Chapter 3

Overview and key provisions of the Bill

3.1 As noted in chapter 1, the Bill seeks to establish a Regulator of Medicinal Cannabis (Regulator) as a listed entity under the *Public Governance, Performance and Accountability Act 2013*.

3.2 The Explanatory Memorandum to the Bill (EM) states that the Regulator would 'be responsible for formulating rules for licensing the production, manufacture, supply, use, experimental use and import and export of medicinal cannabis'.[1]

Overview of the Bill and general provisions

3.3 The Bill is divided into five Parts, as follows:

- Part 1—Preliminary outline: includes commencement provisions, an objects clause, relevant definitions, and application provisions;
- Part 2—Medicinal cannabis: contains seven divisions outlining the responsibilities of the Regulator in relation to medicinal cannabis, including maintaining a register of medicinal cannabis products, developing standards in relation to medical cannabis products and related activities, maintaining an authorised patients and carers scheme, and developing licensing schemes relating to the production, transport, import and export, and provision of medicinal cannabis products;
- Part 3—Regulator of Medicinal Cannabis: contains provisions to establish the Regulator as a listed entity under the *Public Governance, Performance and Accountability Act 2013* and sets out the Regulator's functions, powers and procedures;
- Part 4—Monitoring and investigation powers: contains provisions enabling authorised officers to undertake monitoring and investigation activities in relation to the Bill; and
- Part 5—Miscellaneous: includes provisions relating to reviewable decisions, protection from criminal or civil actions, and a rule-making power enabling the Regulator to prescribe matters relating to the Bill.

3.4 Clause 3 of the Bill states that its objects are to:

(a) establish a Regulator of Medicinal Cannabis to perform the functions of the agency referred to in Article 23 of the Single Convention on Narcotic Drugs 1961, as it applies in relation to cannabis because of Article 28 of the Convention; and

(b) provide for a national system, to apply in participating States and Territories, for regulating the production and use of medicinal cannabis

1 Explanatory Memorandum to the Bill (EM), p. 1.

products, and related activities such as research, in accordance with the Convention.

3.5 Several overarching issues are noteworthy in terms of the construction of the Bill, namely: the stated relationship between the Bill and other Commonwealth laws; the rule-making power to be vested in the Regulator in order to accomplish many of the purposes of the Bill; and the proposed application of the Bill within Australia.

Exemption from the operation of other Commonwealth laws

3.6 The EM states that the Regulator would provide an alternate regulatory framework to the current system, in which cannabis products are regulated under the *Therapeutic Goods Act 1989* (TG Act):

> This Bill provides for a system of regulating medicinal cannabis that is entirely separate from the [TG Act]. A number of provisions of the Bill make it clear that the [TG Act] does not apply to things done in accordance with licences or authorisations issued by the new Regulator of Medicinal Cannabis. However, this would not prevent pharmaceutical companies applying to the Therapeutic Goods Administration to sell medicinal cannabis instead of using the scheme established by this Bill. They will effectively have a choice about which system to use (although the cultivation of medicinal cannabis will only be covered by this Bill).[2]

3.7 In some instances, the application of the TG Act would still apply for limited purposes under specific provisions of the Bill; these are discussed in further detail below.

Rule-making power

3.8 The EM states that the Regulator 'will be responsible for formulating rules for licensing the production, manufacture, supply, use, experimental use and import and export of medicinal cannabis'.[3] The rule-making power of the Regulator is contained in clause 63 of the Bill, which states that the Regulator may, by legislative instrument, make rules prescribing matters: required or permitted by the Bill to be prescribed by the rules; or necessary or convenient to be prescribed for carrying out or giving effect to the Bill.

3.9 Key aspects of the regulatory framework envisaged by the Bill are to be established under the rules, rather than codified in the Bill itself, including aspects relating to the medicinal cannabis licensing scheme, authorised patients and carers scheme, experimental cannabis licensing scheme, import and export licensing scheme, and medicinal cannabis standards.

Application of the Bill only in participating states and territories

3.10 Clause 7 of the Bill provides that the Bill would only apply in participating states or territories in Australia. Under subclause 7(2) of the Bill, the minister may

2 EM, p. 1.

3 EM, p. 1.

make a determination in writing that a state or territory is a participating state or territory if that state or territory has entered into an agreement with the Commonwealth for the Bill to apply in that jurisdiction.

3.11 The EM states:

> The medicinal cannabis system set up by the Bill is to be implemented cooperatively between the Commonwealth and the States and Territories. The States and Territories are likely to have to change their own laws relating to cannabis if they wish to participate.
>
> The Minister may make a determination that a State or Territory that has entered into an arrangement with the Commonwealth to participate in the system is a participating State or Territory. The Ministerial determination is a legislative instrument, but is not subject to disallowance. This reflects the fact that it represents the existence of an agreement between a State or Territory and the Commonwealth.[4]

Responsibilities and powers of the Regulator

3.12 Part 2 of the Bill contains the detailed responsibilities of the Regulator in relation to medicinal cannabis in Australia. Clause 11 of the Bill outlines that the new Regulator would be responsible 'for maintaining a register of regulated medicinal cannabis products, which lists cannabis products approved by the regulator', and that the Regulator would be empowered to make various schemes in relation to the regulation of medicinal cannabis in Australia, namely:

- a medicinal cannabis licensing scheme, under which licenses may be given for the cultivation, production and distribution of medicinal cannabis;
- an authorised patients and carers scheme, for authorising patients, carers and medical practitioners;
- an experimental cannabis licensing scheme, under which licenses may be given for the experimental production and use of medicinal cannabis;
- standards for medicinal cannabis; and
- an import and export licensing scheme, under which licenses may be given for the import and export of medicinal cannabis.

Register of regulated medicinal cannabis products

3.13 Division 2 of Part 2 of the Bill would provide for a register of regulated medicinal cannabis products (Register). Clause 12 of the Bill states that the Regulator must maintain such a Register in the manner prescribed by any rules made by the Regulator.

3.14 Subclause 13(1) of the Bill would provide that a person may apply to the Regulator for a cannabis product to be included in the Register in relation to that person. Subclause 13(2) states that the Regulator may include a cannabis product in the Register in relation to the person that has made the application if it is satisfied that:

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4 EM, p. 3.

- the cannabis product is suitable for medicinal use;
- the cannabis product complies with any standard made under the Bill that applies to the product;
- including the cannabis product in the Register in relation to the person would be consistent with the Single Convention;
- it is appropriate in all the circumstances for the cannabis product to be regulated under the Bill; and
- any requirements prescribed by the rules are met.[5]

3.15 Subclause 13(3) provides that the rules made by the Regulator (under clause 63 of the Bill) may prescribe: the manner in which an application is to be made; matters to which the Regulator may, or must, have regard in making a decision about whether to approve an application; and procedures to be followed by the Regulator in making such a decision.

3.16 Clause 14 of the Bill states that the rules may provide for an entry in the Register to be removed or varied, either on application by the person in relation to whom the entry is registered, or on the Regulator's own initiative.

3.17 The EM states in relation to the Register:

> The register is modelled on the Australian Register of Therapeutic Goods…The Bill leaves detail, such as the manner in which the register is to be maintained, to the rules rather than setting it out in the Bill. The rationale for the register being set out in the rules is to give the Regulator the flexibility to make arrangements appropriate for a new medicinal cannabis industry and to allow the Regulator to align the register with the Australian Register of Therapeutic Goods, as appropriate.[6]

Medicinal cannabis licensing scheme

3.18 Division 3 of Part 2 of the Bill would provide for the creation of a medicinal cannabis licensing scheme.

3.19 Under subclause 16(1) of the Bill, the rules made by the Regulator may prescribe a scheme for the Regulator to issue licences authorising persons to engage in one or more of:

- producing cannabis for medicinal or experimental use;
- transporting or storing cannabis for medicinal or experimental use;
- manufacturing regulated medicinal cannabis products;
- transporting or storing regulated medicinal cannabis products; and

5 Regulator of Medicinal Cannabis Bill 2014, paragraphs 13(2)(b)-(f).

6 EM, pp 3-4.

- providing regulated medicinal cannabis products to authorised patients and authorised carers.[7]

3.20 Under subclause 16(3) of the Bill, the scheme must provide for any medicinal licence granted to be subject to such conditions as would ensure that:

- all cannabis produced, and all cannabis products manufactured, in accordance with the scheme are accounted for; and
- any relevant standards are complied with; and
- the scheme operates in accordance with the Single Convention.[8]

3.21 Under clause 17 of the Bill, a medicinal licence holder would commit an offence if they failed to comply with any conditions imposed under the licence.[9]

Application of other Commonwealth laws to the medicinal cannabis licensing scheme

3.22 Subclause 16(4) of the Bill states that the *Narcotic Drugs Act 1967* (Narcotic Drugs Act) and the *Therapeutic Goods Act 1989* (TG Act) 'do not apply in relation to an activity engaged in, or a thing dealt with, in accordance with a medicinal licence' granted under the Bill.

3.23 Subclause 16(5) would provide, however, that preceding subclause does not prevent the TG Act from applying in relation to:

> (a) the manufacture of therapeutic goods (within the meaning of 3 that Act) from cannabis produced, transported or stored in accordance with a medicinal licence; or
>
> (b) therapeutic goods manufactured as referred to in paragraph (a);
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> if the goods are not included in the register of regulated medicinal cannabis products in relation to the manufacturer.

3.24 The EM explains these provisions as follows:

> Subclause 16(5) allows for cannabis to be produced under a medicinal licence and then used in the manufacture of cannabis-based medicines that are regulated under the Therapeutic Goods Administration (TGA) instead of under this Bill.
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> The medicinal licence that will be issued will therefore sit outside of the scope of Narcotics Drug Act and the TGA. This does not stop applications to the TGA in relation to the manufacture of cannabis-based medicines.[10]

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7 Regulator of Medicinal Cannabis Bill 2014, paragraphs 16(1)(a)-(e).

8 Regulator of Medicinal Cannabis Bill 2014, paragraphs 16(2)(a)-(d).

9 Similar offence provisions are contained in clause 21 (in relation to experimental licences) and clause 25 (in relation to import and export licence holders).

10 EM, p. 4.

Authorised patients and carers scheme

3.25 Division 4 of Part 2 of the Bill would provide for the creation of an authorised patients and carers scheme.

3.26 Under subclause 19(1) of the Bill, the rules may prescribe an 'authorised patients and carers scheme' to provide for the authorisation of patients to use regulated cannabis products, carers to supply such products to authorised patients, and medical practitioners to prescribe regulated medicinal cannabis products.

3.27 Under subclause 19(2), authorisations to patients or carers must only be given on request by a medical practitioner, and be subject to any conditions necessary to ensure that the scheme operates in accordance with the Single Convention.

3.28 Subclause 19(3) would provide that the scheme may be set up to allow for authorisations to be made by the Regulator or by appropriate authorities of participating states and territories.

3.29 Subclause 19(4) states that the Narcotic Drugs Act and TG Act would not apply in relation to actions taken under the authorised patients and carers scheme.

Experimental cannabis licensing scheme

3.30 Division 5 of Part 2 of the Bill deals with the establishment of an experimental cannabis licensing scheme.

3.31 Under subclause 20(1) of the Bill, the rules may prescribe an experimental cannabis licensing scheme for the Regulator to issue experimental licences authorising persons (experimental licence holders) to: produce, manufacture, transport, store, provide, administer, and perform tests on cannabis or cannabis products for an experimental purpose.

3.32 Subclause 20(2) lists a number of purposes to be included as 'experimental purposes' under the scheme, including

- developing and testing varieties of cannabis for medicinal use;
- improving methods of cultivating cannabis for medicinal use;
- developing and testing cannabis products for medicinal use;
- evaluating the efficacy or safety of cannabis products for medicinal use;
- improving methods of using or administering cannabis products for medicinal purposes; and
- performing tests, trials and other experiments for the purposes of making or supporting an application under the Bill or the TG Act, or considering whether to make such an application.[11]

3.33 The EM states in relation to this scheme:

> Research and development of medicinal cannabis is a growing field of science. It is important that research into types and strains of cannabinoids

11 Regulator of Medicinal Cannabis Bill 2014, paragraphs 20(2)(a)-(f).

> and medicinal cannabis be encouraged and furthered by the Regulator… The Regulator will…be responsible for issuing licences and prescribing a scheme for research and experiments with medicinal cannabis.
>
> For example, an experimental purpose may include experimentation in the development of cannabis products, and varieties of cultivated cannabis, that have reduced psychoactive effects while still having therapeutic effects.[12]

3.34 Under subclauses 20(5)–(6), the Narcotic Drugs Act and TG Act would not apply in relation to authorised actions taken under the experimental licensing scheme, except insofar as they would allow the results of an experiment or trial conducted in accordance with an experimental licence being taken into account in a decision made for the purposes of the TG Act.

Medicinal cannabis standards

3.35 Division 6 of Part 2 of the Bill would provide for the determination of standards in relation to medicinal cannabis.

3.36 Under subclause 23(1) of the Bill, the rules may provide for the Regulator to determine, by legislative instrument, standards for cannabis or cannabis products, and activities that may be carried out under a medicinal licence or an experimental licence.

3.37 Subclause 23(2) of the Bill states that such standards may:

- be specified by reference to: quality or quantity of a cannabis product; characteristics of a cannabis variety;
- require that a matter relating to the standard be determined in accordance with a particular test; or
- relate to the packaging and labelling requirements for particular cannabis products or classes of products.

Import and export licensing scheme

3.38 Division 7 of Part 2 of the Bill deals with the creation of an import and export licensing scheme for cannabis and cannabis products.

3.39 Under clause 24, the rules may prescribe a scheme for the regulator to issue licences authorising persons to import and export cannabis or cannabis products for medicinal or experimental purposes. Subclause 24(3) specifies that any import or export licenses granted must be subject to conditions that ensure for the accounting of all cannabis products imported or exported, and ensure that the scheme operates in accordance with the Single Convention.

3.40 Subclause 24(4) states that the Narcotic Drugs Act and TG Act would not apply in relation to actions taken under the import and export licensing scheme.

Establishment of the Regulator

3.41 Part 3 of the Bill deals with the establishment, functions, appointments, staffing and procedures of the Regulator.

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12 EM, pp 4-5.

3.42 Clause 28 of Division 2 of Part 3 of the Bill would establish the Regulator as a listed entity for the purposes of the *Public Governance, Performance and Accountability Act 2013*, with officials consisting of members, a Chief Executive Officer, and staff.

Functions and powers of the Regulator

3.43 Clause 30 of the Bill details the functions and powers of the Regulator. It provides that the Regulator would have the functions of the state agency referred to in Article 23 of the Single Convention, as it applies in relation to cannabis. Additionally, the functions of the Regulator would include:

- to enter into contracts with medicinal licence holders, experimental licence holders, import licence holders and export licence holders;
- to supply cannabis and cannabis products within Australia, for medicinal or experimental purposes, as well as for the manufacturing regulated medicinal cannabis products;
- to investigate possible breaches of the Bill or the rules;
- to advise and make recommendations to the minister on matters relating to medicinal or experimental cannabis and cannabis products;
- to collect, analyse, interpret and disseminate information and statistics relating to medicinal or experimental cannabis and cannabis products;
- to educate and inform patients, carers, health workers and the community about the medicinal use of regulated medicinal cannabis products, and provide relevant training to health workers; and
- to cooperate with its counterparts in other countries and with law enforcement agencies in Australia and overseas.[13]

3.44 Subclause 30(5) specifies that the Narcotic Drugs Act and the TG Act do not apply in relation to the performance of the Regulator's functions or the exercise of its powers.

3.45 Clause 32 of the Bill would allow the minister, by legislative instrument, to give directions to the Regulator if the minister considered that a direction was necessary to ensure that Australia complies with its obligations under the Single Convention.

Membership of the Regulator and staffing arrangements

3.46 Under clause 29 of the Bill, the Regulator would consist of a Chair and 5 other members. The appointment of members is outlined in clause 34 of the Bill, with the Chair to be a full-time appointment made by the minister, and the other members to be part-time appointments made by the minister. Members would be appointed for a period of up to five years.

13 Regulator of Medicinal Cannabis Bill 2014, paragraphs 30(1)(a)-(l).

3.47 Under subclauses 34(3)–(4), appointees would have to have knowledge or experience in one or more of the following fields: medicine, pharmacology, palliative care, botany, horticulture, law, law enforcement, or patient advocacy. Further, the minister would be required to ensure that the membership of the Regulator included at least one medical practitioner, one member of the Australian Federal Police and one member representing patients and users. The EM states that this arrangement 'provides a balance of interests and ensures law enforcement is at the centre of decision making by the Regulator'.[14]

3.48 Clause 49 of the Bill specifies that the Chair should also be appointed as the Chief Executive Officer (CEO) of the Regulator, to be responsible for the management and administration of the Regulator. Under clause 51, staff for the Regulator may be engaged under the *Public Service Act 1999*.

Monitoring and investigation powers

3.49 Part 4 of the Bill contains the monitoring and investigation powers that would be performed by the Regulator. The EM states in relation to these provisions:

> Cannabis is a drug that is not legal in Australian states and territories. As with the Australian poppy industry, cannabis can be used for medicinal purposes as well as being a drug that is not legally available and carries criminal sanctions for cultivation, transport, possession and trafficking. It is necessary that sanctions and penalties apply to any authorised person who abuses or misuses their obligations to the Regulator to provide, supply or use cannabis for medicinal purposes.
>
> Both the public and law enforcement agencies must be confident that there are strict provisions in place so that only those authorised have access to medicinal cannabis and that manufacture and use is conducted under strict guidelines.[15]

3.50 Clause 55 of the Bill would provide that the Regulator may authorise its members, staff and any officers or employees of participating states and territories assisting the Regulator, to carry out monitoring and investigation powers.

3.51 Under clause 56 of the Bill, the monitoring powers available under the Bill would be those contained in Part 2 of the *Regulatory Powers (Standard Provisions) Act 2014* (Regulatory Powers Act). The Bill notes that Part 2 of the Regulatory Powers Act creates a framework for monitoring whether specified provisions have been complied with, including powers of entry, search and inspection.

3.52 Under subclause 56(1), the provisions of the Bill subject to these monitoring provisions would be those provisions of Part 2 relating to the proposed register of medicinal cannabis products, medicinal cannabis licensing scheme, experimental cannabis licensing scheme, import and export licensing scheme, and medicinal cannabis standards.

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14 EM, p. 6.

15 EM, p. 6.

3.53 Clause 57 of the Bill outlines investigation powers that would be available to the Regulator. Under subclause 57(1), any offences committed against the offence provisions of the Bill, as well as offences against the *Crimes Act 1914* or the *Criminal Code Act 1995* that relate to the Bill, would be subject to investigation under Part 3 of the Regulatory Powers Act.[16] Under subclause 57(4), any person authorised under clause 55 of the Bill would be authorised to exercise investigative powers as outlined in Part 3 of the Regulatory Powers Act.

3.54 In relation to why the Bill takes the approach of vesting the Regulator with standard powers under the Regulator Powers Act, the EM notes:

> The monitoring and investigative powers in the Bill apply only to people authorised by the Regulator to cultivate, supply, import, export or experiment with medicinal cannabis. A person or persons applying to the Regulator for a licence will be advised of the monitoring and investigative powers.
>
> That is why this Bill takes the approach of applying the Regulatory Powers (Standard Provisions) Act 2014 (the RP(SP) Act) to give the Regulator certain monitoring and investigation powers. The RP(SP) Act provides a set of standard powers that other Acts establishing regulatory agencies can apply.
>
> The powers conferred by these provisions, such as search, entry and seizure powers, may appear intrusive; however they only apply to people who have applied to become licence holders or authorised users of medicinal cannabis. The powers in the provisions do not apply to the general public or anyone not licenced or authorised by the Regulator.[17]

Other provisions

3.55 Several provisions in Part 5 of the Bill are also of note.

3.56 Clauses 59–60 of the Bill outline a process for reviewing decisions made by the Regulator, including decisions relating to the granting of licences, the inclusion or removal of products from the register of medicinal cannabis products, and authorisations made under the authorised patients and carers scheme. Under clause 60, these decisions would be reviewable on application to the Administrative Appeals Tribunal.

3.57 Clause 62 of the Bill would provide protection against criminal or civil actions for actions taken by a person in good faith in accordance with the Bill or in performance of the Regulator's functions or exercise of its powers. This protection would be available to the minister, members and staff of the Regulator, other Commonwealth authorities, other statutory office holders, and other persons appointed to assist the Regulator in its duties.

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16 The Bill notes that Part 3 of the Regulatory Powers Act created a framework for investigating whether offences that are subject to investigation have been committed, and it includes powers of entry, search, inspection and seizure.

17 EM, p. 7.