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THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA

HOUSE OF REPRESENTATIVES

NARCOTIC DRUGS AMENDMENT (MEDICINAL CANNABIS) BILL 2021

EXPLANATORY MEMORANDUM

(Circulated by authority of the Minister for Health and Aged Care,
the Hon Greg Hunt MP)

NARCOTIC DRUGS AMENDMENT (MEDICINAL CANNABIS) BILL 2021

OUTLINE

The Narcotic Drugs Amendment (Medicinal Cannabis) Bill 2021 (the Bill) makes a number of amendments to the *Narcotic Drugs Act 1967* (the ND Act).

These amendments are part of the second stage of the implementation of recommendations of the Final Report of the McMillan Review by Professor John McMillan AO into the regulation of medicinal cannabis, including in particular to:

a) streamline and consolidate the licensing structure in the ND Act into a single licence replacing the current three-licence structure, to reduce regulatory burden for industry participants undertaking activities across the spectrum of regulated activities - cultivation, production, manufacture and research;
b) create a perpetual licence and periodic permit structure for the majority of activities for which a medicinal cannabis licence is required, to support the long term nature of business investment decisions, whilst maintaining appropriate regulatory oversight; and
c) reaffirm the Australian Government's commitment to patient availability of safe, legal and sustainable supply of cannabis derived medicines.

The Bill also makes minor amendments to the ND Act to address issues identified through the administration of the scheme and the process of implementation of the recommendations of the McMillan Review.

Other recommendations from the McMillan Review are also being implemented administratively and through business process reforms by the Department of Health. This includes reviewing and reforming medicinal cannabis permits issued under the ND Act, which can be done without legislative amendment.

FINANCIAL IMPACT STATEMENT

The activities relating to the administration of the medicinal cannabis scheme are funded through a cost-recovery scheme consistent with the Commonwealth's cost-recovery guidelines. There are no financial implications for the Government.

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) Bill 2021

The Bill is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Bill

The *Narcotic Drugs Act 1967* (ND Act), as amended by the *Narcotic Drugs Amendment Act 2016* (2016 Amendment Act), establishes a licensing scheme for the cultivation and production of cannabis and cannabis resin for medicinal and scientific purposes. The ND Act also makes provisions for licensing the manufacture of other narcotic drugs.

The 2016 Amendment Act introduced a requirement for a review of the medicinal cannabis scheme to be undertaken. This was completed by Professor John McMillan AO, and the Final Report of the McMillan Review was tabled in the Parliament on 5 September 2019.

The Narcotic Drugs Amendment (Medicinal Cannabis) Bill 2021 (the Bill) implements recommendations of the McMillan Review, and makes other minor including consequential amendments.

As a large portion of the amendments reorganise the scheme as set up by the 2016 Amendment Act, the human rights implications are materially the same as those identified in relation to the Bill which became the 2016 Amendment Act.

The amendments in the Bill contribute to ensuring that the regulatory framework strikes a balance between mitigating the risk to the Australian community of the diversion of cannabis and Australia's obligations under international law, with the need to ensure that medicinal cannabis regulation in Australia facilitates ease of compliance for industry participants and does not impede growth and productivity.

The two main measures in the Bill are to:

1. consolidate the licensing structure into a single licence framework instead of the current three-licence structure, to reduce the regulatory burden on industry participants who are undertaking activities across the spectrum of cultivation, production and manufacture; and
2. undertake assessments relating to supply chains later in the application process, at consideration of applications for a permit rather than the earlier licensing stage, to support the long term nature of business investment decisions, whilst maintaining appropriate regulatory oversight.

Human rights implications

The Bill engages the following rights:

- the right to health - Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR);
- the right to a fair trial/fair hearing - Article 14 of the ICCPR, including the right to the presumption of innocence in Article 14 (2) of the ICCPR.

Right to health – Article 12 of the ICESCR

Article 12 of the ICESCR promotes the right of all individuals to enjoy the highest attainable standard of physical and mental health, and includes an obligation to take reasonable measures within available resources to progressively secure broader enjoyment of the right. In *General Comment No.14: The Right to the Highest Attainable Standard of Health* (Art. 12) (2000), the United Nations Committee on Economic, Social and Cultural Rights states that health is a 'fundamental human right indispensable for the exercise of other human rights', and that the right to health is not to be understood as a right to be healthy, but includes the right to a system of health protection which provides equal opportunity for people to enjoy the highest attainable level of health.

The Bill takes several steps to promote the right to health by facilitating the improved performance of the medicinal cannabis supply chain in Australia by rationalising the regulatory system. Removing unnecessary regulatory steps and easing the regulatory burden on industry is designed to better support the supply and availability of medicinal cannabis products.

The Bill also supports the right to health by mitigating the risk to the Australian community resulting from the potential for diversion of cannabis.

Right to the presumption of innocence – Article 14(2) of the ICCPR

Article 14 of the ICCPR guarantees equality before courts and tribunals, and, in the determination of criminal charges, or any suit at law, the right to a fair and public hearing before a competent, independent and impartial court or tribunal established by law.

Article 14(2) of the ICCPR provides that everyone charged with a criminal offence shall have the right to be presumed innocent until proven guilty according to law. The right to presumption of innocence is also a fundamental common law principle.

The Bill includes two amendments to introduce criminal offences. There are currently offences in Chapter 3 of the ND Act which apply to the manufacture of cannabis drugs. These offences will no longer apply as these activities will be covered by Chapter 2 instead of Chapter 3. Accordingly, the substance of those offences will be reproduced in Chapter 2 in terms analogous to the existing provisions in Chapter 3.

When 'strict liability' applies to an offence, the prosecution is only required to prove the physical elements of an offence, not the fault elements, beyond reasonable doubt in order for the defendant to be found guilty. The defence of honest and reasonable mistake of fact is available to the defendant (see section 9.2 of the Criminal Code).

Strict liability is used in circumstances where there is public interest in ensuring that regulatory schemes are observed and it can reasonably be expected that the person was aware of their duties and obligations. Strict liability offences can be considered a

limitation of the presumption of innocence because the defendant can be found guilty without the prosecution being required to prove fault.

Strict liability offences will not necessarily be inconsistent with the presumption of innocence provided that removal of the presumption of innocence pursues a legitimate objective and is reasonable, necessary and proportionate to achieving that objective. Whether a strict liability provision impermissibly limits the right to the presumption of innocence will depend on the circumstances of the case and the particular justification for an offence being a strict liability offence.

The following are strict liability offences introduced by the Bill (as well as fault-based offences):

- manufacturing a cannabis drug without authorisation; and
- breach of a condition of a manufacture licence.

Offences in materially the same terms are already applicable to the above (sections 13E and 13F of the ND Act refer).

These strict liability offences have been maintained for manufacturing activities relating to cannabis drugs to reflect the strong public interest in ensuring that the provisions of the licence are properly followed and that monitoring powers are effective to ensure that the overall objective of preventing diversion is met.

The strict liability provisions are not punishable by imprisonment. They are punishable by a fine of up to 60 penalty units (300 penalty units for a body corporate) which reflects the Attorney-General's *Guide to Framing Commonwealth Offences, Infringement Notices and Enforcement Powers*.

The strict liability offences in the Bill are regulatory in nature and act as a deterrent to behaviour that would compromise the operation of the cultivation, production and manufacturing scheme. They are compatible with Article 14(2) of the ICCPR, as they pursue a legitimate objective in acting as a deterrent to unauthorised activities that may otherwise represent a risk to public health, and they are reasonable and proportionate in achieving that outcome.

Conclusion

The Bill is compatible with human rights as it promotes the right to health, and to the extent it may limit human rights, those limitations are reasonable, necessary and proportionate.

The Hon Greg Hunt MP, Minister for Health and Aged Care

NARCOTIC DRUGS AMENDMENT (MEDICINAL CANNABIS) BILL 2021

NOTES ON CLAUSES

Clause 1 – Short title

This clause provides that the Bill, once enacted, may be cited as the *Narcotic Drugs Amendment (Medicinal Cannabis) Act 2021*.

Clause 2 – Commencement

This clause provides the timetable for the commencement of various provisions in the Bill:

- sections 1 to 3 commence on the day that the Bill receives Royal Assent; and
- Schedules 1 and 2 commence on a date to be fixed by Proclamation. However, if the provisions in those Schedules do not commence within the period of 6 months from the day the Bill receives Royal Assent, they commence on the first day after the end of that period.

The commencement of Schedules 1 and 2 by Proclamation reflects that the amendments in the Bill will require supporting amendments to subordinate legislation, and related administrative arrangements.

Clause 3 – Schedules

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

Schedule 1 — AMENDMENTS

Summary
This Schedule amends the ND Act to:

- implement recommendation 7 of the McMillan Review, to replace the current licensing structure of the medicinal cannabis framework in the ND Act (which is based on medicinal cannabis licences, cannabis research licences and manufacture licences) with a new, single licence for cannabis drugs;
- relocate the assessment of required supply chains from the licence stage to the permit stage;
- implement recommendation 10 of the McMillan Review, allowing licences relating to medicinal cannabis to be granted for a maximum of five years, but through granting a licence on a perpetual basis, subject to revocation or surrender, rather than specifying a fixed period;
- give effect to recommendation 1 of the McMillan Review, for a patient focussed addition to the object of the ND Act, by including a clear statement of the purpose of the regulatory scheme for medicinal cannabis - an assurance that medicinal cannabis products are available to patients for therapeutic purposes;
- implement other recommendations of the McMillan Review to ensure consistency of what is regulated with the Single Convention on Narcotic Drugs 1961 and to improve its workability, for example, clarifying the activities that, and persons who, are authorised by a medicinal cannabis licence and the persons who may be considered business associates of a licence applicant when considering their fitness to be granted a licence; and
- make a number of other structural or technical amendments.

Consolidating the current medicinal cannabis licensing structure into a single licence is designed to reduce the regulatory burden on industry participants and remove duplication in application processes.

Relocating consideration of supply chains for medicinal cannabis from the application for a licence to the application for a permit brings the licence application process closer to practice that infrastructure and contracts are only in place after licence grant.

The Bill partially implements the McMillan Review recommendation 9, to remove the restriction on uses for which manufactured cannabis drug may be supplied. All jurisdictions, including the Commonwealth, are concerned that unrestricted supply pathways for medicinal cannabis, referred to in the Bill as cannabis drug, risks allowing its use without appropriate oversight, particularly for ‘terminally ill patients’ and compounding of cannabis by pharmacies. The Bill, therefore, maintains the current specified supply pathways for medicinal cannabis including for pathways the McMillan Review recommended - clinical trials (involving the administration of drugs to humans) under the Therapeutic Goods Act, approvals or authorities under that Act; medical and scientific research (provided that it does not involve administration to humans); and the development of reference standards which are essential for industry and use in research. There is a separate regulation making power to prescribe additional supply pathways anticipated to ensure compliance with the good manufacturing requirements under the Therapeutic Goods Act

Narcotic Drugs Act 1967

Item 1 – Section 3 (Simplified Outline)
This items introduces a new simplified outline to the ND Act to reflect that there are two separate licensing and permit schemes:

- the scheme in Chapter 2 which deals with the cultivation of cannabis plants, the production of cannabis and cannabis resin, and the manufacture of cannabis drugs (which will be defined by the amendment in Item 4).
- the scheme in Chapter 3 which deals with the manufacture of narcotic drugs covered by the Single Convention other than cannabis, or drugs obtained from the cannabis plant.

Items 2, 3, 9, 99, 100, 101, 102, 103, 105, 108, 111, 112, 114, 116, 118, 120, 122, 125, 127, 134, 135, 136, 137, 138 and 139 - Dividing 'drugs' into 'cannabis drugs' and 'narcotic drugs'
While the Bill does not amend the definition of 'drug' in the ND Act, it introduces two new terms for which items 3 and 9 (respectively) provide definitions - 'cannabis drug' and 'narcotic drug'. These terms are subsets of 'drug', and any 'drug' will be either a 'cannabis drug' or a 'narcotic drug'. These terms are defined to clarify the scope of Chapter 2 and Chapter 3 respectively.

'cannabis drug'
Item 3 inserts a new definition of 'cannabis drug'. Paragraphs (a)-(d) of the defined term reflect the entry in Schedule I of the Single Convention which refers to cannabis, cannabis resin, and extracts and tinctures of cannabis.

Paragraph (e) covers a drug that includes, or is from, any part of the cannabis plant.

To be a cannabis drug, a substance must first be a 'drug'. That is, it must be a drug for the purposes of the Single Convention (or otherwise prescribed by the regulations).

A substance may fall within more than one of the paragraphs of the definition of 'cannabis drug'.

Items that make amendments to adopt the term 'cannabis drug' will be explained in the notes to the relevant clauses.

'narcotic drug'
Item 9 inserts a new definition of 'narcotic drug'. This term is defined to mean a drug other than a cannabis drug. This definition will be adopted to ensure there is no ambiguity as to which chapter applies in relation to manufacture.

In the ordinary meaning of the term, cannabis drugs are narcotic drugs. However, the definition of 'narcotic drug' to exclude cannabis drugs reflects that the proposed single licence structure in Chapter 2 creates a specific and separate scheme that deals with cannabis. It clarifies that Chapter 3 does not apply to cannabis drugs (including drugs obtained from the cannabis plant).

The other listed items make consequential amendments to various provisions in Chapter 3 to update references to 'drug' to 'narcotic drug' (and in some cases to update references to 'narcotic preparation' to 'narcotic preparation that contain such a drug') to reflect the introduction of the new term.

Items 4, 34, 38, 43, 44, 45, 47, 55, 56, 57, 60, 61, 63, , 66, 67, 68, 69, 70, 72, 73, 74, 75, 76, 77, 79, 81, 85, 86, 87, 88, 90, 91, 92, 93, 94, 95, 96, 97, 152, 155 and 156 – Definitions of 'cannabis licence' and 'cannabis permit' and updating references to reflect the single licence framework

Item 4 repeals the definition of cannabis licence and cannabis permit. These definitions previously provided an umbrella term to refer to medicinal cannabis licences and cannabis research licences, and medicinal cannabis permits and cannabis research permits, respectively. As the concept of a separate cannabis research licence and permit will be removed from the ND Act, these definitions are no longer required.

However, there are currently provisions which apply to a 'cannabis licence' or 'cannabis permit'. As the 'medicinal cannabis' equivalents of these will now cover all relevant activities relating to cannabis, any such references require updating.

Where provisions currently refer to 'cannabis licence' or 'cannabis permit', the above issue will be addressed by inserting the word 'medicinal' before those terms. Where a provision refers to 'a licence' and is not relevant to a licence under Chapter 3, 'a licence' will be replaced by 'a medicinal cannabis licence'.

Item 5 – Definition of 'cannabis plant'

This item repeals the current definition of cannabis plant and adopts the definition in the Single Convention. This is designed to implement Recommendation 3 of the McMillan Review to align the definition of 'cannabis plant' to that used in the Single Convention.

Items 6, 7 and 10 – Definitions of 'cannabis research licence', 'cannabis research permit' and 'permit'

These items repeal the definition of cannabis research licence and cannabis research permit, remove cannabis research licence from the definition of licence, and remove cannabis research permit from the definition of permit.

As the concept of a separate cannabis research licence and permit will be removed from the ND Act, these definitions are no longer required.

Items 8 and 13 – Definition of 'medicinal cannabis product'

Item 8 repeals the definition of 'medicinal cannabis product'. This definition is no longer to be used in the ND Act as a defined term in order to better distinguish between medicinal cannabis manufactured under the ND Act and therapeutic goods manufactured under the *Therapeutic Goods Act 1989*.

Given the separate regulation of cannabis drugs and narcotic drugs (as defined) by Chapters 2 and 3 respectively, and the removal of the definition of 'medicinal cannabis product', subsection 4(1A) is no longer required. Item 13 repeals that subsection.

Item 11 – 'permitted supply'
This item inserts a new definition of 'permitted supply'.

The circumstances which are included in 'permitted supply' are broadly based on the pathways outlined in current section 11K. The purpose of this concept is to ensure that cannabis that is manufactured will be used for appropriate medicinal or scientific purposes.

Paragraph (a) provides for the supply of a cannabis drug for use in a clinical trial that is, or is likely to be, approved by the Secretary or notified to the Secretary under the *Therapeutic Goods Act 1989*. The requirements for such clinical trials can be found in that Act. This paragraph replicates current 11K(2)(b)(i).

Paragraph (b) provides for the supply of a cannabis drug in accordance with an approval or authority under that Act. This paragraph replicates current 11K(2)(b)(ii).

Paragraph (c) provides for the supply of a cannabis drug for use in medical or scientific research where that research is not a clinical trial approved or notified under the *Therapeutic Goods Act 1989* and does not involve the drug being administered to a human. This largely reflects the availability of a pathway for medical or scientific research (other than clinical trials, which form only one type of research for medical or scientific purposes) under current 11K(2)(a). However, the requirements to be satisfied as to financial resources, other resources and expertise have been removed. This is because these requirements were duplicative of matters that are considered when assessing whether an applicant is a fit and proper person to hold a licence.

Paragraph (d) provides for the supply of a cannabis drug for use as a reference standard for medical or scientific testing purposes. This is a new permitted supply and reflects the necessity of pharmaceutical reference standards for cannabis drugs.

Paragraph (e) provides for the regulations to prescribe further circumstances in which supply is permitted. This paragraph replicates current 11K(2)(b)(ii).

Item 12 and items 22, 24, 26, 51, 63, 82, 83, 106, 109, 121, 132, 133, 146, 147, 155, 156, 159, 160, 165, 166 and 167 - Clarification of 'premises' and removal of references to land
Item 12 clarifies the definition of 'premises' in the ND Act. Currently, the ND Act refers variously to 'premises' and 'land or premises'. The current definition of 'premises' is a broad definition which includes 'a place'.

The amendment removes any uncertainty as to whether 'land or premises' has a different meaning to 'premises' by adopting one term ('premises').

A reference to the extent of the land will be retained in section 8M of the ND Act which sets out the matters to be specified in a medicinal cannabis licence. This is for the purposes of compliance with Australia's obligations under the Single Convention, which requires such specification on a licence relating to cannabis and for information about the extent of land to be reported to the International Narcotics Control Board.

Items 14 - 16 – Subsection 7A(1) and paragraphs 7A(1)(a)-(c)
Item 14 amends section 7A of the ND Act, which deals with the interaction of the ND Act with State and Territory laws. As section 25A of the ND Act will be repealed, the reference to this section is no longer required in subsection (1).

Item 15 amends paragraphs 7A(1)(a) and (b) of the ND Act to remove the word 'related'. This amendment is intended to bring the formulation into closer alignment with the phrase 'medical or related scientific purposes' from the Single Convention on which the ND Act relies and therefore for which it is appropriate that it, as a Commonwealth law relying on the external affairs legislative power, specifies the exclusion of State and Territory law.

Item 16 amends paragraph 7A(1)(c) to remove the reference to section 25A, which will be repealed. In a drafting change, the paragraph will also be re-framed in two subparagraphs to clarify that this paragraph does not exclude State and Territory law to the extent that they relate to the manufacture of cannabis drugs.

Item 17 – Section 8D
This amendment rectifies an inconsistency between section 8A and section 8B aligning the requirements of section 8B with section 8A. This will ensure that the consideration of whether an applicant for a licence, or a business associate, is a fit and proper person will be conducted in a consistent and effective way.

Items 18 and 19 – Chapter 2 (heading) and simplified outline of Chapter 2
These items amend the heading of Chapter 2 of the ND Act, introduce a new simplified outline for Chapter 2 (new section 8D refers) and insert a new section 8DA which outlines the purposes of the Chapter.

New section 8D
The new simplified outline incorporates reference to the manufacture of cannabis drugs for a permitted supply and related activities which will now be authorised under a Chapter 2 licence. These activities were previously authorised under a Chapter 3 licence.

New section 8DA
This new section implements Recommendation 1 of the McMillan Review which recommended that the objects clause in section 2A of the ND Act be amended to include a statement along the lines that an object of the ND Act is to enable cultivation, production, manufacture and research to ensure medicinal cannabis products are available to Australian patients for therapeutic purposes. However, the objects clause in section 2A applies to the ND Act as a whole rather than being limited to the regulation of cannabis. Accordingly, the recommendation is appropriately implemented as a purpose specific to Chapter 2 of the ND Act.

In line with Recommendation 1, emphasis is placed on the purpose of facilitating the availability of medicinal cannabis to patients in Australia for therapeutic purposes.

Item 20 – Subsection 8E(1)
This item repeals and substitutes subsection 8E(1) of the ND Act to reflect the authorised activities under the new single licence.

The ND Activities currently authorised under a cannabis research licence are included in paragraphs (a) and (b) through the reference to activities that are undertaken for scientific purposes.

The activities currently authorised under a manufacture licence are reflected in paragraph (c) but reframed in line with the new definition of 'permitted supply' which performs the role of current section 11K.

Paragraph (d) refers to incidental and ancillary activities including but not limited to the activities listed in the subparagraphs. Subparagraphs (i), (ii) and (iv) reflect the analogous provisions under the three licence structure. Subparagraph (iii) has been included to make it clearer that the taking of samples and their testing is an activity that can be authorised as an incidental or ancillary activity.

Item 21 – Paragraph 8F(3)(b)
This item replaces paragraph 8F(3)(b) of the ND Act specifying discretionary considerations for granting a medicinal cannabis licence with a new paragraph that includes a reference to a cannabis drug manufactured under the licence.

In a drafting change, it also reformulates the paragraph using subparagraphs to improve readability and clarity.

Item 23 – Paragraph 8F(3)(d)
This item amends the mandatory ground of refusal (to grant a licence) in paragraph 8G(1)(d) of the ND Act to replace the reference to 'cannabis or cannabis resin' with a reference to 'cannabis drugs', and to include manufacture in subparagraph (ii).

This is a consequence of activities, currently authorised under a manufacture licence, being included in the new medicinal cannabis licence as a single licence. This will now require the Secretary, before granting a licence to authorise activities, to be satisfied that the applicant will take all reasonable measures to ensure the physical security of cannabis plants or cannabis drugs which are cultivated, produced and manufactured.

Item 25 – Section 8J
This item repeals and replaces section 8J. The new section 8J is materially different to current section 8J.

The current section provides particular circumstances in which the Secretary is required to refuse to grant a medicinal cannabis licence that authorises cultivation or production. Those grounds relate to ensuring that:

- Cultivation activities are undertaken for the purposes of supply to a holder of a licence that authorises production or that the licence holder had such a licence themselves;

- Production activities are undertaken for the purposes of supply to the holder of a licence that authorises manufacture or that the licence holder had such a licence themselves.

However, experience has shown that the licensing phase is not the most appropriate time to be assessing these supply pathways for cultivation and production related activities. Applications for these licences are often made significantly ahead of works being undertaken to construct the facilities at which activities will be undertaken. The assessment of issues relating to supply pathways will be better dealt with at the permit stage.

The new section 8J to be inserted by this item reflects the substance of current section 11K. It requires the Secretary to refuse to grant a medicinal cannabis licence that authorises the manufacture of a cannabis drug unless the Secretary is satisfied that the drug will be supplied for a permitted supply.

Recommendation 9 of the McMillan Review recommended repealing 11K. However, Australian jurisdictions, including the Commonwealth, have expressed concern at having no limitations on the supply and use of manufactured cannabis drugs. To this end, providing a clear illustration of the allowable pathways will aid in certainty as to the permissible uses of cannabis drugs manufactured under the ND Act.

Some of the potential supply pathways the McMillan Review recommended being allowed for, such as reference standards and medical research outside a clinical trial will be provided for in the new definition of permitted supply.

The circumstances in which supply is a permitted supply which are currently set out in regulations will be retained. The ability to prescribe additional permitted supplies will ensure that if other permissible pathways are identified, they can be provided for in regulations.

Item 26 – Paragraph 8M(c)
This item amends paragraph 8M(c) which relates to what must be specified in a medicinal cannabis licence.

It includes the manufacture activities which are currently covered under a manufacture licence and will be covered by a medicinal cannabis licence as a single licence.

Consistent with the revision made by item 10 to the definition of ‘premise’ to include ‘land’, reference to ‘land or’ is removed. However, the licence will still be required to specify the extent of land as required by new paragraph (da) to be inserted by Item 28.

It has also been reframed to make the provision clearer in light of the additional activities that are being included in this paragraph.

Item 27 – Paragraph 8M(d)
This item amends paragraph 8M(d) to include in the matters to be specified in a medicinal cannabis licence manufacturing activities which are currently covered

under a manufacture licence and will be covered by a medicinal cannabis licence as a single licence.

Item 28 – After paragraph 8M(d)
This item inserts a new paragraph 8M(da) to specifically require a licence that authorises cultivation to specify the extent of the land on which the cultivation of cannabis plants is authorised. The specific reference to land is required to comply with Australia's obligations under the Single Convention to specify the extent of the land on the licence and to report this information to the International Narcotics Control Board.

Items 29 and 113 – Paragraph 8M(e) and Paragraph 11N(e)
Item 29 replaces current paragraph 8M(e) requiring the medicinal cannabis licence specify the persons authorised by the licence to engage in activities authorised by the licence with a provision for the regulations to prescribe the persons who are authorised by the licence to engage in the activities authorised by the licence. This change implements Recommendation 15 of the McMillan Review to include a more flexible requirement for inclusion of persons authorised by the licence to carry out activities.

The regulations will therefore prescribe categories of persons who are to be prescribed on the licence. This will ensure that only those persons who are prescribed will be authorised persons which will avoid the necessity of listing every person working in the licence holder's business on the licence.

Item 113 replaces paragraph 11N(e) in the same way and for the same purposes, for manufacture licences under Chapter 3.

Item 30 – Paragraphs 8M(g) and (h)
This item repeals current paragraphs 8M(g) and (h) and inserts new paragraphs 8M(g), (h), (i) and (j).

The current requirement in paragraph (g) to specify the period that the licence is in force is replaced by the requirements in new paragraphs (g) and (h). This reflects the perpetual licence framework by requiring that a licence only specify the day on which the licence comes into force. However, paragraph (h) preserves the ability to grant a time-limited licence by allowing for the specification of the period the licence is to be in force.

The current requirement in current paragraph (h) to specify the Secretary's power to direct that certain things be destroyed is replicated in new paragraph (i). This paragraph includes a reference to narcotic preparations that contain cannabis drugs because these licences will now include manufacture activities.

Item 31 – Section 8N
This item amends current section 8N which relates to the period for which a medicinal cannabis licence is in force. This amendment is made to reflect the perpetual licence framework.

A licence will be in force until the day it is revoked or surrendered under the regulations made for the purpose of section 11A. If a licence is both revoked and surrendered, then the licence will cease to be in force on whichever is earlier of the date of revocation and the date of surrender as worked out under the regulations.

Subsection (3) provides that where the Secretary grants a time-limited licence by specifying a period, then it will cease to be in force at the end of the period specified unless revoked or surrendered with effect at an earlier time. Paragraph 8M(h), to be inserted by Item 30, preserves the ability for the Secretary to grant a time-limited licence by specifying the period that it is in force.

Item 32 – After paragraph 9(4)(b)
This item inserts new paragraphs 9(4)(c) and 9(4)(d) which reproduce the content of current section 8J, which will be repealed by item 25.

This replaces the consideration of forward supply pathways from being relevant as a mandatory ground of refusal of a licence, with a mandatory ground of refusal of a permit.

It will now be a mandatory ground of refusal for a medicinal cannabis permit if the Secretary is not satisfied that:

- For a licence that authorises cultivation but not production – that the cultivation is for the purposes of supply to the holder of a medicinal cannabis licence that authorises production or for a purpose prescribed by the regulations;
- For a licence that authorises production but not manufacture – that the production is for the purposes of supply to the holder of a medicinal cannabis licence that authorises manufacture or for a purpose prescribed by the regulations.

This reflects the reality that supply chain considerations are more relevant to the grant of the permit which will actually authorise the relevant activities. Applicants for a licence are often making their application some time before they are ready to operate. In these circumstances, it is more difficult to prove an authorised supply chain is in place for the purposes of the grant of the licence.

As a permit is required for activities to be carried out, and permits are generally sought closer to the actual carrying out of those activities, it will be more practical for a licence holder to prove that they have the necessary supply chain arrangements at the point of consideration of an application for a permit.

Item 33 – At the end of section (after the note)
This item inserts new subsection 9(5) which provides for the Secretary, for the purposes of deciding whether to grant a medicinal cannabis permit, to require the applicant to provide access to premises at which the activities authorised by the relevant medicinal cannabis licence will take place. This provision is analogous to paragraph 8F(3)(d) which provides for the Secretary to require the applicant to provide access for the purposes of deciding whether to grant a licence.

Similar to the change implemented by Item 32, this change reflects the reality that at the time of the application for a licence, an applicant's facilities are typically not at an advanced stage of development. Accordingly, licences are generally issued based on the proposed site and plans, rather than with reference to the site as it will operate.

However, as it is as a practical matter not possible, in these cases, to examine the actual site, a confirmatory assessment to ensure that the premises are developed as proposed may need to be carried out at the permit application stage.

This will ease the burden on an applicant by allowing a licence to be obtained prior to the construction of the facility, but allowing any necessary inspections of the site to be carried out at the permit stage. At the point of application for a permit, a licence holder should have finalised their arrangements relating to the premises (including security), and therefore this time is more suitable for an inspection if it is necessary.

Item 35 – Paragraph 9B(1)(e)
This item repeals current paragraph 9B(1)(e) and substitutes new paragraphs 9B(1)(e) and (ea) providing for the specification of the date on which the permit relating to a licence authorising cultivation comes into force, while maintaining the ability of the Secretary to specify the period that the permit is in force.

Items 36 and 37 – Subsection 9B(1) (notes 1 and 2)
Item 36 renumbers the notes to reflect that there is now only one note.

Item 37 repeals Note 2 to reflect the amendment, made by Item 5, that the definition of cannabis plant is consistent with the meaning used in the Convention.

Item 39 – Paragraph 9B(2)(d)
This item repeals current paragraph 9B(2)(d) and substitutes new paragraphs 9B(2)(d) and (da) providing for the specification of the date on which the permit relating to a licence authorising production comes into force, while maintaining the ability of the Secretary to specify the period that the permit is in force.

Item 40 – At the end of section 9B
This item inserts a new subsection 9B(3) which sets out matters that may be set out in a permit relating to a medicinal cannabis licence that authorises the manufacture of a cannabis drug.

This new subsection reproduces current section 12C to reflect that activities that were previously authorised by a Chapter 3 manufacture licence may now be specified in a medicinal cannabis licence.

Consistently with current section 9B and section 12C, the listed matters are simply examples of matters that can be specified. They do not all have to be specified, and other matters may be specified.

Item 41 – Section 9C - Period that a permit is in force
This item replaces current section 9C which relates to the period for which a medicinal cannabis permit is in force as it relates to revocation, surrender and if a permit ceases to be in force.

Subsection (1) provides that if a permit is revoked, it will cease to be in force on the day specified in the notice of revocation.

Subsection (2) confirms the operation of subsection 10P(4). Subsection 10P(4) provides that if a medicinal cannabis licence is revoked, then any permits that relate to the licence is taken to be revoked at the time of the revocation of the licence.

Subsection (3) provides that if a permit is surrendered under regulations made for the purposes of section 11A, it will cease to be in force on the day as worked out under those regulations. However, if a permit is both surrendered and revoked, or if a permit is both surrendered and the licence to which it relates is revoked, then the permit will cease to be in force on whichever of the following dates is earliest:

- the date the permit ceases to be in force as worked out under the regulations in relation to surrender;
- the date that the permit is to cease to be in force due to its revocation, and
- the date that a permit ceases to be in force due to the revocation of the licence to which it relates.

Subsection (4) provides that where the Secretary grants a time-limited permit by specifying a period, then it will cease to be in force at the end of the period specified. The following paragraphs preserve the ability of the Secretary to grant a time-limited permit by specifying the period that it is in force:

- paragraph 9B(1)(ea), to be inserted by Item 35;
- paragraph 9B(2)(da), to be inserted by Item 39; and
- paragraph 9B(3)(e), to be inserted by Item 40.

This section does not cover the circumstances where the licence to which the permit relates is surrendered. Subsection 10P(4) does not apply in this circumstance. However, this circumstance will be better dealt with in the Regulations, as the cessation of a permit will involve considerations relating to any ongoing activities and may also affect the surrender of the licence as well. It would also be appropriate in such a case to revoke the permit, on the basis that the activities have ceased.

Item 42 – Repeal - cannabis research licences and permits
This item repeals Division 2 of Part 2 of Chapter 2.

This Division currently deals with cannabis research licences and permits. Under the single licence structure, the activities that relate to a cannabis research licence will be authorised by a medicinal cannabis licence. As cannabis research licences and permits will no longer be a separate concept under the single licence structure, this Division is no longer required.

Item 46 – Paragraph 10C(c)
This item omits a reference to section 9J. As that section will be repealed, this reference is no longer necessary in paragraph 10C(c) imposing licence conditions.

Items 48, 49, 50, 52, 53, 54 and 55– Conditions that may be imposed on a licence
These items make amendments to section 10D, which sets out examples of conditions that may be prescribed and imposed on a licence. The section continues to be a non-

exhaustive list of examples of conditions that may be imposed on a licence under section 8K and 10M.

The changes made by these items are necessary to reflect that manufacture activities for cannabis drugs will now occur under a medicinal cannabis licence. This requires the insertion of references to manufacture and the replacement of references of cannabis and cannabis resin with a reference to cannabis drugs.

Item 48 repeals and substitutes paragraphs 10D(1)(b) and (c). Paragraph (b) will now contain a reference to a cannabis drug manufactured under the licence in accordance with a permit. Paragraph (c), for a condition relating to the use of names or symbols suggesting or implying a particular effect on humans, is expanded to cover all cannabis drugs without being limited to cannabis and cannabis resin.

Items 49 (condition related to destruction) and 53 (condition related to advertising) replace a reference to cannabis and cannabis resin to insert a reference to a cannabis drug and relevant narcotic preparations (and by-products).

Item 50 (condition related to facilities and containment) inserts a reference to manufacture.

Item 52 repeals and substitutes paragraph 10D(1)(o) (condition relating to loss, theft, spoilage and destruction) to use a new drafting structure as well as including references to a cannabis drug manufactured under, or purportedly under, the licence as well as a narcotic preparation that contains such a drug.

Item 54 inserts new paragraph 10D(1)(t) (condition dealing with the labelling of cannabis drugs). This paragraph is a reproduction of paragraph 12F(t) which will be repealed by Item 111.

Item 55 amends subsection 10D(2) (condition related to insurance) to replace the term ‘Cannabis licence conditions’ with ‘The conditions of a medicinal cannabis licence that authorises the cultivation of cannabis plants, or the production of cannabis or cannabis resin’. This amendment both replaces the now outdated reference to ‘cannabis licence’ (see Item 4) and clarifies exactly which licences are referred to in this subsection.

Item 58 – After paragraph 10DE(1)(b) (condition that licence holder inform people of obligations)

This item inserts new paragraph 10E(1)(ba). This amendment is required as a Chapter 2 medicinal cannabis licence will now also authorise manufacture of a cannabis drug. Accordingly, the obligation to inform identified persons of various obligations must be expanded to include persons authorised by the licence to engage in manufacture of a cannabis drug or related activities.

Item 59 – Subsection 10E(3)

This item replaces subsection 10E(3) so as to impose the notification obligation even where the licence has been surrendered. It also makes a drafting change in the structure of the subsection.

Previously, surrender was not dealt with meaning that it was unclear how this condition would operate in that circumstance. This change will ensure that the obligation to notify applies consistently, whether the licence ceases to be in force due to a revocation or a surrender.

Item 62 – Section 10G
This item repeals and replaces section 10G imposing a condition for activities to only be carried out under permit. This is a drafting change to bring the condition in section 10G into alignment with the language of section 8E specifying the activities authorised by the medicinal cannabis licence are only authorised in accordance with a permit. This is analogous to 12J dealing with manufacture licence conditions to be modified by Item 126.

Paragraphs 8E(1)(a), (b) and (c) as amended by item 20 refer to activities being undertaken in accordance with a permit, while paragraph 8E(1)(d) will not do so. By limiting the condition in section 10G, it will be consistent with the requirements of section 8E.

Item 63 – Section 10H
This item repeals and substitutes condition in section 10H relating to monitoring and inspection to include references to manufacture of a cannabis drug which may now be authorised by a medicinal cannabis licence under Chapter 2. It will also update the terminology in line with the other changes made to the structure of the ND Act.

Item 64 – Paragraphs 10J(2)(c) and (d)
This item amends the condition in subsection 10J which relates to the requirement for a medicinal cannabis licence holder to be party to certain contracts. As the manufacture of cannabis drugs may now be authorised by a medicinal cannabis licence, the reference to a separate manufacture licence must be replaced by a reference to a medicinal cannabis licence which authorises the manufacture of a cannabis drug.

Item 65 – New section 10JA
This item inserts new section 10JA making it a condition of a medicinal cannabis licence that authorises the manufacture of a cannabis drug for one or more permitted supplies that the supply of those drugs is in accordance with those permitted supplies.

Item 71 – Paragraph 10M(4)(b)
Consistent with the consolidation of a cannabis research licence into the single medicinal cannabis licence, this item removes the reference in paragraph 10M(4)(b) to section 9J dealing with variations which currently deals with conditions may be imposed on a cannabis research licence. The removal of the reference to ‘paragraph (a) of this subsection’ also clarifies that conditions are imposed either under section 8K or the variation power in section 10M, rather than any separate power created by paragraph 10M(4)(a).

Item 78 and 80, 130 and 131 – Revocation and ‘business associates’
Item 78 amends section 10P providing for the revocation of a medicinal cannabis licence or permit to insert the word ‘relevant’ before the words ‘business associate’. Item 80 inserts new subsection 10P(1A) in terms similar to existing subsection 8G(2)

dealing with the general circumstance obliging a refusal of a grant of a medicinal cannabis licence.

These items implement the substance of Recommendation 19 of the McMillan Review which recommended that the relationship between a business associate and a licence holder be a discretionary ground for the revocation of a licence rather than a mandatory ground.

While not implementing the exact terms of the recommendation the amendment does give full effect to its intent. That is, it introduces a discretionary element by mirroring in section 10P dealing with revocation, the existing discretion in section 8G(2) relating to business associates at the licence grant stage.

When assessing the business associates to be taken into account in determining whether there is a mandatory ground of refusal under section 8G, the Secretary has a discretion to determine who is a relevant business associate for the purposes of considering their eligibility as a fit and proper person. This means that the Secretary can take into account business associates where it is reasonable to do so, that is, for example, where the associated relationship might impact the conduct of operations or where the associate presents an unacceptable risk of diversion.

Accordingly, by amending the reference in paragraph 10P(1)(c) to 'relevant business associate', and inserting new subsection 10P(1A) in similar terms to current section 8G(2), the mandatory ground of revocation will only be engaged where the Secretary considers that the business associate who is not a fit and proper person is relevant to the licence holder. This will avoid the result identified as problematic by the McMillan Review because issues raised by the conduct or integrity of a third party will only affect the licence holder by raising a mandatory ground of revocation if the Secretary considers that they are relevant.

Items 130 and 131 make the same changes to Chapter 3 in order to ensure consistency.

Item 84 – Paragraph 10P(2)(h)
This item amends section 10P providing for the revocation of a medicinal cannabis licence or permit to amend the reference to 'cannabis or cannabis resin' to substitute 'cannabis drugs or narcotic preparations that contain such a drug'.

This amendment reflects that a medicinal cannabis licence may now authorise activities that involve the manufacture of cannabis drugs as defined. This means that the physical security of further things, such as cannabis drugs or narcotic preparations which contain such a drug will now be an issue that may give rise to a ground of revocation.

This change also brings the discretionary ground of revocation into line with the amendment to the mandatory ground of refusal in paragraph 8G(1)(d), to be amended by Item 23.

Item 89 – Part 3 of Chapter 2 (heading)
This item amends the heading to Part 3 of Chapter 2 to replace the reference to 'medicinal cannabis' with a reference to 'cannabis plants and cannabis drugs'.

As 'cannabis' is a defined term in the ND Act and the Single Convention, this change clarifies that the Part relates to cannabis plants as well as cannabis drugs. It also clarifies that this Part will now contain offences relating to the manufacture of cannabis drugs.

There are no changes to the offences relating to cannabis plants. The new offences included in this Part wholly relate to the manufacture of cannabis drugs. They are reproductions of offences in Chapter 3, and are required as that Chapter (including the offences) will no longer apply to the manufacture of a cannabis drug.

Item 98 – At the end of Part 3 of Chapter 2
This item inserts new sections 11EA and 11EB. These sections introduce offences relating to the manufacture of cannabis drugs.

Subsections 11EA(2) and 11EB(2) create fault-based offences. Subsections 11EA(4) and 11EB(4) are civil penalty provisions.

Subsections 11EA(3) and 11EB(3) are strict liability offences. As was the case for the strict liability offences in subsections 13E(3) and 13F(3), these are required to reflect the strong interests of the public in ensuring that the provisions of the licence are properly followed and that the overall objective of preventing diversion is met.

The strict liability provisions are not punishable by imprisonment. They are punishable by a fine of up to 60 penalty units (or 300 penalty units for a body corporate).

New section 11EA
This section is a new offence relating to the unauthorised manufacture of cannabis drugs.

While this is a new offence, it substantially reproduces section 13E which currently applies to the unauthorised manufacture of drugs, including cannabis drugs. It must be included since Chapter 3, which contains section 13E, will no longer apply to the unauthorised manufacture of a cannabis drug.

There are minor modifications to replace references to 'drugs' with 'cannabis drug', and to replace references to 'manufacture licence' with 'medicinal cannabis licence'.

New section 11EB
This section is a new offence relating to a breach of a condition of a medicinal cannabis licence relating to manufacture.

While this is a new offence, it substantially reproduces section 13F which currently applies to a breach of a condition of a manufacture licence, including a licence which authorises the manufacture of cannabis drugs. It must be included since a medicinal

cannabis licence will now authorise the manufacture of a cannabis drug, and Chapter 3, which contains section 13F, will no longer apply.

There are minor modifications to replace references to ‘drugs’ with ‘cannabis drug’, and to replace references to ‘manufacture licence’ with ‘medicinal cannabis licence’.

Item 99 – Chapter 3 (heading)
This item amends the heading to Chapter 3 as this chapter now deals with ‘narcotic drugs’.

Items 100 and 101 – Section 11F
Consequential on the comprehensive regulation by Chapter 2 of cannabis drugs including its manufacture, these items modify the simplified outline of Chapter 3 dealing with manufacture of narcotic drugs to remove any references to cannabis, and to replace references to ‘drug’ with references to ‘narcotic drug’.

Item 104 – Subsection 11H(2)
This item is a consequential amendment which removes the reference in subsection 11H(2) dealing with decisions made on application for a manufacture licence to section 11K, since section 11K will be repealed and manufacture of cannabis drugs is not regulated under Chapter 3.

Item 107 – Paragraph 11J(1)(b)
This item is a consequential amendment to section 11J setting out the circumstances for refusal of a manufacture licence which omits the words ‘subject to subsection 11K(3)’ from paragraph 11J(1)(b), since section 11K will be repealed and manufacture of cannabis drugs is not regulated under Chapter 3.

More details about the repeal of section 11K is set out under the notes for Item 110.

Item 108 – Paragraph 11J(1)(d)
This item amends paragraph 11J(1)(d), to replace ‘drugs or narcotic preparations’ with ‘narcotic drugs or narcotic preparations that contain such a drug’.

The reference to ‘drugs’ will be replaced with ‘narcotic drugs’. This will also require qualification of ‘narcotic preparation’, since that term is defined in relation to a drug generally. Under the amended reference, paragraph 11J(1)(d) will relate to narcotic preparations that contain at least one drug that is not a cannabis drug.

If a narcotic preparation to be manufactured under a licence will contain both a cannabis drug and a narcotic drug (as defined), then the physical security of that narcotic preparation it will be relevant to this paragraph as well as paragraph 8G(1)(d) where the licence holder also holds a medicinal cannabis licence.

Item 110 – Repeal of 11K
This item repeals section 11K in its entirety. Subsection 11K(1) provides that the section only applies to licences that will authorise the manufacture of a drug that includes, or is from, any part of the cannabis plant. As all such licences will be provided for under Chapter 2 and not Chapter 3, section 11K is no longer required.

The concepts, relating to particular circumstances that must exist to avoid a mandatory ground of refusal, which are currently dealt with by subsection 11K (2) will be reproduced in amended section 8J, as repealed and substituted by Item 21B.

Recommendation 9 of the McMillan Review recommended that section 11K be repealed. It is clear in the context of the Recommendation that it related to the restrictions on supply and use and not to the exception in subsection 11K(3).

This Recommendation will not be fully implemented, as all Australian jurisdictions have expressed concerns at the potential risks of removing all restrictions on the supply of cannabis drugs. The restrictions that are currently in subsection 11K(2) will be reproduced in section 8J read together with the new definition of 'permitted supply'.

However, the Recommendation will be partially implemented by expanding the provisions to specifically allow the supply of material for use in medical and scientific research other than clinical trials and use as a reference standard (or use in creating a reference standard – see notes to the new definition of 'permitted supply' in section 4), thus allowing some of the supply pathways that were envisioned by the Recommendation as permitted by a repeal of section 11K.

Subsection 11K(3) contains an exception relevant to serious offences that relate specifically to cannabis and is in the same terms as current section 8H. As this exception is specific to a licence that authorises the manufacture of a cannabis drug, it is no longer required in Chapter 3 and is covered by existing section 8H in Chapter 2. This subsection never applied to a licence to manufacture a narcotic drug as defined by the Bill.

Item 114 – Paragraphs 11N(h) and (i)
Consequential on the comprehensive regulation by Chapter 2 of manufacture of a cannabis drug, this item repeals paragraphs 11N(h) and (i) and substitutes new paragraph (h).

This item has two effects amending section 11N (matters to be specified in a manufacture licence):

- to update paragraph (h) to refer to 'narcotic drugs' and to consequentially qualify 'narcotic preparations' (similarly to Item 99);
- to repeal paragraph (i) as it relates to medicinal cannabis products, which are no longer relevant in Chapter 3.

Item 115 – Section 11P
This item repeals and substitutes section 11P which makes provision for the period for which a manufacture licence is in force. The provision is analogous to substituted section 8N which provides for the period for which a medicinal cannabis licence under Chapter 2 is in force.

A licence will be in force until the day it is revoked or surrendered under the regulations made for the purpose of section 13D. If a licence is both revoked and surrendered, then the licence will cease to be in force on whichever is earlier of the date of revocation and the date of surrender as worked out under the regulations.

Subsection (3) provides that where the Secretary grants a time-limited licence by specifying a period, then it will cease to be in force at the end of the period specified unless revoked or surrendered with effect at an earlier time. Section 11N will continue to require that the period for which the licence is in force is specified. Accordingly, unlike a medicinal cannabis licence, a manufacture licence will always specify the period during which the licence is in force.

Item 117 – Section 12D
This item replaces current section 12D which relates to the period for which a manufacture permit is in force. This amendment is similar to the new section 9C which provides for the period for which a medicinal cannabis permit is in force.

Subsection (1) provides that if a permit is revoked, it will cease to be in force on the day specified in the notice of revocation.

Subsection (2) confirms the operation of subsection 13B(4). Subsection 13B(4) provides that if a manufacture is revoked, then any permits that relates to the licence is taken to be revoked at the time of the revocation of the licence.

Subsection (3) provides that if a permit is surrendered under the regulations made for the purposes of section 13D, it will cease to be in force on the day as worked out under those regulations. However, if a permit is both surrendered and revoked, or if a permit is both surrendered and the licence to which it relates is revoked, then the permit will cease to be in force on whichever of the following dates is earliest:

- the date the permit ceases to be in force as worked out under the regulations in relation to surrender;
- the date that the permit is to cease to be in force due to its revocation, and
- the date that a permit ceases to be in force due to the revocation of the licence to which it relates.

Subsection (4) provides that where the Secretary grants a time-limited permit by specifying a period, then it will cease to be in force at the end of the period specified. Paragraph 12C(d), which will not be amended by this Act, gives the Secretary the ability to grant a time-limited permit by specifying the period that it is in force.

Item 119 – Paragraph 12F(c)
This item consequentially repeals paragraph 12F(c) concerning conditions which may be imposed on a Chapter 3 manufacture licence as it relates to cannabis, which is no longer regulated under Chapter 3.

Items 123 and 124 – Paragraphs 12F(r) – (t)
Item 124 repeals paragraphs 12F(s) and (t) concerning the advertising to the public of drugs or narcotic preparations that contain cannabis plants and the labelling of medicinal cannabis products, as they relate to cannabis, which is no longer regulated under Chapter 3. Item 123 changes the punctuation in paragraph 12F(r) to reflect that it is now the final paragraph.

Item 126 – Section 12J
This item repeals and replaces section 12J relating to the condition that manufacture of drugs is in accordance with a manufacture permit. This is a drafting change to bring the condition in section 12J into alignment with the language of section 11G that the manufacture of drugs is authorised only in accordance with a permit. This change is analogous to the amendment to section 10G.

Currently paragraph 11G(1)(a) refers to the manufacture of a drug in accordance with one or more manufacture permits, while paragraph 11G(1)(b) does not stipulate that those activities must be done in accordance with manufacture permits. By limiting the condition in section 12J, it will be consistent with the requirement for a permit for activities only under paragraph 11G(1)(a).

Item 128 – Sections 12L and 12M
This item repeals sections 12L and 12M as they relate to cannabis, which is no longer relevant to a manufacture licence under Chapter 3.

The substance of the provision in section 12L, that a manufactured cannabis drug must only be supplied in accordance with a permitted pathway, will be reproduced in new section 10JB to relate to a medicinal cannabis licence under Chapter 2.

The condition in section 12M concerning conditions imposed on a cannabis research licence is no longer required as a standalone condition for manufacture.

Item 129 – Paragraph 13(4)(b)
This amendment is consistent with Item 71 which amends the parallel provision in Chapter 2. The removal of the reference to 'paragraph (a) of this subsection' clarifies that conditions are imposed under section 11L or the variation power in section 13, rather than another power created by paragraph 13(4)(a).

Item 140 – After paragraph 13P(1)(c)
This item amends section 13P to provide that the strict liability offences in subsections 11EA(3) and 11EB(3) for unauthorised manufacture of cannabis drugs and breach of a condition of a medicinal cannabis licence authorising manufacture are subject to an infringement notice under Part 5 of the *Regulatory Powers (Standard Provisions) Act 2014*.

As noted in relation to the item which inserts sections 11EA and 11EB, these offences mirror current offences in sections 13E and 13F which apply to the manufacture of drugs (including manufacture of a cannabis drug). However, as Chapter 3 will no longer deal with the manufacture of a cannabis drug, and Chapter 2 will now deal with such manufacture, an offence in the same terms is required in Chapter 2.

Items 141 and 146 Section 14D and paragraphs 14P(1)(a)-(d)
This item amends section 14D imposing requirements on authorised inspectors when entering a premises, subsection 14E(1) providing for the occupier to observe the exercise of powers, and subsection 14F(1) obliging the occupier to provide specified assistance to the authorised inspectors, to replace a reference to 'premises' with 'licensed premises'.

This is a drafting amendment for the purposes of consistency as sections 14D, 14E and 14F cross-refer specifically to section 14C, which relates to entry into 'licensed premises'. These amendments are not intended to change the operation of any of these sections.

Item 143 and 144 – Section 14H and subsection 14P(1)
Item 143 makes amendments to the simplified outline of Chapter 5 dealing with "administrative" matters to update the terminology relating to cannabis drugs and narcotic drugs to be consistent with the new definitions introduced by the Bill.

Item 144 omits the parts of the simplified outline which relate to sections to be repealed.

Item 145
As current subsection (2) of section 14P providing for directions to be given will be repealed by Item 147 (consequential amendment removing a reference to 'land' – see Item 12), there is no longer a need for section 14P to be divided into subsections. This item removes the subsection numbering for current subsection 14P(1).

Item 148 and 149 – Subsection 15(1) and paragraphs 15(2)(a) and (4)(a)
Item 148 amends section 15 of the ND Act, dealing with directions with respect to destruction of specified products, to repeal current subsection 15(1) and replaces it with new subsections 15(1) and (1A). New subsection 15(1) deals with matters that are particular to a medicinal cannabis licence. New subsection 15(1A) applies to both cannabis drugs and narcotic drugs and narcotic preparations that contain any drug. The substance of the new provisions accords with current subsection 15(1).

Item 149 updates the remainder of section 15 to reflect new subsection 15(1A).

Item 150 and Item 153 – Section 15A and paragraph 15E(1)(u)
Item 150 amends section 15A providing for directions for manufacturing and labelling to omit the word 'manufacture' from the phrase 'manufacture licence' from section 15A, making it clear that this power will now be relevant to licences under both Chapter 2 and 3.

Item 153 reflects this change in the list of reviewable decisions.

Item 151 and 154 – Reviewable decisions in repealed Division
These items remove references to the decisions in Division 2 of Part 2 of Chapter 2 in section 15E, as that Division providing for existing cannabis research licences will be repealed, and paragraphs (a) to (e) are sufficient to provide for review of all relevant decisions for medicinal cannabis licences. Transitional provisions will provide for the McMillan Review, after commencement, of decisions under Division 2.

Item 157 – Subsection 23(1)
This item amends subsection 23(1) authorising the Secretary to require records are kept and information furnished to further exclude from the persons who may be required to keep records or furnish information a holder of a medicinal cannabis licence that authorises the manufacture of a cannabis drug.

This is consistent with existing section 23. It is not intended to allow the service of a notice on them despite their activities being now conducted under a medicinal cannabis licence. The objective of section 23 is to allow Australia to fulfil its reporting obligations under the Single Convention. Where a person is a licence holder under the ND Act, the relevant information will already be furnished to the Secretary under those licences and therefore a section 23 notice is not required for those persons.

Item 158 – Section 25A
This item repeals section 25A and implements Recommendation 23 of the McMillan Review because it is a spent provision.

Item 161 – At the end of paragraph 26(1)(a)
This item is a drafting amendment to section 26, service of notice, insert the word 'or'. It is not intended to change the operation of the section.

Item 162 and 163 – After paragraph 26(1)(b) and subsection 26(2)
These items expressly insert electronic methods of services as a manner that is permitted under section 26 and make clarifications to subsection 26(2).

While subsection 26(2) already refers to electronic methods of service, for clarity it is also included expressly in 26(1).

Item 164 – Section 26A
This item repeals section 26A. This section provided for the McMillan Review, and is therefore no longer required.

Item 168 – After paragraph 27(4)(a)
This item includes a new head of regulation making power to cover issues relating to the scientific uses of samples.

Item 169 – Paragraph 27(4)(f)
This item amends paragraph 27(4)(f), providing for regulations to, broadly, regulate supply, to update the terminology consistently with the remainder of the ND Act to use cannabis drugs and narcotic preparations that contain such a drug.

Item 170 – Paragraph 27(4)(g)
This item amends the regulation making power which relates to the modification of Chapters 2 and 3 to include a reference to an agency of the Commonwealth, in addition to the existing references to agencies of a State or a Territory.

The reasons that support the modification of Chapters 2 and 3 of the ND Act, where an applicant for a licence or a licence holder is an agency of a State or Territory, would equally support such modification where the applicant for a licence or a licence holder is an agency of the Commonwealth.

For example, some aspects of the 'fit and proper' test would not be relevant to evaluating an application from an agency of the Commonwealth. As noted in the Explanatory Memorandum to the Bill which became the 2016 Amendment, such

regulations would have to be consistent with Australia's obligations under the Single Convention.

Schedule 2 – APPLICATION, SAVING AND TRANSITIONAL PROVISIONS

Summary
There are currently several licences and permits in force under the three licence framework. The amendments in this Schedule contain a number of application, saving and transitional provisions, including to provide for these licences to be transitioned to the single licence framework in a way that reflects the activities that were authorised under the individual licences.

Narcotic Drugs Amendment (Medicinal Cannabis) Act 2021

Part 1 – Introduction

Item 1 - Definitions
This item defines certain terms that will be used for the purposes of application, savings and transitional provisions.

'Cannabis licence application' is defined as an application for a medicinal cannabis licence, a cannabis research licence or a cannabis manufacture licence. 'Cannabis manufacture licence' is in turn defined as a manufacture licence that authorises the manufacture of a drug that includes, or is from, any part of the cannabis plant or activities relating to such manufacture. This term covers all applications for a licence under current Chapter 2, and those manufacture licences under Chapter 3 which relate to medicinal cannabis.

'Non-commercial cannabis licence' is defined as a licence in relation to which the Secretary made a notification to the licence holder that the activities will be undertaken for non-commercial purposes. These notifications are currently governed by the Narcotic Drugs Regulation 2016. In relation to cannabis research licences, paragraph (a) refers to the circumstances in subsection 54A(2) of that Regulation. In relation to manufacture licences, paragraph (b) refers to the circumstances in subsection 54AB(3), and paragraph (c) refers to the circumstances in subsection 54AA(3) respectively.

Transition time is defined as the commencement of Schedule 2.

Preserved licences and *permits*, and *converted licences* and *permits*, are defined with reference to Items 2 and 3 which set out the operation of those licences and permits.

Part 2 – Licences and permits in force immediately before transition time

Item 2 – Preservation of single licence etc.
This item provides for the preservation of licences and permits under the three licence framework that are in force at the transition time to the single licence framework.

Preservation of licences and permits refers to the situation where, at the transition time, a licence holder holds only one licence under the three licence framework. That licence will be preserved under the single licence framework and made perpetual (except where the licence is a non-commercial cannabis licence).

Subitem (1)
This subitem provides that Item 2 only applies to a licence holder who holds only one licence at the transition time. This licence is called the original licence.

Subitem (2)
This subitem preserves the original licence as the 'preserved licence'. This preserved licence will have effect as if the original licence had been granted under the single licence framework.

Any conditions that were imposed on the licence prior to its preservation will also apply to the preserved licence as if those conditions were imposed on the preserved licence.

The preserved licence will also be subject to the statutory conditions in sections 10E to 10K as they are in force from time to time.

Subitems (3) and (4)
These subitems provide that preserved licences, other than non-commercial cannabis licences, will be perpetual. This includes 'commercial' cannabis research licences – cannabis research licences that are not a non-commercial cannabis licence. Revocation or surrender remain available.

Subitem (5)
This subitem preserves a notice to surrender a licence where the licence will become a preserved licence under this item. This contrasts with converted licences under Item 3, which will not preserve notices of surrender in relation to any of the licences.

The regulations relating to surrender set out a method for working out when a licence will cease to be in force after a notice of surrender is given. The default position is 20 business days, although there are provisions for that period to be extended where relevant activities have not yet ceased. There are also provisions for the Secretary and the licence holder to come to an agreement about when the licence will cease to be in force. This means that it is possible that the transition time will occur during the period after a notice of surrender is given, but before the licence ceases to be in force.

In such a circumstance, the licence will be preserved as a preserved licence, and the licence holder can do such things as would be permitted by the preserved licence. However, it will cease to be in effect on the day that would have been worked out under the regulations if the amendments had not been made.

Subitem (6)
This subitem preserves any permits that relate to the licence being preserved. It is intended that the preservation will not affect the practical operation of the permit. It will specify the same things that the permit specified prior to the transition time.

Permits will not be made perpetual. The preserved permit will expire at the conclusion of the period that was specified in the permit prior to the transition time.

Item 3 – Conversion of multiple licences etc.
This item provides for the conversion of licences and permits under the three licence framework that are in force at the transition time to the single licence framework.

Conversion of licences and permits refers to the situation where, at the transition time, a licence-holder holds more than one licence under the three licence framework. Those licences will be consolidated into one medicinal cannabis licence under the new licence framework.

Subitem (1)
This sub item provides that Item 3 only applies to a licence holder who holds more than one licence at the transition time. These licences are called the original licences.

Subitems (2), (3) and (4) – Conversion of licences
Subitem (2) converts the content of the original licences into a 'converted licence'.

Subitem (3) sets out the effects of the conversion. The converted licence authorises all of the activities that were authorised by the original licences, and is subject to the same conditions as the original licences. However, the licences will become perpetual as the periods will no longer be specified.

If one of the original licences was a non-commercial cannabis research licence or manufacture licence, then the activities related to that licence will be authorised by the converted licence without a time limit (unless the licence is revoked or varied to remove those activities). However, the converted licence will receive the benefit of any reduction or exemption in fees and charges.

Paragraph (3)(d) provides for the particular circumstance where the licence-holder holds both a non-commercial cannabis research licence and a non-commercial cannabis-related manufacture licence. This is currently possible as these are separate licence types. In this circumstance, these licences will be converted into a single licence that permits the relevant research and manufacture activities. However, consistently with the treatment of single non-commercial licences, it will not be made perpetual. The converted licence will cease to be in force on the day that the original licence that expires last ceases to be in force.

Subitem (4) – Continuation of permits
Subitem (4) provides for the continuation of permits that related to the original licences. They will continue to have effect as 'converted permits' and may be dealt with as if they were granted under the new single licence framework.

While the permits which relate to the above licences will be continued as converted permits, these are not consolidated into one permit. Where each licence that is being converted into a converted licence has a relevant permit, the permits will become separate converted permits. A converted licence may have multiple converted permits which relate to it.

Subitem (5) – Copy of converted licence
Subitem (6) provides that the Secretary has a discretion to provide licence holders with a copy of the converted licence. While legally not necessary, it may be desirable

to have a copy of the converted licence issued to clarify what the content of the converted licence is without requiring a reference to several licences and the transitional provisions. For non-commercial licences, providing a copy of the converted licence will provide certainty as to when the converted licence will cease to be in force.

Part 3 – Pending applications for new licences etc.

Item 4 – Pending applications for new licences – applications by persons who do not hold a converted or preserved licence

This item preserves applications for a medicinal cannabis licence, a cannabis research licence or a cannabis manufacture licence that is made prior to the transition time and on which a decision has not been made.

Subitem (1) provides that this item applies only to new applicants – that is, applicants who do not hold a licence immediately at the transition time.

Subitems (2) and (3) provide that where this item applies, the application or applications will be taken to be a single application made under the single licence framework, that is, under Part 2 of Chapter 2 of the Act as amended.

Item 5 – Pending applications for new licences – applications by persons who hold converted or preserved licences

This item preserves applications for a medicinal cannabis licence, a cannabis research licence or a cannabis manufacture licence that is made prior to the transition time if the applicant already has a licence.

Subitem (1) provides that this item applies to existing licence-holders. An applicant for a licence would be an existing licence-holder where:

- they were granted a licence and subsequently they applied for a further licence; or
- they applied for multiple licences concurrently but a decision to grant was made only on one of them by the transition time.

Subitems (2) and (3) deem these applications to be an application to vary the preserved or converted licence (as relevant) to add the relevant activities.
The following examples illustrate how these provisions will operate:

- An applicant who holds no licences makes an application for a cannabis research licence that authorises cultivation. At the transition time, no decision has been made to grant or refuse this licence. After the transition time, the application will become a deemed application for a medicinal cannabis licence which authorises cultivation for scientific purposes.
- An applicant holds a cannabis research licence and makes an application for a cannabis manufacture licence. At the transition time, no decision has been made to grant or refuse the cannabis manufacture licence. After the transition time, the cannabis research licence will be preserved as a medicinal cannabis licence that authorises activities for scientific purposes. The application for a cannabis manufacture licence will become a deemed application for a variation of the preserved medicinal cannabis licence to add further authorised activities relating to manufacture.

- An applicant who holds no licences applies for a medicinal cannabis licence, a cannabis research licence and a cannabis manufacture licence. At the transition time, the Secretary has made a decision to grant the medicinal cannabis licence but has not yet made a decision to grant or refuse to gran the cannabis research licence and cannabis manufacture licence. After the transition time, the medicinal cannabis licence will be preserved, and the applications for the cannabis research licence and cannabis manufacture licence will be deemed to be a single application to vary the preserved medicinal cannabis licence to add further authorised activities relating to scientific purposes and manufacture.

Item 6 – Pending applications for new permits
This item preserves applications for a medicinal cannabis permit, a cannabis research permit or a cannabis-related manufacture permit that is made prior to the transition time.

If there are multiple applications, then they are each taken to be a separate application for a medicinal cannabis permit under the new single licence structure under Part 2 of Chapter 2.

Item 7 and 8 – Pending applications for variation of existing licences and permits
These items preserve applications for variations of existing licences and permits which will be preserved or converted by Part 2 of the Schedule.

Part 4 – Other matters

Items 9, 10 and 11 – Review of pre-transition reviewable decisions – cannabis research licence, cannabis licence and review by the Administrative Appeals Tribunal
This item provides for the review of decisions which will be affected by the amendments. These involve decisions under provisions to be repealed (relating to cannabis research licences and permits), and provisions to be amended (relating to cannabis licences and permits generally).

These items preserve the review provisions so that they apply as if the relevant repeal had not happened or the relevant amendments had not been made.

If a decision on review, whether on internal review or on review by the Administrative Appeals Tribunal, varies or substitutes a decision for the primary decision, then the transitional provisions will apply to the decision as varied or substituted as if it had been made prior to the transition time.

As an internal reviewer and the AAT have the power to set aside a decision and to substitute a new decision, a decision that related to a provision that is repealed or amended can be replaced with a relevant decision under the analogous section after the transition time.

Item 12 – Saving of directions relating to destruction etc.
This item provides for the preservation of a notice directing the destruction of materials under subsection 15(1). The notice is preserved as if the amendments to section 15 had not happened.

Part 5 – Transitional rules

Item 13 – Transitional rules
This item provides for the making of rules by the Minister, by legislative instrument, to prescribe matters of a transitional nature.