

EXPLANATORY STATEMENT

Narcotic Drugs Act 1967

Narcotic Drugs Amendment (Cannabis) Regulations 2018

The object of the *Narcotic Drugs Act 1967* (the Act) is to give effect to certain of Australia's obligations under the *Single Convention on Narcotic Drugs, 1961*, as in force from time to time. The Act implements a licensing and permit scheme that regulates the cultivation of cannabis plants and cannabis resin, the production of cannabis or cannabis resin and the manufacture of drugs.

Subsection 27(1) of the Act provides that the Governor-General may make regulations prescribing matters required or permitted to be prescribed by the Act or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

The purpose of the *Narcotic Drugs Amendment (Cannabis) Regulations 2018* (the Regulations) is to amend the *Narcotic Drugs Regulation 2016* to permit exports of medicinal cannabis products, to allow a drug that is a medicinal cannabis product and raw cannabis and cannabis resin to be supplied directly to the holder of a manufacture licence under the *Therapeutic Goods Act 1989* for subsequent supply to Australian patients or for export, and to make other minor and technical amendments.

The minor and technical amendments support the streamlined operation of the Act, provide support to the amendments to the Act made by the *Narcotic Drugs Legislation Amendment Act 2016* on November 2016, and provide consistency in relation to the requirements applying to the different licences under the Act.

The amendments include the following:

- non-disclosure of sensitive law enforcement information in the provision of a notice to a licence holder stating the reasons for the proposed suspension of a licence;
- prescribing the periods for the provision of specified information;
- prescribing general grounds for the refusal of a licence under the Act;
- additional information requirements in relation to the supply of cannabis plants or parts of the cannabis plant by the cannabis research licence holder;
- additional information requirements in relation to the business associates of the applicant that are bodies corporate;
- prescribing of substances for the purposes of the definition of a “drug” under the Act; and
- waiving the “fit and proper person” requirement where the applicant or a licence holder is an agency of a State or Territory.

Minor corrections (resulting in decreases) are also made in relation to some fees.

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

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

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

The Regulations commence on the day after registration.

Consultation

Stakeholders were consulted in June and July 2017 on options on the export of medicinal cannabis products. The consultation process included seeking written submissions, holding two industry seminars on the regulatory scheme (including discussing the proposal for export) and hosting over a dozen private industry meetings on narcotic drug licencing and export related issues.

Changes to the regulations have been the subject of discussions with the Australian Advisory Council on the Medicinal use of Cannabis (the Council), the State and Territory Law Enforcement Working Group on Medicinal Cannabis, and the State and Territory Cultivation and Production Working Group on Medicinal Cannabis.

Feedback received from stakeholders, the Council and Working Groups is reflected in the Regulations.

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

Details of the *Narcotic Drugs Amendment (Cannabis) Regulations 2018*

Section 1 – Name

This section provides for the Regulations to be referred to as the *Narcotic Drugs Amendment (Cannabis) Regulations 2018 (Amendment Regulations)*.

Section 2 – Commencement

This section provides for the Amendment Regulations to commence on the day after registration.

Section 3 – Authority

This section provides that the Amendment Regulations are made under the *Narcotic Drugs Act 1967* (the Act).

Section 4 – Schedules

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

Schedule 1 – Amendments

Narcotic Drugs Regulation 2016

Item 1 At the end of Part 1

Item 1 inserts a new section 4A for the purpose of prescribing substances under paragraph (a) of the definition of the term “drug” under section 4(1) of the Act. “Drug” is defined under the Act as any substance that is a drug for the purposes of the *Single Convention on Narcotic Drugs, 1967* as amended from time to time (the Single Convention), any substance prescribed by the regulations for the purposes of paragraph (a) of the definition, and any substance prescribed by the regulations under section 8 of the Act. Relying on the definition of “drug” under the Single Convention has the effect of limiting the drugs that include, or are from any parts of a cannabis plant. Only cannabis, cannabis resin, and extracts and tinctures of cannabis are mentioned in the Single Convention. Cannabinoids such as cannabidiol, tetrahydrocannabinol and other forms of tetrahydrocannabinols are not specifically listed in the Single Convention.

In view of that limitation, new section 4A lists tetrahydrocannabinol (including all isomeric forms, their salts and acid forms), cannabidiol (including all isomers and their salts) and dronabinol. Stereoisomers are included within the scope of the term “isomers”.

Items 2-12 Paragraphs 5(3)(d) to (f), 5(3)(m) to (n), 5(4)(f) to (g)

Items 2-7 and 10-12 amend paragraphs 5(3) (information requirements for a medicinal cannabis licence where the applicant is an individual) and 5(4) (information requirements for a medicinal cannabis licence where the applicant is a body corporate) to now require applicants for a medicinal cannabis licence to provide information about their business associates who can be individuals or bodies corporate or both, consistent with the application of sections 8A and 8B of the Act.

Section 5 of the *Narcotic Drugs Regulation 2016* (the primary Regulation) specifies the information that an applicant for a medicinal cannabis licence is required to provide with their application for a licence. Thus, the amendments to subsections 5(3) and 5(4) of the primary Regulation now require appropriate information from the applicant (a natural person or a body corporate) in relation to the identity of a business associate who is a body corporate, including the nature and length of that association.

Sections 8A and 8B of the Act set out the matters that the Secretary of the Department of Health (the Secretary) may have regard to when determining if an applicant or licence holder or any business associate of the applicant or the licence holder, is fit and proper. Section 8A concerns individuals and section 8B, bodies corporate. Sections 8A and 8B relevantly provide that without limiting the matters to which the Secretary may have regard in deciding whether the person is a fit and proper person to hold a licence, or to be associated with the holder of the licence, the Secretary may have regard to the connections and associations that the person has with other persons (paragraph 8A(d) and paragraph 8B(e)). Both sections will need to be taken into consideration in relation to a particular application for a licence under the Act, where an applicant is a body corporate and specified business associates are natural persons, or where the applicant is a natural person and specified business associates are bodies corporate. These combinations are possible in view of the definition of ‘business associate’ in the Act and reflect commercial realities. Business associate is defined in section 4 of the Act as the following:

business associate: 2 or more persons are ***business associates***, in relation to a business, if each person:

- (a) both
 - (i) holds a relevant financial interest, or is entitled to exercise a relevant power (whether in his or her own right, or on someone else’s behalf), in the business; and
 - (ii) because of that interest or power, is able to exercise a significant influence over, or with respect to, the management or operation of the business; or
- (b) holds any relevant position (whether in his or her own right, or someone else’s behalf) in the business

Despite the coverage of the term “business associate” as defined in the Act, subsection 5(3) of the primary Regulation implies that an applicant who is a natural person will only have associates that are natural persons. This is reflected in the information requirements set out in paragraph 5(3)(e) (the person’s name and date of birth with whom the applicant is connected or associated), and paragraph 5(3)(f) (name and date of birth of persons who holds relevant financial interest). Similarly, the information requirements listed in subsection 5(4) of the primary Regulation in relation to an applicant for a medicinal cannabis licence implies that an applicant who is body corporate cannot be associated with another body corporate. Paragraphs 5(4)(f) to (g) limit the information requirements to business associations with natural persons only.

Item 2 inserts the words “(each of whom is a connected person)” after the words “other persons” in paragraph 5(3)(d) of the primary Regulation. The words “connected person” is a person who has a connection or association with the applicant and whose details are required to be provided by the applicant as mentioned in paragraph 5(3)(e) and new paragraph 5(3)(ea).

Item 3 omits the words “person mentioned in paragraph (d) with whom the applicant is connected or associated” and substitutes the words “connected person who is a natural person” in paragraph 5(3)(e) of the primary Regulation. This amendment is consequential to the amendment made by Item 2 to paragraph 5(3)(d) of the primary Regulation. Paragraph 5(3)(e) lists the details of a natural person with whom an applicant (who is an individual) is connected or associated must provide with the application for a medicinal cannabis licence.

Item 4 inserts a new paragraph 5(3)(ea). Paragraph 5(3)(ea) lists the information that is required to be provided by the applicant, who is an individual, in relation to each connected person that is a body corporate. Thus, assuming the applicant has a connected person that is a body corporate, the applicant is required to provide details of that body corporate and the length and nature of the connection or association with that body corporate as listed in subparagraphs (i) to (vi).

Item 5 inserts the word “natural” after the words “of each” in paragraph 5(3)(f) of the primary Regulation. This amendment makes it clear that the information requirement relates to details of a natural person who holds a relevant financial interest, or who is entitled to exercise a relevant power in relation to the applicant’s business that will undertake the activities or in relation to other business of the applicant that provides a substantial proportion of the applicant’s current income.

Item 6 omits the words “his or her own right or on someone else’s behalf” and substitutes them with the words “the natural person’s own right or on behalf of another person”, in paragraph 5(3)(f). This amendment is consequential on the amendment made by Item 5.

Item 7 inserts a new paragraph 5(3)(fa). While paragraph 5(3)(f) requires the details of a natural person who holds relevant financial interest or who is entitled to exercise a relevant power in relation to the applicant’s business, new paragraph 5(3)(fa) requires the details of a body corporate who holds relevant financial interest or who is entitled to exercise relevant power in relation to the applicant’s business.

Item 8 is a consequential amendment in view of the repeal of paragraph 5(3)(n) (item 9 refers).

Item 9 omits paragraph 5(3)(n). The information required from the applicant under paragraph 5(3)(n) relates to the applicant’s history of compliance with the Act. The Department of Health already holds this information and therefore it is not necessary to be provided by the applicant for a medicinal cannabis licence.

Item 10 inserts the words “(each of whom is a connected person)” after the words “other persons” in paragraph 5(4)(f) of the primary Regulation. Subsection 5(4) of the primary Regulation lists the information required to be provided by an applicant for a medicinal cannabis licence who is a body corporate. The words “connected person” is a person who has a connection or association with the applicant and whose details are required to be provided by the applicant as mentioned in paragraph 5(4)(g) and new paragraphs 5(4)(ga) to (gd) (Item 12 refers).

Item 11 omits the words “person mentioned in paragraph (f) with whom the body corporate, its directors or officers are connected or associated” and substitutes the words “connected person who is a natural person” in paragraph 5(4)(g) of the primary Regulation. This

amendment is consequential to the amendment made by Item 10 to paragraph 5(4)(f) of the primary Regulation.

Item 12 inserts new paragraphs 5(4)(ga), (gb), (gc) and (gd). New paragraph 5(4)(ga) requires the applicant who is a body corporate to provide details of the connections or associations that the applicant has with a person that is a body corporate. The details required include the identity of each of the body corporate and the length of the connection or association with that particular body corporate. New paragraph 5(4)(gb) has the effect of requiring the applicant to provide information about the identity of each natural person who holds a relevant financial interest, or who is entitled to exercise relevant power in relation to the applicant's business or in relation to other business of the applicant that provides a substantial proportion of the applicant's current income. New paragraph 5(4)(gb) is identical to the information requirements applying to an applicant for a medicinal cannabis licence who is a natural person that are specified in paragraph 5(3)(f) of the primary Regulation. New paragraph 5(4)(gc) requires the applicant for a medicinal cannabis licence to provide details about each body corporate that holds a relevant financial interest, or who is entitled to exercise relevant power in relation to the applicant's business or in relation to other business of the applicant that provides a substantial proportion of the applicant's current income. New paragraph 5(4)(gd) requires the applicant that is a body corporate to provide information in relation to each person who holds any relevant position in relation to the applicant's business that will undertake the activities under the medicinal cannabis licence.

Item 13 After section 7

Item 13 inserts new sections 7A and 7B.

New section 7A provides for the general grounds for the Secretary to refuse the granting of a medicinal cannabis licence for the purposes of paragraph 8G(1)(f) of the Act. Subsection 8G(1) of the Act lists the circumstances, the existence or non-existence of which, requires the Secretary to refuse to grant a medicinal cannabis licence. The Secretary must refuse to grant a medicinal cannabis licence if the Secretary is satisfied on reasonable grounds that one or more circumstances exist that are prescribed in the regulations as circumstances in which a licence must not be granted (paragraph 8G(1)(f)). New section 7A provides that the circumstances in which a medicinal cannabis licence must not be granted if neither of the following apply:

- (a) the applicant will be carrying out the cultivation of cannabis plants referred to in paragraph 8E(1)(a) of the Act, or the production of cannabis or cannabis resin referred to in paragraph 8E(1)(b) of the Act;
- (b) one or more persons, under the direct supervision of the applicant for the licence, will be carrying out that cultivation or production.

An applicant that proposes to carry out the activities of cultivation of cannabis plants, or the production of cannabis or cannabis resins as referred to in paragraphs 8E(1)(a) and (1)(b), respectively, primarily through a third party, such as a contractor, will be refused a medicinal cannabis licence. The conditions attached to the medicinal cannabis licence are imposed on the licence holder, such as security requirements, employment of staff, reporting requirements and other requirements to ensure that the risk of diversion of the cannabis or cannabis resin is prevented. Thus, it is important that the primary activities referred to under paragraphs 8E(1)(a) and (b) of the Act are actually carried out by the applicant for the licence, or through one or more persons under the direct supervision of the applicant for the licence.

New section 7B also prescribes particular grounds for the refusal of a medicinal cannabis licence for the purposes of paragraph 8J(2)(c) of the Act. Subsection 8J(2) of the Act provides that the Secretary must refuse to grant a medicinal cannabis licence that authorises the production of cannabis or cannabis resin (whether or not that licence also authorises cultivation of cannabis plants) if the Secretary is not satisfied on reasonable grounds that:

- (a) the production of cannabis or cannabis resin for medicinal purposes is for the purposes of supply to the holder of a licence under the Act that authorises:
 - (i) the manufacture of one or more drugs that are medicinal cannabis products; or
 - (ii) the manufacture of a drug for the purposes of research relating to medicinal cannabis products; or
- (b) the applicant holds a licence that authorises such manufacture; or
- (c) the production of cannabis or cannabis resin for medicinal purposes is for a purpose described by the regulations.

New section 7B now has the effect of allowing the Secretary to grant a medicinal cannabis licence (assuming all other requirements and criteria are met) if the applicant proposes to supply cannabis or cannabis resin to a person who holds a manufacture licence under the *Therapeutic Goods Act 1989* (the TG Act), for use by that person in the manufacture of medicine and where one of the following circumstances apply:

- (a) that medicine is to be supplied by a pharmacist in a public hospital in accordance with the TG Act;
- (b) that medicine is to be supplied in circumstances mentioned in subparagraph 11K(2)(b)(i) (for clinical trials) or (ii) (under an approval or authority granted under the TG Act).
- (c) that medicine is to be supplied by way of export from Australia in accordance with a licence and permission under the *Customs (Prohibited Exports) Regulations 1958*.

Item 14 After paragraph 11(2)(i)

Item 14 inserts a new subparagraph 11(2)(ia) that has the effect of requiring an applicant for a cannabis research licence to provide information about the details of the supply of cannabis plants or parts of cannabis plants as mentioned in subparagraph 9D(1)(c)(ia) of the Act to a holder of a licence that authorises cultivation.

Paragraph 9D(1)(c) of the Act was amended on 23 November 2016 by the *Narcotic Drugs Legislation Amendment Act 2016* to allow cannabis research licence holders to supply cannabis plants (including parts of a cannabis plant) to the holder of a licence under the Act that authorises the cultivation of cannabis plants. The information requirement mentioned in new subparagraph 11(2)(ia) is consequential to that amendment and is necessary to allow the Secretary to make a decision for the granting of a cannabis research licence that authorises the supply of cannabis plants to those other licence holders.

Items 15 to 25, Paragraphs 11(3)(d) to (f), (m) and (n) and 11(4)(f) to 11(4)(g).

Items 15-20 and 23 to 25 amend subsections 11(3) (information requirements for a cannabis research licence where the applicant is an individual) and 11(4) (information requirements for a cannabis research licence where the applicant is a body corporate) to require the applicants to provide information about their business associates who can be individuals or bodies corporate or both, consistent with the application of sections 8A and 8B of the Act.

Section 11 of the primary Regulation specifies the information that an applicant for a cannabis research licence is required to provide with their application for a licence. Thus, the amendments to subsections 11(3) and 11(4) of the primary Regulation now require appropriate information from the applicant (a natural person or a body corporate) in relation to the identity of a business associate who is a body corporate, including the nature and length of that association. The discussion for the reasons of the amendments to subsection 5(4) and 5(3) that are made by Items 1-12 equally applies to the amendments by Items 15-20, and 23-25.

Item 15 inserts the words “(each of whom is a connected person)” after the words “other persons” in paragraph 11(3)(d) of the primary Regulation. The words “connected person” is a person who has a connection or association with the applicant and whose details are required to be provided by the applicant as mentioned in paragraph 11(3)(e) and new paragraph 11(3)(ea).

Item 16 omits the words “person mentioned in paragraph (d) with whom the applicant is connected or associated” and substitutes the words “connected person who is a natural person” in paragraph 11(3)(e) of the primary Regulation. This amendment is consequential to the amendment made by Item 15 to paragraph 11(3)(d) of the primary Regulation. Paragraph 11(3)(e) lists the details of a natural person, with whom an applicant (who is an individual) is connected or associated, must provide with the application for a cannabis research licence.

Item 17 inserts a new paragraph 11(3)(ea). Paragraph 11(3)(ea) lists the information that is required to be provided by the applicant, who is an individual, in relation to each connected person that is a body corporate. Thus, assuming the applicant has a connected person that is a body corporate, the applicant is required to provide details of that body corporate as listed in subparagraphs (i) to (vi) that relate to the identity of the body corporate and the length and nature of the connection or association with that body corporate.

Item 18 inserts the word “natural” after the words “of each” in paragraph 11(3)(f) of the primary Regulation. This amendment makes it clear that the information requirement relates to details of a natural person who holds a relevant financial interest, or who is entitled to exercise a relevant power in relation to the applicant’s business that will undertake the activities or in relation to other business of the applicant that provides a substantial proportion of the applicant’s current income.

Item 19 omits the words “his or her own right or on someone else’s behalf” and substitutes them with the words “the natural person’s own right or on behalf of another person”, in paragraph 11(3)(f). This amendment is consequential on the amendment made by Item 18.

Item 20 inserts a new paragraph 11(3)(fa). While paragraph 11(3)(f) requires the details of a natural person who holds relevant financial interest or who is entitled to exercise a relevant power in relation to the applicant’s business, new paragraph 11(3)(fa) requires the details of a body corporate who holds relevant financial interest or who is entitled to exercise relevant power in relation to the applicant’s business.

Item 21 is a consequential amendment in view of the repeal of paragraph 5(3)(n) (Item 22 refers).

Item 22 omits paragraph 11(3)(n). The information required from the applicant under paragraph 11(3)(n) relates to the applicant's history of compliance with the Act. The Department of Health already holds this information and therefore it is not necessary to be provided by the applicant for a cannabis research licence.

Item 23 inserts the words “(each of whom is a connected person)” after the words “other persons” in paragraph 11(4)(f) of the primary Regulation. Subsection 11(4) of the primary Regulation lists the information required to be provided by an applicant for a cannabis research licence who is a body corporate. The words “connected person” is a person who has a connection or association with the applicant and whose details are required to be provided by the applicant as mentioned in paragraph 11(4)(g) and new paragraphs 11(4)(ga) to (gd) (Item 25 refers).

Item 24 omits the words “person mentioned in paragraph (f) with whom the body corporate, its directors or officers are connected or associated” and substitutes the words “connected person who is a natural person” in paragraph 11(4)(g) of the primary Regulation. This amendment is consequential to the amendment made by Item 23 to paragraph 11(4)(f) of the primary Regulation.

Item 25 inserts new paragraphs 11(4)(ga), (gb), (gc) and (gd). New paragraph 11(4)(ga) requires the applicant who is a body corporate to provide details of the connections or associations that the applicant has with a person that is a body corporate. The details required include the identity of the each of the body corporate and the length of the connection or association with that particular body corporate. New paragraph 11(4)(gb) has the effect of requiring the applicant to provide information about the identity of each natural person who holds a relevant financial interest, or who is entitled to exercise relevant power in relation to the applicant's business or in relation to other business of the applicant that provides a substantial proportion of the applicant's current income. New paragraph 11(4)(gc) requires the applicant for a cannabis research licence to provide details about each body corporate that holds a relevant financial interest, or who is entitled to exercise relevant power in relation to the applicant's business or in relation to other business of the applicant that provides a substantial proportion of the applicant's current income. New paragraph 11(4)(gd) requires the applicant that is a body corporate to provide information in relation to each person who holds any relevant position in relation to the applicant's business that will undertake the activities under the cannabis research licence.

Item 26 After section 13

Item 26 inserts new section 13A

New section 13A provides for the general grounds for the Secretary to refuse the granting of a cannabis research licence for the purposes of paragraph 9F(1)(f) of the Act. Subsection 9F(1) of the Act lists the circumstances, the existence or non-existence of which, requires the Secretary to refuse to grant a cannabis research licence. The Secretary must refuse to grant a cannabis research licence if the Secretary is satisfied on reasonable grounds that one or more circumstances exist that are prescribed in the regulations as circumstances in which a licence must not be granted (paragraph 9F(1)(f)).

New section 13A provides that the circumstances in which a cannabis research licence must not be granted if neither of the following apply:

- (c) the applicant will be carrying out the cultivation of cannabis plants referred to in paragraph 9D(1)(a) of the Act, or the production of cannabis or cannabis resin referred to in paragraph 9D(1)(b) of the Act;
- (d) one or more persons, under the direct supervision of the applicant for the licence, will be carrying out that cultivation or production.

An applicant that proposes to carry out the activities of cultivation of cannabis plants, or the production of cannabis or cannabis resin as referred to in paragraphs 9D(1)(a) and (1)(b), respectively, primarily through a third party, such as a contractor, will be refused a cannabis research licence. The conditions attached to the cannabis research licence are imposed on the licence holder, such as security requirements, employment of staff, reporting requirements and other requirements to ensure that the risk of diversion of the cannabis or cannabis resin is prevented. Thus, it is important that the primary activities referred to under subsection 8E(1)(a) and (b) are actually carried out by the applicant for the licence, or through one or more persons under the direct supervision of the applicant for the licence.

Item 27 At the end of subsection 14(2)

Item 27 inserts a new paragraph 14(2)(d) to the primary Regulation. Section 14 of the primary Regulation prescribes the information required to be provided in an application for a cannabis research permit by the cannabis research licence holder. As a consequence of the addition of subparagraph 9D(1)(c)(ia) made by the *Narcotic Drugs Legislation Amendment Act 2016*, a cannabis research licence holder can now be authorised to supply cannabis plants or parts of a cannabis plant to a cannabis licence holder that is authorised to carry out cultivation of cannabis plants under that licence. Information in relation to that supply activity is therefore required to be included in the application for a cannabis research licence and the cannabis research permit so as to inform the Secretary of the proposed activity. New paragraph 14(2)(d) requires the licence holder applying for a cannabis research permit to provide information mentioned in subparagraphs (i) to (iv), if one of the activities authorised under the licence is about an activity that is covered by subparagraph 9D(1)(c)(ia) of the Act.

Item 28 At the end of section 15(2)

Item 28 repeals the current subsection 15(2) of the primary Regulation and substitutes a new subsection 15(2).

Section 15 of the primary Regulation specifies the documents that must accompany an application by the holder of a cannabis research licence for a cannabis research permit. As the existence of contracts between the applicant for a cannabis research licence that would authorise cultivation and the holder of a cannabis research licence under the Act that authorises production is not required under the Act, paragraph 15(2)(a) is repealed, and a new subsection 15(2) is substituted without the current paragraph 15(2)(a).

Item 29 At the end of section 19

Item 29 inserts new subsection 19(9) and (10).

Subsection 10J(3) of the Act relevantly provides that a contract referred to in subsection 10J(1) or 10J(2) of the Act is not required to be in existence, in the circumstances (if any) prescribed by the regulations, or if the Secretary of the Department of Health determines in a particular case that such a contract is not required to be in existence. The relevant contract

under subsection 10J(2) is a contract between the medicinal cannabis licence holder that is authorised to carry out the production of cannabis or cannabis resin and the holder of a manufacture licence under the Act that is authorised to manufacture one or more drugs that is a medicinal cannabis product or the manufacture of a drug for the purposes of research in relation to medicinal cannabis.

New subsection 19(9) provides that for the purposes of paragraph 10J(3)(a) of the Act, the circumstances referred to in subsection 19(10) are prescribed as circumstances in which a contract referred to in subsection 10J(2) of the Act is not required to be in existence.

New subsection 19(10) describes the circumstances in which a contract referred to in subsection 10J(2) is not required to be in existence. The circumstances are that the production of the cannabis or cannabis resin is for the supply of these materials to a person who holds a manufacture licence under the TG Act for use by that person in the manufacture of a medicine and where one or more of the following apply:

- (a) that medicine is to be supplied by a pharmacist in a public hospital in accordance the TG Act;
- (b) that medicine is to be supplied in circumstances mentioned in subparagraph 11K(2)(b)(i) or (ii);
- (c) that medicine is supplied by way of export from Australia in accordance with a licence and permission under the *Customs (Prohibited Exports) Regulations 1958*.

Items 30-32 Section 20

The current section 20 of the primary Regulation prescribes the conditions applying to a cannabis licence for the purposes of paragraph 10K(d) of the Act. As Item 32 adds a new subsection (2), amendments are required to renumber section 20. Item 30 inserts (1) before the words “For the”. Item 31 corrects the reference to the relevant paragraph under the Act, and thus omits the words “paragraph 10K(d)” and substitutes it with correct reference being “10K(1)(d)”.

It is a condition of a cannabis licence that the licence holder notifies the Secretary if any of the matters set out in paragraphs 10K(1)(a) to (d) of the ND Act comes to the attention of the licence holder. Subsection 10K(2) of the ND Act provides that the holder must notify the Secretary of a matter referred to in subsection (1):

- (a) if the regulations prescribe a period within which the matter must be notified to the Secretary- before the end of that period; or
- (b) otherwise - as soon as reasonably practicable after the matter comes to the attention of the licence holder.

Item 32 adds a new subsection 20(2) for the purposes of paragraph 10K(2)(a) of the Act, and provides that the period for a matter covered by paragraph 20(1)(a), (b), (c), (d), (e) or (f) is 72 hours starting when the matter comes to the attention of the licence holder. The matters covered by these paragraphs include security breach, theft or suspected theft of cannabis plants, cannabis or cannabis resin, and loss or suspected loss of these materials.

Item 33 At the end of section 28

Item 33 adds a new subsection 28(6) to the primary Regulation. Section 28 of the primary Regulation provides for the notification of the proposed suspension of cannabis licence or permit to a cannabis licence holder. New subsection 28(6) prohibits the disclosure of

information identified as sensitive law enforcement information under subsection 14LA(1) or (2) of the Act in the provision of a notice to a licence holder stating the reasons for the proposed suspension. New subsection 28(6) also requires the Secretary to, if he or she relies upon such information in relation to the proposed suspension, consult the giver of the information before giving the notice. The prohibition of the disclosure of sensitive law enforcement information in a notice of a decision and the consultation requirement are consistent with the requirements under the Act (e.g. refer to subsection 15J(4) of the Act).

Items 34-44 Paragraphs 35(3)(d), (e), (f), (m), (n) and paragraphs 35(4)(f) to (g)

Items 34 to 39 and 42 to 44 amend subsections 35(3) (information requirements for a manufacture licence where the applicant is an individual) and 35(4) (information requirements for a manufacture licence where the applicant is a body corporate) to now require the applicants to provide information about their business associates who can be individuals or bodies corporate or both, consistent with the application of sections 8A and 8B of the Act.

Section 35 of the primary Regulation specifies the information that an applicant for a manufacture licence is required to provide with their application for a licence. Thus, the amendments to subsections 35(3) and 35(4) of the primary Regulation now require appropriate information from the applicant (a natural person or a body corporate) in relation to the identity of a business associate who is a body corporate, including the nature and length of that association. The discussion for the reasons of the amendments to subsection 5(4) and 5(3) of the primary Regulation that are made by Items 1-12 equally apply to the amendments made by Items 34-39, and 42 to 44.

Item 34 inserts the words “(each of whom is a connected person)” after the words “other persons” in paragraph 35(3)(d) of the primary Regulation. The words “connected person” is a person who has a connection or association with the applicant and whose details are required to be provided by the applicant as mentioned in paragraph 35(3)(e) and new paragraph 35(3)(ea).

Item 35 omits the words “person mentioned in paragraph (d) with whom the applicant is connected or associated” and substitutes the words “connected person who is a natural person” in paragraph 35(3)(e) of the primary Regulation. This amendment is consequential to the amendment made by Item 34 to paragraph 35(3)(d) of the primary Regulation. Paragraph 35(3)(e) lists the details of a natural person, with whom an applicant (who is an individual) is connected or associated, must provide with the application for a manufacture licence.

Item 36 inserts a new paragraph 35(3)(ea). Paragraph 35(3)(ea) lists the information that is required to be provided by the applicant, who is an individual, in relation to each connected person that is a body corporate. Thus, assuming the applicant has a connected person that is a body corporate, the applicant is required to provide details of that body corporate as listed in subparagraphs (i) to (vi) that relate to the identity of the body corporate and the length and nature of the connection or association with that body corporate.

Item 37 inserts the word “natural” after the words “of each” in paragraph 35(3)(f) of the primary Regulation. This amendment makes it clear that the information requirement relates to details of a natural person who holds a relevant financial interest, or who is entitled to exercise a relevant power in relation to the applicant’s business that will undertake the

activities or in relation to other business of the applicant that provides a substantial proportion of the applicant's current income.

Item 38 omits the words "his or her own right or on someone else's behalf" and substitutes them with the words "the natural person's own right or on behalf of another person", in paragraph 35(3)(f). This amendment is consequential on the amendment made by Item 37.

Item 39 inserts a new paragraph 35(3)(fa). While paragraph 35(3)(f) requires the details of a natural person who holds relevant financial interest or who is entitled to exercise a relevant power in relation to the applicant's business, new paragraph 35(3)(fa) requires the details of a body corporate who holds relevant financial interest or who is entitled to exercise relevant power in relation to the applicant's business.

Item 40 is a consequential amendment in view of the repeal of paragraph 35(3)(n) (item 41 refers).

Item 41 repeals paragraph 35(3)(n). The information required from the applicant under paragraph 35(3)(n) relates to the applicant's history of compliance with the Act. As mentioned previously, the Department of Health already holds this information and therefore it is not necessary to be provided by the applicant for a medicinal cannabis licence.

Item 42 inserts the words "(each of whom is a connected person)" after the words "other persons" in paragraph 35(4)(f) of the primary Regulation. Subsection 35(4) of the primary Regulation lists the information required to be provided by an applicant for a manufacture licence who is a body corporate. The words "connected person" is a person who has a connection or association with the applicant and whose details are required to be provided by the applicant as mentioned in paragraph 35(4)(g) and new paragraphs 35(4)(ga) to (gd) (Item 44 refers).

Item 43 omits the words "person mentioned in paragraph (f) with whom the body corporate, its directors or officers are connected or associated" and substitutes the words "connected person who is a natural person" in paragraph 35(4)(g) of the primary Regulation. This amendment is consequential to the amendment made by Item 42 to paragraph 35(4)(f) of the primary Regulation.

Item 44 inserts new paragraphs 35(4)(ga), (gb), (gc) and (gd). New paragraph 35(4)(ga) requires the applicant who is a body corporate to provide details of the connections or associations that the applicant has with a person that is a body corporate. The details required include the identity of each of the body corporate and the length of the connection or association with that particular body corporate. New paragraph 35(4)(gb) has the effect of requiring the applicant to provide information about the identity of each natural person who holds a relevant financial interest, or who is entitled to exercise relevant power in relation to the applicant's business or in relation to other business of the applicant that provides a substantial proportion of the applicant's current income. New paragraph 35(4)(gc) requires the applicant for a manufacture licence to provide details about each body corporate that holds a relevant financial interest, or who is entitled to exercise relevant power in relation to the applicant's business or in relation to other business of the applicant that provides a substantial proportion of the applicant's current income. New paragraph 35(4)(gd) requires the applicant that is a body corporate to provide information in relation to each person who holds any relevant position in relation to the applicant's business that will undertake the activities under the manufacture licence.

Item 45 At the end of paragraph 35(8)(b)

Item 45 adds a new subparagraph (iii) in paragraph 35(8)(b) of the primary Regulation. Subsection 35(8) requires the provision of additional information described in paragraphs (a) and (b), if the applicant for a manufacture licence proposes to manufacture a drug that includes, or is derived from any part of a cannabis plant. As a consequence of the amendment to section 37 of the primary Regulation (Item 50 refers) where the licence holder can supply the drug in the circumstances specified in that section, additional information is required under paragraph 35(8)(b) in relation to details of the supply and details of any arrangements in place between the applicant and that person relating to the proposed end use of the medicine referred to in paragraph 37(c).

Item 46 Paragraph 36(2)(e)

Item 46 repeals paragraph 36(2)(e) of the primary Regulation. Section 36 of the primary Regulation prescribes the documents required to be provided by the applicant for a manufacture licence. Paragraph 36(2)(e) requires the applicant for a manufacture licence to provide a copy of the standard operating procedures and policies that will be used to undertake the activities. As these documents are not currently assessed by the delegate of the Secretary in making a decision to grant or refuse a manufacture licence, these documents are no longer be required to be provided by the applicant for a manufacture licence.

Items 47 and 48 Paragraph 36(2)(e) and (f)

Item 48 repeals paragraph 36(2)(g). Paragraph 36(2)(g) requires the applicant for a manufacture licence to provide a national police certificate issued by the Australian Federal Police (AFP), or by a police force of a State or Territory, in respect of each person employed by the applicant to carry out activities authorised by the licence. As the Department of Health may be able to directly liaise with the AFP to request for a National Police Check in relation to a person, and there are other available statutory powers under the Act for these documents to be requested from the licence holder or the applicant, paragraph 36(2)(g) can be repealed. Item 47 is a consequential amendment to the repeal of paragraph 36(2)(g).

Item 49 After section 36

Item 49 inserts a new section 36A that relates to general grounds for refusal of a manufacture licence. New section 36A provides for the general grounds for the Secretary to refuse the granting of a manufacture licence for the purposes of paragraph 11J(1)(f) of the Act. Subsection 11J(1) of the Act lists the circumstances, the existence or non-existence of which, requires the Secretary to refuse to grant a manufacture licence. The Secretary must refuse to grant a manufacture licence if the Secretary is satisfied on reasonable grounds that one or more circumstances exist that are prescribed in the regulations as circumstances in which a licence must not be granted (paragraph 11K(1)(f) of the Act).

New section 36A provides that a circumstance in which a manufacture licence must not be granted is if neither of the following apply:

- (a) the applicant will be carrying out the manufacture of the drug referred to in paragraph 11G(1)(a) of the Act;

- (b) one or more persons, under the direct supervision of the applicant for the licence, will be carrying out that manufacture.

Item 50 Section 37

Item 50 repeals the current section 37 and substitutes it with a new section 37.

Subsection 11K(2) of the Act provides that the Secretary must refuse to grant a manufacture licence unless the Secretary is satisfied on reasonable grounds of at least one of the circumstances described in paragraphs 11K(2)(a) to (c). Subsection 11K(2) applies to the manufacture of a drug that includes, or is from, any part of the cannabis plant.

Thus, in view of the need to satisfy at least one of the criterion for the granting of a manufacture licence as described in subsection 11K(2) of the Act, the supply of unregistered or unapproved medicinal cannabis products in Australia is limited to the following (refer to paragraph 11K(2)(b) of the Act:

- (a) for the purposes of use in a clinical trial that is, or is likely to be, approved under the TG Act or notified to the Secretary under that Act (subparagraph 11K(2)(b)(i)); or
- (b) otherwise supplied in accordance with an approval or authority under the TG Act (subparagraph 11K(2)(b)(ii));
- (c) supplied in circumstances prescribed in the regulations (subparagraph 11K(2)(b)(iii)).

The current section 37 of the primary Regulation provides a circumstance in which a medicinal cannabis product can be supplied for the purposes of subparagraph 11K(2)(b)(iii), that is where the medicinal cannabis product will be supplied by a pharmacist in a public hospital in accordance with the TG Act.

The new section 37 adds other circumstances that the drug will be supplied for the purposes of subparagraph 11K(2)(b)(iii). These circumstances are the following:

- (a) by a pharmacist in a public hospital in accordance with the TG Act; or
- (b) by way of export from Australia in accordance with a licence and permission under the *Customs (Prohibited Exports) Regulations 1958*; or
- (c) to a person who holds a manufacture licence under the TG Act for use by that person in the manufacture of a medicine, where:
 - (i) that medicine is to be supplied by a pharmacist in a public hospital in accordance with the TG Act; or
 - (ii) that medicine is to be supplied in circumstances mentioned in subparagraph 11K(2)(b)(i) or (ii) of the Act; or
 - (iii) that medicine is supplied by way of export from Australia in accordance with a licence and permission under the *Customs (Prohibited Exports) Regulations 1958*.

Section 37 allows the export to be carried out by the manufacture licence holder under the Act if they hold a licence or permit under the *Customs (Prohibited Exports) Regulations* (export licence and permit), or by another person who holds that licence or permit. Similarly, the export can be carried out by the manufacture licence holder under the TG Act (if they hold an export licence and permit) or another person who holds an export licence or permit

If supply is to the holder of a licence under the TG Act, applicants must also provide evidence to support that that supply will be in accordance with 11K(2)(b)(i) or (ii) of the Act.

Although the export of a medicinal cannabis product is now allowed by virtue of new section 37, applicants proposing the supply of medicinal cannabis products by export would be required to provide information and details on how arrangements will be made in place to ensure that Australian patients will always have reliable access to medicinal cannabis products despite the export of such products.

In addition, conditions will be imposed by the Secretary on the manufacture licence to ensure that Australian patients have reliable access to medicinal cannabis products despite the export of the manufactured products.

Item 51-52 Paragraphs 38(2)(i), (j) and (k).

Item 52 repeals paragraphs 38(2)(j) and (k) of the primary Regulation, and Item 51 is a consequential on the repeal of those paragraphs. Section 38 of the primary Regulation prescribes the information required to be provided by an applicant for a manufacture licence. Paragraphs 38(2)(j) and (k) require the applicant to provide information about how the applicant will comply with the condition in section 12L or 12M of the Act. Instead of requiring information in relation to the compliance of these conditions, compliance will be monitored after the manufacture licence is granted.

Items 53 to 55 Section 40

The current section 40 of the primary Regulation prescribes the conditions applying to a manufacture licence for the purposes of paragraph 12N(1)(d) of the Act. As Item 55 adds a new subsection (2), amendments are required to renumber and restructure section 40. Item 53 inserts “(1)” before the words “For the”. Item 54 corrects the reference to the relevant paragraph under the Act, and thus omits the words “paragraph 12N(d)” and substitutes it with the correct reference being “12N(1)(d)”.

It is a condition of a manufacture licence that the licence holder notifies the Secretary if any of the matters set out in paragraphs 12N(1)(a) to (d) of the Act comes to the attention of the licence holder. Subsection 12N(2) of the Act provides that the holder must notify the Secretary of a matter referred to in subsection (1):

- (a) if the regulations prescribe a period within which the matter must be notified to the Secretary- before the end of that period; or
- (b) otherwise - as soon as reasonably practicable after the matter comes to the attention of the licence holder.

Item 55 adds a new subsection 40(2) for the purposes of paragraph 12N(2)(a) of the Act, and provides that the period for a matter covered by paragraph 40(1)(a), (b), (c), (d), (e) or (f) is 72 hours starting when the matter comes to the attention of the licence holder. The matters covered by these paragraphs include security breach in the premises, theft or suspected theft of cannabis plants, cannabis or cannabis resin from the premises, and loss or suspected loss of these materials from the premises.

Item 56 At the end of section 46

Item 56 adds a new subsection 46(6). Section 46 of the primary Regulation provides for the notification of the proposed suspension of manufacture licence or permit to a manufacture licence holder. New subsection 46(6) prohibits the disclosure of information identified as sensitive law enforcement information under subsection 41LA(1) or (2) of the Act in the provision of a notice to a licence holder stating the reasons for the proposed suspension. Subsection 46(6) also requires the Secretary to, if he or she relies upon such information in relation to the proposed suspension, consult the giver of the information before giving the notice. The prohibition of the disclosure of sensitive law enforcement information in a notice of a decision and the consultation requirement are consistent with the requirements under the Act (e.g. refer to subsection 15J(4) of the Act).

Item 57 At the end of Division 2 of Part 5

Item 57 adds new section 56 to the primary Regulation. New section 56 modifies the operation of Chapters 2 and 3 of the Act in relation to an agency of a State or Territory.

Paragraph 27(4)(g) of the Act enables the making of regulations for the purpose of modifying the operation of Chapters 2 and 3 of the Act (cannabis licences and permits, and manufacture licences and permits, respectively) in circumstances where the applicant for a licence, or a licence holder, is an agency of a State or Territory.

New section 56 in effect removes the fit and proper person requirements in relation to the granting of a licence, revocation of a licence and condition of a licence under the Act, where the applicant for a licence or the licence holder is an agency of a State or Territory. An agency of a State or Territory is defined under section 4 of the Act.

Item 58 After Part 5

Item 58 inserts Part 6 – Application, saving and transitional provisions.

New section 57 provides for the application provisions in relation to the amendments made by the Amendment Regulations.

Subsection 57(1) provides that the amendments made to section 5 made by this amendment Regulation apply to medicinal cannabis licence applications under section 8E of the Act made on or after the commencement of this section.

Subsection 57(2) provides that new sections 7A and 7B apply in relation to applications made under section 8E of the Act on or after the commencement of this section.

Subsection 57(3) provides that the amendments of section 11 amendments apply in relation to applications for a cannabis research licence made under section 9D of the Act on or after the commencement of this section.

Subsection 57(4) provides new section 13A applies to cannabis research licence application under section 9D of the Act made on or after the commencement of this section.

Subsection 57(5) provides that the amendments to section 14 and 15, apply in relation to applications for a cannabis research permit under section 9N of the Act made on or after the commencement of this section.

Subsection 57(6) provides that the amendments made to section 19 (adding new subsections 19(9) and 19(10)) apply in relation to medicinal cannabis licences granted under the Act on or after the commencement of this section.

Subsection 57(7) provides that new subsection 20(2) applies in relation to matters arising on or after the commencement of this section, irrespective of whether the cannabis licence was granted before the commencement of this section, or on or after the commencement of this section.

Subsection 57(8) provides that new subsection 28(6) applies in relation to notices given under subsection 28(1) of the primary Regulation on or after the commencement of this section.

Subsection 57(9) provides that the amendments of section 35 and 36 apply in relation to applications for a manufacture licence under section 11G of the Act made on or after the commencement of this section.

Subsection 57(10) provides that new section 36A applies in relation to applications for a manufacture licence made on or after the commencement of this section.

Subsection 57(11) provides that new section 37 applies in relation to applications for a manufacture licence applications under section 11G made on or after the commencement of this section.

Subsection 57(12) provides that the amendments made to section 38 of the primary Regulation apply in relation to applications for a manufacture permit made under section 12 of the Act on or after the commencement of this section.

Subsection 57(13) provides that new subsection 40(2) applies in relation to matters arising on or after the commencement of this section, irrespective of whether the manufacture licence was granted under the Act before, on or after the commencement of this section.

Subsection 57(14) provides that new subsection 46(6) applies in relation to notices given under subsection 46(1) on or after the commencement of this section.

Subsection 57(15) provides that new section 56 applies in relation to:

- (a) in the case of paragraphs 56(a), (b) and (e) – applications for a medicinal cannabis licence, cannabis research licence and manufacture licence made on or after the commencement of this section;
- (b) in the case of paragraphs 56(c), (d), (f) and (g) – licences granted on or after the commencement of this section.

Subsection 57(16) provides that the amendments in relation to fees apply in relation to applications made on or after the commencement of this section.

Items 59 to 60 Clause 1 of Schedule (table Items 1, 3, 5 and 7)

Schedule 1 to the primary Regulation lists the applicable fees for applications specified in the Table.

Item 59 omits “5,290” and substitutes “5,040” in table Items 1 and 3. Thus, the application fee for a medicinal cannabis licence or a cannabis research licence is reduced from \$5,290 to \$5,040.

Item 60 omits “4,150” and substitutes “3,900 in table Items 5 and 7. Thus, the application fee for a variation of a medicinal cannabis licence or a cannabis research licence is reduced from \$4,150 to \$3,900.

These amendments ensure consistency with the agreed cost recovery arrangement.

Statement of Compatibility with Human Rights

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

Narcotic Drugs Amendment (Cannabis) Regulations 2018

The *Narcotic Drugs Amendment (Cannabis) Regulations 2018* (the Amendment Regulations) 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 Amendment Regulations are made under subsection 27(1) of the *Narcotic Drugs Act 1967*. The Amendment Regulations amend the *Narcotic Drugs Regulation 2016* (the Regulation).

The purpose of the Amendment Regulations is to permit exports of medicinal cannabis products, to allow a drug that is a medicinal cannabis product and raw cannabis and cannabis resin to be supplied directly to the holder of a manufacture licence under the *Therapeutic Goods Act 1989* for subsequent supply to Australian patients or for export, and to make other minor and technical amendments.

The minor and technical amendments support the streamlined operation of the Act, would provide support to the amendments to the Act made by the *Narcotic Drugs Legislation Amendment Act 2016* on November 2016 and provide consistency in relation to the requirements applying to the different licences under the Act. The amendments include the following:

- non-disclosure of sensitive law enforcement information in the provision of a notice to a licence holder stating the reasons for the proposed suspension of a licence;
- prescribing the periods for the provision of specified information;
- prescribing general grounds for the refusal of a licence under the Act;
- additional information requirements in relation to the supply of cannabis plants or parts of the cannabis plant by the cannabis research licence holder;
- additional information requirements in relation to the business associates of the applicant that are bodies corporate;
- prescribing of substances for the purposes of the definition of a “drug” under the Act;
- waiving the “fit and proper person” requirement where the applicant or a licence holder is an agency of a State or Territory; and
- minor corrections to some fees.

Human rights implications

The Amendment Regulations engage, or have the potential to engage, the following human rights:

- right to health in Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESR)
- right to work in Articles 6 and 7 of the ICESR; and
- right to freedom of association in Article 22 of the International Covenant on Civil and Political Rights (ICCPR).

Article 12 of the ICESR

The right to health is fundamental to the exercise of other human rights. It is a right to enjoy the highest standard of physical and mental health.

The Amendment Regulations engage the human right to health under Article 12 of the ICESR by better facilitating access of medicinal cannabis products by Australian patients. The amendments now allow access to medicines containing raw cannabis or cannabis resins when manufactured by manufacturers licensed under the *Therapeutic Goods Act 1989*. The amendments implemented by the Amendments Regulations allow for the supply of medicinal cannabis products (either containing raw cannabis or cannabis resin as ingredients, or manufactured drugs that are medicinal cannabis products) directly to manufacturers licensed under the *Therapeutic Goods Act 1989* for further manufacture into and supply as medicines to Australian patients and for export to overseas patients.

Thus, the Amendment Regulations promote the right to health as they aimed at facilitating better access of good quality medicinal cannabis products by Australian patients.

Articles 6 and 7 of the ICESR

Article 6(1) of the ICESCR protects the right of everyone to the opportunity to gain his or her living by work which he or she freely chooses or accepts, and rights at work while Article 7 recognises the right of everyone to the enjoyment of just and favourable conditions of work. These rights may be subject only to such limitations 'as are determined by law only in so far as this may be compatible with the nature of these rights and solely for the purpose of promoting the general welfare in a democratic society'.

Chapters 1, 2 and 3 of the *Narcotic Drugs Act 1967* (the Act) include provisions that limit these rights in order to ensure that cannabis plants are not cultivated or cannabis and other drugs are not manufactured for illegal purposes. Persons may be prevented from holding a licence under the Act on the basis that they are determined not to be fit and proper to do so or that they may have business associates that are not fit and proper.

The high threshold as reflected in the criteria and information gathering for the granting a licence to cultivate cannabis plants, produce cannabis or cannabis resins, and the manufacture of drugs under the Act ensure that only fit and proper person can be granted a licence.

These requirements and restrictions are necessary to address the high diversion risk associated with cannabis, which is very valuable on the illicit market. It is very likely that without effective regulatory controls in place, this industry will attract organised crime elements looking to profit from the 'black market' under the legitimacy of an authorised cultivation or manufacturing set up. The fit and proper person test, which takes into account convictions, imposition of civil penalties, revocations of drug regulation licences and financial situation, among other things, is designed to exclude persons who have a relevant criminal history, could be either involved in organised crime or might be susceptible to approaches from organised crime.

These limitations are appropriate given the nature of the businesses that are being regulated. The information requirements and details of what information is required to be provided by an applicant are set out in sections 5 (application for a medicinal cannabis licence),

11(application for a cannabis research licence) and 35 (application for a manufacture licence) of the Regulation. The information requirements include details of persons that are associated or have connections with the applicant for a licence.

Accordingly, provisions implemented in the Regulation, including the amendments made by the Amendment Regulations, that require information about a person's suitability to hold a licence, including their business associates, are reasonable and proportionate to achieving the legitimate outcome.

Despite the high threshold as well as the increase in compliance burden to the applicants, licence holders and any of their business associates, the Amendment Regulations are compliant with the right to work, in so far as they do not unjustly deprive work. Staff employed by this industry still has the right to just and favourable conditions of work and safe working conditions.

Article 22

Article 22 of the ICCPR protects the right of individuals to free association with others. It also states that the only permissible limitations to this right are those 'which are prescribed by law and which are necessary in a democratic society in the interests of national security or public safety, public order, the protection of public health or morals or the protection of the rights and freedoms of others'. In all cases, restrictions must be provided for by legislation (or imposed in conformity with legislation), must be necessary to achieve the desired purpose and must be proportionate to the need on which the limitation is based.

Chapters 1, 2 and 3 of the Act and the Regulation, including the amendments described in these Amendment Regulations contain provisions that, together, might be interpreted as limiting this right.

The fit and proper persons test is applied not only to an applicant for a licence and to a licence holder during the period a licence is in force, but also any business associates that the Secretary deems to be relevant. Moreover the test of whether a person is fit and proper (see sections 8A and 8B of the Act) includes consideration of the person's associations and connections with other persons (including relatives), and where the applicant or licence holder is a body corporate, the connections and associations of the directors and officers with other persons (including their families).

Applicants are required to provide information addressing the fit and proper test. The information requirements and details of what information is required to be provided by an applicant is set out in sections 5 (application for a medicinal cannabis licence), 11(application for a cannabis research licence) and 35 (applications for a manufacture licence of the Regulations. The information requirements include details of persons with the applicants are associated or have connections.

This information may give rise to the refusal of the licence, if the Secretary came to the view that a business associate of the applicant was not a fit and proper person. While this could be seen to limit the persons with whom an applicant or a licence holder can associate with, and with the licence holder's ability to make new business associations, in reality, the applicant or licence holder is not prevented from having these associations, though it may put the licence in jeopardy.

These provisions are necessary because of the need to prevent diversion of material that has an extremely high, illicit value. Business associates and others may have influence over the applicant or licence holder such that they may be able to compel the applicant or licence holder to undertake illegal activities on their behalf, through inducement or other means. Further, business associates or family members may be able to use their relationship with the applicant or licence holder to gain direct access to material to be trafficked illegally.

A person seeking the benefit from the Commonwealth in the form of a licence does so in the knowledge that the existence of certain associations, or the entering into in the future of certain relationships, may result in the rejection of an application, or revocation of a licence.

However, despite the associations and connections disclosure obligations under the Amendment Regulations, the amendments are consistent with the right to freedom of association in Article 22 of the ICCPR, as they do not prevent people from forming or joining association.

Conclusion

This legislative instrument is compatible with human rights because it promotes the right to health, and to the extent that it may limit human rights, those limitations are reasonable, necessary and proportionate

Greg Hunt, Minister for Health and Minister for Sport