definitions for the purposes of the Regulation, including for example the definition of a ‘drug related offence’, ‘starting material’ in relation to a drug and definitions of what is an identification document, certified true copy, and category A and B documents in connection with an application for a licence.

A drug related offence is defined as an offence against a law of the Commonwealth or a state or territory that:

- does not involve the cultivation or trafficking of drugs, but does involve the manufacture, supply, possession or use of drugs, or the possession of equipment or instructions for the manufacture of drugs; and
- is punishable by either a monetary penalty of any amount, or a maximum penalty of imprisonment for 12 months or more.

Part 2 – Licensing the cultivation of cannabis plants and the productions of cannabis etc.**Division 1 – Medicinal Cannabis licences and permits**

This Division outlines the information, documents and fees that an applicant would be required to provide as part of an application for a medicinal cannabis licence or permit. These licences and permits would be issued under Division 1 of Part 2 of Chapter 2 of the Act.

Section 5 – Application for medicinal cannabis licence – information requirements.

Section 5 of the Regulation prescribes, for the purposes of paragraph 8E(2)(a) of the Act, the information that an applicant would need to provide as part of an application for a medicinal cannabis licence.

Section 8E of the Act allows a person to apply to the Secretary for a medicinal cannabis licence and subsection 8E(2) of the Act requires, relevantly, that such applications contain the information, and are accompanied by the documents, prescribed in regulations for the purposes of that provision.

Subsection 5(2) requires an applicant to provide personal and other information required to identify the applicant and to enable the Department of Health to contact that person. Subsection 5(2) would also require information that would allow the Secretary of the Department of Health to determine whether any of the grounds identified under subsection 8G(1) of the Act for refusing the licence exist. The information that is required include details about the physical security of the cannabis plants, cannabis or cannabis resin, suitability of the location, facilities or proposed security arrangements at the land or premises where activities authorised by the licence will take place. Article 23 of the Single Convention requires that the licence granted by the national agency to specify the extent of the land to be used in the cultivation. Thus, information about the land and extent of land to be used for cultivation is also required to be provided by the applicant.

An essential requirement under the medicinal cannabis regulatory framework is the existence of legal supply arrangements between the cultivator and producer or a producer and a manufacturer. This is further codified by a requirement that a contract be in place before a permit can be granted. This will ensure that a licence cannot be granted unless the applicant can demonstrate a lawful use for the result of the authorised activities under the licence. This also discourages applications being made unless the applicant has appropriate supply arrangements that contemplate lawful use. In essence, patient demand, as evidenced by a suitable medicinal practitioner willing to prescribe a medicinal cannabis product, determines the amount of drug that can be manufactured and the number of cannabis plants to be cultivated to satisfy that demand. The requirement for that supply arrangement is set out in section 8J(2) to the effect that the Secretary can refuse to grant a licence if this arrangement is not in place.

Thus, information that supports the existence of an arrangement or arrangement that will be in place between the applicant and a producer (if the applicant is proposing to cultivate cannabis plants) and the applicant and a manufacturer (if the applicant proposes to produce cannabis or cannabis resins) must be provided by the applicant.

Subsections 5(3) and 5(4) prescribe the information that would be required for the purposes of establishing whether an applicant (whether a natural person or a body corporate) would be a fit and proper person under section 8A or 8B of the Act. The information required includes details of any convictions of the applicant for an offence against a law of the Commonwealth, a state or territory or another country, details of the connections and associations the applicant has with other persons (including but may not be limited to the applicant's relatives), the names and date of birth of each person who is a business associate (who holds a relevant financial interest or who is entitled to exercise relevant power in relation to the applicant's business or other business), information in relation to each person who holds a

relevant position in relation to the applicant's business that will undertake the activities, the applicant's previous business experience, whether the applicant is affected by bankruptcy and other relevant information.

Subsection 5(5) requires the applicant to provide information about their proposed record-keeping arrangements in relation to the number of cannabis plants and the amounts of cannabis or cannabis resins produced. Statistical returns on these matters are required to be furnished to the International Narcotic Control Board under article 20 of the Convention.

Subsection 5(6) outlines information that would need to be provided in respect of the applicant's procedures for employing or engaging suitable staff will comply with the requirements set out in subsection 10F(1) of the Act. It is a condition of a cannabis licence that the licence holder take all reasonable steps not to employ or engage specified persons to carry out a activities authorised by the licence. The specified persons are the following:

- (a) if the person is aged under 18 years of age; or
- (b) the person has been convicted of a serious offence (defined in section 4 of the Act) during the 5 years before the employment or engagement; or
- (c) the person is taken not to be suitable to carry out activities authorised by the licence under regulations made for the purposes of subsection 10F(2) of the Act; or
- (d) the person is included in a class of persons prescribed by the regulations for the purposes of this paragraph.

Subsection 5(7) outlines the general information about the applicant's security arrangements, including how the applicant will prevent unauthorised access to the location where the activities proposed to be covered by the licence would occur and the arrangements that would be put in place to control persons entering that location and the relevant premises or facilities.

Section 6 – Application for medicinal cannabis licence – document requirements

Section 6 of the Regulation prescribes, for the purposes of paragraph 8E(2)(c) of the Act, the documents that an applicant would need to provide as part of an application for a medicinal cannabis licence. The requirement to provide these documents is, under subsection 8E(2) of the Act, in addition to the information requirements in new section 5 of the Regulation outlined above.

Subsection 6(2) of the Regulation requires the provision of documents that that an applicant must provide to prove their identity under paragraph (2)(a). Applicants would be required to provide three certified true copies of identification documents (a Category A document or a Category B document) as defined under section 4 of the Regulation, one which must be Category A document. Section 4 of the Regulation provides that a copy of the document is a certified true copy if the copy is a certified to be a true copy by a person prescribed for the purposes of regulation 4 of the *Statutory Declarations Regulations 1993*. These regulations prescribe, among other persons, medical practitioners, bank officers, public servants, police officers and justices of the peace.

The other documents that an applicant would be required to provide with their application as listed in subsection 6(2) are the following:

- documents providing evidence that the applicant has a sound and stable financial background, and is not in financial circumstances that may significantly limit the

applicant's capacity to comply with the applicant's obligations under a licence, if granted.

- a site plan showing how the land at the location where the activities proposed to be covered by the licence would be used for the cultivation of cannabis plants and/or the production of cannabis or cannabis resin;
- a detailed floor plan of the relevant premises and facilities;
- standard operating procedures and policies;
- a risk management plan that will be used to manage risks associated with the activities to be carried out by the licence holder under the licence, including risks posed to the health and safety of people, or to the environment

Section 7 – Application fee for medicinal cannabis licence

This section prescribes that, for the purposes of subsection 8E(3) of the Act (which provides that, relevantly, an application for a medicinal cannabis licence must be accompanied by the prescribed application fee), the fee set out in the table in Schedule 1 is prescribed for that purpose.

Section 8 – Application for medicinal cannabis permit – information requirements

This section prescribes, for the purposes of paragraph 8P(2)(a) of the Act, the information that an applicant would need to provide as part of an application for a medicinal cannabis permit.

Section 8P of the Act allows a holder of a medicinal cannabis licence to apply to the Secretary for a medicinal cannabis permit in relation to activities that are authorised by the licence. Before a licence holder can commence any of the authorised activities, the licence holder must be granted a permit in relation to such a licence that specifies the activities, the number of cannabis plants to be cultivated, the number of cannabis plants (or seeds) that can be obtained to enable the licence holder to commence and maintain cultivation of cannabis plants and, if relevant, the amount of cannabis or cannabis resins that can be produced during the period of the licence. Subsection 8P(2) of the Act requires, relevantly, that such applications contain the information and are accompanied by the documents, prescribed in regulations for the purposes of that provision.

Subsection 8(2) of the Regulation prescribes general information requirements for this purpose and would require that an application for a medicinal cannabis permit must contain the applicant's name, licence number of the medicinal cannabis licence held by the applicant and the activities proposed to be authorised by the licence.

Subsections 8(3) and (4) of the Regulation respectively, specify additional information requirements where the permit is requested in relation to a licence holder whose licence authorises the cultivation of cannabis plants (e.g. information about the types and strains of cannabis plants proposed to be cultivated) and where the permit is requested in relation to a licence holder whose licence authorises the production of cannabis (e.g. information about the maximum quantity of cannabis or cannabis resin proposed to be produced).

If both apply, then the licence holder would need to provide both sets of additional information.

Section 9 – Application for medicinal cannabis permit –document requirements

Section 9 of the Regulation prescribes, for the purposes of paragraph 8P(2)(c) of the Act, the documents that an applicant would need to provide as part of an application for a medicinal cannabis permit.

The requirement to provide these documents is, under subsection 8P(2) of the Act, in addition to the information requirements in section 8 outlined above.

Subsection 9(2) of the Regulation requires any holder of a medicinal cannabis licence who applies for a medicinal cannabis permit to provide the documents listed in subparagraphs 9(2)(a)(i) – (iv) with their application. These documents provide support that the cultivation is for the purpose of supply to the holder of a medicinal cannabis licence that authorises production, or the production of the cannabis or cannabis resins for medicinal purposes is for the purposes of supply to the holder of a licence under the Act that authorises the manufacture of one or more drugs that are medicinal cannabis products or the manufacture of a drug for the purpose of research relating to medicinal cannabis products, unless the applicant holds a licence that authorises manufacture. Under paragraph 9(2)(b) of the Regulation, a licence holder who applies for a permit and who proposes to cultivate cannabis plants must also provide evidence of the types and strains of cannabis plants proposed to be cultivated and the range of concentrations of individual major cannabinoids likely to be in those plants.

Section 10 – Application fee for medicinal cannabis permit

Section 10 of the Regulation prescribes that, for the purposes of subsection 8P(3) of the Act (which provides that, relevantly, an application for a medicinal cannabis permit must be accompanied by the prescribed application fee), the fee set out in the table in Schedule 1 is prescribed for that purpose.

Division 2 – Cannabis research licences and permits

This Division outlines the information, documents and fees that an applicant would be required to provide as part of an application for a cannabis research licence or permit. These licences and permits would be issued under Division 2 of Part 2 of Chapter 2 of the Act.

Section 11 – Application for cannabis research licence – information requirements.

Section 11 of the Regulation prescribes, for the purposes of paragraph 9D(2)(a) of the Act, the information that an applicant would need to provide as part of an application for a cannabis research licence.

Subsection 11(2) of the Regulation broadly requires an applicant for a cannabis research licence to provide the same kinds of information as for an applicant for a medicinal cannabis licence (section 5 above refers), such as information identifying the applicant (e.g. name and date of birth in relation to a natural person, and ACN or ABN or ARBN, in the case of a body corporate applicant) and details of the location where the activities that would be covered by the licence are proposed to be carried out and details relating to how the physical security of cannabis plants, cannabis or cannabis resin would be achieved. Some additional, research specific information would also be required under paragraphs 11(2)(f) and (g) with

respect to how the proposed research would relate to medicinal cannabis or medicinal cannabis products and, under paragraph 11(2)(h), with respect to demonstrating that the applicant has the resources and expertise to conduct such research.

ACN, ABN and ARBN have the same meaning given by section 9 of the Corporations Act 2001 (section 4 of the Regulation refers).

Subsections 11(3) and (4) of the Regulation prescribe the information required to be provided for the purposes of establishing whether an applicant who is, respectively, a natural person or a body corporate is a fit and proper person under sections 8A and 8B of the Act respectively – for example, the details of any convictions of the applicant or (in the case of a body corporate) the applicant’s directors or officers, for an offence against a law of the Commonwealth, a state or territory or of another country.

Subsection 11(7) of the Regulation requires an applicant to provide details of the applicant’s proposed security arrangements – these would be equivalent to the requirements for a medicinal cannabis licence applicant outlined under subsection 5(7) above.

Section 12 – Application for cannabis research licence –document requirements.

Section 12 of the Regulation prescribes, for the purposes of paragraph 9D(2)(c) of the Act, the documents that an applicant would need to provide as part of an application for a cannabis research licence.

The requirement to provide these documents is, under subsection 9D(2) of the Act, in addition to the information requirements in section 11 outlined above.

Subsection 12(2) of the Regulation requires the provision of documents that that an applicant must provide to prove their identity under paragraph (2)(a). Applicants would be required to provide three certified true copies of identification documents (a Category A document or a Category B document) as defined under section 4 of the Regulation, one which must be Category A document. Section 4 of the Regulation provides that a copy of the document is a certified true copy if the copy is a certified to be a true copy by a person prescribed for the purposes of regulation 4 of the *Statutory Declarations Regulations 1993*. These regulations prescribe, among other persons, medical practitioners, bank officers, public servants, police officers and justices of the peace.

Under subsection 12(2) of the Regulation, the other documents that an applicant is required to provide with the application are the following:

- documents providing evidence that the applicant has a sound and stable financial background, and is not in financial circumstances that may significantly limit the applicant’s capacity to comply with the applicant’s obligations under a licence, if granted.
- a site plan showing how the land at the location where the activities proposed to be covered by the licence would be used for the cultivation of cannabis plants and/or the production of cannabis or cannabis resin;
- a detailed floor plan of the relevant premises and facilities;
- standard operating procedures and policies;

- a risk management plan that will be used to manage risks associated with the activities to be carried out by the licence holder under the licence, including risks posed to the health and safety of people, or to the environment

Section 13 – Application fee for cannabis research licence

Section 13 of the Regulation prescribes that, for the purposes of subsection 9D(3) of the Act (which provides that, relevantly, an application for a cannabis research licence must be accompanied by the prescribed application fee), the fee set out in the table in Schedule 1 is prescribed for that purpose.

Section 14 – Application for cannabis research permit – information requirements.

Section 14 of the Regulation prescribes, for the purposes of paragraph 9N(2)(a) of the Act, the information that an applicant would need to provide as part of an application for a medicinal cannabis permit.

Section 9N of the Act allows a holder of a cannabis research licence to apply to the Secretary for a cannabis research permit in relation to activities that are authorised by the licence. Subsection 9N(2) of the Act requires, relevantly, that such applications contain the information, and are accompanied by the documents, prescribed in regulations for the purposes of that provision.

Subsection 14(2) of the Regulation prescribes general information requirements for this purpose and would require that an application for a cannabis research permit must contain the applicant's name, licence number that the applicant holds and the activities authorised by the licence.

Subsections 14(3) and (4) of the Regulation, respectively, specify additional information requirements where the permit is requested in relation to a licence holder whose licence authorises the cultivation of cannabis plants (e.g. information about the types and strains of cannabis plants proposed to be cultivated) and where the permit is requested in relation to a licence holder whose licence authorises the production of cannabis (e.g. information about the maximum quantity of cannabis or cannabis resin proposed to be produced).

If both apply, then the licence holder would need to provide both sets of additional information.

Section 15 – Application cannabis research permit – document requirements.

Section 15(1) would prescribe, for the purposes of paragraph 9N(2) of the Act, the documents that an applicant would need to provide as part of an application for a medicinal cannabis permit.

Subsection 15(2) of the Regulation specifies the documents that must accompany the application for a cannabis research permit. An applicant for a cannabis research permit in respect of cultivation must provide evidence of the types and strains of the plants to be cultivated and the concentration of tetrahydrocannabinol, cannabidiol and their precursor acids and other major cannabinoids likely to be contained in the plants proposed to be cultivated. The requirement for the provision of a document evidencing the range of

concentrations takes into the account the fact that concentrations may vary significantly, even if the same strain is used by the applicant for cultivation.

The requirement to provide these documents is, under subsection 9N(2) of the Act, in addition to the information requirements in section 14 of the Regulation outlined above.

Under paragraph 15(2)(a) of the Regulation, any holder of a cannabis research licence who applies for a cannabis research permit is required to provide copies of all relevant contracts between the applicant for the permit and the holder of a licence under the Act that authorise the production of cannabis or cannabis resins. This requirement is necessary to allow the Secretary to determine the existence of a lawful end for the products generated by the authorised activities under the contract. This allows the Secretary to determine how many cannabis plants can be cultivated and supplied to a licenced producer under the Act. Under paragraph 15(2)(b), a cannabis research licence holder who applies for a cannabis research permit and who proposes to cultivate cannabis plants must also provide documents that provide evidence of the types and strains of cannabis plants proposed to be cultivated and the range of concentrations of major cannabinoids likely to be in those plants.

Section 16 – Application for cannabis research permit

This section prescribes that an application for a cannabis research permit would need to be accompanied by the fee set out in Schedule 1.

Section 17 – Matters to be specified in a cannabis research permit

Section 17 of the Regulation prescribes, for the purposes of paragraph 10A(1)(f) of the Act, matters that the Secretary may specify in a cannabis research permit (these matters are in addition to the matters listed in paragraphs 10A(1)(a)-(e) of the Act).

Subsection 17(1) of the Regulation allows the Secretary to specify, in such a permit, the research activity that may be undertaken in relation to particular types or strains of cannabis plants and the purposes of the research that may be undertaken by the permit holder.

This section also prescribes, for the purposes of paragraph 10A(2)(e) of the Act, the matters that the Secretary may specify in a cannabis research permit (these matters are in addition to the matters listed in paragraphs 10A(2)(a)-(d) of the Act).

Subsection 17(2) of the Regulation allows the Secretary to specify, in such a permit, the research activity that may be undertaken in relation to cannabis or cannabis resin and the purposes of the research that may be undertaken by the permit holder.

Division 3 – Conditions of cannabis licence

Section 18 – Condition that cannabis licence holder employ or engage suitable staff

Subsection 18(1) of the Regulation prescribes classes of persons taken to be unsuitable persons and, as a result, a cannabis licence holder must take all reasonable steps not to employ or engage for the purposes of paragraph 10F(1)(d) of the Act. These would be persons who are undertaking or who have undertaken treatment for drug addiction, persons who have a drug addiction and persons who are undischarged bankrupts under the

Bankruptcy Act 1966. Undischarged bankrupts are those persons who are still undergoing bankruptcy proceedings and processes.

Subsection 18(2) of the Regulation prescribes circumstances in which a person is taken not to be suitable to carry out activities authorised by a cannabis licence for the purposes of subsection 10F(2) of the Act. These circumstances would be where the person has, during the previous five years before the person is to be employed, used illicit drugs, been convicted of a drug related offence or been convicted of an offence against a law of the Commonwealth or a state or territory that involve theft or that was punishable by a maximum penalty of imprisonment of three months or more. A drug related offence would be defined in section 4 of the Regulation.

The privilege against self-incrimination does not apply and is not being abrogated in relation to paragraph 18(2)(a) of the Regulation as it would voluntary rather than mandatory to provide information about the use of illicit drugs.

Section 19 – Condition that medicinal cannabis licence holder be part to certain contracts

This section prescribes the matters that at a minimum must be set out in contracts mentioned in section 10J of the Act.

Under subsection 10J(1) of the Act, in specified circumstances, it will be a condition of a medicinal cannabis licence that a contract that deals with matters prescribed in the regulations is in existence between

- (i) the holder of a medicinal cannabis licence authorises cultivation and the obtaining of cannabis plants that has an associated permit that is in force; and
- (ii) a holder of a medicinal cannabis licence that authorises the production of cannabis or cannabis resin

Subsection 19(1) of the Regulation provides that the matters listed in paragraphs (a) to (d) are the matters that must be dealt with by the contract mentioned in that subsection. The matters listed in paragraphs 19(1)(a) to (d) relate to the types and strains of cannabis plants to be supplied under that contract, the number of cannabis plants to be supplied, the range of concentration of tetrahydrocannabinol and cannabidiol that will be contained in the cannabis plants to be supplied, and the details for any transportation, storage, security or disposal of the cannabis plants to be so supplied. However, these are not the only matters that must be included in the contract. .

Under subsection 10J(2) of the Act, in specified circumstances, it will be a condition of a medicinal cannabis licence that a contract that deals with matters prescribed in the regulations is in existence between:

- (i) the holder of a medicinal cannabis licence that authorises the production of cannabis or cannabis resins and a medicinal cannabis permit that relates to such production is in force; and
- (ii) a holder of a specified manufacture licence.

However, subsection 10J(2) of the Act does not require a contract specifying matters prescribed in the regulations is not required if a person holds a:

- (a) medicinal cannabis licence that authorises the production of cannabis or cannabis resins; and;

- (b) a medicinal cannabis permits that relates to such production is in force; and
- (c) a licence that authorises the manufacture of drugs that are medicinal cannabis products or drugs for the purposes of research in relation to medicinal cannabis products.

Subsection 19(2) of the Regulation would require that where a contract is required, the contract between the two licence holders mentioned in subsection 10J(2) above must deal with the matters listed in paragraphs 19(2)(a)-(h).

These would include, for example, the types and strains of cannabis plants to be used to produce the cannabis or cannabis resin to be supplied under the contract, the range of concentration of tetrahydrocannabinol and cannabidiol (and their acid precursors) and other major cannabinoids that will be in the cannabis plants to be used to produce the cannabis or cannabis resin to be so supplied and the quantity of cannabis or cannabis resin to be supplied.

Under subsection 10J(3) of the Act, a contract of a kind referred to in subsections 10J(1) or (2) of the Act is not required to be in place in the circumstances prescribed in regulations for the purposes of that provision. Subsections 19(3), (4) (for cultivation only cannabis licences), and (5) and (6) (for licences that authorise production) of the Regulation prescribe the circumstances for the purposes of paragraph 10J(3)(a) of the Act.

Under subsections 19(3) and (4) of the Regulation, those circumstances would be – for a cultivation-only licence - where the contract has ceased to be in force and the holder of a cultivation-only medicinal cannabis licence is taking steps to arrange a new such contract, or where a cultivation-only licence has been suspended under the Act.

Subsection 19(5) of the Regulation provides that the contract exemption under paragraph 19(4)(a) ceases to apply if the holder of the cultivation only licence fails to make new contractual arrangements within four months of the contract ceasing to be in force.

Under subsections 19(6) and (7) of this Regulation, those circumstances are – for a licence authorising production, where the contract between the licence holder and the holder of a manufacture licence has ceased to be in force and the holder of the licence authorising production is taking steps to arrange a new such contract, or where the licence authorising production has been suspended under the Act.

Subsection 19(8) provides that the contract exemption under paragraph 19(6)(a) will cease to apply if the holder of the production licence fails to make new contractual arrangements within four months of the contract ceasing to be in force.

Section 20 – Condition that licence holder notify the Secretary of certain matters

This section prescribes additional matters that a cannabis licence holder would need to notify the Secretary of for the purposes of paragraph 10K(d) of the Act. These circumstances include, among other things, any instances of suspected or actual loss or theft of cannabis plants, cannabis or cannabis resin, cessation of any activities authorised by the licence and the proposed termination of a contract for the supply of products generated under an activity authorised under a licence. For licence holders that are bodies corporate, they would also be required under section 20 of the Regulation to notify the Secretary of:

- transactions resulting in or proposed transactions that would result in a change to the type, name or number of shares in the body corporate held by a person; and
- a change, or a proposed change, in any of the directors or officers of the body corporate.

The requirements in section 20 of the Regulation are intended to facilitate or support ongoing compliance with the broad scope of conditions of the licence without the Secretary having to request for the provision of specified information by each individual licence holder.

Division 4 – Variation, revocation, suspension and surrender of cannabis licences and cannabis permits

Subdivision A – Variation of cannabis licences and permits

Section 21 – Circumstances in which a cannabis licence or cannabis permit must not be varied

Under subsections 10M(1) and (2) of the Act, the Secretary may vary a cannabis licence or cannabis permit at any time on the Secretary's own initiative, or on application by the licence holder, if the Secretary considers it appropriate in all the circumstances to do so.

However, under subsection 10M(3) of the Act, the Secretary must not vary a cannabis licence or permit in the circumstances listed in paragraphs 10M(3)(a) – (c). Paragraph 10M(3)(a) for example relates to where the Secretary is satisfied on reasonable grounds that the variation of the licence permit would not be consistent with Australia's obligations under the Convention.

Paragraph 10M(3)(b) of the Act, provides that if the Secretary is satisfied on reasonable grounds that one or more prescribed circumstances exist.

Section 21 of this Regulation prescribes circumstances for the purposes of paragraph 10M(3)(b) of the Act and would have the effect that the Secretary would be precluded from varying a cannabis licence or permit, on application by the licence holder, if the requested variation would amount to a grounds on which the Secretary would have been required not to grant the licence under either of sections 8G, 8J, 9F or 9H the Act. Respectively, these provisions set out general grounds, and particular grounds, on which the Secretary must not grant a medicinal cannabis licence and cannabis research licence (e.g. if the Secretary is not satisfied on reasonable grounds that the applicant is a fit and proper person to hold the licence).

Section 22 – Application for variation of cannabis licence or permit – information requirements

This section, for the purposes of paragraph 10N(1)(a) of the Act, prescribes the information that a holder of a cannabis licence or permit seeking to vary their licence or permit must include in their variation application. To avoid prescribing information requirements that would be irrelevant to the proposed variation, section 22 requires applicants for such variations provide information that explains the need for, and the purpose and effect of, the proposed variation.

Section 23 – Application for variation of cannabis licence or permit – document requirements

This section prescribes, for the purposes of paragraph 10N(1)(c) of the Act, the documents required to accompany an application for a variation of a cannabis licence or permit in accordance with paragraph 10N(1)(c) of the Act – being, any documents which would support the application.

Section 24 – Application fee for variation of cannabis licence or permit

This section prescribes, for the purposes of subsection 10N(2) of the Act, that the application fee for an application to vary a cannabis licence or permit would be the fee outlined in Schedule 1.

Subdivision B – Suspension of cannabis licences and permits

Section 25 – Suspension of cannabis licence and permits

This section provides that provisions of this subdivision would be made for the purposes of section 11A of the Act, in relation to the suspension of cannabis licences and permits.

Section 26 – Secretary may suspend cannabis licence and permits

Section 26 of the Regulation allows the Secretary to, by written notice, suspend a cannabis licence or permit if satisfied on reasonable grounds that a ground exists under subsection 10P(2) of the Act to revoke the licence or permit. These are grounds on which the Secretary has the discretion to revoke a holder's licence or permit (and are to be distinguished from the grounds set out in subsection 10P(1) of the Act that set out when the Secretary must revoke a licence or permit).

These grounds on which the Secretary may suspend a licence or permit under section 26 include, among other things, where the Secretary is satisfied on reasonable grounds that there has been a breach of a licence condition, that the licence holder is not taking adequate steps to ensure the security of cannabis plants, cannabis or cannabis resin in their possession or control and that the location, facilities or security arrangements are no longer suitable for the authorised activities. Subsection 26(1) requires the Secretary to provide the licence holder a written notice of the suspension to the cannabis licence holder.

Under subsections 26(2) and (3), a suspension would take effect on the day specified in the notice, being a day at least 20 business days after the day on which notice is given to the holder except where the Secretary is satisfied on reasonable grounds that there is a risk of cannabis plants, cannabis or cannabis resin being lost, diverted or stolen if the suspension does not take effect immediately. In such cases, the suspension would take place on the day the notice is given to the holder.

Subsection 26(4) makes it clear that if a licence is suspended any permit relating to that licence is also suspended.

In terms of when such suspensions would end, subsection 26(5) has the effect that a suspension would end on the earliest occurring of:

- the day specified in the notice given under subsection 26(1) on which the period of suspension is to end - under subsection 26(6) this period must be set out in the notice, and must not be more than 6 months from when the suspension takes effect
- if the licence ceases to be in force during the suspension period – on the day the licence ceases to be in force
- if the suspension is revoked – on the day the suspension is revoked.

Section 27 – Secretary may permit specified production to occur during suspension of cannabis licence or permit

Section 27 of the Regulation provides that a notice issued under section 26(1) suspending a cannabis licence or permit may provide for the continued production of cannabis or cannabis resin, subject to the discretion of the Secretary and subject to any conditions specified by the Secretary in relation to any such continued activity.

Section 28 – Secretary to notify of proposed suspension of cannabis licence or permit

This section requires the Secretary to notify a cannabis licence holder of a proposed suspension of their licence or a permit, before any suspension decision is made– except where the Secretary is satisfied on reasonable grounds that cannabis plants, cannabis or cannabis resin may be lost, diverted or stolen if the suspension does not take effect immediately.

Under subsections 28(3) and (4) of the Regulation, such a notice must state the Secretary’s intention to suspend a cannabis licence or permit, set out the reasons for the proposed suspension and invite the holder to make a written submission in response to the proposed suspension within a reasonable specified period. The Secretary must have regard to any such submissions before making a decision to suspend a licence or a permit (subsection 28(5) refers).

Section 29 – Effect of suspension of cannabis licence or permit

This section sets out particular effects of any suspension of a cannabis licence or permit.

Subsection 29(1) of the Regulation makes it clear that during any period of suspension of a cannabis licence or permit, the licence or permit has no force or effect. Subsection 29(1) also makes it clear that a suspension of a cannabis licence or permit would not affect the duration of the licence or permit - in other words, for any suspended licence or permit, the period for which it is current will continue to run while it is suspended.

Notwithstanding subsection 29(1), however, if the licence that has been suspended authorises the cultivation of cannabis plants, the holder may continue to tend, nurture, harvest or store cannabis plants in their possession or control during the suspension (paragraph 29(2)(c) refers).

Also notwithstanding subsection 29(1), if the licence that has been suspended authorises the production of cannabis or cannabis resin, the holder may continue to engage in the production of cannabis or cannabis resin during the suspension, but only provided that the Secretary has permitted the holder to do so under section 27 of this Regulation (outlined above).

Subsection 29(3) of the Regulation makes similar provision for the continuation of these activities if a permit is suspended.

Subsection (4) of the Regulation provides for the avoidance of any doubt that a suspension of a cannabis licence or permit does not prevent its revocation.

Section 30 – Revocation of suspension of cannabis licence or permit

This section provides that a suspension can be revoked either by the Secretary's own initiative or on application by the licence holder (subsection 30(1) refers).

A holder applying for the suspension to be revoked must provide reasons to be included in the application why the applicant considers the suspension should be revoked (subsection 30(2) refers).

Subsection 30(3) sets out the grounds on which the Secretary may revoke a suspension in response to a request from a licence holder or on the Secretary's own initiative. The Secretary may revoke the suspension where both the following apply:

- where the original grounds for the suspending the licence or permit no longer exist;
- no other grounds on which the licence or permit could be suspended exist.

Section 31 – Matters not affected by suspension of cannabis licence or permit

Subsection 31(1) of the Regulation makes it clear that a licence holder would still be required to comply with the following during any period of suspension:

- a condition applying to a cannabis licence under Division 3 of Part 2 of Chapter 2 of the Act (Conditions of cannabis licences) (other than a condition under section 10J of the Act)
- a notice requiring the licence holder to give the Secretary information or documents
- a direction issued to the holder under Part 3 of Chapter 5 of the Act.

Subsection 31(2) of the Regulation makes it clear that although a cannabis licence, or permit is suspended, the powers of an authorised inspector under Part 4 of Chapter 4 of the Act continue to have effect in relation to the licenced premises.

Section 32 – Offence and civil penalty – breach of condition of permitted production during suspension

Subsection 32(1) of the Regulation provides that a person contravenes this provision if:

- (a) the cannabis licence or cannabis permit that the person holds is suspended under subsection 26(1) of the Regulation; and
- (b) under section 27 of this Regulation the Secretary permits specified production of cannabis or cannabis resin to occur during the period of suspension in accordance with conditions notified to the licence holder under subsection 26(1); and
- (c) the person fails to comply with a condition specified in a notice under subsection 26(1) during the period of suspension of the licence or permit that the person holds.

Subsection 32(2) of the Regulation provides that a person commits an offence if the person contravenes subsection 30(1).

Subsection 32(3) introduce a civil penalty provision if the person contravenes subsection 32(1).

In each case, the maximum penalty would be 50 penalty units.

Subdivision C – Surrender of cannabis licences and permits

Section 33 – Surrender of cannabis licences and permits

This section makes it clear that, for the purposes of section 11A of the Act, Subdivision C makes provision for, and in relation to, the surrender of cannabis licences and permits.

Section 334 – Licence holder may surrender cannabis licence or permit

Subsection 34(1) of this Regulation makes it clear that a holder of a cannabis licence or permit may surrender their licence or permit, by giving the Secretary a written notice of that surrender in accordance with the requirements of subsection 3 4(2).

Subsection 34(2) sets out that such a notice of surrender must be signed by the holder and must include a range of information including for example:

- the details of the licence or permit to be surrendered
- the day on which surrender is proposed to take effect, being a day not less than 20 business days after the day the holder gives the notice to the Secretary
- if the activities authorised by the licence have not yet ceased – the day those activities are expected to cease
- details relating to the manner in which any cannabis plants, cannabis or cannabis resin in the holder’s possession has been, or will be, dealt with, including the name of any other licence holder or end user to whom it has been or will be supplied or – if that material is to be disposed of or destroyed – the day and location relating to any such disposal or destruction and the details of any persons who will carry that activity out.

Subsection 34(3) sets out when a licence or permit ceases to be in force in the event that a holder notifies the Secretary of their proposal to surrender in accordance with section 34.

Part 3 – Licensing the manufacturing of drugs

Division 1 –Manufacture licences and permits

This division outlines the information and documents that an applicant would be required to provide as part of an application for a manufacture licence or permit. These licences and permits would be issued under Division 1 of Part 2 of Chapter 3 of the Act.

Section 35 – Application for manufacture licence – information requirements.

Section 35 of the Regulation prescribes, for the purposes of paragraph 11G(2)(a) of the Act, the information that an applicant would need to provide as part of an application for a manufacture licence.

Subsection 35(2) of the Regulation requires an applicant to provide personal and other information required to identify the applicant and to enable the Department of Health to contact that person. Subsection 35(2) would also require information that would allow the Secretary of the Department of Health to determine whether any of the grounds identified under subsection 11J(1) of the Act for refusing the licence exist. The information that is required include details about the physical security of the cannabis plants, cannabis or cannabis resin, suitability of the location, facilities or proposed security arrangements at the land or premises where activities authorised by the licence will take place.

Subsections 35(3) and (4) prescribe the information required to be provided for the purposes of establishing whether an applicant who is a natural person or a body corporate would be a fit and proper person under sections 8A or 8B of the Act respectively, e.g. details of the connections and associations that the applicant has with other persons (including, but not limited to, their relatives) that may affect the applicant's reputation, character, honesty or professional or personal integrity.

Subsection 35(5) requires the applicant to provide details of their record-keeping arrangements and subsection 35(6) requires the provision of information about the applicant's procedures for ensuring that their employment or engagement of staff will not contravene the requirements of section 12H of the Act (this covers, for example, the requirement to ensure that any such staff are not aged under 18 and have not been convicted of a serious offence in the previous five years).

Subsection 35(7) outlines information that the applicant must provide in relation to the security arrangements that they will put in place to deal with specified matters including, for example, details of how access will be controlled to sensitive facilities at the site, and the equipment used to control such access.

Section 36 – Application for manufacture licence – document requirements

Section 36 of the Regulation, for the purposes of paragraph 11G(2)(c) of the Act, prescribe the information that an applicant would need to provide as part of an application for a manufacture licence under paragraph 11G(2)(c) of the Act.

The requirement to provide these documents would supplement the information requirements in section 35, outlined above.

Subsection 36(2) of the Regulation requires the provision of documents that that an applicant must provide to prove their identity under paragraph (2)(a). Applicants would be required to provide three certified true copies of identification documents (a Category A document or a Category B document) as defined under section 4 of the Regulation, one which must be Category A document. Section 4 of the Regulation provides that a copy of the document is a certified true copy if the copy is a certified to be a true copy by a person prescribed for the purposes of regulation 4 of the *Statutory Declarations Regulations 1993*. These regulations prescribe, among other persons, medical practitioners, bank officers, public servants, police officers and justices of the peace.

The other documents that are required to be included in the application for a manufacture licence are the following as listed under subsection 36(2):

- documents providing evidence that the applicant has a sound and stable financial background, and is not in financial circumstances that may significantly limit the applicant's capacity to comply with the applicant's obligations under a licence, if granted.
- a site plan showing how the land at the location where the activities proposed to be covered by the licence would be used for the cultivation of cannabis plants and/or the production of cannabis or cannabis resin;
- a detailed floor plan of the relevant premises and facilities;
- standard operating procedures and policies that will be used to undertake the activities;
- a risk management plan that will be used to manage risks associated with the activities to be carried out by the licence holder under the licence, including risks posed to the health and safety of people, or to the environment.

Section 37 – Particular rules about manufacture licences involving cannabis etc. medicinal cannabis products

Subsection 11K(2) of the Act provides that the Secretary must refuse to grant the manufacture if the Secretary is not satisfied on reasonable grounds on any of the circumstances specified in paragraphs (a) to (c). Section 37 of the Regulation, for the purposes of subparagraph 11K(2)(b)(ii) of the Act, prescribe that a purpose in which the Secretary may be satisfied of the end use of a drug that is a medicinal cannabis product, is if the medicinal cannabis product would be supplied by a pharmacist in a public hospital in accordance with the terms of the *Therapeutic Goods Act 1989*.

Section 38– Application for manufacture permit – information requirements

This section prescribes, for the purposes of paragraph 12(2)(a) of the Act, the information that an applicant would need to provide as part of an application for a manufacture permit.

Under subsection 38(2), such information includes, for example, information identifying the approved manufacture licence to which the application applies, details of drugs proposed to be manufactured, details of starting materials to be used and details of proposed end use of the manufactured drugs.

Division 2 – Conditions of manufacture licences

Section 39– Condition that manufacture licence holders employ or engage suitable staff

This section prescribes conditions with respect to employees for the purposes of section 12H of the Act.

Subsection 39(1) of the Regulation prescribes classes of persons that a manufacture holder must take all reasonable steps not to employ or engage to carry out activities authorised by a manufacture licence for the purposes of paragraph 12H(1)(d) of the Act – these would be persons undertaking, or who have undertaken, treatment for drug addiction, persons with a drug addiction and undischarged bankrupts under the *Bankruptcy Act 1966*.

Subsection 39(2) prescribes circumstances in which a person would be taken not to be suitable to carry out activities authorised by a manufacture licence for the purposes of subsection 12H(2) of the Act – these would include, for example, if the person has, during the

previous five years, used illicit drugs or been convicted of a drug related offence. A drug related offence is defined in section 4 of this Regulation.

The privilege against self-incrimination does not apply and is not being abrogated in relation to paragraph 39(2)(a) of the Regulation as it would voluntary rather than mandatory to provide information about the use of illicit drugs.

Section 40 – Condition that manufacture licence holder notify the Secretary of certain matters

Under section 12N of the Act, it is a condition of a manufacture licence that the holder inform the Secretary as soon as is reasonably practicable of any of the matters listed in paragraphs 12N(a)-(d) – these include, at paragraph 12N(d), any matter prescribed in regulations for the purposes of that provision.

Section 40 of the Regulation prescribes a number of matters for this purpose, including for example:

- a security breach, or suspected security breach, or an unauthorised access or a suspected unauthorised access, of the location, premises or facilities covered by the licence;
- a theft or suspected theft of drugs or starting material from that location, premises or facilities; and
- a serious incident involving drugs or starting material in the possession of the licence holder or under their control during any transportation of the drugs or starting material;
- adverse finding or a recommendation, relating to security matters, made in a security audit report or other report relating to the location, premises or facilities covered by the licence

Division 3 – Variation, revocation, suspension and surrender of manufacture licences and manufacture permits

Subdivision A – Variation of manufacture licences and permits

Section 41 – Circumstances in which a manufacture licence or permit must not be varied

Under subsections 13(1) and (2) of the Act, the Secretary may vary a manufacture licence or manufacture permit at any time on the Secretary's own initiative, or on application by the licence holder, if the Secretary considers it appropriate in all the circumstances to do so.

However, under subsection 13(3) of the Act, the Secretary must not vary a cannabis licence or permit in the circumstances listed in paragraphs 13(3)(a) – (c).

One of these is, at paragraph 13(3)(b) of the Act, if the Secretary is satisfied on reasonable grounds that one or more prescribed circumstances exist.

Section 41 of this Regulation prescribes circumstances for the purposes of paragraph 13(3)(b) of the Act and would have the effect that the Secretary would be precluded from varying a manufacture licence or permit, on application by the licence holder, if the requested variation would amount to a grounds on which the Secretary would have been required not to grant the licence under either of sections 11J or 11K of the Act. Respectively, these provisions set out general circumstances, and particular circumstances, in which the Secretary must not grant a

manufacture licence (e.g. if the Secretary is not satisfied on reasonable grounds that the applicant is a fit and proper person to hold such a licence).

Section 42 – Application for variation of manufacture licence or permit – information requirements

This section prescribes, for the purposes of paragraph 13A(1)(a) of the Act, information that must be contained in an application by a manufacture licence holder for a variation of their manufacture licence or permit – being, information that explains the need for, and the purpose and effect of, the variation requested by the holder.

Section 43 – Application for variation of manufacture licence or permit – document requirements

This section prescribes, for the purposes of paragraph 13A(1)(c) of the Act, documents that must accompany an application by a manufacture licence holder for a variation of their manufacture licence or permit – being, any documents that support the application.

Subdivision B – Suspension of manufacture licences and permits

Section 44 – Suspension of manufacture licences and permits

This section simply notes that Subdivision A makes provision for and in relation to the suspension of manufacture licences and permits for the purposes of section 13D of the Act.

Section 45 – Secretary may suspend manufacture licences and permits

Section 45 of the Regulation allows the Secretary to, by written notice, suspend a manufacture licence or permit if satisfied on reasonable grounds that a ground exists under subsection 13B(2) of the Act to revoke the licence or permit. These are grounds on which the Secretary has the discretion to revoke a holder's licence or permit (and are to be distinguished from the grounds set out in subsection 13B(1) of the Act that set out when the Secretary must revoke a manufacture licence or permit).

The grounds on which the Secretary may suspend a licence or permit under section 45 of the Regulation includes, among other things, where the Secretary is satisfied on reasonable grounds that there has been a breach of a condition of a manufacture licence, that the licence holder has engaged in conduct that constitutes a breach of the Act or that the licence or permit was obtained or has been varied on the basis of information that was false or misleading in a material particular. Subsection 45(1) requires the Secretary to provide written notice of the suspension to the cannabis licence holder.

Under subsections 45(2) and (3) of this Regulation, a suspension would take effect on the day specified in the notice, being a day at least 20 business days after the day on which notice is given to the holder except where the Secretary is satisfied on reasonable grounds that there is a risk of drugs or narcotic preparations or starting materials being lost, diverted or stolen if the suspension does not take effect immediately. In such cases, the suspension would take place on the day notice is given to the holder.

Subsection 45(4) makes it clear that if a manufacture licence is suspended, any permit relating to that licence is also suspended.

In terms of when such suspensions would end, subsection 45(5) has the effect that a suspension would end on the earliest occurring of:

- the day specified in the notice on which the period of suspension is to end - under subsection 45(6) this period must be set out in the notice given to the licence holder under subsection 45(1), and must not be more than 6 months from when the suspension takes effect subsection 45(6) refers;
- if the manufacture licence ceases to be in force during the suspension period – on the day the licence ceases to be in force;
- if the suspension is revoked – on the day the suspension is revoked.

Section 46 – Secretary to notify of proposed suspension of manufacture licence or permit

This section requires the Secretary to notify a manufacture licence holder of a proposed suspension of their licence or a permit, before any suspension decision is made – except where the Secretary is satisfied on reasonable grounds that cannabis plants, cannabis or cannabis resin may be lost, diverted or stolen if the suspension does not take effect immediately.

Under subsections 46(3) and (4) of the Regulation, such a notice must state the Secretary’s intention to suspend, set out the reasons for the proposed suspension and invite the holder to make a written submission in response to the proposed suspension within a reasonable specified period. The Secretary must have regard to any such submissions by the licence holder before taking any suspension action (subsection 46(5) refers).

Section 47 – Effect of suspension of manufacture licence or permit

This section sets out particular effects of any suspension of a manufacture licence or permit.

Subsection 47(1) of the Regulation makes it clear that during any period of suspension of a manufacture licence or permit, the licence or permit has no force or effect. Subsection 47(1) also makes it clear that a suspension of a cannabis licence or permit would not affect the duration of the licence or permit - in other words, for any suspended manufacture licence or permit, the period for which it is current will continue to run while it is suspended.

Notwithstanding subsection 47(1), if the licence that has been suspended authorises the manufacture of a drug, the holder may continue to store, possess and control any drug, narcotic preparations or starting materials in their possession or control during the suspension (subsection 47(2) of this Regulation refers).

Subsection 47(3) of the Regulation provides for the avoidance of any doubt that a suspension of a cannabis licence or permit does not prevent its revocation.

Section 48 – Revocation of suspension of manufacture licence or permit

This section provides that a suspension of a manufacture licence or permit can be revoked either on the Secretary’s own initiative, or on application by the licence holder.

Subsection 48(1) makes it clear that the Secretary may, by written notice, revoke a suspension of a manufacture licence or permit, by written notice given to the licence holder on the Secretary's initiative or on application by a licence holder.

Subsection 48(2) provides that an application by the licence holder must include the reasons why the applicant considers the suspension should be revoked.

Subsection 48(3) sets out the grounds on which the Secretary may revoke a suspension in response to a request from a licence holder or on the Secretary's initiative (under subsection 48(1)) – being, where both the following apply:

- where the original grounds for the suspending the manufacture licence or permit no longer exist
- no other grounds on which the manufacture licence or permit could be suspended exist.

Section 49 – Matters not affected by suspension of manufacture licence or permit

Subsection 49(1) of the Regulation makes it clear that a manufacture licence holder would still be required to comply with the following during any period of suspension of their licence or permit:

- a condition applying to a manufacture licence under Division 2 of Part 2 of Chapter 3 of the Act (Conditions of manufacture licences)
- a notice issued under subsection 14J(2) of the Act requiring the licence holder to give the Secretary information or documents
- a direction issued to the holder under Part 3 of Chapter 5 of the Act.

Subsection 49(2) of the Regulation makes it also clear that the powers of an authorised inspector under Part 4 of Chapter 4 of the Act in relation to licensed premises are not affected by the suspension of the licence or permit.

Subdivision C– Surrender of manufacture licences and permits

Section 50 – Surrender of cannabis licences and permits

This section makes it clear that, for the purposes of section 13D of the Act, this Subdivision makes provision for, and in relation to, the surrender of manufacture licences and manufacture permits.

Section 51 – Licence holder may surrender manufacture licence or permit

Subsection 51(1) of this Regulation makes it clear that a holder of a manufacture licence or permit may surrender their licence or permit, by giving the Secretary a written notice of that surrender in accordance with the requirements of subsection 51(2).

Subsection 51(2) sets out that such a notice of surrender must be signed by the holder and must include a range of information including for example:

- the details of the licence or permit to be surrendered
- the day on which surrender is proposed to take effect, being a day not less than 20 business days after the day the holder gives the notice to the Secretary

- if the activities authorised by the licence have not yet ceased – the day those activities are expected to cease
- details relating to the manner in which any drugs, narcotic preparations or starting materials in the holder’s possession has been, or will be, dealt with, including the name of any other licence holder or end user to whom it has been or will be supplied or – if that material is to be disposed of or destroyed – the day and location relating to any such disposal or destruction and the details of any persons who will carry that activity out.

Subsection 51(3) sets out when a licence or permit ceases to be in force in the event that a holder notifies the Secretary of their proposal to surrender in accordance with this section.

Part 4 – Review of decisions

Section 52 – Reviewable decisions

This section outlines the decisions of the Secretary under the Regulation that would be reviewable decisions for the purposes of subsection 15E(2) of the Act. These reviewable decisions would be subject to the review processes outlined in Part 4 of the Act.

Part 5 – Other matters

Division 1 – Fees

This division prescribes matters in relation to fees for applications, variations and initial inspections for cannabis licences and permits.

Section 53 – Reduction of fees

Section 53 of the Regulation provides that the Secretary may reduce by up to 75% the amount of an application fee for a cannabis licence specified in the table in clause 1 of schedule 1 if two applications for a licence are lodged by the same applicant and the other circumstances set out in paragraphs (1)(a) to (c) apply.

Subsection 53(1) of the Regulation provides that the Secretary may make such a reduction if the applicant is applying for both a medicinal cannabis licence and a cannabis research licence at the same time, if the activities proposed to be authorised under each licence will occur at the same premises and if the Secretary is satisfied that the information and documents provided in support of each application are sufficiently similar as to allow both applications to be considered together. Subsection 53(2) of the Regulation makes it clear that the reduction in application fee applies to only one of the application. The other application will be charged the full application fee.

The power to make regulations to provide for the reduction of fee in relation to cannabis licence applications rely on subsection 27(1) of the *Narcotic Drugs Act 1967*. Subsection 27(1) relevantly provides that the Governor-General may make regulations prescribing matters that are required or permitted by the Act to be prescribed by the regulations, or necessary or convenient to be prescribed for carrying out or giving effect to the Act. The fees that are due and payable have been determined based on the Commonwealth cost recovery

guidelines. Thus, if Secretary is satisfied that two applications have sufficiently commonality in such a way that the time and regulatory effort required to determine the second application can be considered together, then the fee that is due and payable for the second application can be reduced proportionately.

Section 54—Inspection fees

Section 54 of the Regulation provides for the charging of a fee in accordance with clause 2 of schedule 1 where inspections are carried out by authorised officers of the Department of Health in relation to a licence or a permit. Inspections can be carried out as part of an application for a medicinal cannabis licence or permit, as part of an application for a cannabis research licence or permit, or as part of an application for a variation of a cannabis licence or a permit.

Subsection 54(2) provides that the inspection fee is payable to the Secretary on behalf of the Commonwealth by the applicant for the licence, permit or variation, and must be paid on or before the last day of the last day of payment of the fee shown on the invoice issued to the applicant. The inspection fee is recoverable as a debt due to the Commonwealth.

Other charges that would be such as to amount to taxation would be imposed on the licence in accordance with the *Narcotic Drugs (Licence Charges) Act 2016*.

Division 1 – Fees

Section 55 – Secretary to notify States and Territories of certain matters

Section 55 of the Regulation prescribes the matter which the Secretary would be required to notify the head of a State or Territory agency of for the purposes of subsection 25B(2) of the Act. Broadly, this provision would require the Secretary to inform relevant agency heads of the terms of the granting of a licence or permit under the Act and any proposed changes to a granted licence or permit.

Schedule 1 – Fees

This Schedule provides a list of applicable fees.

The applicable fees have been determined on the basis of the Commonwealth cost recovery guidelines in consultation with the Department of Finance and takes into account the resources involved in the administration of the medicinal cannabis framework and relation to the services to be provided to the applicant or the licence holder.

It is not proposed to impose fees in relation to a manufacture licence.

Statement of Compatibility with Human Rights

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

NARCOTIC DRUGS REGULATION 2016

This Regulation 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 Regulation

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 *Narcotic Drugs Amendment Act 2016* recently amended the Act to implement a medicinal cannabis framework in Australia that 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.

The primary purpose of the *Narcotic Drugs Regulation 2016* is to make regulations necessary for carrying out, or to give effect to, the regulatory framework for the licensing of the cultivation of cannabis and the production of cannabis and cannabis resins for medicinal and scientific purposes, as well as in relation to the manufacture of drugs as provided for under the Act.

The Regulation also specifies the information and documentation that must be provided by an applicant at various key points – e.g. for an application for a licence and for a permit associated with a licence under the Act, for any variation of a licence or permit. The Regulation also sets out the arrangements relating to the suspension and revocation of licences and permits, the surrender of a licence, applicable fees and when fees may be reduced or waived.

Human rights implications

The offence provision on the failure of a holder of a licence to comply with a condition that allows specified production of cannabis or cannabis resin to occur while the licence or associated permit does not derogate from the requirements of Article 14 of the ICCPR which guarantees equality before courts and tribunals, and, in the determination of criminal charges, or any suit at law, the right to a fair and public hearing before a competent, independent and impartial court or tribunal established by law. This guarantee includes respect for the “equality of arms”, which requires that all parties to a proceeding must have a reasonable opportunity of presenting their case under conditions that do not disadvantage them as against other parties to the proceedings. Those charged with a criminal offence have the rights set

out in Article 14(2) to (7), including the right to presumption of innocence under Article 14(2).

A civil penalty provision is also included in this Regulation based on the failure to comply with the condition described above. A person is liable to a maximum penalty of 50 penalty units. The civil penalty is provided as a disciplinary alternative to the punitive or deterrent criminal offence for the same contravention. Civil penalties will enable an effective disciplinary approach to dealing with non-compliance by corporations. The civil penalty only applies to licence holders. The objective of a civil penalty is regulatory or disciplinary in nature and applies to licence holders who can reasonably be expected to be aware of their obligations under the legislation and who have voluntarily sought the approval of the Commonwealth to engage in an activity that is regulated under very clear conditions. Accordingly, the civil penalty provision in the Regulation should not be considered criminal for the purposes of human rights law.

The Secretary of the Department of Health would allow production activities to take place, while the licence is suspended. The maximum penalty of fifty penalty units given the nature of the conduct, will provide incentive for those regulated to comply with the requirements, and ensure that no unauthorised activities are carried out by the licence holder while the cannabis licence or permit is suspended.

Conclusion

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

The Hon Sussan Ley MP, the Minister for Health and Aged Care/Minister for Sport