EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Crimes Act 1914

Therapeutic Goods and Other Legislation Amendment (Narcotic Drugs) Regulation 2016

The *Therapeutic Goods Act 1989* (the Act) establishes and maintains a national system of controls for the safety, quality, efficacy and timely availability of therapeutic goods used in Australia, or exported from Australia. The *Crimes Act 1914* (the Crimes Act) establishes the basis for the enforcement of federal offences in Australia.

Section 63 of the Act provides that the Governor-General may make regulations, not inconsistent with that Act, prescribing matters required or permitted by the Act to be prescribed, or necessary or convenient to be prescribed for carrying out or giving effect to the Act. Section 91 of the Crimes Act authorises the Governor-General to make regulations, prescribing all matters required or permitted by the Act to be prescribed, or necessary or convenient to be prescribed, for carrying out or giving effect to the Crimes Act.

The *Therapeutic Goods and Other Legislation Amendment (Narcotic Drugs) Regulation 2016* (the proposed Regulation) makes amendments to:

- the *Therapeutic Goods Regulations 1990* (the TG Regulations) in relation to access to unapproved medicine in order to provide appropriate regulatory oversight in the import and supply of cannabis used for medicinal purposes (Part 1 of Schedule 2 refers); and
- the *Crimes Regulations 1990* (the Crimes Regulations) to create a new exclusion from the Commonwealth spent convictions scheme that would apply to applicants, licence holders and their business associates in relation to a licence under the *Narcotic Drugs Act 1967* (the ND Act) (Part 2 of Schedule 1 refers).

The Commonwealth spent conviction scheme is in Part VIIC of the Crimes Act and provides that certain types of offences become spent after a waiting period has elapsed in which no further convictions are recorded against the offender. The scheme applies to both natural persons and bodies corporate. The waiting period is 10 years from the date of conviction as an adult and 5 years in the case of a conviction recorded against a minor. Where a conviction for an offence is spent, the offender is not obliged to disclose that prior conviction in specified circumstances. The right of non-disclosure is subject to exclusions listed in section 85ZZH of Division 6, Part VIIC of the Crimes Act, and Schedule 4 to the Crimes Regulations. These exclusions provide that spent conviction information in relation to specified offences must be disclosed by and to certain persons and bodies for certain purposes.

The Regulation amends Schedule 4 to the Crimes Regulations to require the disclosure of convictions of all offences to the Secretary of the Department of Health (the Secretary), which would otherwise be considered spent, by persons for the purpose of assessing their suitability as a fit and

proper person to apply for, or to hold a licence under the ND Act, or to be associated with the holder of such a licence.

The ND Act now allows for the cultivation of cannabis plants and the production of cannabis and cannabis resins under a national licensing scheme. An applicant for a licence and their business associate would have to be found to be a "fit and proper person" according to criteria set out under that Act. The criteria include any conviction by the person for an offence against a law of the Commonwealth, State or Territory. Cultivation of cannabis plants and production of cannabis and cannabis resins carry a particularly high risk of diversion because the product can be readily be used in its raw state, and is likely to be attractive to organised crime seeking to hide illegal activities under cover of a Commonwealth licence. The fit and proper person requirement is designed to address and manage those risks. This requirement also applies to a manufacture licence.

The exclusion from the Commonwealth spent conviction scheme allows the Secretary to consider all convictions that may be relevant to determining the risk that a person could unlawfully divert cannabis products, including convictions for drug offences, fraud, and other offences that may reveal a link to organised crime and financial crime offences. Limiting the exclusion from spent conviction on the basis of convictions for drug offences only would not be appropriate (refer to Items 9-11 of Schedule 4) as they are specifically designed to suit Tasmania's regulation of opium poppies and alkaloids and the particular circumstances of that industry. The exclusion does not apply to other assessments and requirements under the ND Act, such as in relation to other persons employed or engaged to carry out activities authorised under a licence granted under that Act.

Details of the Regulation are set out in the **Attachment**.

The Act and the Crimes Act specify 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.*

Part 1 of Schedule 1 to the Regulation commences at the same time as the Poisons Standard November 2016 commences, and Part 2 of Schedule 1 commences at the same time as Schedule 1 to the *Narcotic Drugs Amendment Act 2016* commences.

Consultation

The Federal Privacy Commissioner and Minister for Justice were consulted on the proposed exclusion and advised that the scope of the exclusion was appropriate. The Minister of Justice has agreed to the amendment of the Crimes Regulations. Commonwealth, State and Territory government agencies relevant to the regulation of medicinal cannabis products have also been consulted and are supportive of the amendments.

Authority: Section 63 of the *Therapeutic Goods Act 1989*
Section 91 of the Crimes Act 1914

ATTACHMENT

Details of the *Therapeutic Goods and Other Legislation Amendment (Narcotic Drugs) Regulation 2016*

Section 1 – Name of Regulation

This section provides that the title of the Regulation is the *Therapeutic Goods and Other Legislation (Narcotic Drugs) Amendment Regulation 2016.*

Section 2 – Commencement

This section provides that the amendments to the Therapeutic Goods Regulations 1990 (the TG Regulations) in Part 1 of Schedule 1 to the Regulation commence at the same time as the *Poisons Standard November 2016*. However, those provisions do not commence at all if that Poisons Standard does not commence. This section also provides that the amendments to the Crimes Regulations 1990 in Part 2 of Schedule 1 to the Regulation commences at the same time as the Schedule 1 to the *Narcotic Drugs Amendment Act 2016* (Amendment Act) commences. Schedule 1 to the Amendment Act consists of the substantive provisions in relation to the medicinal cannabis licensing scheme and amendments to the manufacture licence scheme under the *Narcotic Drugs Act 1967*.

Section 3 – Authority

This section provides that the *Therapeutic Goods and Other Legislation Amendment (Narcotic Drugs) Regulation 2016* is made under the *Crimes Act 1914* and the *Therapeutic Goods Act 1989*.

Section 4 – Schedules

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

Schedule 1 – Amendments

Therapeutic Goods Regulations

Item 1 – Subregulation 12A(1),

Generally, therapeutic goods are required to be included in the Australian Register of Therapeutic Goods (the Register) before they can be lawfully supplied in Australia, unless they are exempt from such a requirement, or are the subject of another approval or authorisation under the *Therapeutic Goods Act 1989* (the TG Act). Before the inclusion of such goods in the Register, they may be required to undergo an evaluation for quality, safety and efficacy. The exemption from inclusion in the Register under section 18 of the TG Act recognises that there are circumstances where patients need access to therapeutic goods that are not in the Register. In some circumstances, these goods have not yet undergone full clinical testing, and are still in the experimental stage. One of the exemptions from the requirement of a therapeutic good to be included in the Register is the Special

Access Scheme (SAS). The SAS is an arrangement which provides for the import and/or supply of an unapproved therapeutic good (not included in the Register) for a single patient, on a case by case basis. Regulation 12A applies to a Category A patient. A Category A patient is defined as "persons who are seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment (subregulation 12A(5) of the TG Regulation refers). These requirements for SAS (Category A) patients do not involve the specific approval of the Secretary.

The exemption from inclusion in the Register that allows for the import and supply of therapeutic goods to specified Category A patients is under subsection 18(1) of the TG Act and regulation 12A of the TG Regulations, and is subject to compliance with the conditions specified in subregulation 12A(2) of the TG Regulations.

This item repeals the current subregulation 12A(1), and inserts a new subregulation 12A(1). The new subregulation provides that for the purposes of subsection 18(1) of the TG Act, subject to subregulation 12A(2), all medicines are exempt from the operation of Part 3-2 of the Act, other than medicines containing substances covered by specified entries in the Poisons Standard which are the following:

(a) the entry for cannabidiol in Schedule 4 to the current Poisons Standard;
(b) entries in Schedule 8 in the current Poisons Standard in relation to cannabis, dronabinol, nabilone, nabiximols, and tetrahydrocannabinols; or
(c) any entry in Schedule 9.

The current exemption from inclusion in the Register provided under regulation 12A already excludes any entry in Schedule 9 to the Poisons Standard from the operation of such an exemption, and therefore preserves the status quo.

The effect of this amendment is that patients will not be able to access medicinal cannabis products or synthetic cannabis products via the Special Access Scheme for Category A patients, which enables medicines that are not on the Register to be supplied to patients who are seriously ill and likely to die within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment. Other approvals under section 19 (clinical trials, special access scheme (category B) and through authorised prescriber scheme) of the Act would still allow for access to these products by patients.

This is consistent with the regulatory requirements relating to the supply of medicinal cannabis products manufactured in Australia under the *Narcotic Drugs Act 1967*, particularly in relation to the importance of ensuring that medicinal cannabis products are principally able to be accessed in circumstances where there are appropriate oversight requirements in place to safeguard public health.

Item 2 – Subregulation 12(1A)

This item provides for a technical change and would amend the wording of subregulation 12A(1A) to make it consistent with the wording for subregulation 12A(1) (Item 1 refers).

Item 3 – Subregulation 12A(2)

This item amends subregulation 12A(2) to make it clear that the exemption from the inclusion in the Register requirement for a medicine (under Part 3-2 of the TG Act) or a biological (under Part 3-2A of the TG Act) is subject to compliance with the conditions listed under subregulation 12A(2).

Item 4 – Schedule 5 (table item 1, column 2, after paragraph (a))

The therapeutic goods or classes of therapeutic goods mentioned in Schedule 5 to the TG Regulations are exempt from the requirement to be included in the Register for therapeutic goods for their lawful supply in Australia (subregulation 12(1) of the TG Regulations refers).

This item inserts a new paragraph (aa) into Item 1 of Schedule 5 to the TG Regulations. Item 1 of Schedule 5 provides for specific exemption for inclusion in the Register for imported medicines that are for the treatment of the importer or the importer's immediate family where the circumstances listed in paragraphs (a) to (d) of Item 1 are met.

The amendment to Item 1 has the effect that therapeutic goods imported by people for the treatment of themselves or their immediate families that contain substances covered by any of the specified entries in Schedule 8 to the current Poisons Standard (cannabis, dronabinol, nabilone or tetrahydrocannabinols), will not be exempt from the requirement to have these goods included in the Register under the TG Act. Therefore, personal importation of these therapeutic goods that are not included in the Register will be unlawful unless they have been otherwise approved or authorised under other provisions of the TG Act.

As the benefits and risks of medicinal cannabis have not been adequately characterised to date, controls around personal importation are necessary to ensure that supply is only permitted through appropriate approval, authorisation or notification mechanisms to ensure that medicinal cannabis is only supplied to patients in appropriate circumstances.

Item 5 – Schedule 5 (table item 6)

This item repeals the existing item 6 in Schedule 5 and substitutes a new item 6.

The current Item 6 of Schedule 5 to the TG Regulations provides that medicines (other than medicines used for gene therapy) that are dispensed, or extemporaneously compounded, for a particular person for therapeutic application to that person, are exempt from the requirement to be included in the Register. The current provision allows pharmacist and medical practitioners to extemporaneously compound medicines for particular patients, without being required to include each of those extemporaneously compounded medicines in the Register where those particular situations set out in Item 6 are met. Item 6 only currently excludes medicines used for gene therapy.

This amendment makes it clear that that the following medicines, in addition to those used in gene therapy, are not covered by that exemption provided for by Item 6 of Schedule 5 to the TG Regulations:

(a) medicines containing any of the substances included in specified entries in the current Poison Standard that relates to cannabis or substances derived from cannabis that are specified in any

of paragraphs 12A (1)(a) to (f) (Item 1 of the proposed Regulation refers) whether sourced from cannabis plants or not; and

(b) medicines that are not dispensed, or extemporaneously compounded, in a public hospital in a State or Territory for a person who is a patient in a public hospital in the State or Territory.

As the benefits and risks of medicinal cannabis have not been adequately characterised to date, controls around dispensed, or extemporaneously compounded, medicinal cannabis for a particular person are necessary to ensure that supply is only permitted through appropriate approval, authorisation or notification mechanisms to ensure that medicinal cannabis is only supplied to patients in appropriate circumstances. This is consistent with the regulatory requirements relating to the supply of medicinal cannabis products manufactured in Australia under the *Narcotic Drugs Act 1967*, particularly in relation to the importance of ensuring that medicinal cannabis products are principally able to be accessed in circumstances where there are appropriate oversight requirements in place to safeguard public health.

Item 6 – Schedule 5A (cell at table item 5, column 2)

This item amends Schedule 5A to the Therapeutic Goods Regulations, which lists therapeutic goods which are exempt from the operation of Parts 3-2 and 3-2A of the TG Act, subject to conditions set out in column 3 for each item.

Item 5 of Schedule 5A excludes therapeutic goods (other than goods referred to in Item 3 of Schedule 5A of the TG Regulation or biological) from the requirement to be included in the Register, subject to conditions listed in column 3 of the Table in relation to Item 5. The exemption relates to therapeutic goods manufactured by a person under a contract between the person and a public hospital, private hospital or a public institution (now referred to as a relevant institution as proposed in this Regulation), in accordance with the formulation specified by the hospital or public institution and goods are for use by, or in connection with a specified patient. The conditions that need to be met are the following:

(a) there are no listed or registered goods that, in all relevant respects, are substantially similar to the goods; and
(b) the person holds a manufacturing licence and manufactures the goods at licensed premises in Australia; and
(c) the person notifies the Secretary of the Department of Health, in accordance with specified requirements and within a specified period (refer to paragraph (c) of Item 5 in column 3)

Item 6 of the Regulation additionally excludes from this exemption, medicines that contain a substance covered by an entry in the current Poisons Standard mentioned in any of new paragraphs 12A(1)(a) to (f) (Item 1 of the proposed Regulation refers). The entries referred to in paragraphs 12A(1)(a) to (f) are the following:

(a) the entry for cannabidiol in Schedule 4; and
(b) the entries for cannabis, dronabinol, nabilone, nabiximols and tetrahydrocannabinols in Schedule 8.

As the benefits and risks of medicinal cannabis have not been adequately characterised to date, controls around contract manufacturing are necessary to ensure that supply is only permitted through appropriate approval, authorisation or notification mechanisms to ensure that medicinal cannabis is only supplied to patients in appropriate circumstances.

This is consistent with the regulatory requirements relating to the supply of medicinal cannabis products manufactured in Australia under the *Narcotic Drugs Act 1967*, particularly in relation to the importance of ensuring that medicinal cannabis products are principally able to be accessed in circumstances where there are appropriate oversight requirements in place to safeguard public health.

Item 7 – Schedule 5A (table item 5, column 3)

This item provides for a consequential amendment proposed in column 2 in relation to the reference to "relevant institution" (Item 6 refers).

Item 8 - Schedule 8 (cell at table item 2, column 3).

Subsection 34(2) of the TG Act provides that the regulations may exempt a person identified in the regulations from the operation of the requirement in relation to manufacture or a step of manufacture of therapeutic goods or classes of therapeutic goods identified in the regulations.

The person specified in column 2 of an item in Schedule 8 to the TG Regulations is exempt from the operation of Part 3-3 of the TG Act (manufacture of therapeutic goods requirements) in relation to the manufacture or steps or manufacture of therapeutic goods specified in column 3 of that item.

Item 2 of Schedule 8 currently exempts pharmacists from the requirement to hold a manufacture licence and other requirements under Part 3-3 of the Act, in the manufacture of therapeutic goods, other than biologicals, if the therapeutic goods are produced by the pharmacist:

(a) in a pharmacy where the pharmacist practices and that pharmacy is open to the public; or
(b) on the premises of a dispensary conducted by a Friendly Society; or
(c) on the premises of a private hospital; and

the goods are for supply (other than by wholesale) on or from those premises.

This item repeals the existing item 2 in Schedule 8, and replaces it with a new item 2 that has the effect of narrowing the current exemption so that pharmacists will only be exempt from the provisions of Part 3-3 of the TG Act under Item 2 of Schedule 8, if they are manufacturing therapeutic goods, other than biological or medicines that contain a substance covered by an entry in the current Poisons Standard mentioned in any of paragraphs 12A(1)(a) to (f) (Item 1 of the proposed Regulation refers). The entries referred to in paragraphs 12A(1)(a) to (f) are the following:

(a) the entry for cannabidiol in Schedule 4; and
(b) the entries for cannabis, dronabinol, nabilone, nabiximols and tetrahydrocannabinols in Schedule 8.

There are known risks to public health associated with medicinal cannabis products of poor quality. Controls around GMP licencing are required to ensure that medicinal cannabis products are of an acceptable quality and are manufactured in a reproducible and robust manner,

Crimes Regulations

Item 8 – Schedule 4 (at the end of the table)

The *Narcotic Drugs Act 1967* (the ND Act) now allows for the lawful cultivation of cannabis plants and the production of cannabis and cannabis resins in Australia under a national licensing scheme, thereby enabling the sustainable supply of safe medicinal cannabis products to Australian patients. Two types of cannabis licences are provided for under the ND Act, these are a medicinal cannabis licence and a cannabis research licence.

The "fit and proper person" requirements in relation to a natural person are set out in section 8A of the ND Act. The "fit and proper person requirements" in relation to a body corporate are set out in section 8B of the ND Act. Sections 8A and 8B of the ND Act set out the matters that the Secretary may have regard in determining if an applicant, or licence holder, or any business associate of the applicant or licence holder, is a fit and proper person.

Subsections 8G(1), 9F(1) and 11J(1) of the ND Act provide that the Secretary must refuse to grant a licence if the Secretary is not satisfied on reasonable grounds that the:

(a) the applicant is a fit and proper person; and
(b) each of the applicant's relevant business associates for the application, whether in relation to a business relating to the licence, or in relation to any other business, is a fit and proper person to be associated with the holder of a licence

An applicant for a licence and their business associate would have to be found to be a "fit and proper person" by the Secretary according to criteria set out under that Act. The criteria include conviction by the person of a Commonwealth, State or Territory offence. Cultivation of cannabis plants and production of cannabis and cannabis resins carry a particularly high risk of diversion because the product can be readily be used in its raw state, and is likely to be attractive to organised crime seeking to hide illegal activities under cover of a Commonwealth licence.

The fit and proper person requirements are designed to address and manage those risks, by ensuring that an applicant or licence holder (and their business associates) does not have ties to criminal activity, has the relevant experience, has the financial resources to participate in the industry, as well as satisfy security and other requirements. This also applies to a manufacture licence.

It is also a ground for the revocation of a licence if the licence holder is no longer a fit and proper person or that a business associate of the licence holder is not a fit and proper person to be associated with the holder of a licence.

Under Part VIIC of the *Crimes Act 1914* (the Crimes Act), the spent conviction scheme allows for partial or complete exclusions in certain circumstances. Both the details of the Commonwealth spent conviction scheme, and the exclusion from the non-disclosure requirements are set out in Part VIIC of that Act. A number of existing exclusions are already provided for under the Crimes Act (refer to section 85ZZH of Division 6 of Part VIIIC for example and others are prescribed in Schedule 4 of the Crimes Regulations 1990 for the purposes of paragraph 85ZZH(k) of the Crimes Act.

The exclusion from the Commonwealth spent conviction scheme allows the Secretary to consider any conviction of the person for an offence against a law of the Commonwealth, State or Territory, that may be relevant to determining the risk that a person could unlawfully divert cannabis products. The convictions could include convictions for drug offences, fraud, and other offences that may reveal a link to organised crime and financial crime offences.

This broad exclusion is necessary because the high illicit value of cannabis and cannabis products is attractive to organised criminal group that could use cannabis to conceal illegal activities and because of the difficulty of identifying specific offences that may indicate a person's propensity to engage in organised crime and illicit drug activity.

Drug offences are not the only offences that may be relevant in assessing whether a person is a fit and proper person to hold a licence. Thus, in determining whether a person is the fit and proper person under the ND Act, the Secretary may have regard to any conviction of the person for an offence against a law of the Commonwealth, a State or a Territory. If the proposed exclusion were to be based solely on convictions for drug offences as set out in Items 9-11 of Schedule 4 of the Crimes Regulations, this would be too limiting as the exclusion was specifically designed to suit Tasmania's regulation of opium poppies and opium alkaloids derived from them, and the particular circumstances of that industry. As discussed previously, the cannabis in its raw state has a high diversion risk and high illicit value, in contrast to poppy plants and poppy straws.

The exclusion will not apply to other assessments and requirements under the ND Act, such as in relation to other persons employed or engaged to carry out activities authorised under a licence granted under that Act.

This item amends Schedule 4 of the *Crimes Regulations 1990* to include a new exclusion from the spent conviction scheme of Part VIIC of the Crimes Act for the purposes of paragraph 85ZZH(k) of that Act. This new exclusion is set out in new Item 25 of Schedule 4. This exclusion has the effect of requiring a person who is an applicant for a licence, a person who holds a licence or a person associated with or to be associated with the holder of the licence, to disclose all convictions for all offences under Commonwealth, State and Territory laws to the Secretary of the Department of Health or his or her delegate for the purpose of assessing whether a person is fit and proper person to hold a licence or to be associated with the holder of such a licence under the ND Act. The exclusion applies to natural persons and bodies corporate.

Statement of Compatibility with Human Rights

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

Therapeutic Goods and Other Legislation Amendment (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 *Therapeutic Goods and Other Legislation Amendment (Narcotic Drugs) Regulation 2016* amends:

- the *Therapeutic Goods Regulations 1990* (the TG Regulations), in relation to access to unapproved medicines, in order to provide appropriate regulatory oversight for the import and supply of cannabis used for medicinal purposes; and
- the *Crimes Regulations 1990* (the Crimes Regulations), to create a new exclusion from the Commonwealth spent convictions scheme that would apply to applicants, licence holders and their business associates in relation to licences under the *Narcotic Drugs Act 1967* (the ND Act).

The changes to the TG Regulations that are set out in this Regulation make a small number of amendments to the arrangements in place under those regulations for accessing unapproved medicines, particularly in order to reflect the importance of ensuring that medicinal cannabis products are principally able to be accessed in circumstances where there are appropriate oversight requirements in place to safeguard public health.

In relation to the changes to the Crimes Regulations set out in this Regulation, the Commonwealth spent conviction scheme is in Part VIIC of the Crimes Act, and provides that certain types of offences become spent after a waiting period has elapsed in which no further convictions are recorded against the offender. The scheme applies to both natural persons and bodies corporate. The waiting period is 10 years from the date of conviction as an adult, and 5 years in the case of a conviction recorded against a minor. Where a conviction for an offence is spent, the offender is not obliged to disclose that prior conviction in specified circumstances. The right of non-disclosure is subject to exclusions listed in section 85ZZH of Division 6, Part VIIC of the Crimes Act, and in Schedule 4 to the Crimes Regulations. These exclusions provide that spent conviction information in relation to specified offences must be disclosed by, and to, certain persons and bodies for certain purposes.

This Regulation amends Schedule 4 to the Crimes Regulations to require the disclosure of convictions of all offences to the Secretary of the Department of Health (the Secretary), which would otherwise be considered spent, by persons for the purpose of assessing their suitability as a fit and proper person to apply for, or to hold a licence under the ND Act, or to be associated with the holder of such a licence.

Human rights implications - Right to privacy

The amendment to the *Crimes Regulations 1990* engages the right to privacy, which is set out in Article 17 of the International Covenant on Civil and Political Rights (the ICCPR). Article 17 of the ICCPR provides for the right not to be subjected to arbitrary or unlawful interference with privacy.

The ND Act requires a person to provide information to the Secretary of the Department of Health or his or her delegate in relation to their suitability to hold or be associated with the holder of a licence under that Act. The information that is required to be provided is in relation to the assessment of the fit and proper person requirements set out in sections 8A (in relation to a natural person) and 8B (in relation to a body corporate) of the ND Act.

The assessment in relation to a person's suitability to hold a licence or to be associated with a person who holds a licence involves the consideration of a number of matters, including the collection of personal information in relation to convictions for any offences under a law of the Commonwealth, State or Territory. Cultivation of cannabis plants and production of cannabis and cannabis resins carry a particularly high risk of diversion because the product can be readily be used in its raw state, and is likely to be attractive to organised crime seeking to hide illegal activities under cover of a Commonwealth licence. The fit and proper person requirement is designed to address and manage those risks. This requirement also applies to a manufacture licence.

The requirement to disclose convictions which would otherwise be spent is part of the disclosure requirements to obtain a licence under the ND Act.

Allowing the cultivation of cannabis, the production of cannabis and cannabis resins, and the manufacture of medicinal cannabis products in Australia, will support the licit supply of high quality and safe medicinal cannabis products to patients who are in need of these products. There are associated therapeutic and economic benefits associated with the implementation of the new regulatory framework on medicinal cannabis. However, given the high illicit value of raw cannabis, there is also social interest in ensuring that Australia's medicinal cannabis industry, and any manufacture of drugs in Australia, is protected from infiltration and diversion to criminal elements.

Although the exclusion to the spent conviction scheme affects the privacy protections of individuals who are applicants, licence holders and business associates of the licence holders, the exclusion contributes to the Government's objectives of supplying medicinal cannabis products to patients in Australia in an efficient and safe way. The supply of medicinal cannabis products under the new scheme also promotes the social interest in the domestic production of medicinal cannabis products for therapeutic and economic reasons, and the protection of that new industry from illicit activity.

Participation in this scheme, and the provision of information to obtain a licence, is voluntary. The risk of diversion of cannabis and products derived from cannabis under this scheme must be addressed, and the criminal history of licence holders and their business associates is highly relevant to assessing this risk.

It is submitted that this limitation on the right to privacy is proportionate in the circumstances.

Conclusion

This Regulation is compatible with the human rights and freedoms recognised or declared in the international instruments listed in the definition of human rights in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. To the extent that the measures in the Regulation may limit those rights and freedoms, such limitations are reasonable, necessary and proportionate in achieving the intended outcomes of the Regulation.

Sussan Ley, Minister for Health and Aged Care