2015 (No.5)

2015

Parliament of Tasmania

LEGISLATIVE COUNCIL
GOVERNMENT ADMINISTRATION COMMITTEE "A"

FINAL REPORT

ON

Legalised Medicinal Cannabis

Members of the Committee Inquiry:

Hon Robert Armstrong MLC

Hon Craig Farrell MLC (Committee Chair)

Hon Ruth Forrest MLC (Inquiry Chair)

Hon Mike Gaffney MLC

Hon Leonie Hiscutt MLC

Hon Tony Mulder MLC

EXECUTIVE SUMMARY

Government Administration Committee "A" (the Committee) was established on 4 July 2014 to investigate the use of natural botanical medicinal cannabis flower and extracted cannabinoids for medical purposes.

The Committee tabled an Interim Report on 20 November 2014 containing information that it believed to be time critical for the Tasmanian Government to be aware of prior to the next meeting of the Council of Australian Governments (COAG), and be placed on the public record.

Since the tabling of the Interim Report, a number of significant developments have occurred at the Federal level and in other States, including the introduction of the *Regulator of Medicinal Cannabis Bill 2014* to the Senate, and the commitment of the NSW Government to clinical trials to further explore the use of cannabis and/or cannabis products in providing relief for patients suffering from a range of debilitating or terminal illnesses.

The Committee considers that continuing the current Inquiry in light of these significant developments may be duplicative and unnecessary. The Committee will keep a watching brief on the developments at the Federal level and in other jurisdictions, and will give consideration to an inquiry into any matters raised by these key developments in the future. Should a future Committee be established to do so, this would involve a new Inquiry with new specific Terms of Reference.

The Committee has agreed to conclude the current Inquiry and intends that this Report be read in conjunction with the Interim Report and considered in its entirety as the Final Report of the Committee. This Final Report outlines the reasons for the conclusion of the Inquiry.

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ABBREVIATIONS

COAG	Council of Australian Governments
TGA	*Therapeutic Goods Act 1989*

INTRODUCTION

At the meeting of the Legislative Council Government Administration Committee "A" on Friday 4 July 2014, it was resolved that an inquiry be established to investigate the use of natural botanical medicinal cannabis flower and extracted cannabinoids for medical purposes, with the following Terms of Reference:

1. The efficacy and safety of natural botanical medicinal cannabis flower and extracted cannabinoids for medical purposes.
2. If, and how, natural botanical medicinal cannabis flower and extracted cannabinoids could and/or should be supplied for medical use.
3. The legal implications and barriers to the medicinal use of natural botanical medicinal cannabis flower and extracted cannabinoids in Tasmania.
4. The legal implications and barriers to the growing and commercialisation of cannabis flower and extracted cannabinoids in Tasmania to ensure:
    a. a scientific-based approach;
    b. quality control;
    c. consistency;
    d. reliability; and
    e. ongoing research and development of cannabis-based medicines.
5. The potential impact on agricultural or other sectors within Tasmania.
6. Any other matters incidental thereto.

Seventy-seven submissions were received by the Committee. Public hearings were held in Hobart on 18, 19 and 22 September 2014. Twenty-three groups or individuals gave verbal evidence to the Committee at these hearings.

The Hansard transcripts of these hearings are available at http://www.parliament.tas.gov.au/ctee/Council/GovAdminA_LMC.htm. The transcripts should be read in conjunction with both the Interim Report and the Final Report.

On 20 November 2014, an Interim Report was tabled in the Legislative Council. The purpose of the Interim Report was to report on the Committee's preliminary findings and provide information to the Tasmanian Government to inform further debate at the next COAG meeting. At the time of tabling, it was the intention of the Committee to

continue the inquiry and to conduct further hearings with key witnesses in NSW, the ACT and Victoria prior to the release of a final report.

A number of significant developments have occurred at the Federal level, specifically the proposal of a national regulatory framework for the cultivation, production and use of medicinal cannabis products, and the commitment of the NSW Government to clinical trials to further explore the use of medicinal cannabis products. These developments have eventuated as a consequence of the Tasmanian inquiry as well as the significant Federal and interstate attention focussed on this issue since the establishment of this Committee in July 2014.

The Committee has reviewed the recent developments, and resolved on Friday 27 February 2015 to conclude the current inquiry and release a Final Report outlining the reasons for doing so.

The Committee relies on all the material obtained and tabled as part of the Interim Report, and intends for the Interim Report to be the primary and Final Report of the Committee.

The Committee looks forward to the Tasmanian Government providing a substantive response to the Final Report and all the comprehensive work the Committee has completed as part of the inquiry.

KEY DEVELOPMENTS

There have been two key developments since the establishment of the Tasmanian inquiry:

1. The introduction of the *Regulator of Medicinal Cannabis Bill 2014* to the Australian Parliament; and
2. The commitment of the NSW Government to a program of clinical trials to further explore the use of cannabis and/or cannabis products in providing relief for patients suffering from a range of debilitating or terminal illnesses.

The key developments are outlined as follows.

1. Regulator of Medicinal Cannabis Bill 2014

The *Regulator of Medicinal Cannabis Bill 2014* (the Bill) is a private members bill introduced to the Senate by Greens Senator Richard Di Natale, Liberal Senator Ian Macdonald, Liberal Democrat Senator David Leyonhjelm and Labor Senator Anne Urquhart. The Bill was introduced and read for the first time on 27 November 2014 (refer to Appendix A).

The Bill:

> *establishes a Regulator of Medicinal Cannabis to be responsible for formulating rules and monitoring compliance with those rules for licensing the production, manufacture, supply, use, experimental use and import and export of medicinal cannabis; and provides for a national system to regulate the cultivation, production and use of medicinal cannabis products, and related activities such as research.*[1]

The Regulator may approve medicinal cannabis products for inclusion in the register of regulated medicinal cannabis products. Products included in the register are regulated under this Bill, rather than under the *Therapeutic Goods Act 1989* (the TGA).

This Bill provides for a system of regulating medicinal cannabis that is entirely separate from the Therapeutic Goods Administration. A number of provisions of the Bill make it clear that the TGA 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

[1] Parliament of Australia, 2015, *Regulator of Medicinal Cannabis Bill 2014*, http://www.aph.gov.au/Parliamentary_Business/Bills_Legislation/Bills_Search_Results/Result?bId=s987.

this Bill, meaning that companies would have a choice about which system to use (although the cultivation of medicinal cannabis will only be covered by this Bill).

The *Narcotic Drugs Act 1967* provides for a mechanism for authorising the cultivation and production of drugs (including cannabis) in accordance with the *Single Convention on Narcotic Drugs 1961*. The Tasmanian poppy industry, for example, operates in accordance with the *Narcotic Drugs Act 1967*, although it is also subject to significant State based regulation. This Bill is designed to be a parallel system for authorising the cultivation and production of cannabis for medicinal use and research.[2]

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 Bill is not intended to override State and Territory laws.

The Bill was referred by the Senate to the Legal and Constitutional Affairs Legislation Committee on 12 February 2015 for inquiry and report. A report of the Committee is due on 21 April 2015.[3]

2. NSW Government Clinical Trials

In December 2014, the NSW Government announced its commitment to clinical trials to further explore the use of cannabis and/or cannabis products in providing relief for patients suffering from a range of debilitating or terminal illnesses.

The NSW Government will invest up to $9 million over the next five years to support these initiatives. The trials will be led by the NSW Government, and are expected to start enlisting participants in 2016. The Commonwealth and other State Governments have indicated their support for this NSW initiative.

Of particular note, a clinical trial of cannabis derived products will be established for children with severe, drug-resistant epilepsy, through a partnership with the Sydney Children's Hospitals Network. NSW Health also intends to work with the research community to assess interest in proceeding with trials in the areas of:

1. Adults with terminal illness, focusing on improving quality of life, and symptoms such as pain, nausea and vomiting.
2. Adults with chemotherapy-induced nausea and vomiting where standard treatment is ineffective.

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[2] Parliament of the Commonwealth of Australia, Senate *Regulator of Medicinal Cannabis Bill 2014*: Explanatory Memorandum, http://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;query=Id%3A%22legislation%2Fems%2Fs987_ems_c8ebba75-32ee-4174-85e4-f749d8e8b3d8%22.

[3] Parliament of Australia, 2015, Regulator of Medicinal Cannabis Bill 2014, http://www.aph.gov.au/Parliamentary_Business/Bills_Legislation/Bills_Search_Results/Result?bId=s987

These trials will meet national and international standards and will be led by an expert panel. The trials will seek to enhance available evidence to better understand the appropriate use of cannabis and cannabis derived products for medical purposes.[4]

[4] NSW Government, 2015, Clinical Trials: Medical Use of Cannabis, Fact Sheet, http://www.health.nsw.gov.au/cannabis/Documents/fs-cannabis-trials.pdf

CONCLUSION

On Friday 27 February 2015, the Committee resolved to conclude the current inquiry into legalised medicinal cannabis, and to prepare a Final Report outlining the reasons for doing so.

The Committee intends for the Interim Report tabled on 20 November 2014 to be the primary and Final Report of the Committee. The Committee would like to conclude the inquiry with the following observations and conclusions.

1. The Committee notes the *Regulator of Cannabis Bill 2014 (Cth)*, and that the Bill has broad support as evidenced by the cross-party endorsement of the Bill.

2. The Bill seeks to establish an independent regulator responsible for licensing the growing, manufacturing and distribution of medicinal cannabis. It is proposed that clinical evidence will be used to determine the limited set of conditions for which medicinal cannabis can be prescribed. This approach responds to challenges of registering medicinal cannabis products under the *Therapeutic Goods Act 1989*.

3. Legislative change will be required in Tasmania if Tasmanians are to legally access medicinal cannabis in the future.

4. Further legislative change will most likely be required in Tasmania should the *Regulator of Cannabis Bill* 2014 *(Cth)* be supported.

5. The Committee supports the program of clinical trials established by the NSW Government. The Committee recommends that the Tasmanian Government support a cooperative approach with NSW throughout the clinical trials process, and provide support and assistance wherever possible.

6. In light of the agreement to progress clinical trials in NSW and the potential legalisation of medicinal cannabis for medical purposes, the Committee notes that Tasmania has a proven security record under the *Single Convention on Narcotic Drugs 1961* as evidenced by the Tasmanian poppy industry, that could be applied to the cultivation, extraction and processing of cannabis products for medical purposes.

7. The Committee looks forward to the Tasmanian Government providing a substantive response to the Final Report and the work the Committee has completed as part of the Inquiry.

8. The Interim Report incorporating the Final Report, should be a primary reference to assist the Premier at future COAG meetings when medicinal cannabis is listed as an agenda item.

Hon Craig Farrell MLC
Committee Chair
19 March 2015

Hon Ruth Forrest MLC
Inquiry Chair
19 March 2015

DISSENTING STATEMENT OF HON LEONIE HISCUTT MLC

Dissenting Report as Tabled by the Hon. Leonie Hiscutt MLC

11-March 2015

At the tabling of the final report, and in line with Sessional Order (24), I submit that a Minority Report be included in the Legislative Council Committee A Final Report on Legalised Medicinal Cannabis.

My one and only dissent is in relation to Recommendation 1:

> *"The Tasmanian Government introduces legislation to immediately provide protection to individuals who are currently using medicinal cannabis from criminal charges associated with possession and administration of medicinal cannabis on compassionate grounds."*

I dissent from this recommendation as I was, and still am confident that the Government has already addressed this issue to my satisfaction and that the need for legislation is moot.

I felt that the recommendation was fraught with danger if implemented and such a recommendation may have unintended consequences such as recreational cannabis users deliberately using such legislation to justify their use or grasped upon by medical patients who ordinarily might not require medicinal cannabis, but are desperate for medication to ease their various conditions, thus creating an unsupervised, unsafe situation.

I felt that Minister Ferguson has addressed the problem sufficiently in his media release as below.

20 November 2014

Michael Ferguson, Minister for Health

Interim Report on medicinal cannabis

The Liberal Government is supportive of trials and potential use of medicinal cannabis in Tasmania, subject to a proper evidence-based approach, strong local regulatory framework and appropriate approvals from national regulators.

The Premier put the issue of a national approach to medicinal cannabis use on the COAG agenda earlier this year, and as a result Health Ministers from across the country are working together to explore the potential for use of cannabis-derived products for medicinal purposes.

I note that the committee's recommendations endorse the Liberal Government's position regarding cooperation on clinical research and trials between jurisdictions and a national approach regarding a regulatory framework.

We have previously said we will not be moving to legislate, as recommended by the Legislative Council committee today, as advice from Tasmania Police is it's not necessary and could potentially create a new set of problems including opening up the risk that people would self-medicate, with no licensing or limit to quantity.

The Police Commissioner has said Tasmania Police will not seek to criminally pursue terminally ill users of cannabis, or people who have appeared before the Legislative Council inquiry, or commented on the benefits of medicinal cannabis.

The Government will review the report and will await the committee's final report and recommendations.

END

Hon. Leonie Hiscutt MLC

L Hiscutt MLC

APPENDIX A -

REGULATOR OF MEDICINAL CANNABIS BILL 2014

2013-2014

The Parliament of the
Commonwealth of Australia

THE SENATE

Presented and read a first time

Regulator of Medicinal Cannabis Bill 2014

No. , 2014

(Senators Di Natale, Macdonald, Leyonhjelm and Urquhart)

A Bill for an Act to establish the Regulator of Medicinal Cannabis, and for related purposes

Contents

A Bill for an Act to establish the Regulator of Medicinal Cannabis, and for related purposes

The Parliament of Australia enacts:

Part 1—Preliminary

1 Short title

This Act may be cited as the *Regulator of Medicinal Cannabis Act 2014*.

2 Commencement

(1) Each provision of this Act specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	**Column 2**	**Column 3**
Provision(s)	**Commencement**	**Date/Details**
1. Sections 1 and 2 and anything in this Act not elsewhere covered by this table	The day this Act receives the Royal Assent.	
2. Sections 3 to 63	A single day to be fixed by Proclamation. However, if the provision(s) do not commence within the period of 6 months	

Commencement information		
Column 1	**Column 2**	**Column 3**
Provision(s)	**Commencement**	**Date/Details**
	beginning on the day this Act receives the Royal Assent, they commence on the day after the end of that period.	

Note: This table relates only to the provisions of this Act as originally enacted. It will not be amended to deal with any later amendments of this Act.

(2) Any information in column 3 of the table is not part of this Act. Information may be inserted in this column, or information in it may be edited, in any published version of this Act.

3 Objects of this Act

The objects of this Act 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 products, and related activities such as research, in accordance with the Convention.

4 Simplified outline of this Act

This Act sets up the Regulator of Medicinal Cannabis to perform the functions of the agency referred to in Article 23 of the Single Convention on Narcotic Drugs, 1961 in relation to cannabis.

The regulator may approve medicinal cannabis products for inclusion in the register of regulated medicinal cannabis products. Products included in the register are regulated under this Act, rather than under the *Therapeutic Goods Act 1989*.

The regulator may make rules for licensing the production, use, experimental use and import and export of medicinal cannabis. The regulator has powers to monitor compliance with this Act and the rules, and investigate breaches.

This Act applies only in participating States and Territories. A State or Territory may enter into an arrangement with the Commonwealth to become a participating State or Territory.

5 Definitions

In this Act:

authorised carer has the meaning given by section 19.

authorised patient has the meaning given by section 19.

authorised patients and carers scheme means the scheme prescribed for the purposes of subsection 19(1).

cannabis has the same meaning as in the Convention, and also includes cannabis resin and cannabis plants (within the meaning of the Convention).

cannabis product means:

(a) cannabis, or a product derived from cannabis, that is intended for medicinal use; or

(b) a synthetic version, that is intended for medicinal use, of a product derived from cannabis.

Chair means the Chair of the regulator.

Chief Executive Officer means the Chair.

Convention means the Single Convention on Narcotic Drugs, 1961 done at New York on 30 March 1961.

Note: The Convention could in 2014 be viewed in the Australian Treaties Library on the AustLII website (http://www.austlii.edu.au).

evidential material has the same meaning as in the Regulatory Powers Act.

experimental cannabis licensing scheme means the scheme prescribed for the purposes of subsection 20(1).

experimental licence means a licence issued under the experimental cannabis licensing scheme.

experimental licence holder has the meaning given by subsection 20(1).

export licence holder has the meaning given by paragraph 24(1)(b).

import and export licensing scheme means the scheme prescribed for the purposes of subsection 24(1).

import licence holder has the meaning given by paragraph 24(1)(a).

indications, in relation to cannabis products, means the specific medicinal uses of the products.

label, in relation to cannabis products, means a display of printed information:

(a) on or attached to the products; or

(b) on or attached to a container or primary pack in which the products are supplied; or

(c) supplied with such a container or pack.

manufacture, in relation to cannabis products, means:

(a) to produce the products; or

(b) to engage in any part of the process of producing the products or of bringing the products to their final state, including engaging in the processing, assembling, packaging, labelling, storage, sterilising, testing or releasing for supply of the products or of any component or ingredient of the products as part of that process.

medical practitioner means a person who is registered, in a State or Territory, as a medical practitioner.

medicinal cannabis licensing scheme means the scheme prescribed for the purposes of subsection 16(1).

medicinal licence means a licence issued under the medicinal cannabis licensing scheme.

medicinal licence holder has the meaning given by subsection 16(1).

member includes the Chair.

participating State or Territory has the meaning given by section 7.

quality, in relation to cannabis products, includes the composition, strength, potency, stability, sterility and purity of the products.

register of regulated medicinal cannabis products means the register maintained under section 12.

regulated medicinal cannabis product means a cannabis product included in the register of regulated medicinal cannabis products.

regulator means the Regulator of Medicinal Cannabis established by section 28.

Regulatory Powers Act means the *Regulatory Powers (Standard Provisions) Act 2014*.

reviewable decision has the meaning given by section 59.

rules means the rules made under section 63.

standard means a standard determined under section 23.

6 Extension to external Territories

Subject to section 7, this Act extends to every external Territory.

7 Act applies only in participating States and Territories

(1) This Act applies only in a State or Territory that is a participating State or Territory.

(2) The Minister may determine, in writing, that a State or Territory is a ***participating State or Territory*** if the State or Territory has entered into an arrangement with the Commonwealth for this Act to apply in the State or Territory.

(3) A determination under subsection (2) is a legislative instrument, but section 42 (disallowance) of the *Legislative Instruments Act 2003* does not apply to the determination.

(4) A Territory that is not a self-governing Territory is taken to be a participating State or Territory.

8 Relationship with State and Territory laws

This Act is not intended to apply to the exclusion of a law of a State or a Territory to the extent that the law is capable of operating concurrently with this Act.

9 Act to bind Crown

This Act binds the Crown in right of the Commonwealth and of each of the States and Territories, but nothing in this Act renders the Crown liable to be prosecuted for an offence.

10 Arrangements with participating States and Territories

(1) The Minister may make arrangements with the appropriate Minister of a State, or a self-governing Territory, that is a participating State or Territory for the carrying out by that State or Territory, on behalf of the Commonwealth, of functions under this Act.

(2) An arrangement under this section may provide for the payment to a participating State or Territory of amounts in respect of the performance of functions under the arrangement.

Part 2—Medicinal cannabis

Division 1—Simplified outline

11 Simplified outline

The regulator is responsible for maintaining a register of regulated medicinal cannabis products, which lists cannabis products approved by the regulator.

The regulator may make:

(a) a medicinal cannabis licensing scheme, under which licences may be given for the cultivation, production and distribution of medicinal cannabis; and

(b) an authorised patients and carers scheme, for authorising patients, carers and medical practitioners; and

(c) an experimental cannabis licensing scheme, under which licences may be given for the experimental production and use of medicinal cannabis; and

(d) standards for medicinal cannabis; and

(e) an import and export licensing scheme, under which licences may be given for the import and export of medicinal cannabis.

Division 2—Regulated medicinal cannabis products

12 Register of regulated medicinal cannabis products

The regulator must maintain a ***register of regulated medicinal cannabis products*** in the manner prescribed by the rules.

13 Registration

(1) A person may apply to the regulator for a cannabis product to be included in the register of regulated medicinal cannabis products in relation to the person.

(2) The regulator may include a cannabis product in the register of regulated medicinal cannabis products in relation to a person if:
   (a) the person has made an application under subsection (1) for the cannabis product to be included in the register in relation to the person; and
   (b) the regulator is satisfied that the cannabis product is suitable for medicinal use; and
   (c) the regulator is satisfied that the cannabis product complies with any standard under this Act that applies to the product; and
   (d) the regulator is satisfied that including the cannabis product in the register of regulated medicinal cannabis products in relation to the person would be consistent with the Convention; and
   (e) the regulator is satisfied that it is appropriate in all the circumstances for the cannabis product to be regulated under this Act; and
   (f) any requirements prescribed by the rules are met.

(3) The rules may prescribe:
   (a) the manner in which an application under subsection (1) is to be made; and
   (b) matters to which the regulator may, or must, have regard in making a decision under subsection (2); and
   (c) procedures to be followed by the regulator in making such a decision.

14 Removal or variation of entries in the register of regulated medicinal cannabis

The rules may provide for an entry in the register of regulated medicinal cannabis to be removed or varied on application by the person in relation to whom the entry is registered, or on the regulator's own initiative.

15 Cannabis products

For the purposes of this Act, cannabis products are to be taken to be separate and distinct from other cannabis products if they have:
   (a) a different formulation, composition or design specification; or
   (b) a different strength or size (disregarding pack size); or
   (c) a different dosage form or model; or
   (d) a different name; or
   (e) different indications; or

(f) different directions for use; or
(g) a different type of container (disregarding container size).

Division 3—Medicinal cannabis licensing scheme

16 Medicinal cannabis licensing scheme

(1) The rules may prescribe a scheme (the ***medicinal cannabis licensing scheme***) for the regulator to issue licences (***medicinal licences***) authorising persons (***medicinal licence holders***) to engage in one or more of the following activities:

(a) producing cannabis for medicinal or experimental use;

(b) transporting or storing cannabis for medicinal or experimental use;

(c) manufacturing regulated medicinal cannabis products;

(d) transporting or storing regulated medicinal cannabis products;

(e) providing regulated medicinal cannabis products to authorised patients and authorised carers;

(f) other activities incidental to the activities referred to in paragraphs (a) to (e).

Note: The medicinal cannabis licensing scheme must be consistent with the Convention (see subsection 63(2)).

(2) A medicinal licence may authorise individuals to engage in activities referred to in subsection (1) on behalf of the medicinal licence holder.

(3) The medicinal cannabis licensing scheme must provide for a medicinal licence to be subject to such conditions as are appropriate for ensuring that:

(a) all cannabis produced in accordance with the scheme is accounted for; and

(b) all regulated medicinal cannabis products manufactured in accordance with the scheme are accounted for; and

(c) any relevant standards are complied with; and

(d) the scheme operates in accordance with the Convention.

(4) The *Narcotic Drugs Act 1967* and the *Therapeutic Goods Act 1989* do not apply in relation to an activity engaged in, or a thing dealt with, in accordance with a medicinal licence.

(5) Subsection (4) does not prevent the *Therapeutic Goods Act 1989* applying in relation to:

(a) the manufacture of therapeutic goods (within the meaning of 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);

if the goods are not included in the register of regulated medicinal cannabis products in relation to the manufacturer.

17 Offence of failing to comply with a condition of a medicinal licence

(1) A medicinal licence holder must comply with the conditions of the medicinal licence.

(2) A person commits an offence if:

(a) the person is a medicinal licence holder; and

(b) the medicinal licence is subject to a condition; and

(c) the condition is not complied with.

Penalty: 300 penalty units.

18 Register of medicinal licences

(1) The medicinal cannabis licensing scheme must require the regulator to maintain a register of medicinal licences, in the manner specified in the scheme.

(2) The register must not be made available to the public.

Division 4—Authorised patients and carers scheme

19 Authorised patients and carers scheme

(1) The rules may prescribe a scheme (the ***authorised patients and carers scheme***) to provide for the authorisation of:

(a) individuals (***authorised patients***) to use regulated medicinal cannabis products; and

(b) individuals (***authorised carers***) to supply regulated medicinal cannabis products to authorised patients; and

(c) authorised patients and authorised carers to do things incidental to an authorisation referred to in paragraph (a) or (b); and

(d) medical practitioners, or classes of medical practitioners, to prescribe regulated medicinal cannabis products.

Note: The authorised patients and carers scheme must be consistent with the Convention (see subsection 63(2)).

(2) The authorised patients and carers scheme must provide for an authorisation given under the scheme to an authorised patient or an authorised carer:

(a) to be given only on request by a medical practitioner in accordance with the scheme; and

(b) to be subject to such conditions as are appropriate for ensuring that the scheme operates in accordance with the Convention.

(3) The authorised patients and carers scheme may provide for an authorisation to be given by:

(a) the regulator; or

(b) an appropriate authority of a participating State or Territory.

(4) The *Narcotic Drugs Act 1967* and the *Therapeutic Goods Act 1989* do not apply in relation to an activity engaged in, or a thing dealt with, in accordance with an authorisation under the authorised patients and carers scheme.

Division 5—Experimental cannabis licensing scheme

20 Experimental cannabis licensing scheme

(1) The rules may prescribe a scheme (the ***experimental cannabis licensing scheme***) for the regulator to issue licences (***experimental licences***) authorising persons (***experimental licence holders***) to engage in one or more of the following activities for an experimental purpose:

(a) producing cannabis;

(b) manufacturing cannabis products;

(c) transporting or storing cannabis or cannabis products;

(d) providing or administering cannabis products;

(e) performing tests on cannabis or cannabis products;

(f) other activities incidental to the activities referred to in paragraphs (a) to (e).

Note: The experimental cannabis licensing scheme must be consistent with the Convention (see subsection 63(2)).

(2) Without limiting subsection (1), the reference in that subsection to an ***experimental purpose*** includes the following purposes:

(a) developing and testing varieties of cannabis for medicinal use;

(b) improving methods of cultivating cannabis for medicinal use;

(c) developing and testing cannabis products for medicinal use;

(d) evaluating the efficacy or safety of cannabis products for medicinal use;

(e) improving methods of using or administering cannabis products for medicinal purposes;

(f) performing tests, trials and other experiments for the purposes of making or supporting an application under this Act or the *Therapeutic Goods Act 1987*, or considering whether to make such an application.

(3) An experimental licence may authorise individuals to use, possess, supply or administer cannabis products to the extent necessary for the experimental purpose.

Note: For example, an experimental licence authorising clinical trials of a cannabis product for medicinal use may authorise test subjects to use the cannabis product and staff to possess and administer the cannabis product.

(4) The experimental cannabis licensing scheme must provide for an experimental licence to be subject to such conditions as are appropriate for ensuring:

(a) that any cannabis produced or dealt with in accordance with the scheme is accounted for; and

(b) that any cannabis products manufactured or dealt with in accordance with the scheme are accounted for; and

(c) that the scheme operates in accordance with the Convention.

(5) The *Narcotic Drugs Act 1967* and the *Therapeutic Goods Act 1989* do not apply in relation to an activity engaged in, or a thing dealt with, in accordance with an experimental licence.

(6) Subsection (5) does not prevent 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 *Therapeutic Goods Act 1989*.

21 Offence of failing to comply with a condition of an experimental licence

A person commits an offence if:

(a) the person is an experimental licence holder; and

(b) the experimental licence is subject to a condition; and

(c) the condition is not complied with.

Penalty: 300 penalty units.

22 Register of experimental licences

(1) The experimental cannabis licensing scheme must require the regulator to maintain a register of experimental licences, in the manner specified in the scheme.

(2) The register must not be made available to the public.

Division 6—Medicinal cannabis standards

23 Determination of standards

(1) The rules may provide for the regulator to determine, by legislative instrument, standards for:

(a) cannabis or cannabis products; or

(b) an activity that may be carried out under a medicinal licence or an experimental licence.

(2) Without limiting subsection (1), a standard may:

(a) be specified by reference to:

(i) the quality of a cannabis product; or

(ii) the quantity of a cannabis product when contained in specified containers; or

(iii) the characteristics of a variety of cannabis for cultivation; or

(iv) a monograph in the British Pharmacopoeia, the European Pharmacopoeia or the United States Pharmacopeia-National Formulary; or

(v) a monograph in another publication approved by the regulator for the purposes of this subsection; or

(vi) such a monograph as modified in a manner specified in the standard; or

(vii) a standard published by Standards Australia; or

(viii) such other matters as the regulator thinks fit; or

(b) require that a matter relating to the standard be determined in accordance with a particular test; or

(c) require that cannabis, cannabis products or a class of cannabis or cannabis products identified in the standard be labelled or packaged in a manner, or kept in containers that comply with requirements, specified in the standard.

(3) Without limiting paragraph (2)(c), a standard may require that there be set out, in a manner specified in the standard, on:

(a) cannabis, cannabis products or a class of cannabis or cannabis products identified in the standard; or

(b) a container or package containing cannabis, cannabis products or a class of cannabis or cannabis products identified in the standard; or

(c) a label of cannabis, cannabis products or a class of cannabis or cannabis products identified in the standard;

such particulars as are required by the standard.

Division 7—Import and export licensing scheme

24 Import and export licensing scheme

(1) The rules may prescribe a scheme (the ***import and export licensing scheme***) for the regulator to:

(a) issue licences (***import licences***) authorising persons (***import licence holders***) to import cannabis or cannabis products into Australia for medicinal or experimental purposes in accordance with this Act; and

(b) issue licences (***export licences***) authorising persons (***export licence holders***) to export cannabis or cannabis products from Australia for medicinal or experimental purposes.

Note: The import and export licensing scheme must be consistent with the Convention (see subsection 63(2)).

(2) An import licence or an export licence may authorise individuals to engage in activities referred to in subsection (1) on behalf of the holder of the licence.

(3) The import and export licensing scheme must provide for an import licence or an export licence to be subject to such conditions as are appropriate for ensuring:

(a) that any cannabis or cannabis products imported or exported in accordance with the scheme are accounted for; and

(b) that the scheme operates in accordance with the Convention.

(4) The *Narcotic Drugs Act 1967* and the *Therapeutic Goods Act 1989* do not apply in relation to an activity engaged in, or a thing dealt with, in accordance with an import licence or an export licence.

25 Offence of failing to comply with a condition of an import licence or an export licence

A person commits an offence if:

(a) the person holds an import licence or an export licence; and

(b) the licence is subject to a condition; and

(c) the condition is not complied with.

Penalty: 300 penalty units.

26 Register of import licences and export licences

The import and export licensing scheme must require the regulator to:

(a) maintain a register of import licences and export licences, in the manner specified in the scheme; and

(b) make the register available to the public.

Part 3—Regulator of Medicinal Cannabis

Division 1—Simplified outline

27 Simplified outline

The regulator is established under the *Public Governance, Performance and Accountability Act 2013*.

The regulator has functions relating to medicinal cannabis, which it must perform in a manner consistent with the Convention.

Division 2—Establishment, functions and powers of the regulator

28 Establishment

(1) The Regulator of Medicinal Cannabis (the ***regulator***) is established by this section.

(2) For the purposes of the finance law (within the meaning of the *Public Governance, Performance and Accountability Act 2013*):

(a) the regulator is a listed entity; and

(b) the members are the accountable authority of the regulator; and

(c) the following persons are officials of the regulator:

(i) the members;

(ii) the Chief Executive Officer;

(iii) the staff of the regulator; and

(d) the purposes of the regulator include the functions of the regulator referred to in section 30.

29 Constitution

The regulator consists of:

(a) a Chair; and

(b) 5 other members.

Note: The regulator does not have a legal identity separate from the Commonwealth.

30 Functions and powers

(1) The regulator has the following functions:

(a) the functions of the agency referred to in Article 23 of the Convention, as it applies in relation to cannabis because of Article 28 of the Convention;

(b) to enter into contracts with medicinal licence holders, experimental licence holders, import licence holders and export licence holders;

(c) to supply cannabis within Australia for the purposes of manufacturing regulated medicinal cannabis products;

(d) to supply regulated medicinal cannabis products within Australia for medicinal purposes;

(e) to supply cannabis and cannabis products within Australia for experimental purposes;

(f) to investigate whether this Act or the rules have been or are being complied with;

(g) to advise and make recommendations to the Minister on matters relating to medicinal or experimental cannabis and cannabis products, if requested by the Minister or on its own initiative;

(h) to collect, analyse, interpret and disseminate information and statistics relating to medicinal or experimental cannabis and cannabis products;

(i) to educate and inform patients, carers, health workers and the community about the medicinal use of regulated medicinal cannabis products;

(j) to provide training to health workers in relation to the medicinal use of regulated medicinal cannabis products;

(k) to cooperate with its counterparts in other countries;

(l) to cooperate with law enforcement agencies in Australia and in other countries;

(m) such other functions as are conferred on the regulator by or under this Act or any other Commonwealth law.

(2) The regulator may perform its functions within or outside Australia.

(3) The regulator has the power to do all things that are necessary or convenient to be done for or in connection with the performance of its functions.

(4) The regulator must perform its functions and exercise its powers in a manner consistent with the Convention.

(5) The *Narcotic Drugs Act 1967* and the *Therapeutic Goods Act 1989* do not apply in relation to the performance of the regulator's functions or the exercise of its powers.

31 Independence of the regulator

Subject to section 32, the regulator is not subject to direction from anyone in relation to the performance of its functions or the exercise of its powers.

32 Minister may give directions to the regulator

(1) The Minister may, by legislative instrument, give a direction to the regulator if the Minister considers that the direction is necessary to ensure that Australia complies with its obligations under the Convention.

Note: Section 42 (disallowance) and Part 6 (sunsetting) of the *Legislative Instruments Act 2003* do not apply to the direction (see sections 44 and 54 of that Act).

(2) The regulator must comply with a direction given under subsection (1).

33 The regulator has privileges and immunities of the Crown

The regulator has the privileges and immunities of the Crown in right of the Commonwealth.

Division 3—Appointment of members

34 Appointment

(1) The Chair is to be appointed by the Minister, by written instrument, on a full-time basis.

(2) The members other than the Chair are to be appointed by the Minister, by written instrument, on a part-time basis.

(3) The Minister is to appoint a person as a member only if the Minister is satisfied that the person is qualified for appointment because of his or her knowledge of, or experience in, one or more of the following fields:

(a) medicine;
(b) pharmacology;
(c) palliative care;
(d) botany;
(e) horticulture;
(f) law;
(g) law enforcement;
(h) advocacy for patients and other users of medical services.

(4) In making appointments under this section, the Minister must ensure that:

(a) at least one member is a medical practitioner; and
(b) at least one member is a member of the Australian Federal Police; and
(c) at least one member represents the interests of patients and other users of medical services.

35 Term of appointment

A member holds office for the period specified in the instrument of appointment. The period must not exceed 5 years.

Note: For reappointment, see section 33AA of the *Acts Interpretation Act 1901*.

36 Remuneration and allowances

(1) A member is to be paid the remuneration that is determined by the Remuneration Tribunal. If no determination of that remuneration by the Tribunal is in operation, the member is to be paid the remuneration that is determined, in writing, by the Minister.

(2) A member is to be paid the allowances that are determined, in writing, by the Minister.

(3) This section has effect subject to the *Remuneration Tribunal Act 1973*.

37 Leave of absence

(1) The Chair has the recreation leave entitlements that are determined by the Remuneration Tribunal.

(2) The Minister may grant the Chair leave of absence, other than recreation leave, on the terms and conditions as to remuneration or otherwise that the Minister determines.

(3) The Chair may grant leave of absence to a member other than the Chair on the terms and conditions that the Chair determines.

38 Outside employment

(1) The Chair must not engage in paid employment outside the duties of his or her office without the Minister's approval.

(2) A member other than the Chair must not engage in any paid employment that, in the Minister's opinion, conflicts or may conflict with the proper performance of his or her duties.

39 Disclosure of interests to the Minister

(1) A member must give written notice to the Minister of all interests, pecuniary or otherwise, that the member has or acquires that conflict or could conflict with the proper performance of the member's functions.

(2) The notice must be given to the Minister as soon as practicable after the member becomes aware of the potential for conflict of interest.

40 Other terms and conditions

A member holds office on the terms and conditions (if any) in relation to matters not covered by this Act that are determined, in writing, by the Minister.

41 Resignation

(1) A member may resign his or her appointment by giving the Minister a written resignation.

(2) The resignation takes effect on the day it is received by the Minister or, if a later day is specified in the resignation, on that later day.

Note: If the Chair resigns, he or she also resigns his or her position as the Chief Executive Officer. This does not prevent a person who is both the Chair and Chief Executive Officer from being reappointed only as a member.

42 Termination of appointment

The Minister may terminate the appointment of a member:

(a) for misbehaviour; or

(b) if the member is unable to perform the duties of his or her office because of physical or mental incapacity; or

(c) if the member:

(i) becomes bankrupt; or

(ii) applies to take the benefit of any law for the relief of bankrupt or insolvent debtors; or

(iii) compounds with his or her creditors; or

(iv) makes an assignment of his or her remuneration for the benefit of his or her creditors; or

(d) if the member is absent, except on leave of absence, for 14 consecutive days or for 28 days in any 12 months; or

(e) if the member engages in paid employment contrary to section 38; or

(f) if the member fails, without reasonable excuse, to comply with section 39 or 46.

43 Acting appointments

Acting Chair

(1) The Minister may, by written instrument, appoint a member to act as the Chair:

(a) during a vacancy in the office of the Chair (whether or not an appointment has previously been made to the office); or

(b) during any period, or during all periods, when the Chair:

(i) is absent from duty or from Australia; or

(ii) is, for any reason, unable to perform the duties of the office.

Acting member

(2) The Minister may, by written instrument, appoint a person to act as a member (other than the Chair):

(a) during a vacancy in the office of the member (whether or not an appointment has previously been made to the office); or

(b) during any period, or during all periods, when the member:

(i) is absent from duty or from Australia; or

(ii) is, for any reason, unable to perform the duties of the office.

Requirements before appointing a person to act

(3) A person may only be appointed to act as the Chair, or as a member, if the Minister is satisfied that the person has appropriate qualifications, knowledge or experience.

Note: For rules that apply to acting appointments, see sections 33AB and 33A of the *Acts Interpretation Act 1901*.

Division 4—Procedures of the regulator

Subdivision A—Meetings

44 Times and places of meetings

(1) The Chair must ensure that such meetings are held as are necessary for the efficient performance of the regulator's functions.

(2) Meetings are to be held at such times and places as the Chair decides.

(3) The Chair must convene a meeting if requested, in writing, by at least 2 of the other members.

45 Conduct of meetings

Presiding at meetings

(1) The Chair presides at all meetings at which he or she is present.

(2) If the Chair is not present at a meeting, a member:
  (a) nominated by the Chair; and
  (b) present at the meeting;
must preside.

Quorum

(3) At a meeting of the regulator, a quorum is constituted by 4 members.

Rules of procedure

(4) The regulator may, subject to this Division, regulate proceedings at its meetings as it considers appropriate.

Note: Section 33B of the *Acts Interpretation Act 1901* provides for participation in meetings by telephone etc.

Voting

(5) The person presiding at a meeting of the regulator has a deliberative vote but, if the votes are equal, does not have a casting vote.

Minutes

(6) The regulator must ensure that minutes of its meetings are kept.

46 Disclosure of interests

(1) If a member has an interest, pecuniary or otherwise, in a matter being considered, or about to be considered, at a meeting, the member must disclose the nature of that interest to the other members.

(2) The disclosure must be made as soon as possible after the relevant facts have come to the member's knowledge.

(3) The disclosure must be recorded in the minutes of the meeting.

(4) Unless the regulator otherwise determines, the member:
  (a) must not be present during the regulator's deliberation on the matter; and
  (b) must not take part in the regulator's decision on the matter.

(5) For the purposes of the regulator making a determination under subsection (4), the member:
  (a) must not be present during any of the regulator's deliberations for the purpose of making the determination; and
  (b) must not take part in making the determination.

(6) A determination under subsection (4) must be recorded in the minutes of the meeting.

Subdivision B—Decisions without meetings

47 Decisions without meetings

(1) A decision is taken to have been made at a meeting of the regulator if:
  (a) without meeting, a majority of members indicate agreement with the proposed decision in accordance with the method determined by the regulator under subsection (2); and
  (b) all members were informed of the proposed decision, or reasonable efforts were made to inform all members of the proposed decision.

(2) Subsection (1) applies if the regulator:
  (a) has determined that it applies; and
  (b) has determined the method by which members are to indicate agreement with proposed decisions.

48 Record of decisions

The regulator must keep a record of decisions made in accordance with section 47.

Division 5—Chief Executive Officer

49 Chief Executive Officer

(1) There is to be a Chief Executive Officer of the regulator.

(2) The Chair is the Chief Executive Officer.

50 Functions and powers of the Chief Executive Officer

(1) The Chief Executive Officer is responsible for the management and administration of the regulator.

(2) All acts and things done in the name of, or on behalf of, the regulator by the Chief Executive Officer are taken to have been done by the regulator.

Division 6—Staff and persons assisting the regulator

51 Staff

(1) The staff of the regulator are to be persons engaged under the *Public Service Act 1999*.

(2) For the purposes of the *Public Service Act 1999*:

(a) the Chief Executive Officer and the staff of the regulator together constitute a Statutory Agency; and

(b) the Chief Executive Officer is the Head of that Statutory Agency.

52 Persons assisting the regulator

The regulator may be assisted:

(a) by employees of Agencies (within the meaning of the *Public Service Act 1999*); or

(b) by officers or employees of a participating State or Territory; or

(c) by officers or employees of authorities of the Commonwealth or a participating State or Territory;

whose services are made available to the regulator in connection with the performance of the regulator's functions.

53 Consultants

(1) The regulator may, on behalf of the Commonwealth, engage persons having suitable qualifications and experience as consultants to the regulator.

(2) The consultants are to be engaged on the terms and conditions that the regulator determines in writing.

Part 4—Monitoring and investigation powers

Division 1—Simplified outline

54 Simplified outline

The regulator may authorise members, members of staff and officers and employees of participating States and Territories who are assisting the regulator to exercise monitoring and investigation powers under the Regulatory Powers Act.

Division 2—Monitoring and investigation powers

55 Authorised officers

The regulator may, in writing, authorise any of the following people for the purposes of subsection 56(4) or (5) or 57(3) or (4):

(a) a member;

(b) a member of the staff of the regulator;

(c) with the agreement of a participating State or Territory—an officer or employee of the State or Territory, or of an authority of the State or Territory, who is assisting the regulator in accordance with section 52.

56 Monitoring powers

Provisions subject to monitoring

(1) The following provisions (the ***monitoring powers provisions***) are ***subject to monitoring*** under Part 2 of the Regulatory Powers Act:

(a) Part 2 (other than Division 4) of this Act;

(b) rules made for the purposes of Part 2 (other than Division 4) of this Act.

Note: Part 2 of the Regulatory Powers Act creates a framework for monitoring whether these provisions have been complied with. It includes powers of entry, search and inspection (see section 20 of that Act).

Information subject to monitoring

(2) Information given in compliance or purported compliance with a monitoring powers provision is ***subject to monitoring*** under Part 2 of the Regulatory Powers Act.

Note: Part 2 of the Regulatory Powers Act creates a framework for monitoring whether the information is correct. It includes powers of entry, search and inspection (see section 20 of that Act).

Related provisions

(3) For the purposes of Part 2 of the Regulatory Powers Act, a provision for an offence against the *Crimes Act 1914* or the *Criminal Code* that relates to a monitoring powers provision is ***related*** to the monitoring powers provision and the information mentioned in subsection (2).

Authorised applicant

(4) For the purposes of Part 2 of the Regulatory Powers Act, a person authorised under section 55 of this Act for the purposes of this subsection is an ***authorised applicant*** in relation to:

(a) the monitoring powers provisions; and

(b) the information mentioned in subsection (2).

Authorised person

(5) For the purposes of Part 2 of the Regulatory Powers Act, a person authorised under section 55 of this Act for the purposes of this subsection is an ***authorised person*** in relation to:

(a) the monitoring powers provisions; and

(b) the information mentioned in subsection (2).

Issuing officer

(6) For the purposes of Part 2 of the Regulatory Powers Act, a magistrate, or a Judge of the Federal Circuit Court, is an ***issuing officer*** in relation to:

(a) the monitoring powers provisions; and

(b) the information mentioned in subsection (2).

Relevant chief executive

(7) For the purposes of Part 2 of the Regulatory Powers Act, the Chief Executive Officer is the ***relevant chief executive*** in relation to:

(a) the monitoring powers provisions; and

(b) the information mentioned in subsection (2).

Relevant court

(8) For the purposes of Part 2 of the Regulatory Powers Act, each of the following courts is a ***relevant court*** in relation to the listed provisions and the information mentioned in subsection (2):

(a) the Federal Court of Australia;

(b) the Federal Circuit Court of Australia;

(c) the Supreme Court of a State or Territory.

Person assisting

(9) For the purposes of Part 2 of the Regulatory Powers Act, a person authorised under section 55 of this Act for the purposes of subsection (4) or (5) of this section may be assisted by a member (or members) of the staff of the regulator in exercising powers or performing functions in relation to:

(a) the monitoring powers provisions; or

(b) the information mentioned in subsection (2).

57 Investigation powers

*Offences that are **subject to investigation***

(1) The following are ***subject to investigation*** under Part 3 of the Regulatory Powers Act:

(a) an offence against this Act;

(b) an offence against the *Crimes Act 1914* or the *Criminal Code* that relates to this Act.

Note: Part 3 of the Regulatory Powers Act creates a framework for investigating whether offences that are subject to investigation have been committed. It includes powers of entry, search, inspection and seizure (see section 50 of that Act).

Related provisions

(2) For the purposes of Part 3 of the Regulatory Powers Act, each of the following is ***related*** to evidential material that relates to an offence mentioned in subsection (1):

(a) a provision for an offence against this Act;

(b) a provision for an offence against the *Crimes Act 1914* or the *Criminal Code* that relates to this Act.

Authorised applicant

(3) For the purposes of Part 3 of the Regulatory Powers Act, a person authorised under section 55 of this Act for the purposes of this subsection is an ***authorised applicant*** in relation to evidential material that relates to an offence mentioned in subsection (1).

Authorised person

(4) For the purposes of Part 3 of the Regulatory Powers Act, a person authorised under section 55 of this Act for the purposes of this subsection is an ***authorised person*** in relation to evidential material that relates to an offence mentioned in subsection (1).

Issuing officer

(5) For the purposes of Part 3 of the Regulatory Powers Act, a magistrate, or a Judge of the Federal Circuit Court, is an ***issuing officer*** in relation to evidential material that relates to an offence mentioned in subsection (1).

Relevant chief executive

(6) For the purposes of Part 3 of the Regulatory Powers Act, the Chief Executive Officer is the ***relevant chief executive*** in relation to evidential material that relates to an offence mentioned in subsection (1).

Relevant court

(7) For the purposes of Part 3 of the Regulatory Powers Act, each of the following courts is a ***relevant court*** in relation to evidential material that relates to an offence mentioned in subsection (1):

(a) the Federal Court;

(b) the Federal Circuit Court;

(c) the Supreme Court of a State or Territory.

Person assisting

(8) For the purposes of Part 3 of the Regulatory Powers Act, a person authorised under section 55 of this Act for the purposes of subsection (3) or (4) of this section may be assisted by a member (or members) of the staff of the regulator in exercising powers or performing functions in relation to evidential material that relates to an offence mentioned in subsection (1).

Use of force in executing a warrant

(9) In executing an investigation warrant:

(a) an authorised person may use such force against things as is necessary and reasonable in the circumstances; and

(b) a person assisting the authorised person may use such force against things as is necessary and reasonable in the circumstances.

Part 5—Miscellaneous

58 Simplified outline

This Part deals with miscellaneous matters, such as delegations, rules and review of decisions.

59 Reviewable decisions

(1) For the purposes of this Act, each of the following decisions made under this Act is a ***reviewable decision***:

(a) a decision not to include a cannabis product in the register of regulated medicinal cannabis products in relation to a person;

(b) a decision to remove or vary, or not to remove or vary, an entry in the register of regulated medicinal cannabis products;

(c) a decision not to issue a medicinal licence;

(d) a decision to revoke or vary a medicinal licence, or to impose a condition on a medicinal licence;

(e) a decision not to give an authorisation under the authorised patients and carers scheme;

(f) a decision to revoke or vary an authorisation under the authorised patients and carers scheme, or to impose a condition on such an authorisation;

(g) a decision not to issue an experimental licence;

(h) a decision to revoke or vary an experimental licence, or to impose a condition on an experimental licence;

(i) a decision not to issue an import licence or an export licence;

(j) a decision to revoke or vary an import licence or an export licence, or to impose a condition on an import licence or an export licence.

(2) The rules may provide that a decision made under the rules is a ***reviewable decision*** for the purposes of this Act.

60 Application for review by the Administrative Appeals Tribunal

An application may be made to the Administrative Appeals Tribunal for review of a reviewable decision.

61 Delegation

(1) The regulator may, by writing, delegate any or all of the regulator's functions and powers to:

(a) a member; or

(b) an SES employee, or acting SES employee, who is a member of the staff of the regulator; or

(c) with the agreement of a participating State or Territory—an officer or employee of the State or Territory, or of an authority of the State or Territory, who:

(i) is assisting the regulator in accordance with section 52; and

(ii) holds, or acts in, an office or position at a level equivalent to that of an SES employee.

(2) Subsection (1) does not apply to the power to make rules under section 63 or to the power to make any of the following decisions:

(a) a decision to include a cannabis product in the register of regulated medicinal cannabis products in relation to a person;

(b) a decision to remove or vary an entry in the register of regulated medicinal cannabis products;

(c) a decision to issue or vary a medicinal licence, or to impose a condition on a medicinal licence;

(d) a decision to issue or vary an experimental licence, or to impose a condition on an experimental licence;

(e) a decision to issue or vary an import licence or an export licence, or to impose a condition on an import licence or an export licence.

(3) In performing functions or exercising powers under a delegation, the delegate must comply with any written directions of the regulator.

62 Protection from criminal or civil actions

(1) No action, suit or proceeding (whether criminal or civil) lies against a protected person in relation to anything done, or omitted to be done, in good faith by the person:

(a) in accordance, or purportedly in accordance, with this Act; or

(b) in the performance, or purported performance, of the regulator's functions; or

(c) in the exercise, or purported exercise, of the regulator's powers.

Note: This section extends to, for example, a thing done in good faith in accordance with a delegation under section 61.

(2) The ***protected persons*** are as follows:

(a) the Minister;

(b) a member;

(c) a member of the staff of the regulator;

(d) a Commonwealth authority;

(e) a person who holds any office or appointment under a law of the Commonwealth or of a State or Territory;

(f) a person assisting the regulator in accordance with section 52.

63 Rule-making power

(1) The regulator may, by legislative instrument, make rules prescribing matters:

(a) required or permitted by this Act to be prescribed by the rules; or

(b) necessary or convenient to be prescribed for carrying out or giving effect to this Act.

(2) The rules must be consistent with the Convention.

Fees

(3) The rules may prescribe fees that the regulator may charge for things done in the performance of its functions.

(4) The rules may prescribe the way in which a fee is to be worked out.

(5) Fees prescribed by the rules must not be such as to amount to taxation.