EXPLANATORY STATEMENT

Narcotic Drugs Act 1967

Narcotic Drugs Amendment (Medicinal Cannabis) Regulations 2021

These Regulations reduce regulatory burden for applicants for, and holders of, licences and permits for medicinal cannabis, improving the availability of product for supply for the treatment of patients with conditions for which medicinal cannabis is indicated.

The *Narcotic Drugs Act 1967* (the Act) gives effect to certain of Australia's obligations under the Single Convention on Narcotic Drugs, 1961, as in force from time to time (the Convention). The Convention, as amended by the 1972 Protocol, is set out in Schedule 1 to the Act.

The *Narcotic Drugs Amendment (Medicinal Cannabis) Act 2021* (the Amendment Act) finalises implementation of recommendations of the final report of the McMillan Review by Professor John McMillan AO requiring legislative change. On commencement, six months from its passage, being on 24 December 2021, it consolidates the medicinal cannabis licensing structure introduced to the Act in 2016 into a single licence framework; enables assessments relating to supply chains to be undertaken at the permit stage rather than the earlier licensing stage; and creates a perpetual licence and periodic permit structure for the majority of activities for which a licence is required. It delivers the Australian Government's commitment to the availability of the safe, legal and sustainable supply of cannabis derived medicines.

Section 27 of the Act provides that the Governor-General may make regulations 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.

The *Narcotic Drugs Regulation 2016* (the Principal Regulations) prescribe various matters required or permitted by the Act to be prescribed by the regulations for the purposes of the medicinal cannabis scheme in the Act.

The purpose of the *Narcotic Drugs Amendment (Medicinal Cannabis) Regulations 2021* (the Regulations) is to amend the Principal Regulations to support the reforms to the Act to be implemented by the Amendment Act, principally to reduce regulatory burden for applicants for, and holders of, licences and permits for medicinal cannabis, thereby improving the availability of treatments for patients.

The statutorily required review of the medicinal cannabis scheme was completed by tabling in the Parliament the final report of the McMillan Review on 5 September 2019.

The Amendment Act implements recommendations of the McMillan Review and makes other minor, including consequential, amendments.

During 2019–20, the Department consulted industry stakeholders on the detailed policy measures required to implement the recommendations of the McMillan Review through publication of consultation papers and conducting a number of forums held in Brisbane, Sydney and Melbourne. On 17 November 2020, the Department conducted a further industry

information session on the proposed measures. During 2021, the Department has continued its consultation with industry by hosting a number of webinars.

The Act specifies no conditions that need to be satisfied before the power to make the proposed Regulations may be exercised. The Regulations is a legislative instrument for the purposes of the *Legislation Act 2003*.

The Regulations commence on the later of the day after the proposed Regulations are registered, and immediately after the commencement of the *Narcotic Drugs Amendment (Medicinal Cannabis) Regulations 2021*.

Details of the Regulations are set out in the Attachment.

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

ATTACHMENT

Details of the *Narcotic Drugs Amendment (Medicinal Cannabis) Regulations 2021*

Section 1 – Name
This section provides that the title of the Regulations is the *Narcotic Drugs Amendment (Medicinal Cannabis) Regulations 2021*.

Section 2 – Commencement
This section provides for the Regulations to commence on the later of the day on which Schedule 1 to the *Narcotic Drugs Amendment (Medicinal Cannabis) Act 2021* (the Amendment Act) commences and the day after registration of the Regulations on the Federal Register of Legislation.

Section 3 – Authority
The Regulations are made under the *Narcotic Drugs Act 1967* (the Act).

Section 4 – Schedules
This section gives legal effect to the amendments in the Schedules.

Schedule 1 – Amendments

Item [1] Section 4 (paragraph (a) of the note to the heading)
This item repeals paragraph (a) of the note to the heading, consequential to the absence of any reference to the term "business associate" in the Principal Regulations.

Item [2] Section 4 (after paragraph (b) of the note to the heading)
This item inserts new paragraph (ba) of the note to the heading, consequential to the insertion of the definition of "cannabis drug" in the Act.

Item [3] Section 4 (paragraph (g) of the note to the heading)
This item substitutes new paragraph (g) for existing paragraph (g) of the note to the heading, consequential to the repeal (by the Amendment Act) from the Act of the definition of "medicinal cannabis product" and the insertion of the definition of "narcotic drug" into the Act.

Item [4] Section 4
Consequential to the Amendment Act provision of a single licence, for any of the activities of cultivation, production or manufacture of medicinal cannabis and also consequential to the proposed identification of two classes of medicinal cannabis licence on which to impose (and calculate) charge, the definitions of "cannabis-related licence", "cannabis-related manufacture licence", "cannabis-related manufacture permit" and "cannabis-related permit" are redundant. Accordingly, this item repeals these defined terms.

Item [5] Section 4 (definition of *certified true copy*)
This item replaces "under regulation 4 of the *Statutory Declarations Regulations 1993*", with "by section 7 of the *Statutory Declarations Regulations 2018*".

Item [6] Section 4
This item inserts into section 4 a definition for "commercial medicinal cannabis licence" by directing the reader to subsection 54A(4). The term is used to identify the imposition and calculation of charge.

This item also inserts into section 4, for the purposes of determining fees payable to the Secretary on an application for variation of a licence or a permit, definitions for a "minor

licence variation" or a "minor permit variation". Those fees are set out at items 5 and 7 of the table in Schedule 1 of the Principal Regulations (as amended by the Regulations).

In the case of the minor licence variation, it means a variation to the period for which the licence is in force where that licence specifies a period for which the licence is in force; or to remove a person specified by the licence as a person who is authorised by the licence to engage in the activities authorised by the licence; or if the licence holder is a body corporate – and the body's name changes – to update the name of the licence holder.

A minor permit variation means a variation to, if the permit specifies the size of the cannabis crop that may be cultivated—reduce the size of the cannabis crop that may be cultivated; or if the permit specifies the types of cannabis plants that may be cultivated, the number of each type of cannabis plants that may be cultivated, provided the variation does not increase the total number of cannabis plants that are of a type that has a higher level of tetrahydrocannabinol and could be cultivated under the permit before the variation.

Finally, the item directs readers to subsection 54A(1) of the Regulations for the definition of "non-commercial medicinal cannabis licence". The term is also used to identify the imposition and calculation of charge.

Item [7] Section 4 (definition of '*starting material'*)
This item clarifies the definition of "starting material" by replacing the existing definition of "starting material" (including the note) with a new definition. It provides that starting material, in relation to a cannabis or narcotic drug, means a drug used in the manufacture of the cannabis or narcotic drug. This is consequential to the new definition of "cannabis drug" inserted into the Act by the Amendment Act.

Item [8] Section 4 (definition of '*variation application classification document'*)
Consistent with the clarification of the kinds of applications for licence and permit variations and the fees they attract for the Secretary's consideration, this item repeals the redundant definition of "variation application classification document".

Item [9] At the end of Part 1
To complete the pathways by which it ensures that a cannabis drug manufactured under the Act is to be used for appropriate medicinal or scientific purposes, this item, for the purposes of paragraph (e) of the definition of "permitted supply" in subsection 4(1) of the Act, adds section 4B of the Regulations. It prescribes the following circumstances of supplies of a cannabis drug: to a pharmacist in a public hospital for the purposes of that pharmacist dispensing the drug in accordance with the *Therapeutic Goods Act 1989*; for export from Australia in accordance with a licence and permission under the *Customs (Prohibited Exports) Regulations 1958*; to a person who holds a licence under Part 3-3 of the *Therapeutic Goods Act 1989* for use by that person in the manufacture of a medicine (within the meaning of that Act); where the cannabis drug is registered goods within the meaning of the *Therapeutic Goods Act 1989*; and the supply of a cannabis drug to a person who holds a medicinal cannabis licence that authorises the manufacture of a cannabis drug

Item [10] Part 2 (heading)
Reflecting the single licence to authorise any of the activities of cultivation, production or manufacture, this item repeals the existing heading of Part 2, "Licensing the cultivation of cannabis plants and the production of cannabis etc" and replaces it with the more general new heading "Part 2—Medicinal cannabis licences and permits".

Item [11] Paragraph 5(2)(f) (note)
This item, following the clarification of subsection 8E(1) of the Act authorising a person to apply for a medicinal cannabis licence, repeals the note at the foot of paragraph 5(2)(f) of the Regulations.

Item [12] Paragraphs 5(2)(g), to (o)
This item repeals existing paragraphs 5(2)(g), (h), (m) and (o) and replaces them with new paragraphs 5(2)(g), (h), (i), (j), (k) and (l), prescribing what an application for a medicinal cannabis licence must contain (additional to that already prescribed by paragraphs 5(2)(a) to (f) inclusive). The replacements are made, following over 5 years of experience with the regulation of medicinal cannabis under the Act and the Principal Regulations, to clarify the information the Secretary requires to ensure a robust supply pathway and to reduce the risk of diversion, without increasing regulatory burden.

The revised paragraph 5(2)(g) clarifies the details required for inclusion in the medicinal cannabis licence relating to the location where the activities are authorised by the licence will be undertaken to include: the physical address or, if there is no physical address, the location expressed in geographic coordinates, the total area of land at the location and the area of that land that will be used for the activities, details of the premises and facilities at the location where the activities will be undertaken; the zoning of the land at the location; the applicant's legal right to use or occupy the premises at the location.

The revised paragraph 5(2)(h) requires details of the measures that the applicant is to take to ensure the following in relation to cannabis plants or cannabis drugs that are in the applicant's possession or control and that are obtained, cultivated, produced or manufactured under, or purportedly under, the licence: the physical security of the cannabis plants or cannabis drugs; the safety and security of the supply, delivery and transportation of the cannabis plants or cannabis drugs; and the establishment of arrangements between the applicant and emergency services (including a police service or relevant local government authority) to deal with loss, theft, spoilage, disposal and destruction of the cannabis plants or cannabis drugs.

New paragraph 5(2)(i) requires details of the measures that the applicant is to take to ensure the suitability of persons employed or engaged by the applicant for the purposes of carrying out activities authorised by the licence.

New paragraph 5(2)(j), if the applicant proposes to supply to a recipient cannabis plants cultivated, or cannabis or cannabis resin produced, under, or purportedly under, the licence, requires information of the purpose for which the cannabis plants, cannabis or cannabis resin are to be supplied.

New paragraph 5(2)(k), if the applicant is seeking a decision of the Secretary under paragraph 54A(1)(c) that the activities that the applicant proposes to undertake under the licence will be undertaken for, or primarily for, medical or scientific research that is for a non-commercial purpose, require details of: the primary purpose of the activities and research; who will benefit from the activities and research; how any products that may be developed as a result of the activities and research will be used; the source of the funds for the activities and research; and who owns and operates the facilities at which the activities and research are to be undertaken.

New paragraph 5(2)(l) requires the name of each person who is authorised by the licence to engage in the activities authorised by the licence.

Items [13 and 14] Paragraphs 5(3)(d) and 5(4)(f)
For consistency with the Act obligation that the Secretary refuse to grant a medicinal cannabis licence if the applicant is not a fit and proper person, these items replace the requirement for an individual's and a body corporate's application to, in the case of the individual, include details of connected persons that may affect the applicants "reputation, character, honesty or professional or personal integrity", with "whether the applicant is a fit and proper person to hold a licence". In the case of the body corporate the phrase "the reputation, character, honesty or professional or personal integrity of such directors and officers" is replaced with "whether the applicant is a fit and proper person to hold a licence".

Item [15] After subsection 5(4) (before the note)
Reflecting the single licence to authorise any of the activities of cultivation, production or manufacture of medicinal cannabis, and what the Act and the Regulations prescribe as lawful permitted supply, this item inserts a new subsection 5(5) which requires an applicant for the proposed manufacture of a cannabis drug to include in the application: if the drug is to be supplied for use in a clinical trial that is, or is likely to be, approved under the *Therapeutic Goods Act 1989* or notified to the Secretary under that Act—information about the clinical trial in which the drug is to be used; if the drug is to be supplied in accordance with an approval or authority under that Act—information about that approval or authority; if the drug is to be supplied to a person who holds a licence under Part 3-3 of that Act for use by that person in the manufacture of a medicine (within the meaning of that Act)—information about the licence and the holder of the licence; if the drug is registered goods within the meaning of that Act—the number assigned to the registered goods on the Australian Register of Therapeutic Goods maintained under section 9A of that Act; if the drug is to be supplied to a pharmacist in a public hospital for the purposes of the pharmacist dispensing the drug in accordance with that Act—information about the hospital; if the drug is to be supplied for use in medical or scientific research where that research is not a clinical trial referred to in paragraph (a) and does not involve the drug being administered to humans—information about the research including the name of the entity undertaking the research; if the drug is to be supplied for use as a reference standard for medical or scientific testing purposes—information about the proposed use of the reference standard; and if the drug is to be supplied for export from Australia in accordance with a licence and permission under the *Customs (Prohibited Exports) Regulations 1958*—information about the licence and permission; and if the drug is to be supplied to a person who holds a medicinal cannabis licence that authorises the manufacture of a cannabis drug—information about the licence and the holder of the licence.

Item [16] After paragraph 6(2)(a)
This item inserts a new requirement for documents to accompany an application for a medicinal cannabis licence: a current and historical company extract search of the records of the Australian Securities and Investments Commission in relation to the applicant that is carried out no more than 30 days before the application is made.

Item [17] Paragraphs 6(2)(c) to (f)
This item, consistent with the clarity in paragraph 5(2)(g) of what information is required to be included with an application, replaces paragraphs 6(2)(c) to (f) to provide greater clarity in relation to some of the documents required to accompany the application for a medicinal cannabis licence, particularly insofar as the documents are described by reference to the proposed location, the facility and the premises at which the activities are carried out.

The required documents are: a site plan for the location where the activities to be authorised by the licence will be undertaken showing how the land at the location will be used; a

detailed floor plan of the facilities at the location where the activities to be authorised by the licence will be undertaken; a copy of the standard operating procedures and policies that deal with the matters in relation to the location where the activities to be authorised by the licence will be undertaken: the measures to be used to prevent unauthorised access (physical and electronic); the equipment to be used to prevent, monitor, detect and record unauthorised access and the measures to be used for physical security at the location; and such documents as are necessary to establish the applicant's legal right to use or occupy the premises where the activities to be authorised by the licence will be undertaken.

Items [18, 22, 26, 32, 34, 43, 45, 46, 57, 61, 63, 65, 68, 70, 71, 78, 81, 83, 84, 90, 94, 132, 134] section 7A, subsection 8(3), subsection 8(4), Division 3 of Part 2 (heading), section 18 (heading), paragraph 19(7)(a), section 20 (heading), subsection 20(1), Division 4 of Part 2 (heading), section 22, section 23, section 24, section 25, subsections 26(1) and (2), paragraph 26(3)(a), subsections 28(1), (3) and (5), subsection 30(1), subsection 31(1), subsection 31(2), section 33, subsection 34(1), subparagraph 34(2)(e)(i), paragraph 52(a), paragraph 52(d)
Consistent with the key reform to be made by the Amendment Act, these items have the effect that the reference to "a licence" in each of the provisions is replaced with a reference to "a medicinal cannabis licence" in those provisions.

Item [19] Section 7B
This item replaces existing section 7B, prescribing, for the purposes of new paragraph 8M(e) of the Act, the persons the medicinal cannabis licence is required to specify who are authorised to engage in the activities authorised by the licence: the licence holder; the person who holds a managerial or supervisory position that has direct control over the activities authorised by the licence; and the person responsible for controlling on a daily basis the activities authorised by the licence. The phrase "controlling on a daily basis", in accordance with the ordinary meaning of 'daily', captures persons who are responsible for controlling activities on a day of a week, whether the responsibility is for a full or part day.

Item [20] Paragraph 8(2)(c)
Reflecting that the single licence authorises any of the activities of cultivation, production or manufacture, this item, for the purposes of specifying the information required to be included in the application for a permit, repeals ", in relation to cultivation or production, or cultivation and production,".

Item [21] At the end of subsection 8(2)
This item, by the insertion of new paragraphs 8(2)(d) and (e), supplements the existing obligations for information to be contained with the application to include: the period for which the permit is to be in force; and details of how access is provided to the premises at which activities authorised by the licence are to be undertaken for the purposes of the Secretary, or a person authorised by the Secretary, inspecting such premises.

Item [23] After paragraph 8(3)(b)
This item, by the insertion of paragraph 8(3)(c), supplements the existing obligation for information to be contained with the application for a medicinal cannabis permit that relates to a licence that authorises the cultivation of cannabis plants, to include the total area, and geographic coordinates, of the land to be used to cultivate the proposed plants.

Item [24] Paragraph 8(3)(g)
Consistent with the reduction in regulatory burden by the next item, which repeals the existing paragraph 8(3)(h), this item replaces the reference to 'propagation;' with 'propagation.', signalling the end of the information required to be included with an

application for a medicinal cannabis permit relating to a licence that authorises the cultivation of cannabis plants.

Item [25] Paragraph 8(3)(h)
As anticipated in the text for the previous item, this item reduces regulatory burden on applicants for a medicinal cannabis permit relating to a licence that authorises the cultivation of cannabis plants by repealing the existing information requirement prescribed by the paragraph.

Item [27] Paragraph 8(4)(b)
This item omits ", including for the lawful supply of cannabis or cannabis resin" as its reference would be redundant.

Item [28] At the end of section 8
Reflecting the single licence which authorises the activities of any of cultivation, production or manufacture, new subsection 8(5) prescribes the information which must be contained in the application for a medicinal cannabis permit that relates to a medicinal cannabis licence that authorises the manufacture of a cannabis drug. It includes information on: the cannabis drug proposed to be manufactured; the proposed use of the manufactured cannabis drug; the maximum quantity of the cannabis drug that is proposed to be manufactured; the maximum quantity of the cannabis drug that, in the opinion of the applicant, having regard to prevailing market conditions, it will be necessary for the applicant to have in the applicant's possession or control at any time for the normal conduct of business; the period during which the cannabis drug is to be manufactured; and the starting materials to be used in the manufacture of the cannabis drug, the source of the starting materials and the amounts of the starting materials required to manufacture the cannabis drug.

Item [29] Section 9
This item repeals existing section 9 prescribing, for the purposes of paragraph 8P(2)(c) of the Act, the documents which must accompany an application for a medicinal cannabis permit and replaces it with new section 9.

Reflecting the new arrangements for information included at the more practically relevant permit stage when the documents will be available (in lieu of at the stage of licence application), the new section, without increasing existing regulatory burden, prescribes with greater clarity than existing obligations, the following documents that must accompany an application for a medicinal cannabis permit: if the application is for the first permit relating to the location where the activities authorised by the licence will be undertaken—a copy of the risk management plan that is used to manage risks associated with the activities authorised by the licence, including risks posed to the health and safety of people and risks posed to the environment; if the application is for the first permit relating to the location where the activities authorised by the licence will be undertaken—a copy of the standard operating procedures and policies that deal with the following matters in relation to that location: how persons entering the location will be controlled; how unauthorised access at the location will be prevented, monitored, detected and recorded; the physical security being used to prevent, monitor and detect the loss of cannabis plants, cannabis drugs and starting materials relating to such drugs; the loss and theft of cannabis plants, cannabis drugs and starting materials relating to such drugs; the disposal and destruction of cannabis plants, cannabis drugs and starting materials relating to such drugs; the supply, delivery and transportation of cannabis plants, cannabis drugs and starting materials relating to such drugs; the arrangements with emergency services (including a police service or relevant local government authority) to deal with loss, theft, spoilage, disposal and destruction of cannabis plants, cannabis drugs and

starting materials relating to such drugs; the retention of records; the engagement and retention of suitable staff; as well as if the application is for a permit that relates to a medical cannabis licence that authorises the cultivation of cannabis plants or the production of cannabis or cannabis resin but does not authorise the manufacture of a cannabis drug—copies of all contracts that are in place between the applicant for the permit and a person who is authorised by a medicinal cannabis licence to do any of the following: supply cannabis plants; produce cannabis or cannabis resin; and manufacture a cannabis drug. The purpose of this latter requirement is, under new paragraphs 9(4)(c) and (d) of the Act, to support decisions of the Secretary for permits relating to medicinal cannabis licences. Specifically, the requirement allows the Secretary to determine whether he or she is satisfied on reasonable grounds that (for a licence authorising cultivation of cannabis plants but not production of cannabis or cannabis resin) the cultivation of cannabis plants or (for a licence authorising the production of cannabis or cannabis resin but not the manufacture of a cannabis drug) the production of cannabis or cannabis resin is for the supply specified by those paragraphs.

Item [30] At the end of Division 1 of Part 2

This item inserts new section 11, application for medicinal cannabis permit—particular grounds for refusal of permit, for the purposes of subparagraph 9(4)(d)(ii) of the Act, which is inserted into the Act by the Amendment Act. The purpose is to prescribe the additional and exclusive purpose of supply of cannabis or cannabis resin authorised for production under a medicinal cannabis licence which does not also authorise the manufacture of a cannabis drug.

Accordingly, the purpose is the supply of the cannabis or cannabis resin to a person where one or more of the following apply: the person holds a licence under Part 3-3 of the *Therapeutic Goods Act 1989* for use by that person of cannabis or cannabis resin in the manufacture of a medicine (within the meaning of that Act); the person is a pharmacist in a public hospital and the supply is for the purposes of that person dispensing the cannabis or cannabis resin in accordance with that Act; the person holds an approval under subsection 19(1) of that Act to supply cannabis or cannabis resin for use solely for experimental purposes in humans; the person is authorised under State or Territory legislation to obtain, possess and hold cannabis or cannabis resin for testing or research; and the person holds a licence under the *Customs (Prohibited Exports Regulations 1958* to export cannabis or cannabis resin.

Item [31] Division 2 of Part 2

Reflecting the single licence which authorises the activities of any of cultivation, production or manufacture, including for activities related to research, this item repeals existing Division 2 of Part 2 (which presently provides for the regulation of cannabis research licences and permits).

Item [33] Before section 18

This item inserts seven new sections prescribing conditions for the purposes of paragraph 10C(b) of the Act, to which medicinal cannabis licences are subject. The inclusion in the Regulations of these conditions implements recommendation 13 of the McMillan Review that the Department review the conditions to ensure they are not imposed unnecessarily and that conditions are framed appropriately and aid clarity. Further, because they are consistent with conditions specified in a medicinal cannabis licence held before commencement of the Regulations there would be no increase in regulatory burden.

First, new section 17 prescribes that it is a condition of a medicinal cannabis licence that the licence holder must only use seeds, cultivars or other genetic material of cannabis plant obtained in a way that is permitted by the laws of Australia.

The second new condition prescribed by new section 17A, prescribes that it is a condition of a medicinal cannabis licence that, if the licence holder receives a request, in writing, from the Secretary for information relating to the activities authorised by the licence, the licence holder must provide the requested information within the period specified in the request (which must not be less than 14 days). A request may be a 'standing' request, that is, it is made once requiring that the report is made annually on a specified date; the request does not have an expiry date. The request may be for information that exists or an estimate or forecast of information for a specified period.

Section 17B, also inserted by this item, prescribes the third condition of a medicinal cannabis licence, that the holder must keep records that relate to the activities authorised by the licence for the period beginning when the record came into existence and ending 5 years after that time. Examples of such records include records documenting supply transactions such as contracts, invoices, receipts and bank records; if the cannabis drug has been tested for its content of THC, for example, records of test results; and records of crop failure or destruction. The purpose of the requirement is that records are retained sufficient for the purposes of supporting, with evidence, a response to a request for information made under the condition imposed by section 17A.

The item also inserts new section 17C, which prescribes under paragraph (a) that it is a condition of a medicinal cannabis licence that the licence holder must ensure that the following information is provided to the fire service and police service that have responsibility for the area in which the activity authorised by the licence is undertaken: the address of the premises at which the activity authorised by the licence is undertaken; the name, position and contact details of a contact person from whom information may be obtained; and a general description of the activity authorised by the licence. Paragraph(b) prescribes that the information provided under paragraph (a) is kept up-to-date. This anticipates the need for emergency services to be aware of the activities being carried out at the premises in the event of an emergency, such as a flood or bushfire, and what action might therefore be required.

The item also inserts section 17D which prescribes the fifth condition of a medicinal cannabis licence, that the licence holder must ensure that the following information is provided to the Secretary, in writing, before commencing an activity authorised by the licence for the first time: the name, position, phone number and email address of a contact person from whom information about the activity may be obtained; if the licence holder is a body corporate—the name, position with the licence holder, phone number and email address of an officer or employee of the licence holder that has authority to act, or receive notices, for the licence holder; and any changes to that information provided within 72 hours of that change occurring.

The item also inserts new section 17E, the sixth condition, which prescribes that it is a condition of a medicinal cannabis licence that the licence holder must when undertaking activities authorised by the licence, operate in accordance with: the risk management plan that relates to the management of risks associated with the activities authorised by the licence; and the standard operating procedures and policies that relate to the activities authorised by the licence.

Finally, the item also inserts new section 17F, which prescribes that it is a condition of a medicinal cannabis licence that the licence holder must maintain at all times a system of security that prevents illegal or unauthorised removal of cannabis plants or cannabis drugs from the location where the activities authorised by the licence are undertaken.

Item [35] Paragraphs 18(1)(a)
This item repeals paragraph 18(1)(a) with the effect of removing the existing condition for a medicinal cannabis licence, having the effect of excluding a person undertaking treatment for drug addiction from being engaged by a licence holder. Similarly to the repeal of paragraph 39(1)(a) for a manufacturing licence, this is consistent with recommendation 14 of the McMillan Review that the existing restriction is more restrictive than the Act, which provides that a licence holder shall take reasonable steps not to employ a person convicted of a serious offence in the previous five years (see paragraph 10F(1)(b) of the Act). The McMillan Review also considered that it was relevant that the Secretary, in deciding whether a person is fit and proper to hold a licence under the Act, can decide to excuse the fact that the person has been convicted of a serious offence during the previous ten years. An additional difficulty noted in the McMillan Review was that the 'undertaking treatment' restriction could act as a disincentive to seeking treatment.

Items [37, 38, 41 and 44] Subsection 19(2)), subsection 19(6) and subsection 19(9)
Consequential to the addition of paragraph 10J(2)(c) to the Act by the Amendment Act, this item makes a technical amendment to replace the reference to subsection 10J(2) with paragraph 10J(2)(c).

Item [39] Subsection 19(3)
This item makes a technical amendment to subsection 19(3) to clarify that the reference to subsection (4) is a reference to subsection (4) of this section. This is consistent with references to other subsections in section 19.

Item [40] Subsection 19(6)
This item makes a technical amendment to subsection 19(6) to clarify that the reference to subsection (7) is a reference to subsection (7) of this section. This is consistent with references to other subsections in section 19.

Items [42 and 43] Subparagraph 19(7)(a)(ii) and paragraph 19(7)(a)
Reflecting the single licence which authorises the activities of any of cultivation, production or manufacture, these items simplify and clarify that the circumstance in which a contract prescribed by paragraph 10J(2)(c) is not required to be in existence is where the contract between the first licence holder (defined in subparagraph 19(7)(a)(i)), and the holder of another medicinal cannabis licence that authorises the manufacture of a cannabis drug has ceased and the first licence holder is taking steps to arrange a new contract with another holder of a medicinal cannabis licence that authorises such manufacture.

Items [47, 48, 49, 50, 51 and 72] Paragraphs 20(1)(b) to (d), paragraph 20(1)(e), paragraph 20(1)(f), paragraph 26(3)(b)
Consistent with the new definition of "cannabis drug" which is inserted into the Act by the Amendment Act, and which includes "cannabis" and "cannabis resin", as well as with the new definition of "starting material" which is inserted into the Principal Regulations by the Regulations, each of these items replace the reference to "cannabis or cannabis resin", wherever occurring, with "cannabis drugs or starting materials in relation to such drugs" (items 46, 47, 49 and 71) or "cannabis drugs or starting materials" (item 48).

Item [52] Subparagraph 20(1)(h)(iii)
Consistent with one of the key reforms to be made by the Amendment Act, this item has the effect that the reference to "a permit" is replaced with a reference to "a medicinal cannabis permit".

Item [53] After paragraph 20(1)(h)
This item inserts new paragraph 20(1)(ha) which, in accordance with paragraph 10K(1)(d) of the Act, makes it a condition of a medicinal cannabis licence that the holder notify the Secretary if it commences to manufacture a cannabis drug under the licence.

Item [54] After paragraph 20(1)(i)
Reflecting the single licence which would authorise the activities of any of cultivation, production or manufacture, this item replaces the reference to "cultivation, production or any other activities" with the broader phrase "an activity".

Item [55] Subparagraph 20(1)(n)(ii)
This item replaces existing subparagraph 20(1)(n)(ii) with a new subparagraph: the holder of another medicinal cannabis licence that authorises the manufacture of a cannabis drug.

Item [56] Subsection 20(2)
This item repeals existing subsection 20(2) with new subsection 20(2) (including paragraphs (a), (b) and (c)) prescribing, for the purposes of paragraph 10K(2)(a) of the Act, a period within which the Secretary must be notified by the licence holder: for a matter covered by paragraph (1)(a), (b), (c), (d), (e) or (f) of this section—within 24 hours starting when the matter comes to the attention of the licence holder; for a matter covered by paragraph (1)(g) of this section—within 20 business days starting on the day the licence holder is notified of the finding or recommendation; and for a matter covered by paragraph (1)(l) of this section—within 20 business days starting on the day the licence holder is notified of the inquiry or investigation.

Items [58, 60, 62, 64, 66, 67, 69, 77, 80, 88, 89, 91] Subdivision A of Division 4 of Part 2 (heading), section 22 (heading), section 23 (heading), section 24 (heading), Subdivision B of Division 4 of Part 2 (heading), section 25 (heading), section 26 (heading), section 28 (heading), section 30 (heading), section 31 (heading), subdivision C of Division 4 of Part 2 (heading), section 33 (heading), section 34 (heading)
Consistent with the key reform made by the Amendment Act these items have the effect that the reference to the plural "cannabis licence and permits" or the singular "cannabis licence and permit" in each of the provisions is replaced with a reference to "medicinal cannabis licences and medicinal cannabis permits" in those provisions or the singular as the case may be.

Item [59] Section 21
This item replaces existing section 21, made for the purposes of paragraph 10M(3)(b) of the Act, prescribing circumstances in which the Secretary is prohibited from varying a licence or permit, with new section 21.

Subsection 21(2) provides that the Secretary is prohibited from making a variation of a medicinal cannabis licence on application by the licence holder if, had the proposed variation been included as part of the application for the licence, the Secretary would have been required to refuse to grant the licence under section 8G or 8J of the Act. Sections 8G and 8J specify the general and particular circumstances in which the Secretary is required to refuse an application for a licence. For example, paragraph 8G(1)(d) prohibits the grant of an application for a licence if the Secretary is not satisfied on reasonable grounds that the applicant will take all reasonable measures to (broadly) ensure the physical security of cannabis plants or cannabis drugs. Accordingly, the Secretary is required to refuse the variation application if it would mean that he or she is not satisfied on reasonable grounds

that the applicant will take all reasonable measures to (broadly) ensure the physical security of cannabis plants or cannabis drugs.

Subsection 21(3) prohibits the Secretary from making a variation of a medicinal cannabis permit on application by the licence holder if, had the proposed variation been included as part of the application for the permit, the Secretary would have been required to refuse to grant the permit under subsection 9(4) of the Act. For example, paragraph 9(4)(aa) obliges the Secretary to refuse to grant a permit if he or she is not satisfied on reasonable grounds that applicable standards have been or will be met. Accordingly, the Secretary is obliged to refuse the variation application if he or she is not satisfied on reasonable grounds that applicable standards have been or will be met.

Item [73] Subsection 26(4)
This item repeals redundant subsection 26(4) (providing for the effect of suspension of a medicinal cannabis licence on a related permit) because section 29 deals exclusively with the effect of a licence suspension.

Item [74] Paragraph 26(5)(b)
This item replaces existing paragraph 26(5)(b), so as to include provision for cessation of the permit, in addition to the existing provision for cessation of the licence during the period of the suspension; it provides that if the licence or permit ceases to be in force during the period of the suspension, the suspension ends on the earlier of the day the licence or permit ceases to be in force.

Item [75] Subsection 26(6)
This item makes a technical amendment to insert “the” after “period of” so that the reference would be to “the suspension”.

Item [76] Section 27
This item repeals current section 27 and substitutes new section 27, including a new heading, Secretary may permit specified activities to occur during suspension of medicinal cannabis licences, if, as subsection (1) prescribes, a medicinal cannabis licence is suspended by the Secretary under subsection 26(1). Specifically, the item provides that the Secretary may, in the notice given under subsection 26(1) relating to the suspension, permit the licence holder during the period of the suspension to do any of the following: if the suspended licence authorised the cultivation of cannabis plants—engage in specified cultivation of cannabis plants in accordance with conditions specified in the notice; if the suspended licence authorised the production of cannabis or cannabis resin—engage in specified production of cannabis or cannabis resin in accordance with conditions specified in the notice; if the suspended licence authorised the manufacture of a cannabis drug—engage in specified manufacture of a cannabis drug in accordance with conditions specified in the notice; and if the suspended licence authorised activities relating to the cultivation of cannabis plants, the production of cannabis or cannabis resin or the manufacture of a cannabis drug—engage in specified activities relating to such cultivation, production or manufacture in accordance with conditions specified in the notice.

The item also inserts new section 27A, providing for the Secretary to permit specified activities to occur during suspension of medicinal cannabis permits. The item provides that section 27A applies if a medicinal cannabis permit is suspended by the Secretary under subsection 26(1) and the permit relates to a medicinal cannabis licence that has not been suspended under that subsection. Specifically, the Secretary may, in the notice given under subsection 26(1) relating to the suspension, permit the licence holder during the period of the suspension to do any of the following: if the suspended permit relates to a licence that

authorises the cultivation of cannabis plants—engage in specified cultivation of cannabis plants authorised by the licence in accordance with the permit in accordance with conditions specified in the notice; if the suspended permit relates to a licence that authorises the production of cannabis or cannabis resin—engage in specified production of cannabis or cannabis resin authorised by the licence in accordance with the permit in accordance with conditions specified in the notice; and if the suspended permit relates to a licence that authorises the manufacture of a cannabis drug—engage in specified manufacture of a cannabis drug authorised by the licence in accordance with the permit in accordance with conditions specified in the notice.

Item [79] Section 29

This item repeals existing section 29 and substitutes a new section to clarify the effect of suspension of medicinal cannabis licences. Specifically, new subsection 29(1) provides that if a medicinal cannabis licence is suspended under subsection 26(1): activities authorised by the licence must not be carried out during the period of the suspension; any medicinal cannabis permit that relates to the licence is suspended while the licence is suspended; and the licence, and any permit that relates to the licence, remains in force while the licence is suspended. Nevertheless, subsection 29(2) provides that, despite subsection (1), the licence holder may, during the period of the suspension, if the Secretary specified activities in the notice given to the licence holder under subsection 26(1) in relation to the suspended licence—engage in the specified activities subject to any conditions specified in the notice.

Irrespective of the terms of the Secretary's notice under subsection 26(1) and the suspension of the medicinal cannabis licence, the balance of subsection 29(2) separately authorises the licence holder to carry out specified activities. The purpose of the remainder of the item is to ensure that the minimum of activities would be authorised to prevent crop failure and to allow storage, possession and control of produced or manufactured cannabis drug. Specifically, paragraph 29(2)(b) provides, if the suspended licence authorised the cultivation of cannabis plants, the licence holder is authorised to tend, nurture, harvest or store cannabis plants in the licence holder's possession or control as authorised by the licence at the time of the suspension of the licence. Paragraph 29(2)(c) provides, if the suspended licence authorised the production of cannabis or cannabis resin, the licence holder is authorised to store, possess and control cannabis or cannabis resin in the licence holder's possession or control as authorised by the licence at the time of the suspension of the licence. Paragraph 29(2)(d) provides, if the suspended licence authorised the manufacture of a cannabis drug, the licence holder is authorised to store, possess and control: the cannabis drugs in the licence holder's possession or control as authorised by the licence at the time of the suspension; and starting material relating to such drugs in the licence holder's possession or control at the time of the suspension.

Section 29A

New section 29A is a complement to section 29 and provides for the effect of suspension of medicinal cannabis permits. Its purpose is the equivalent for permits as section 29 is for licences. Subsection 29A(1) provides that if a medicinal cannabis permit is suspended under subsection 26(1) and the permit relates to a medicinal cannabis licence that is not suspended under that subsection: activities authorised by the licence to be undertaken in accordance with the permit must not be carried out during the period that the permit is suspended; and the permit remains in force while it is suspended.

Subsection 29A(2) provides, that despite subsection (1), the licence holder may, during the period of the suspension: if the Secretary specified activities in the notice given to the licence holder under subsection 26(1) in relation to the suspended permit—engage in the specified

activities subject to any conditions specified in the notice; and if the suspended permit relates to a licence that authorises the cultivation of cannabis plants—tend, nurture, harvest or store cannabis plants in the licence holder's possession or control as authorised by the licence at the time of the suspension of the permit; and if the suspended permit relates to a licence that authorises the production of cannabis or cannabis resin—store, possess and control cannabis or cannabis resin in the licence holder's possession or control as authorised by the licence at the time of the suspension of the permit; and if the suspended permit relates to a licence that authorises the manufacture of a cannabis drug—store, possess and control: the cannabis drugs in the licence holder's possession or control as authorised by the licence at the time of suspension of the permit; and starting material relating to such drugs in the licence holder's possession or control at the time of the suspension.

Item [85] Section 32 (heading)
Reflecting the Amendment Act single licence (in accordance with a medicinal cannabis permit), which authorises the activities of any of cultivation, production or manufacture, this item replaces the present limited reference in the heading to section 32 dealing with the commission of an offence and civil penalty contravention for breach of a condition of a licence, from "production during suspension" with "activity during suspension of licence or permit".

Item [86] Subsection 32(1)
This item repeals current subsection 32(1) and, by substituting new subsection 32(1), clarifies that a person exposes themselves to commission of a criminal offence or civil penalty contravention if the person is the holder of a medicinal cannabis licence; and the licence, or a medicinal cannabis permit that relates to the licence, is suspended under subsection 26(1); and the Secretary permitted specified activities to occur during the period of the suspension in accordance with conditions specified in the notice given under subsection 26(1); and the person fails to comply with a condition.

Item [87] Subsections 32(2) and (3) (note)
This item repeals the note at the foot of each of subsections 32(2) and (3) to reflect current drafting practice that such notes are generally no longer used.

Item [93] Paragraph 34(2)(e)
Consistent with the new definition of "cannabis drug" inserted into the Act by the Amendment Act, and which includes "cannabis" and "cannabis resin", this item replaces the reference to "plants, cannabis or cannabis resin", with "plants or cannabis drug".

Item [95] Paragraph 34(2)(f)
Reflecting the Amendment Act single licence (in accordance with a medicinal cannabis permit) which authorises the activities of any of cultivation, production or manufacture, this item expands the activities to which notice of surrender must make reference to now include manufacture (additional to cultivation and production).

Item [96] Part 3 (heading)
Reflecting the regulation of manufacture of cannabis drugs separately to manufacture of narcotic drug and consequential to the Amendment Act, repeal of the definition of medicinal cannabis product and insertion of the definition of narcotic drug in the Act, this item clarifies that Part 3 deals with licensing manufacturing of narcotic drugs, that is drugs other than cannabis drugs.

Item [97] Paragraph 35(2)(fa)
Consequential to the repeal of the redundant section 54AB, prescribing classes of cannabis-related manufacture licences, this item repeals paragraph 35(2)(fa) prescribing information requirements for an application for the redundant decision of the Secretary under subsection 54AB(3).

Items [98, 99, 100, 106, 107, 108, 109, 110, 119] Paragraph 35(2)(g), paragraph 35(2)(h), subparagraph 35(2)(i)(i), paragraphs 38(2)(c), (e), (f), (g) and (h), and paragraph 40(1)(i) 6
Reflecting the regulation of manufacture of cannabis drugs separately to the manufacture of narcotic drugs and consequential to the Amendment Act, repeal of the definition of medicinal cannabis product and insertion of the definition of narcotic drug in the Act (a drug other than a narcotic drug) these items have the effect of replacing the existing references to "drugs"' with "narcotic drug".

Items [101, 138 and 140] Subparagraph 35(2)(i)(vi), subsection 54(1) section 55
Consistent with the clarification in Part 2, regulating cultivation, production or manufacture of medicinal cannabis, of the distinction between the location, the facility and the premises (and removal of reference to land), at which the activities authorised by the licence will be undertaken, this item would remove references to "land" (wherever occurring).

Items [102, 113, 114, 115, 116, 117, 124 and 131] Paragraph 35(2)(j), paragraphs 40(1)(b), (c) and (d), paragraph 40(1)(e), paragraph 40(1)(f), paragraph 45(3)(b) and paragraph 51(2)(e)
Reflecting the regulation of the manufacture of cannabis drugs separately to the manufacture of narcotic drug and consequential to the Amendment Act repeal of the definition of medicinal cannabis product and insertion of the definition of narcotic drug in the Act these items have the effect of omitting "drugs or starting material", and substitute "narcotic drug or starting material in relation to such a drug" (including, as necessary, wherever occurring).

Item [103] Subsection 35(8) (not including the note)
Reflecting the regulation of manufacture of cannabis drugs under Part 2 of the Principal Regulations, separately to manufacture of narcotic drug under Part 3 of the Principal Regulations, this item repeals existing subsection 35(8) (not including the note) (specifying information requirements for an application to manufacture a medicinal cannabis product).

Item [104] Section 36AA
Reflecting the regulation of the manufacture of cannabis drugs under Part 2 of the Principal Regulations, separately to the manufacture of narcotic drug under Part 3 of the Principal Regulations, this item repeals existing section 36AA prescribing an application fee for the redundant "cannabis-related manufacture licence".

Item [105] Section 37
Reflecting the regulation of manufacture of cannabis drugs under Part 2 of the Principal Regulations, separately to manufacture of narcotic drug under Part 3 of the Principal Regulations, this item repeals existing section 37 and substitutes new section 37 which provides, for the purposes of paragraph 11N(e) of the Act, the following persons are prescribed as the persons who are authorised by a manufacture licence for narcotic drugs other than cannabis drugs to engage in the activities authorised by the licence: the licence holder; the person who holds a managerial or supervisory position that has direct control over the activities authorised by the licence; and the person responsible for controlling on a daily basis the activities authorised by the licence. This is the equivalent for a manufacture licence under Part 3, as revised section 7B provides for a medicinal cannabis licence under Part 2.

The phrase "controlling on a daily basis", in accordance with the ordinary meaning of 'daily', captures persons who are responsible for controlling activities on a day of a week, whether the responsibility is for a full or part day.

Item [111] Section 38A
Reflecting the regulation of the manufacture of cannabis drugs under Part 2 of the Principal Regulations, separately to the manufacture of narcotic drug under Part 3 of the Principal Regulations, this item repeals existing section 38A prescribing an application fee for the redundant "cannabis-related manufacture permit".

Item [113] Paragraphs 39(1)(a)
This item repeals paragraph 39(1)(a) which means that persons who are undertaking or who have undertaken treatment for drug addiction are no longer included in the class of persons the manufacture licence holder must, by way of statutory condition, take all reasonable steps not to employ or engage.

Similarly to the repeal of paragraph 18(1)(a) (for a medicinal cannabis licence), this is consistent with recommendation 14 of the McMillan Review that the existing restriction is more restrictive than the Act which provides that a licence holder shall take reasonable steps not to employ a person convicted of a serious offence in the previous five years (see paragraph 12H(1)(d) of the Act). The McMillan Review also considered that it was relevant that the Secretary, in deciding whether a person is fit and proper to hold a licence under the Act, can decide to excuse the fact that the person has been convicted of a serious offence during the previous ten years. An additional difficulty noted by the McMillan Review was that the "undertaking treatment" restriction could act as a disincentive to seeking treatment.

Item [118] Subparagraph 40(1)(h)(iii)
This item clarifies, for the purposes paragraph 12N(1)(d) of the Act prescribing conditions attached to a manufacture licence, that the obligation to notify the Secretary of a change made or proposed to be made in relation to premises, security arrangements, conduct of activities, record-keeping etc, in response to a variation of a permit is a variation of a "manufacture" permit.

Item [120] Paragraph 40(1)(j)
This item repeals existing paragraph 40(1)(j) and substitutes new paragraph 40(1)(j), for the purposes of paragraph 12N(1)(d) of the Act prescribing conditions attached to a manufacture licence, that the licence holder must, in addition to the present obligation to notify the Secretary if it ceases to undertake the manufacture of a narcotic drug or any other activities authorised by the licence, notify the Secretary if it proposes to cease undertaking such activities.

Item [121] Section 41
This item repeals existing section 41 and substitutes new section 41 providing, for the purposes of paragraph 13(3)(b) of the Act, the circumstances in which a manufacture licence (subsection 41(2)) or manufacture permit (subsection 41(3)) must not be varied. In effect, this replicates in Part 3, new section 21 in Part 2. Subsection (2) provides that a manufacture licence must not be varied on application by the licence holder if, had the proposed variation been included as part of the application for the licence, the Secretary would have been required to refuse to grant the licence under section 11J of the Act. For example, subparagraph 11J(1)(d)(ii) of the Act (would after the Amendment Act would commence) oblige the Secretary to refuse to grant a manufacture licence if not satisfied on reasonable grounds that the applicant will take all reasonable measures to ensure the physical security of narcotic drug or narcotic preparations that contain such a drug in the licence holder's

possession or control and manufactured under or purportedly under the licence. Accordingly, if the Secretary is not satisfied on reasonable grounds that the applicant for the variation takes all reasonable measures to ensure the physical security of narcotic drugs or narcotic preparations that contain such a drug in the licence holder's possession or control and manufactured under or purportedly under the licence, the Secretary must refuse the application.

Subsection (3) provides that a manufacture permit that relates to a manufacture licence must not be varied on application by the licence holder if, had the proposed variation been included as part of the application for the permit, the Secretary would have been required to refuse to grant the permit under subsection 12A(4) of the Act. For example, paragraph 12A(4)(a) of the Act obliges the Secretary to refuse to grant a manufacture permit if the application fee has not been paid. The Secretary is required to refuse a variation application if an application fee for the variation is not paid.

Item [122] Section 43A
Reflecting the regulation of the manufacture of cannabis drugs under Part 2 of the Principal Regulations, separately to the manufacture of narcotic drug under Part 3 of the Principal Regulations, this item repeals existing section 43A prescribing an application fee for variation of the redundant "cannabis-related manufacture licence or permit".

Item [123] Section 44
This item clarifies the operation of section 44; that for the purposes of section 13D of that Act, that Subdivision B of Division 3 of Part of the Principal Regulations makes provision for and in relation to the suspension of manufacture licences or manufacture permits by inserting "manufacture" before "permits".

Item [125] Subsection 45(4)
This item repeals redundant subsection 45(4), providing for the effect of suspension of a manufacture licence on a related permit because section 47 deals exclusively with the effect of a licence suspension.

Item [126] Paragraph 45(5)(b)
This item replaces existing paragraph 45(5)(b), so as to include provision for cessation of the permit as well as a licence during the period of the suspension; it provides that if the licence or permit ceases to be in force during the period of the suspension, the suspension ends on the earlier of the day the licence or permit ceases to be in force.

Item [127] Subsection 45(6)
This item makes a minor technical amendment to insert "the" after "period of" so that the reference would be to "the suspension".

Item [128] Subsection 46(6)
This item makes a minor technical amendment to insert "manufacture" before "licence holder".

Item [129] Section 47
This item repeals existing section 47 and substitutes new section 47 which prohibits activities authorised by the licence being carried out during the period of the suspension; suspend any manufacture permit that relates to the licence while the licence is suspended; and clarify that the licence, and any permit that relates to the licence, remains in force while the licence is suspended.

Subsection 47(2) provides that despite subsection (1), the licence holder is authorised during the period of the suspension to store, possess and control any narcotic drugs in the licence holder's possession or control as authorised by the licence at the time of the suspension. The purpose is to ensure that the minimum of activities is authorised to allow storage, possession and control of produced or manufactured narcotic drugs.

Section 47A
This item also inserts new section 47A, which is a complement to section 47, and provides for the effect of suspension of manufacture permits. Its purpose is the equivalent for permits as section 47 would be for licences. It provides that if a manufacture permit is suspended under subsection 45(1) and the permit relates to a manufacture licence that is not suspended under that subsection: the activities authorised by the licence to be undertaken in accordance with the permit must not be carried out during the period that the permit is suspended; and the permit remains in force while it is suspended.

Subsection 47A(2) provides that, despite subsection (1), the licence holder is authorised during the period of the suspension to store, possess and control any narcotic drugs in the licence holder's possession or control as authorised by the permit at the time of the suspension.

Item [130] Section 49(1)
This item corrects a minor typographical error by replacing the second occurring "b" with "c".

Item [131] Paragraph 51(2)(e)
Because the new definition of narcotic drug inserted into the Act by the Amendment Act necessarily includes each of drug, narcotic preparations and starting materials, this item would replace that phrase with "a narcotic drug".

Item [133] Paragraphs 52(b) and (c)
This item amends the prescribed list of decisions which are reviewable to replace the existing decisions under paragraphs 52(b) and (c), to refuse, during the period of suspension of a medicinal cannabis licence or permit, to permit production of cannabis and cannabis resin, with new paragraphs 52(b) and (c). Those paragraphs include, as reviewable decisions, the proposed more broadly expressed decision under subsection 27(2) to refuse to permit specified activities during a period of suspension of a medicinal cannabis licence: and a decision under subsection 27A(2) to refuse to permit specified activities during a period of suspension of a medicinal cannabis permit.

Item [135] Paragraph 52(h)
Reflecting the repeal of Division 2 of Part 2 of Chapter 2 of the Act, dealing with cannabis research licences and permits, this item amends the prescribed list of decisions which are reviewable to replace the existing decision under paragraph 52(h), a decision expressed as a refusal of a proposed research application, with a new paragraph 52(h), a decision under paragraph 54A(1)(c) about whether the activities an applicant proposes to undertake under a medicinal cannabis licence will be undertaken for, or primarily for, medicinal or scientific research that is for a non-commercial purpose.

Item [136] Paragraphs 52(i) and (j)
This item repeals existing paragraphs 52(i) and (j) because they include within the list of reviewable decisions, decisions for which the Amendment Act would no longer make provision.

Item [138] Sections 54A, 54AA and 54AB
This item repeals existing sections 54A, 54AA and 54AB, providing for charges for licences, cannabis research licences and cannabis-related manufacture licences, which, following commencement of the Amendment Act and the making of the Regulations, no longer exist.

The item also introduces a new section 54A which specifies classes of medicinal cannabis licence for the purposes of charge: a non-commercial medicinal cannabis licence and a commercial medicinal cannabis licence. In short, the latter is defined by reference to medicinal cannabis licence which is not a non-commercial medicinal cannabis licence. The item clarifies the status of cannabis research licences in existence before the commencement of the Regulations as either one of a non-commercial medicinal cannabis licence or a commercial medicinal cannabis licence.

Paragraph 54A(1)(a) provides that a medicinal cannabis licence is a non-commercial medicinal cannabis licence if the licence was in effect on the commencement of this section because the licence was preserved under item 2 of Schedule 2 to the Amendment Act—the Secretary had, in relation to the licence, given a notice under subsection 54A(2), 54AA(3) or 54AB(3) of this instrument, as in force immediately before the commencement of this section. The Secretary's notification under those previous subsections had the effect that each of the specified cannabis licences was a kind of non-commercial licence, either a non-commercial cannabis research licence or a non-commercial cannabis-related manufacture licence. Accordingly, the effect of subsection 54A(1)(a) is to 'transition' those licences as non-commercial medicinal cannabis licences.

Paragraph 54A(1)(b) complements paragraph 54A(1)(a) by providing for the circumstances in which the licence holder held several licences before commencement of the section which were, on commencement, converted from multiple licences into a single licence under item 3 of Schedule 2 to the Amendment Act. In this case, the medicinal cannabis licence is a non-commercial medicinal cannabis licence if the Secretary had, in relation to one of those licences existing prior to commencement of this section, given a notice under subsection 54A(2), 54AA(3) or 54AB(3) of this instrument, as in force immediately before the commencement of this section.

Paragraph 54A(1)(c) provides that medicinal cannabis licence is a non-commercial medicinal cannabis licence if, when granting the licence the Secretary notifies the applicant for the licence in writing that the Secretary is reasonably satisfied that the activities the applicant proposes to undertake under the licence will be undertaken: for medical or scientific research that is for a non-commercial purpose or primarily for medical or scientific research that is for a non-commercial purpose. For the purposes of making a decision under paragraph 54A(1)(c) about the activities that the applicant proposes to undertake, subsection 54A(2) provides that the Secretary must have regard to the matters mentioned in paragraph 5(2)(j) of the Regulations (that, if the applicant proposes to supply to a recipient cannabis plants cultivated, or cannabis or cannabis resin produced, under, or purportedly under, the licence the application includes information on the purpose for which the cannabis plants, cannabis or cannabis resin are to be supplied). Subsection 54A(3) provides that subsection 54A(2) does not limit the matters to which the Secretary may have regard in making a decision about the activities that the applicant proposes to undertake.

Subsection 54A(4) provides that, for the purposes of paragraph 28(1)(e) of the Act, a medicinal cannabis licence is a commercial medicinal cannabis licence if a notice referred to in paragraph (1)(a), (b) or (c) has not been given in relation to the licence.

Item [140] Subparagraph 55(b)(iii)
Reflecting the inclusion of seven conditions by the Regulations, this item amends subparagraph 55(b)(iii) to insert "or prescribed by these regulations" after "the Act". The effect is that, if in receipt of a notice from that head of a State or Territory agency that the head wishes to be advised of a licence or permit that relates to premises situated wholly or partly in the State or Territory, the Secretary is required to notify the head of the conditions of the licence.

Item [141] Paragraph 56(a)
This item replaces "a State or Territory", with "the Commonwealth, a State or a Territory" with the effect that section 8G(1)(a) of the Act, requiring the Secretary to refuse to grant a medicinal cannabis licence for (broadly) failure of the applicant to be a "fit and proper person", does not apply if the applicant for a medicinal cannabis licence is an agency of any of the three different jurisdictions.

Item [142] Paragraph 56(b)
Reflecting the repeal of Division 2 of Part 2 of Chapter 2 of the Act, dealing with cannabis research licences and permits, this item repeals paragraph 56(b) for being redundant.

Item [143] Paragraphs 56(c) and (d)
This item, for each of paragraphs 56(c) and (d), omits "cannabis licence is an agency of a State or Territory", and substitutes "medicinal cannabis licence is an agency of the Commonwealth, a State or a Territory". For the amendment to paragraph 56(c), the effect is that paragraph 10K(1)(a) of the Act, making it a condition of a medicinal cannabis licence for the licence holder to notify the Secretary of a matter affecting (broadly) the fit and proper person requirement to hold a licence, does not apply if the holder is an agency of any of the three different jurisdictions. Similarly, the equivalent amendment to paragraph 56(d) has the effect that paragraph 10P(1)(b), obliging the Secretary to revoke a medicinal cannabis licence if the holder is no longer a fit and proper person, does not apply to an agency of any of the three different jurisdictions.

Item [144] Paragraphs 56(e) to (g)
This item, for each of paragraphs 56(e) to (g), omit "a State or Territory", and substitute "the Commonwealth, a State or a Territory" with effect that for each of sections 11J(1)(a), 12N(1)(a) and 13B(1)(b), dealing with the general grounds for refusal of an application for a manufacture licence, the statutory condition to notify the Secretary of certain matters and the obligation on the Secretary to revoke the licence related to (broadly) the requirement for the applicant and the holder of the licence to be a fit and proper person does not apply to an agency of any of the three different jurisdictions.

Item [145] At the end of Part 6
This item inserts section 62, being an application provision for the Regulations. Subsection 62(1) applies sections 17, 17A, 17B, 17C, 17D, 17E and 17F, as inserted by Schedule 1 to the Regulations, specifying the conditions which apply to a medicinal cannabis licence, to a licence held at the commencement of this section or granted on or after the commencement of this section. The application of these conditions implements recommendation 13 of the McMillan Review that the Department review the conditions to ensure they are not imposed unnecessarily and that conditions are framed appropriately, aid clarity. Further, because they are consistent with conditions specified in a medicinal cannabis licence held before commencement of the Regulations, there is no increase in regulatory burden for existing licence holders.

Subsection 62(2) applies the amendments of sections 20 and 40, made by Schedule 1 to the Regulations in relation to a matter that comes to the attention of a licence holder on or after the commencement of this section, whether in relation to a licence held at the commencement of this section or granted on or after the commencement of this section. The effect is, by operation of subsection 10K(1) or paragraph 12N(1)(d) of the Act, to require the medicinal cannabis licence holder or the manufacture licence holder, respectively, to make the relevant notifications to the Secretary.

Subsection 62(3) provides for the legal outcome if the Secretary had, before commencement of section 62, under subsection 26(1) or 45(1) of the Principal Regulations, given to the holder of what was then known as a cannabis licence or a manufacture licence, a notice in writing of the suspension of the licence or a permit that relates to the licence and either the suspension had not come into effect or the period of the suspension had started but not ended and the transitional provision in the Amendment Act (item 2 or 3 of Schedule 2 to the Amendment Act) has the effect that the licence or permit is preserved or converted. The effect would be that after commencement of section 62, the preserved or converted licence or permit is taken to be suspended under Subdivision B of Division 4 of Part 2 of this instrument as amended by Schedule 1 to the Regulations. The suspension is able to be dealt with under Subdivision B as amended by Schedule 1 to the Regulations and if the suspension is still to come into effect because the day specified in the notice of suspension has not occurred, the suspension takes effect in accordance with the suspension notice. If the suspension notice permits specified activities to occur during the period of the suspension, the permitted activities are able to occur during the period of the suspension in accordance with the conditions specified in the suspension notice.

Subsection 62(4) continues in effect Part 4 of Chapter 5 of the Act, dealing with review of decisions, in relation to the decisions specified in paragraphs 52(b), (c), (h), (i) or (j) for which the period within which an application for review may be made, as if the amendments to decisions which may be the subject of review had not been made; the review continues to be conducted in accordance with the Act as it was before the commencement of Amendment Act.

Subsection 62(5) continues in effect sections 15L, 15M and 15N of the Act, dealing with review of decisions by the Administrative Appeals Tribunal, in relation to internal review decisions (to which paragraph 62(4)(b) would apply) made under section 15H of the Act before the commencement of this section.

Subsection 62(6) apply the amendments made to section 56 by the Regulations to: in the case of paragraphs 56(a) and (e)—applications made on or after the commencement of this section; and in the case of paragraphs 56(c), (d), (f) and (g)—licences granted on or after the commencement of this section. The effect is to remove the Commonwealth (as well as a State or Territory) from the specified obligations.

Subsection 62(7) applies the application fees specified in clause 1 of Schedule 1 of the Regulations to applications of the kind specified in the table in that Schedule which are made on or after the commencement of section 62(7).

Item [146] Schedule 1

This item repeals Schedule 1 and replaces it with a new Schedule of application fees. The new Schedule does not change the amount of fees as previously specified, but revises the description of the kind of application consequential to the single licence amendments to the Act made by the Amendment Act.

Statement of Compatibility with Human Rights

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

Narcotic Drugs Amendment (Medicinal Cannabis-) Regulations 2021

The *Narcotic Drugs Amendment (Medicinal Cannabis) Regulations 2021* (the Amendment Regulations) are compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Legislative Instrument

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

The purpose of the Amendment Regulations is to finalise implementation of the recommendations of the final report of the McMillan Review by Professor John McMillan AO. It consolidates the medicinal cannabis licensing structure introduced to the Act in 2016 into a single licence framework; enables assessments relating to supply chains to be undertaken at the permit stage rather than the earlier licensing stage; and creates a perpetual licence and periodic permit structure for the majority of activities for which a licence is required. It delivers the Australian Government's commitment to the availability of the safe, legal and sustainable supply of cannabis derived medicines.

Human rights implications

The Amendment Regulations engage, or have the potential to engage, the human right to health in Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESR).

Article 12 of the ICESR

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

The Amendment Regulations engage the human right to health under Article 12 of the ICESR by providing for assessment of the supply chain to occur at the later more relevant permit stage thereby reducing regulatory burden for those engaged or proposing to engage in cultivating, producing or manufacturing medicinal cannabis. The anticipated downstream effect is facilitation of less costly access to good quality medicinal cannabis products by Australian patients.

Conclusion

The Amendment Regulations are compatible with human rights because it promotes the right to health.

Greg Hunt, Minister for Health