Narcotic Drugs Regulation 2016

made under the

Narcotic Drugs Act 1967

Compilation No. 6

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About this compilation

This compilation

This is a compilation of the *Narcotic Drugs Regulation 2016* that shows the text of the law as amended and in force on 1 July 2021 (the ***compilation date***).

The notes at the end of this compilation (the ***endnotes***) include information about amending laws and the amendment history of provisions of the compiled law.

Uncommenced amendments

The effect of uncommenced amendments is not shown in the text of the compiled law. Any uncommenced amendments affecting the law are accessible on the Legislation Register (www.legislation.gov.au). The details of amendments made up to, but not commenced at, the compilation date are underlined in the endnotes. For more information on any uncommenced amendments, see the series page on the Legislation Register for the compiled law.

Application, saving and transitional provisions for provisions and amendments

If the operation of a provision or amendment of the compiled law is affected by an application, saving or transitional provision that is not included in this compilation, details are included in the endnotes.

Editorial changes

For more information about any editorial changes made in this compilation, see the endnotes.

Modifications

If the compiled law is modified by another law, the compiled law operates as modified but the modification does not amend the text of the law. Accordingly, this compilation does not show the text of the compiled law as modified. For more information on any modifications, see the series page on the Legislation Register for the compiled law.

Self-repealing provisions

If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

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Part 1—Preliminary

1 Name

This is the *Narcotic Drugs Regulation 2016*.

3 Authority

This instrument is made under the *Narcotic Drugs Act 1967*.

4 Definitions

Note: A number of expressions used in this instrument are defined in the Act, including the following:

(a) business associate;
(b) cannabis;
(c) cannabis plant;
(d) cannabis resin;
(e) drug;
(f) licensed premises;
(g) medicinal cannabis product;
(h) premises;
(i) relevant financial interest;
(j) relevant position;
(k) supply.

In this instrument:

ABN has the meaning given by section 41 of the *A New Tax System (Australian Business Number) Act 1999*.

ACN has the meaning given by section 9 of the *Corporations Act 2001*.

Act means the *Narcotic Drugs Act 1967*.

ARBN has the meaning given by section 9 of the *Corporations Act 2001*.

cannabis-related licence means:

(a) a cannabis licence; or
(b) a cannabis-related manufacture licence.

cannabis-related manufacture licence means a manufacture licence that will authorise the manufacture of a drug that includes, or is from, any part of the cannabis plant.

cannabis-related manufacture permit means a manufacture permit relating to the manufacture of a drug that includes, or is from, any part of the cannabis plant.

cannabis-related permit means:

(a) a cannabis permit; or

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(b) a cannabis-related manufacture permit.

category A document, in relation to an applicant for a licence, means:

(a) a birth certificate issued by a State or a Territory; or

(b) a current passport issued by the Commonwealth; or

(c) a citizenship certificate issued by the Commonwealth, or documentary evidence that the applicant has been registered by the Commonwealth as an Australian citizen by descent; or

(d) a current passport issued by a foreign government.

category B document, in relation to an applicant for a licence, means:

(a) a driver's licence or a learner's permit, issued under a law of a State or a Territory, that includes a photograph of the applicant, the applicant's signature and a street address that is the same as the address stated in the application for the licence; or

(b) a medicare card; or

(c) documentary evidence that the applicant is an Australian permanent resident within the meaning of the *Migration Act 1958*.

certified true copy: a copy of a document is a ***certified true copy*** of the document if the copy is certified to be a true copy by a person who is prescribed under regulation 4 of the *Statutory Declarations Regulations 1993*.

drug related offence means an offence against a law of the Commonwealth, a State or a Territory that:

(a) does not involve the cultivation of, or trafficking in, drugs but involves any of the following:

(i) the manufacture, supply, possession or use, of drugs;

(ii) the possession of equipment or instructions for the manufacture of drugs; and

(b) is punishable by:

(i) a monetary penalty of any amount; or

(ii) a maximum penalty of imprisonment for not less than 12 months.

identification document means a category A document or a category B document.

medicare card has the meaning given by subsection 84(1) of the *National Health Act 1953*.

starting material, in relation to a drug, means a raw material, an intermediate substance, or a form of a drug substance, that is used in the production of the drug.

Note: A starting material may be a plant, cannabis, cannabis resin or other substances that are drugs.

variation application classification document means the document *Specification of variation applications* published on the Department's website, as in force from time to time.

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4A Prescription of substances

For the purposes of paragraph (a) of the definition of ***drug*** in subsection 4(1) of the Act, the following substances are prescribed:

(a) tetrahydrocannabinol (including all isomers, salts and acids);

(c) dronabinol.

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Part 2—Licensing the cultivation of cannabis plants and the production of cannabis etc.

Division 1—Medicinal cannabis licences and permits

5 Application for medicinal cannabis licence—information requirements

(1) For the purposes of paragraph 8E(2)(a) of the Act, the information specified in this section is prescribed in relation to an application by a person (the ***applicant***) for a medicinal cannabis licence.

General information

(2) The application must contain the following information:
- (a) the name of the applicant;
- (b) if the applicant is a natural person—the applicant's date of birth;
- (c) if the applicant is a body corporate—the applicant's ACN, ABN or ARBN;
- (d) the applicant's mailing address and email address;
- (e) a telephone contact number for the applicant;
- (f) details of the activities the applicant proposes to undertake under the licence, being activities mentioned in subsection 8E(1) of the Act;

  Note: Under subsection 8E(1) of the Act, an applicant is not restricted to applying for a licence authorising activities expressly mentioned in that subsection and may, in accordance with paragraph 8E(1)(c) of the Act, apply for a licence authorising activities related to cultivation or production. Such activities could include, for example, testing cannabis to determine the concentration of tetrahydrocannabinol in the leaves and flowering heads of cannabis plants, or the transport of such plants to persons carrying out testing of the plants for the purposes of supply.
- (g) the following details of the location where the activities will be undertaken under the licence:
  - (i) the address of the premises at which the obtaining or cultivation of cannabis plants, and the production of cannabis or cannabis resin, as the case requires, will be undertaken;
  - (ii) the address of the premises at which other activities relating to such obtaining, cultivation or production will be undertaken;
  - (iii) the total area, and geographic coordinates, of the land at the location;
  - (iv) details of the premises and facilities at the location where the activities will be undertaken;
  - (v) whether the premises are owned or leased by the applicant and, if leased, the name and address of the landlord;
  - (vi) details of how access will be provided to the land, premises and facilities at the location for the purposes of the Secretary inspecting the land, premises and facilities;
- (h) details of the measures that the applicant will take to ensure the physical security of cannabis plants, cannabis or cannabis resin:
  - (i) in the applicant's possession or control; and

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(ii) obtained, cultivated or produced under, or purportedly under, the licence;

(m) if the applicant proposes to supply to a recipient cannabis plants, cannabis or cannabis resin cultivated or produced under, or purportedly under, the licence—details of:

(i) the arrangements for the supply; and

(ii) the proposed use of the plants, cannabis or resin by the recipient; and

(iii) what licences, or other authorisations to use or deal with the plants, cannabis or resin, the recipient holds (if any);

(o) whether the applicant has applied, or proposes to apply, for any other licence under the Act and, if so, the kind of licence.

Information about whether applicant is a fit and proper person—natural persons

(3) If the applicant is a natural person, the application must also contain the following information:

(a) details of any conviction, at any time, of the applicant for an offence against a law of the Commonwealth, a State, a Territory or another country;

(b) details of any civil penalty (however described) imposed, at any time, upon the applicant under a law of the Commonwealth, a State or a Territory;

(c) details of any revocation or suspension of a licence or permit (however described) held by the applicant under a law of the Commonwealth, a State, a Territory or another country, being a law relating to the prohibition or regulation of drugs;

(d) details of the connections and associations that the applicant has with other persons (each of whom is a ***connected person***) (including but not limited to the applicant's relatives) that may affect the applicant's reputation, character, honesty or professional or personal integrity;

(e) the following details in relation to each connected person who is a natural person:

(i) the name and date of birth of the person;

(ii) the length of the connection or association with the person;

(iii) the nature of the connection or association;

(ea) the following details in relation to each connected person that is a body corporate:

(i) the name of the body corporate;

(ii) the body corporate's ACN (if any);

(iii) the body corporate's ABN (if any);

(iv) the body corporate's ARBN (if any);

(v) the length of the connection or association with the body corporate;

(vi) the nature of the connection or association;

(f) the name and date of birth of each natural person who holds a relevant financial interest, or who is entitled to exercise a relevant power (whether in the natural person's own right or on behalf of another person):

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(i) in relation to the applicant's business that will undertake the activities; or

(ii) in relation to any other business of the applicant that provides a substantial proportion of the applicant's current income;

(fa) the name, ACN (if any), ABN (if any) and ARBN (if any) of each body corporate that holds a relevant financial interest, or that is entitled to exercise a relevant power (whether in the body corporate's own right or on behalf of another person):

(i) in relation to the applicant's business that will undertake the activities; or

(ii) in relation to any other business of the applicant that provides a substantial proportion of the applicant's current income;

(g) the following information in relation to each person who holds any relevant position (whether in his or her own right or on someone else's behalf) in relation to the applicant's business that will undertake the activities:

(i) the name and date of birth of the person;

(ii) the position in the business held by the person;

(h) details of the applicant's previous business experience;

(l) details of any matters that may affect whether the applicant is of good repute, being matters going to the applicant's character, honesty and professional and personal integrity;

(m) details of any licence that the applicant holds, or has previously held, under the Act.

Information about whether applicant is a fit and proper person—bodies corporate

(4) If the applicant is a body corporate, the application must also contain the following information:

(a) details of any conviction, at any time, of the body corporate, or any of its directors or officers, for an offence against a law of the Commonwealth, a State, a Territory or another country;

(b) details of any civil penalty (however described) imposed, at any time, upon the body corporate, or any of its directors or officers, under a law of the Commonwealth, a State or a Territory;

(c) if there is such a conviction or imposition of a civil penalty upon the body corporate:

(i) whether the offence concerned was committed, or the conduct to which the civil penalty relates occurred, at a time when any person who is presently a director or officer of the body corporate was a director or officer; and

(ii) whether the offence concerned was committed, or the conduct to which the civil penalty relates occurred, at a time when any shareholder of the body corporate who is presently in a position to influence the management of the body corporate was such a shareholder;

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(d) details of any revocation or suspension of a licence or permit (however described) held by the body corporate under a law of the Commonwealth, a State, a Territory or another country, being a law relating to the prohibition or regulation of drugs;

(e) the names, and dates of birth, of the directors and officers of the body corporate;

(f) details of the connections and associations that the body corporate, and its directors and officers, have with other persons (each of whom is a ***connected person***) (including but not limited to the relatives of such directors and officers) that may affect the reputation, character, honesty or professional or personal integrity of such directors and officers;

(g) the following details in relation to each connected person who is a natural person:

(i) the name and date of birth of the person;

(ii) the length of the connection or association with the person;

(iii) the nature of the connection or association;

(ga) the following details in relation to each connected person that is a body corporate:

(i) the name of that body corporate;

(ii) that body corporate's ACN (if any);

(iii) that body corporate's ABN (if any);

(iv) that body corporate's ARBN (if any);

(v) the length of the connection or association with that body corporate;

(vi) the nature of the connection or association;

(gb) the name and date of birth of each natural person who holds a relevant financial interest, or who is entitled to exercise a relevant power (whether in the natural person's own right or on behalf of another person):

(i) in relation to the applicant's business that will undertake the activities; or

(ii) in relation to any other business of the applicant that provides a substantial proportion of the applicant's current income;

(gc) the name, ACN (if any), ABN (if any) and ARBN (if any) of each body corporate that holds a relevant financial interest, or that is entitled to exercise a relevant power (whether in the body corporate's own right or on behalf of another person):

(i) in relation to the applicant's business that will undertake the activities; or

(ii) in relation to any other business of the applicant that provides a substantial proportion of the applicant's current income;

(gd) the following information in relation to each person who holds any relevant position (whether in his or her own right or on someone else's behalf) in relation to the applicant's business that will undertake the activities:

(i) the name and date of birth of the person;

(ii) the position in the business held by the person;

(h) details of the previous business experience of the directors and officers of the body corporate, and of the shareholders of the body corporate who are in a position to influence the management of the body corporate;

(k) details of any matters that may affect whether the directors and officers of the body corporate are of good repute, being matters going to their character, honesty and professional and personal integrity;

(l) the body corporate's history of compliance with the Act.

Note: A person may commit an offence if the person provides false or misleading information (see section 137.1 of the *Criminal Code*).

6 Application for medicinal cannabis licence—document requirements

(1) For the purposes of paragraph 8E(2)(c) of the Act, the documents specified in this section are prescribed as the documents that must accompany an application by a person (the ***applicant***) for a medicinal cannabis licence.

(2) The following documents must accompany the application:

(a) if the applicant is a natural person—certified true copies of 3 identification documents identifying the applicant, at least one of which must be a category A document;

(b) documents that provide evidence that the applicant has a sound and stable financial background and is not in financial circumstances that may significantly limit the applicant's capacity to comply with the applicant's obligations under a licence;

Note: Such documents could include, for example, bank statements or audited financial statements.

(c) a site plan showing how land at the location where the activities will be undertaken will be utilised for either or both of the following:

(i) cultivation of cannabis plants;

(ii) production of cannabis or cannabis resin;

(d) a detailed floor plan of the premises and facilities at the location where the activities will be undertaken;

(e) a copy of the standard operating procedures and policies that will be used to undertake the activities;

(f) a risk management plan that will be used to manage risks associated with the activities, including risks posed to the health and safety of people, or to the environment.

Note: A person may commit an offence if the person provides false or misleading documents (see section 137.2 of the *Criminal Code*).

7 Application fee for medicinal cannabis licences

For the purposes of subsection 8E(3) of the Act, the application fee set out in the table in clause 1 of Schedule 1 for a medicinal cannabis licence is prescribed.

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7A Application for medicinal cannabis licence—general grounds for refusal of licence

For the purposes of paragraph 8G(1)(f) of the Act, a circumstance in which a licence must not be granted is that the applicant for the licence is reasonably likely:

(a) not to be a resident of Australia; and

(b) not to carry on business in Australia;

at a time when the licence is proposed to be in force.

7B Application for medicinal cannabis licence—particular grounds for refusal of licence

For the purposes of paragraph 8J(2)(c) of the Act, a purpose is the supply of the cannabis or cannabis resin 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).

8 Application for medicinal cannabis permit—information requirements

(1) For the purposes of paragraph 8P(2)(a) of the Act, the information specified in this section is prescribed in relation to an application by the holder of a medicinal cannabis licence (the ***applicant***) for a medicinal cannabis permit.

General information

(2) The application must contain the following information:

(a) the name of the applicant;

(b) the licence number of the medicinal cannabis licence held by the applicant;

(c) the activities, in relation to cultivation or production, or cultivation and production, that are proposed to be authorised by the licence in accordance with the permit.

Medicinal cannabis permits—cultivation

(3) An application for a medicinal cannabis permit that relates to a licence that authorises the cultivation of cannabis plants must also contain the following information:

(a) the types of cannabis plants (the ***proposed plants***) proposed to be cultivated in accordance with the permit;

(b) the range of concentration of tetrahydrocannabinol that will be contained in the proposed plants;

(d) the maximum size of the cannabis crop proposed to be cultivated during the period of the permit;

(e) the maximum number of cannabis plants (including the number of cannabis plants that will be required to propagate cannabis plants for seeds and maintenance of strains) that, in the opinion of the applicant, 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;

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(f) the period during which, under the permit, the plants are proposed to be cultivated for the purposes of producing cannabis or cannabis resin;

(g) the period during which, under the permit, any plants are proposed to be cultivated for the purposes of propagation;

(h) details of the source (whether in Australia or in another country) of the proposed plants, including:

(i) the name, address and contact details of the supplier of the plants; and

(ii) the amount of plants proposed to be supplied by the supplier during the period of the permit; and

(iii) if any plants will be propagated by the applicant from existing plants in the applicant's possession during the period of the permit—the number of plants proposed to be so propagated.

Medicinal cannabis permits—production

(4) An application for a medicinal cannabis permit that relates to a licence that authorises the production of cannabis or cannabis resin must also contain the following information:

(a) the maximum quantity of cannabis or cannabis resin that is proposed to be produced in accordance with the permit;

(b) the maximum quantity of cannabis or cannabis resin that, in the opinion of the applicant, 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, including for the lawful supply of cannabis or cannabis resin;

(c) the period during which cannabis or cannabis resin is proposed to be produced in accordance with the permit.

9 Application for medicinal cannabis permit—document requirements

(1) For the purposes of paragraph 8P(2)(c) of the Act, the documents specified in this section are prescribed as the documents that must accompany an application by the holder of a medicinal cannabis licence (the ***applicant***) for a medicinal cannabis permit.

(2) This subsection specifies copies of all relevant contracts that are in place between the applicant and a person who is authorised by a licence under the Act to do any of the following:

(a) supply cannabis plants;

(b) produce cannabis or cannabis resin;

(c) manufacture one or more drugs that are medicinal cannabis products;

(d) manufacture a drug for the purposes of research relating to medicinal cannabis products.

10 Application fee for medicinal cannabis permit

For the purposes of subsection 8P(3) of the Act, the application fee set out in the table in clause 1 of Schedule 1 for a medicinal cannabis permit is prescribed.

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Division 2—Cannabis research licences and permits

11 Application for cannabis research licence—information requirements

(1) For the purposes of paragraph 9D(2)(a) of the Act, the information specified in this section is prescribed in relation to an application by a person (the ***applicant***) for a cannabis research licence.

General information

(2) The application must contain the following information:

(a) the name of the applicant;

(b) if the applicant is a natural person—the applicant's date of birth;

(c) if the applicant is a body corporate—the applicant's ACN, ABN or ARBN;

(d) the applicant's mailing address and email address;

(e) a telephone contact number for the applicant;

(f) details of the activities the applicant proposes to undertake under the licence, being activities mentioned in subsection 9D(1) of the Act;

Note: Under subsection 9D(1) of the Act, an applicant is not restricted to applying for a licence authorising activities expressly mentioned in that subsection and may, in accordance with paragraph 9D(1)(c) of the Act, apply for a licence authorising activities related to cultivation or production. Such activities could include, for example, testing cannabis to determine the concentration of tetrahydrocannabinol in the leaves and flowering heads of cannabis plants, or the transport of such plants to persons carrying out testing of the plants for the purposes of supply.

(fa) if the applicant seeks a decision of the Secretary under subsection 54A(2) in relation to the research that the applicant proposes to undertake under the licence—the following details about the research:

(i) the primary purpose of the research;

(ii) who will benefit from the research;

(iii) how any products that may be developed as a result of the research will be used;

(iv) the source of the funds for the research;

(v) who owns or operates the research facilities in which the research will be undertaken;

(g) if the application is for a licence that will authorise the cultivation of cannabis plants—details of how the research that the applicant proposes to undertake relates to medicinal cannabis;

(h) if the application is for a licence that will authorise the production of cannabis or cannabis resin—details of how the research that the applicant proposes to undertake relates to medicinal cannabis or medicinal cannabis products;

(i) details of the applicant's financial resources, other resources and expertise that will enable the applicant to carry out the research mentioned in paragraphs (g) and (h) (as applicable);

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(ia) if the application is for a licence that will authorise the supply of cannabis plants as mentioned in subparagraph 9D(1)(c)(ia) of the Act—details of that supply;

(j) the following details of the location where the activities will be undertaken under the licence:

(i) the address of the premises at which the obtaining or cultivation of cannabis plants, and the production of cannabis or cannabis resin, as the case requires, will be undertaken;

(ii) the address of the premises at which other activities relating to such obtaining, cultivation or production will be undertaken;

(iii) the total area, and geographic coordinates, of the land at the location;

(iv) details of the premises and facilities at the location where the activities will be undertaken;

(v) whether the premises are owned or leased by the applicant and, if leased, the name and address of the landlord;

(vi) details of how access will be provided to the land, premises and facilities at the location for the purposes of the Secretary inspecting the land, premises and facilities;

(k) details of the measures that the applicant will take to ensure the physical security of cannabis plants, cannabis or cannabis resin:

(i) in the applicant's possession or control; and

(ii) obtained, cultivated or produced under, or purportedly under, the licence;

(p) if applicable, details of an approval from a research committee, or a research grant issued by a research institution or government organisation, in relation to the medicinal cannabis research;

(q) whether the applicant has applied, or proposes to apply, for any other licence under the Act and, if so, the kind of licence.

Information about whether applicant is a fit and proper person—natural persons

(3) If the applicant is a natural person, the application must also contain the following information:

(a) details of any conviction, at any time, of the applicant for an offence against a law of the Commonwealth, a State, a Territory or another country;

(b) details of any civil penalty (however described) imposed, at any time, upon the applicant under a law of the Commonwealth, a State or a Territory;

(c) details of any revocation or suspension of a licence or permit (however described) held by the applicant under a law of the Commonwealth, a State, a Territory or another country, being a law relating to the prohibition or regulation of drugs;

(d) details of the connections and associations that the applicant has with other persons (each of whom is a ***connected person***) (including but not limited to the applicant's relatives) that may affect the applicant's reputation, character, honesty or professional or personal integrity;

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(e) the following details in relation to each connected person who is a natural person:
  (i) the name and date of birth of the person;
  (ii) the length of the connection or association with the person;
  (iii) the nature of the connection or association;

(ea) the following details in relation to each connected person that is a body corporate:
  (i) the name of the body corporate;
  (ii) the body corporate's ACN (if any);
  (iii) the body corporate's ABN (if any);
  (iv) the body corporate's ARBN (if any);
  (v) the length of the connection or association with the body corporate;
  (vi) the nature of the connection or association;

(f) the name and date of birth of each natural person who holds a relevant financial interest, or who is entitled to exercise a relevant power (whether in the natural person's own right or on behalf of another person):
  (i) in relation to the applicant's business that will undertake the activities; or
  (ii) in relation to any other business of the applicant that provides a substantial proportion of the applicant's current income;

(fa) the name, ACN (if any), ABN (if any) and ARBN (if any) of each body corporate that holds a relevant financial interest, or that is entitled to exercise a relevant power (whether in the body corporate's own right or on behalf of another person):
  (i) in relation to the applicant's business that will undertake the activities; or
  (ii) in relation to any other business of the applicant that provides a substantial proportion of the applicant's current income;

(g) the following information in relation to each person who holds any relevant position (whether in his or her own right or on someone else's behalf) in relation to the applicant's business that will undertake the activities:
  (i) the name and date of birth of the person;
  (ii) the position in the business held by the person;

(h) details of the applicant's previous business experience;

(l) details of any matters that may affect whether the applicant is of good repute, being matters going to the applicant's character, honesty and professional and personal integrity;

(m) details of any licence that the applicant holds, or has previously held, under the Act.

Information about whether applicant is a fit and proper person—bodies corporate

(4) If the applicant is a body corporate, the application must also contain the following information:

(a) details of any conviction, at any time, of the body corporate, or any of its directors or officers, for an offence against a law of the Commonwealth, a State, a Territory or another country;

(b) details of any civil penalty (however described) imposed, at any time, upon the body corporate, or any of its directors or officers, under a law of the Commonwealth, a State or a Territory;

(c) if there is such a conviction or imposition of a civil penalty upon the body corporate:

(i) whether the offence concerned was committed, or the conduct to which the civil penalty relates occurred, at a time when any person who is presently a director or officer of the body corporate was a director or officer; and

(ii) whether the offence concerned was committed, or the conduct to which the civil penalty relates occurred, at a time when any shareholder of the body corporate who is presently in a position to influence the management of the body corporate was such a shareholder;

(d) details of any revocation or suspension of a licence or permit (however described) held by the body corporate under a law of the Commonwealth, a State, a Territory or another country, being a law relating to the prohibition or regulation of drugs;

(e) the names, and dates of birth, of the directors and officers of the body corporate;

(f) details of the connections and associations that the body corporate, and its directors and officers, have with other persons (each of whom is a ***connected person***) (including but not limited to the relatives of such directors and officers) that may affect the reputation, character, honesty or professional or personal integrity of such directors and officers;

(g) the following details in relation to each connected person who is a natural person:

(i) the name and date of birth of the person;

(ii) the length of the connection or association with the person;

(iii) the nature of the connection or association;

(ga) the following details in relation to each connected person that is a body corporate:

(i) the name of that body corporate;

(ii) that body corporate's ACN (if any);

(iii) that body corporate's ABN (if any);

(iv) that body corporate's ARBN (if any);

(v) the length of the connection or association with that body corporate;

(vi) the nature of the connection or association;

(gb) the name and date of birth of each natural person who holds a relevant financial interest, or who is entitled to exercise a relevant power (whether in the natural person's own right or on behalf of another person):

(i) in relation to the applicant's business that will undertake the activities; or

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(ii) in relation to any other business of the applicant that provides a substantial proportion of the applicant's current income;

(gc) the name, ACN (if any), ABN (if any) and ARBN (if any) of each body corporate that holds a relevant financial interest, or that is entitled to exercise a relevant power (whether in the body corporate's own right or on behalf of another person):

(i) in relation to the applicant's business that will undertake the activities; or

(ii) in relation to any other business of the applicant that provides a substantial proportion of the applicant's current income;

(gd) the following information in relation to each person who holds any relevant position (whether in his or her own right or on someone else's behalf) in relation to the applicant's business that will undertake the activities:

(i) the name and date of birth of the person;

(ii) the position in the business held by the person;

(h) details of the previous business experience of the directors and officers of the body corporate, and of the shareholders of the body corporate who are in a position to influence the management of the body corporate;

(k) details of any matters that may affect whether the directors and officers of the body corporate are of good repute, being matters going to their character, honesty and professional and personal integrity;

(l) the body corporate's history of compliance with the Act.

Note: A person may commit an offence if the person provides false or misleading information (see section 137.1 of the *Criminal Code*).

12 Application for cannabis research licence—document requirements

(1) For the purposes of paragraph 9D(2)(c) of the Act, the documents specified in this section are prescribed as the documents that must accompany an application by a person (the ***applicant***) for a cannabis research licence.

(2) The following documents must accompany the application:

(a) if the applicant is a natural person—certified true copies of 3 identification documents identifying the applicant, at least one of which must be a category A document;

(b) documents that provide evidence that the applicant has a sound and stable financial background and is not in financial circumstances that may significantly limit the applicant's capacity to comply with the applicant's obligations under a licence;

Note: Such documents could include, for example, bank statements or audited financial statements.

(c) a site plan showing how land at the location where the activities will be undertaken will be utilised for either or both of the following:

(i) cultivation of cannabis plants;

(ii) production of cannabis or cannabis resin;

(d) a detailed floor plan of the premises and facilities at the location where the activities will be undertaken;

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(e) a copy of the standard operating procedures and policies that will be used to undertake the activities;

(f) a risk management plan that will be used to manage risks associated with the activities, including risks posed to the health and safety of people, or to the environment.

Note: A person may commit an offence if the person provides false or misleading documents (see section 137.2 of the *Criminal Code*).

13 Application fee for cannabis research licence

For the purposes of subsection 9D(3) of the Act, the application fee set out in the table in clause 1 of Schedule 1 for a cannabis research licence is prescribed.

13A Application for cannabis research licence—general grounds for refusal of licence

For the purposes of paragraph 9F(1)(f) of the Act, a circumstance in which a licence must not be granted is that the applicant for the licence is reasonably likely:

(a) not to be a resident of Australia; and

(b) not to carry on business in Australia;

at a time when the licence is proposed to be in force.

14 Application for cannabis research permit—information requirements

(1) For the purposes of paragraph 9N(2)(a) of the Act, the information specified in this section is prescribed in relation to an application by the holder of a cannabis research licence (the ***applicant***) for a cannabis research permit.

General information

(2) The application must contain the following information:

(a) the name of the applicant;

(b) the licence number of the cannabis research licence held by the applicant;

(c) the activities, in relation to cultivation or production, or cultivation and production, that are proposed to be authorised by the licence in accordance with the permit;

(d) if one of those activities is an activity covered by subparagraph 9D(1)(c)(ia) of the Act—the following information:

(i) the name and address of the holder of the medicinal cannabis licence or the holder of the other cannabis research licence;

(ii) the number of cannabis plants that are proposed to be supplied to that holder;

(iii) the dates on which those cannabis plants are proposed to be supplied to that holder;

(iv) the range of concentration of tetrahydrocannabinol that is likely to be contained in those cannabis plants.

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Cannabis research permits—cultivation

(3) An application for a cannabis research permit that relates to a licence that authorises the cultivation of cannabis plants must also contain the following information:

(a) the types of cannabis plants (the ***proposed plants***) proposed to be cultivated in accordance with the permit;

(b) the range of concentration of tetrahydrocannabinol that will be contained in the proposed plants;

(d) the maximum size of the cannabis crop proposed to be cultivated during the period of the permit;

(e) the maximum number of cannabis plants (including the number of cannabis plants that will be required to propagate cannabis plants for seeds and maintenance of strains) that, in the opinion of the applicant, 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;

(f) the period during which, under the permit, the plants are proposed to be cultivated for the purposes of producing cannabis or cannabis resin;

(g) the period during which, under the permit, any plants are proposed to be cultivated for the purposes of propagation;

(h) details of the source (whether in Australia or in another country) of the proposed plants, including:

(i) the name, address and contact details of the supplier of the plants; and

(ii) the amount of plants proposed to be supplied by the supplier during the period of the permit; and

(iii) if any plants will be propagated by the applicant from existing plants in the applicant's possession during the period of the permit—the number of plants proposed to be so propagated.

Cannabis research permits—production

(4) An application for a cannabis research permit that relates to a licence that authorises the production of cannabis or cannabis resin must also contain the following information:

(a) the maximum quantity of cannabis or cannabis resin proposed to be produced in accordance with the permit;

(b) the maximum quantity of cannabis or cannabis resin that it is necessary for the licence holder to produce at any time for conducting the research authorised by the licence;

(c) the period during which the cannabis or cannabis resin is proposed to be produced in accordance with the permit.

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16 Application fee for cannabis research permit

For the purposes of subsection 9N(3) of the Act, the application fee set out in the table in clause 1 of Schedule 1 for a cannabis research permit is prescribed.

17 Matters to be specified in cannabis research permit

Cannabis research permit—cultivation

(1) For the purposes of paragraph 10A(1)(f) of the Act, the following matters are prescribed:
  (a) the research activity that may be undertaken in relation to medicinal cannabis;
  (b) the purpose of the research that may be undertaken.

Cannabis research permit—production

(2) For the purposes of paragraph 10A(2)(e) of the Act, the following matters are prescribed:
  (a) the research activity that may be undertaken in relation to cannabis or cannabis resin;
  (b) the purpose of the research that may be undertaken.

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Division 3—Conditions of cannabis licences

18 Condition that cannabis licence holder employ or engage suitable staff

Classes of unsuitable persons

(1) Each of the following classes of persons is prescribed for the purposes of paragraph 10F(1)(d) of the Act:
  (a) persons who are undertaking, or who have undertaken, treatment for drug addiction;
  (b) persons who have a drug addiction;
  (c) persons who are undischarged bankrupts under the *Bankruptcy Act 1966*.

Circumstances in which persons are taken not to be suitable

(2) For the purposes of subsection 10F(2) of the Act, the following circumstances are prescribed as circumstances in which a person is taken not to be suitable to carry out activities authorised by a cannabis licence at a particular time:
  (a) the person has, during the period of 5 years (the ***exclusion period***) before that time, used illicit drugs;
  (b) the person has, during the exclusion period, been convicted of a drug related offence;
  (c) the person has, during the exclusion period, been convicted of an offence against a law of the Commonwealth, a State or a Territory that:
    (i) involves theft; and
    (ii) is punishable by a maximum penalty of imprisonment for not less than 3 months.

19 Condition that medicinal cannabis licence holder be party to certain contracts

Licences authorising cultivation but not production

(1) For the purposes of subsection 10J(1) of the Act, the following matters are prescribed as matters that must be dealt with by a contract referred to in that subsection:
  (a) the range of concentration of tetrahydrocannabinol that will be contained in the cannabis plants to be supplied;
  (b) the number of cannabis plants to be supplied.

Licences authorising production

(2) For the purposes of subsection 10J(2) of the Act, the following matters are prescribed as matters that must be dealt with by a contract referred to in that subsection:

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(a) the range of concentration of tetrahydrocannabinol that will be contained in the cannabis plants to be used to produce the cannabis or cannabis resin to be supplied;

(b) the quantity of cannabis or cannabis resin to be supplied.

Circumstances in which contract not required—licences authorising cultivation but not production

(3) For the purposes of paragraph 10J(3)(a) of the Act, the circumstances referred to in subsection (4) are prescribed as circumstances in which a contract referred to in subsection 10J(1) of the Act is not required to be in existence.

(4) For the purposes of subsection (3), the circumstances are that:

(a) a contract between:

(i) the holder (the ***first licence holder***) of a medicinal cannabis licence of a kind referred to in paragraph 10J(1)(a) of the Act; and

(ii) the holder of another medicinal cannabis licence that authorises the production of cannabis or cannabis resin;

has ceased to be in existence and the first licence holder is taking steps to arrange a new contract with another holder of a medicinal cannabis licence that authorises the production of cannabis or cannabis resin; or

(b) the first licence holder's licence has been suspended under the Act.

(5) Paragraph (4)(a) ceases to apply in relation to the first licence holder if the first licence holder fails to arrange a new contract within 4 months after the contract mentioned in that paragraph has ceased to be in existence.

Circumstances in which contract not required—licences authorising production

(6) For the purposes of paragraph 10J(3)(a) of the Act, the circumstances referred to in subsection (7) are prescribed as circumstances in which a contract referred to in subsection 10J(2) of the Act is not required to be in existence.

(7) For the purposes of subsection (6), the circumstances are that:

(a) a contract between:

(i) the holder (the ***first licence holder***) of a medicinal cannabis licence of a kind referred to in paragraph 10J(2)(a) of the Act; and

(ii) the holder of a licence under the Act that authorises the manufacture of one or more drugs that are medicinal cannabis products or the manufacture of a drug for the purposes of research in relation to medicinal cannabis products;

has ceased to be in existence and the first licence holder is taking steps to arrange a new contract with another holder of a licence under the Act that authorises such manufacture; or

(b) the first licence holder's licence has been suspended under the Act.

(8) Paragraph (7)(a) ceases to apply in relation to the first licence holder if the first licence holder fails to arrange a new contract within 4 months after the contract mentioned in that paragraph has ceased to be in existence.

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(9) For the purposes of paragraph 10J(3)(a) of the Act, the circumstances referred to in subsection (10) of this section are prescribed as circumstances in which a contract referred to in subsection 10J(2) of the Act is not required to be in existence.

(10) For the purposes of subsection (9), the circumstances are that the production of the cannabis or cannabis resin is for the supply of the cannabis or cannabis resin 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).

20 Condition that cannabis licence holder notify the Secretary of certain matters

(1) For the purposes of paragraph 10K(1)(d) of the Act, the following matters are prescribed in relation to a cannabis licence:

(a) a security breach, a suspected security breach, an unauthorised access or a suspected unauthorised access, in relation to the location, premises or facilities covered by the licence;

(b) a theft, or a suspected theft, of cannabis plants, cannabis or cannabis resin from the location, premises or facilities covered by the licence;

(c) a loss, or a suspected loss, of cannabis plants, cannabis or cannabis resin at the location, premises or facilities covered by the licence;

(d) a discrepancy, or a suspected discrepancy, in the number or quantity of cannabis plants, cannabis or cannabis resin in the possession or under the control of the licence holder;

(e) a loss, or a suspected loss, of cannabis plants, cannabis or cannabis resin in the possession or under the control of the licence holder, other than at the location, premises or facilities covered by the licence, including during transportation of the cannabis plants, cannabis or cannabis resin;

(f) a serious incident involving cannabis plants, cannabis or cannabis resin in the possession or under the control of the licence holder during transportation of the cannabis plants, cannabis or cannabis resin;

(g) an adverse finding or a recommendation, relating to security matters, made in a security audit report or other report relating to the location, premises or facilities covered by the licence;

(h) a change made, or proposed to be made, by the licence holder in relation to premises, security arrangements, conduct of activities, record-keeping, staff or contractors, or other arrangements relating to the licence, in response to any of the following:

(i) a direction of the Secretary under section 14P of the Act;

(ii) a new condition imposed on the licence under the Act;

(iii) a variation of the licence or permit that relates to the licence;

(iv) a finding or a recommendation notified to the licence holder and arising from the monitoring, inspection or investigation of the activities covered by the licence;

(i) the licence holder ceases to undertake, or proposes to cease undertaking, cultivation, production or any other activities authorised by the licence;

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(j) if the licence holder is a body corporate—a transaction that results in, or a proposed transaction that will result in, a change to the type, name or number of shares in the body corporate that are held by a person;

(k) if the licence holder is a body corporate—a change, or a proposed change, in any of the directors or officers of the body corporate;

(l) the licence holder has been notified that a Commonwealth, State or Territory agency has commenced to inquire into, or investigate, any actions, conduct or activities relating to the location, premises or facilities covered by the licence;

(m) if the licence holder is the holder of a medicinal cannabis licence of a kind referred to in paragraph 10J(1)(a) of the Act—a contract between:

(i) the licence holder; and

(ii) the holder of another medicinal cannabis licence that authorises the production of cannabis or cannabis resin;

is no longer in existence or is proposed to be terminated;

(n) if the licence holder is the holder of a medicinal cannabis licence of a kind referred to in paragraph 10J(2)(a) of the Act—a contract between:

(i) the licence holder; and

(ii) the holder of a licence under the Act that authorises the manufacture of one or more drugs that are medicinal cannabis products or the manufacture of a drug for the purposes of research in relation to medicinal cannabis products;

is no longer in existence or is proposed to be terminated.

(2) For the purposes of paragraph 10K(2)(a) of the Act, the period for a matter covered by paragraph (1)(a), (b), (c), (d), (e) or (f) of this section is 72 hours starting when the matter comes to the attention of the licence holder.

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Division 4—Variation, suspension and surrender of cannabis licences and cannabis permits

Subdivision A—Variation of cannabis licences and permits

21 Circumstances in which a cannabis licence or cannabis permit must not be varied

For the purposes of paragraph 10M(3)(b) of the Act, a cannabis licence or cannabis permit must not be varied on application by a licence holder if, had the proposed variation been included as part of the application for a cannabis licence, the Secretary would have been required to refuse to grant the licence under section 8G, 8J, 9F or 9H of the Act.

22 Application for variation of cannabis licence or permit—information requirements

For the purposes of paragraph 10N(1)(a) of the Act, an application by the holder of a cannabis licence for a variation of the cannabis licence or a cannabis permit that relates to the licence must contain information that explains the need for, and the purpose and effect of, the proposed variation.

23 Application for variation of cannabis licence or permit—document requirements

For the purposes of paragraph 10N(1)(c) of the Act, an application by the holder of a cannabis licence for a variation of the cannabis licence or a cannabis permit that relates to the licence must be accompanied by documents that support the application.

24 Application fee for variation of cannabis licence or permit

For the purposes of subsection 10N(2) of the Act, the application fee set out in the table in clause 1 of Schedule 1 for a variation of a cannabis licence or cannabis permit is prescribed.

Subdivision B—Suspension of cannabis licences and permits

25 Suspension of cannabis licences and permits

For the purposes of section 11A of the Act, this Subdivision makes provision for and in relation to the suspension of cannabis licences and cannabis permits.

26 Secretary may suspend cannabis licences and permits

(1) The Secretary may, by notice in writing given to the holder of a cannabis licence, suspend the licence, or a cannabis permit that relates to the licence, if the

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Secretary is satisfied on reasonable grounds that a ground exists under subsection 10P(2) of the Act to revoke the licence or permit.

(2) The suspension of a cannabis licence or a cannabis permit takes effect on the day specified in the notice under subsection (1).

(3) The day specified in the notice must be:
  (a) if paragraph (b) does not apply—at least 20 business days after the day the notice is given to the holder of the cannabis licence; or
  (b) if the Secretary is satisfied on reasonable grounds that there is a risk that cannabis plants, cannabis or cannabis resin may be lost, diverted or stolen if the suspension does not take effect immediately—the day the notice is given to the holder of the licence.

(4) If a cannabis licence is suspended, any cannabis permit that relates to the licence is taken to be suspended at the time of the suspension of the licence.

(5) The suspension ends on the earlier of the following:
  (a) the day specified in the notice under subsection (1);
  (b) if the licence ceases to be in force during the period of suspension—on the day the licence ceases to be in force;
  (c) if the suspension is revoked—on the day the suspension is revoked.

(6) The period of suspension must not be more than 6 months and must be set out in the notice under subsection (1).

27 Secretary may permit specified production to occur during suspension of cannabis licence or permit

Specified production may be permitted while cannabis licence is suspended

(1) If a cannabis licence that authorises the production of cannabis or cannabis resin is suspended, the Secretary may, in the notice under subsection 26(1), permit the licence holder to engage in specified production of cannabis or cannabis resin during the period of the suspension in accordance with conditions specified in the notice.

Specified production may be permitted while cannabis permit is suspended

(2) If a cannabis permit that relates to a cannabis licence that authorises the production of cannabis or cannabis resin in accordance with the permit is suspended, the Secretary may, in the notice under subsection 26(1), permit the permit holder to engage in specified production of cannabis or cannabis resin authorised by the licence in accordance with the permit during the period of the suspension in accordance with conditions specified in the notice.

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28 Secretary to notify of proposed suspension of cannabis licence or permit

(1) Before suspending under section 26 a cannabis licence, or a cannabis permit that relates to a cannabis licence, the Secretary must give written notice of the proposed suspension to the licence holder.

(2) Subsection (1) does not apply if the licence or permit is suspended in the circumstances mentioned in paragraph 26(3)(b).

(3) A notice under subsection (1) in relation to a cannabis licence or a cannabis permit must:
  (a) state that the Secretary proposes to suspend the licence or permit, as the case requires, and the reasons for the proposed suspension; and
  (b) invite the licence holder to make a written submission to the Secretary about the proposed suspension.

(4) A notice under subsection (1) must specify a period within which the licence holder may make a submission under paragraph (3)(b). The period must be a reasonable period in the circumstances.

(5) In deciding whether to suspend a cannabis licence or a cannabis permit, the Secretary must have regard to any submission made under paragraph (3)(b).

(6) If this section requires a notice to be given to a licence holder stating the reasons for a proposed suspension, the Secretary:
  (a) must not disclose information identified as sensitive law enforcement information under subsection 14LA(1) or (2) of the Act in the notice; and
  (b) if the Secretary relies upon such information in relation to the proposed suspension—must, in the case of information identified under subsection 14LA(1) of the Act, consult the giver of the information before giving the notice.

29 Effect of suspension of cannabis licence or permit

(1) During the period of suspension of a cannabis licence or cannabis permit, the licence or permit has no force or effect, but the period of currency of the licence or permit continues to run.

Effect of suspension of cannabis licence

(2) Despite subsection (1), if, under section 26, the Secretary suspends a cannabis licence that authorises either or both of the following activities:
  (a) the cultivation of cannabis plants (whether or not it also authorises the obtaining of cannabis plants for the purposes of such cultivation);
  (b) the production of cannabis or cannabis resin;

the following provisions have effect during the period of suspension:
  (c) if the licence authorises 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;

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(d) if the licence authorises the production of cannabis or cannabis resin—the licence holder is authorised to engage in the production of cannabis or cannabis resin if, but only if, under section 27, the Secretary permits that production to occur in accordance with conditions specified in the notice of suspension.

Effect of suspension of cannabis permit

(3) Despite subsection (1), if, under section 26, the Secretary suspends a cannabis permit that relates to a cannabis licence that authorises either or both of the following activities:

(a) the cultivation of cannabis plants (whether or not it also authorises the obtaining of cannabis plants for the purposes of such cultivation);

(b) the production of cannabis or cannabis resin;

the following provisions have effect during the period of suspension:

(c) if the permit relates to a licence that authorises the cultivation of cannabis plants—the permit holder is authorised to tend, nurture, harvest or store cannabis plants covered by the permit and in the permit holder's possession or control at the time of the suspension of the permit;

(d) if the permit relates to a licence that authorises the production of cannabis or cannabis resin—the permit holder is authorised to engage in the production of cannabis or cannabis resin covered by the permit if, but only if, under section 27, the Secretary permits that production to occur in accordance with conditions specified in the notice of suspension.

(4) The suspension of a cannabis licence or cannabis permit does not prevent the revocation of the licence or permit.

30 Revocation of suspension of cannabis licence or permit

Revocation of suspension

(1) If a cannabis licence, or a cannabis permit that relates to the licence, is suspended, the Secretary may revoke the suspension, by written notice given to the licence holder:

(a) on the Secretary's own initiative; or

(b) on application by the licence holder.

Applicant must provide reasons for revocation

(2) An application under paragraph (1)(b) must include reasons why the applicant considers the suspension should be revoked.

Grounds for revoking suspension

(3) The Secretary may revoke the suspension of the licence or permit if the Secretary is satisfied on reasonable grounds that:

(a) the grounds for suspending the licence or permit no longer exist; and

(b) no other grounds exist for suspending the licence or permit.

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31 Matters not affected by suspension of cannabis licence or permit

(1) To avoid doubt, the following continue to have effect according to their terms during a period of suspension of a cannabis licence or a cannabis permit that relates to the licence:

(a) a condition to which the cannabis licence is subject under Division 3 of Part 2 of Chapter 2 of the Act (other than the condition under section 10J of the Act);

(b) a notice under subsection 14J(2) of the Act requiring a holder of a licence to give the Secretary further information or documents;

(c) a direction under Part 3 of Chapter 5 of the Act given to a person who is a licence holder.

(2) To avoid doubt, the suspension of a cannabis licence, or a permit that relates to the licence, does not affect the powers of an authorised inspector under Part 4 of Chapter 4 of the Act in relation to licensed premises.

32 Offence and civil penalty—breach of condition of permitted production during suspension

(1) A person contravenes this section if:

(a) the person is the holder of a cannabis licence; and

(b) the licence authorises the production of cannabis or cannabis resin in accordance with a cannabis permit; and

(c) the cannabis licence or cannabis permit is suspended under subsection 26(1); and

(d) under section 27 the Secretary permits specified production of cannabis or cannabis resin to occur during the period of suspension in accordance with conditions specified in the notice under subsection 26(1); and

(e) the person fails to comply with a condition.

Fault-based offence

(2) A person commits an offence if the person contravenes subsection (1).

Penalty: 50 penalty units.

Note: If a body corporate is convicted of an offence against this subsection, subsection 4B(3) of the *Crimes Act 1914* allows a court to impose a fine of up to 5 times the penalty stated above.

Civil penalty provision

(3) A person is liable to a civil penalty if the person contravenes subsection (1).

Civil penalty: 50 penalty units.

Note: If a body corporate contravenes subsection (1), subsection 82(5) of the *Regulatory Powers (Standard Provisions) Act 2014* allows a court to order the body corporate to pay a pecuniary penalty of up to 5 times the pecuniary penalty stated above.

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Subdivision C—Surrender of cannabis licences and permits

33 Surrender of cannabis licences and permits

For the purposes of section 11A of the Act, this Subdivision makes provision for and in relation to the surrender of cannabis licences and cannabis permits.

34 Licence holder may surrender cannabis licence or permit

(1) The holder of a cannabis licence or cannabis permit may surrender the licence or permit by giving the Secretary a written notice of surrender in accordance with this section.

(2) The notice must be signed by the holder and must contain the following information:

(a) details of the licence or permit to be surrendered;

(b) the day on which the surrender is proposed to take effect;

(c) if the activities authorised by the licence or permit have not ceased—the day the activities are expected to cease;

(d) if the activities authorised by the licence or permit have ceased—the day the activities ceased;

(e) details of the manner in which any cannabis plants, cannabis or cannabis resin (the ***authorised product***), in the holder's possession or control as authorised by the licence or permit, have been, or will be, dealt with by the holder, including the following details:

(i) if the authorised product has been supplied, or will be supplied, to another holder of a licence under the Act—the name of that other holder, when the authorised product was, or will be, supplied to that other holder, and the amount of authorised product supplied, or that will be supplied, to that other holder;

(ii) if the authorised product has been supplied, or will be supplied, to an end user of the authorised product—the name of that end user, when the authorised product was, or will be, supplied to that end user, and the amount of authorised product supplied, or to be supplied, to that end user;

(iii) if the authorised product has been, or will be, disposed of or destroyed—the day on which, and the location at which, the disposal or destruction took place, or will take place, and details of all persons who carried out, or will carry out, the disposal or destruction;

(f) details of the manner in which any equipment or material used for the cultivation or production of the authorised product has been, or will be, disposed of by the holder;

(g) the address at which the holder's records, books, electronic data and other documents relating to the licence or permit will be kept after the licence or permit is surrendered;

(h) the name, address, telephone number and email address of a person who the Secretary may contact for further information after the licence or permit has been surrendered.

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(3) If the holder notifies the Secretary in accordance with this section, the licence or permit ceases to be in force on the later of the following:

(a) the day specified in the notice as the day on which the surrender is to take effect;

(b) if, on the day the person gives the Secretary the notice of surrender, the activities authorised by the licence or permit have ceased and the authorised product has been disposed of or destroyed—20 business days after the day the holder gives the Secretary the notice of surrender;

(c) if, on the day the person gives the Secretary the notice of surrender, the activities authorised by the licence or permit have not ceased and the authorised product has not been disposed of or destroyed—20 business days after the day the holder gives the Secretary a further notice in writing stating that the activities authorised by the licence or permit have ceased and the authorised product has been disposed of or destroyed.

(4) However, if, after the holder notifies the Secretary in accordance with this section, the Secretary gives the holder written notice that the licence or permit is to cease to be in force on a specified day that:

(a) is earlier or later than the day worked out under subsection (3); and

(b) is agreed by the holder and the Secretary;

the licence or permit ceases to be in force on the specified day.

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Part 3—Licensing the manufacturing of drugs

Division 1—Manufacture licences and permits

35 Application for manufacture licence—information requirements

(1) For the purposes of paragraph 11G(2)(a) of the Act, the information specified in this section is prescribed in relation to an application by a person (the ***applicant***) for a manufacture licence.

General information

(2) The application must contain the following:

(a) the name of the applicant;

(b) if the applicant is a natural person—the applicant's date of birth;

(c) if the applicant is a body corporate—the applicant's ACN, ABN or ARBN;

(d) the applicant's mailing address and email address;

(e) a telephone contact number for the applicant;

(f) details of the activities the applicant proposes to undertake under the licence, being activities mentioned in subsection 11G(1) of the Act;

(fa) if the applicant seeks a decision of the Secretary under subsection 54AB(3) that the manufacturing that the applicant proposes to undertake under the licence is for, or primarily for, research for non-commercial purposes—the following details about the manufacturing and research:

(i) the primary purpose of the manufacturing and research;

(ii) who will benefit from the manufacturing and research;

(iii) how any products that may be developed as a result of the manufacturing and research will be used;

(iv) the source of the funds for the manufacturing and research;

(v) who owns or operates the manufacturing facilities in which the manufacturing and research will be undertaken;

(g) details of the drugs proposed to be manufactured;

(h) details of the proposed end use of the manufactured drugs;

Note: End use may, for example, include export, use in research, supply for clinical trials, manufacture of other drugs or supply to patients in accordance with State or Territory laws.

(i) the following details of the location where the activities will be undertaken under the manufacture licence:

(i) the address of the premises at which drugs will be manufactured;

(ii) the address of the premises at which other activities relating to such manufacture will be undertaken;

(iii) the total area, and geographic coordinates, of the land at the location;

(iv) details of the premises and facilities at the location where the activities will be undertaken;

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(v) whether the premises are owned or leased by the applicant and, if leased, the name and address of the landlord;

(vi) details of how access will be provided to the land, premises and facilities at the location for the purposes of the Secretary inspecting the land, premises and facilities;

(j) details of the measures that the applicant will take to ensure the physical security of drugs or starting material:

(i) in the applicant's possession or control; and

(ii) manufactured under, or purportedly under, the licence;

(o) whether the applicant has applied, or proposes to apply, for any other licence under the Act and, if so, the kind of licence.

Information about whether applicant is a fit and proper person—natural persons

(3) If the applicant is a natural person, the application must also contain the following information:

(a) details of any conviction, at any time, of the applicant for an offence against a law of the Commonwealth, a State, a Territory or another country;

(b) details of any civil penalty (however described) imposed, at any time, upon the applicant under a law of the Commonwealth, a State or a Territory;

(c) details of any revocation or suspension of a licence or permit (however described) held by the applicant under a law of the Commonwealth, a State, a Territory or another country, being a law relating to the prohibition or regulation of drugs;

(d) details of the connections and associations that the applicant has with other persons (each of whom is a ***connected person***) (including but not limited to the applicant's relatives) that may affect the applicant's reputation, character, honesty or professional or personal integrity;

(e) the following details in relation to each connected person who is a natural person:

(i) the name and date of birth of the person;

(ii) the length of the connection or association with the person;

(iii) the nature of the connection or association;

(ea) the following details in relation to each connected person that is a body corporate:

(i) the name of the body corporate;

(ii) the body corporate's ACN (if any);

(iii) the body corporate's ABN (if any);

(iv) the body corporate's ARBN (if any);

(v) the length of the connection or association with the body corporate;

(vi) the nature of the connection or association;

(f) the name and date of birth of each natural person who holds a relevant financial interest, or who is entitled to exercise a relevant power (whether in the natural person's own right or on behalf of another person):

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(i) in relation to the applicant's business that will undertake the activities; or

(ii) in relation to any other business of the applicant that provides a substantial proportion of the applicant's current income;

(fa) the name, ACN (if any), ABN (if any) and ARBN (if any) of each body corporate that holds a relevant financial interest, or that is entitled to exercise a relevant power (whether in the body corporate's own right or on behalf of another person):

(i) in relation to the applicant's business that will undertake the activities; or

(ii) in relation to any other business of the applicant that provides a substantial proportion of the applicant's current income;

(g) the following information in relation to each person who holds any relevant position (whether in his or her own right or on someone else's behalf) in relation to the applicant's business that will undertake the activities:

(i) the name and date of birth of the person;

(ii) the position in the business held by the person;

(h) details of the applicant's previous business experience;

(l) details of any matters that may affect whether the applicant is of good repute, being matters going to the applicant's character, honesty and professional and personal integrity;

(m) details of any licence that the applicant holds, or has previously held, under the Act.

Information about whether applicant is a fit and proper person—bodies corporate

(4) If the applicant is a body corporate, the application must also contain the following information:

(a) details of any conviction, at any time, of the body corporate, or any of its directors or officers, for an offence against a law of the Commonwealth, a State, a Territory or another country;

(b) details of any civil penalty (however described) imposed, at any time, upon the body corporate, or any of its directors or officers, under a law of the Commonwealth, a State or a Territory;

(c) if there is such a conviction or imposition of a civil penalty upon the body corporate:

(i) whether the offence concerned was committed, or the conduct to which the civil penalty relates occurred, at a time when any person who is presently a director or officer of the body corporate was a director or officer; and

(ii) whether the offence concerned was committed, or the conduct to which the civil penalty relates occurred, at a time when any shareholder of the body corporate who is presently in a position to influence the management of the body corporate was such a shareholder;

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(d) details of any revocation or suspension of a licence or permit (however described) held by the body corporate under a law of the Commonwealth, a State, a Territory or another country, being a law relating to the prohibition or regulation of drugs;

(e) the names, and dates of birth, of the directors and officers of the body corporate;

(f) details of the connections and associations that the body corporate, and its directors and officers, have with other persons (each of whom is a ***connected person***) (including but not limited to the relatives of such directors and officers) that may affect the reputation, character, honesty or professional or personal integrity of such directors and officers;

(g) the following details in relation to each connected person who is a natural person:

(i) the name and date of birth of the person;

(ii) the length of the connection or association with the person;

(iii) the nature of the connection or association;

(ga) the following details in relation to each connected person that is a body corporate:

(i) the name of that body corporate;

(ii) that body corporate's ACN (if any);

(iii) that body corporate's ABN (if any);

(iv) that body corporate's ARBN (if any);

(v) the length of the connection or association with that body corporate;

(vi) the nature of the connection or association;

(gb) the name and date of birth of each natural person who holds a relevant financial interest, or who is entitled to exercise a relevant power (whether in the natural person's own right or on behalf of another person):

(i) in relation to the applicant's business that will undertake the activities; or

(ii) in relation to any other business of the applicant that provides a substantial proportion of the applicant's current income;

(gc) the name, ACN (if any), ABN (if any) and ARBN (if any) of each body corporate that holds a relevant financial interest, or that is entitled to exercise a relevant power (whether in the body corporate's own right or on behalf of another person):

(i) in relation to the applicant's business that will undertake the activities; or

(ii) in relation to any other business of the applicant that provides a substantial proportion of the applicant's current income;

(gd) the following information in relation to each person who holds any relevant position (whether in his or her own right or on someone else's behalf) in relation to the applicant's business that will undertake the activities:

(i) the name and date of birth of the person;

(ii) the position in the business held by the person;

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(h) details of the previous business experience of the directors and officers of the body corporate, and of the shareholders of the body corporate who are presently in a position to influence the management of the body corporate;

(k) details of any matters that may affect whether the directors and officers of the body corporate are of good repute, being matters going to their character, honesty and professional and personal integrity;

(l) the body corporate's history of compliance with the Act.

Additional information required if applicant proposes to manufacture medicinal cannabis product for research, clinical trial or supply to the public

(8) If the applicant proposes to manufacture a drug that includes, or is derived from, any part of a cannabis plant, the application must also contain the following:

(a) if the drug is for the purpose of research relating to medicinal cannabis products—information about:

(i) the research proposed to be carried out and the purpose of such research; and

(ii) the applicant's financial resources and other resources to enable the applicant to carry out such research; and

(iii) the qualifications and expertise of the persons employed or engaged by the applicant to carry out such research;

(b) if the drug is a medicinal cannabis product—information about:

(i) if the product is to be used in a clinical trial—the clinical trial in which the product is to be used; or

(ii) if the drug is to be supplied to the public—information about the authority or approval under the *Therapeutic Goods Act 1989* under which the supply is to occur; or

(iii) if the drug is to be supplied to a person as mentioned in paragraph 37(c)—details of that supply and details of any arrangements in place between the applicant and that person relating to the proposed end use of the medicine referred to in that paragraph.

Note: A person may commit an offence if the person provides false or misleading information (see section 137.1 of the *Criminal Code*).

36 Application for manufacture licence—document requirements

(1) For the purposes of paragraph 11G(2)(c) of the Act, the documents specified in this section are prescribed as the documents that must accompany an application by a person (the ***applicant***) for a manufacture licence.

(2) The following documents must accompany the application:

(a) if the applicant is a natural person—certified true copies of 3 identification documents identifying the applicant, at least one of which must be a category A document;

(b) documents that provide evidence that the applicant has a sound and stable financial background and is not in financial circumstances that may significantly limit the applicant's capacity to comply with the applicant's obligations under a licence;

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Note: Such documents could include, for example, bank statements or audited financial statements.

(c) a site plan showing how land at the location where the activities will be undertaken will be utilised;

(d) a detailed floor plan of the premises and facilities at the location where the activities will be undertaken;

(f) a risk management plan to manage risks associated with the activities, including risks posed to the health and safety of people, or to the environment.

Note: A person may commit an offence if the person provides false or misleading documents (see section 137.2 of the *Criminal Code*).

36AA Application fee for cannabis-related manufacture licence

For the purposes of subsection 11G(3) of the Act, the application fee set out in the table in clause 1 of Schedule 1 for a cannabis-related manufacture licence is prescribed.

36A Application for manufacture licence—general grounds for refusal of licence

For the purposes of paragraph 11J(1)(f) of the Act, a circumstance in which a licence must not be granted is that the applicant for the licence is reasonably likely:

(a) not to be a resident of Australia; and

(b) not to carry on business in Australia;

at a time when the licence is proposed to be in force.

37 Particular rules about manufacture licences involving cannabis etc.—medicinal cannabis products

For the purposes of subparagraph 11K(2)(b)(iii) of the Act, the circumstances are that the drug will be supplied:

(a) by a pharmacist in a public hospital in accordance with the *Therapeutic Goods Act 1989*; or

(b) by way of export from Australia in accordance with a licence and permission under the *Customs (Prohibited Exports) Regulations 1958*; or

(c) 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).

38 Application for manufacture permit—information requirements

(1) For the purposes of paragraph 12(2)(a) of the Act, the information specified in this section is prescribed in relation to an application by the holder of a manufacture licence (the ***applicant***) for a manufacture permit.

(2) The application must contain the following information:

(a) the name of the applicant;

(b) the licence number of the manufacture licence held by the applicant;

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(c) details of the drugs proposed to be manufactured;

(d) details of the proposed end use of the manufactured drugs;

Note: End use may, for example, include export, use in research, supply for clinical trials, manufacture of other drugs or supply to patients in accordance with State or Territory laws.

(e) details of the starting materials to be used, the source of the starting materials and the amounts of the starting materials required, to manufacture the drugs;

(f) details of the maximum quantities of the drugs that are proposed to be manufactured;

(g) details of the maximum quantities of the drugs 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;

(h) the period during which the drugs are to be manufactured;

(i) the period for which the permit is proposed to be in force.

38A Application fee for cannabis-related manufacture permit

For the purposes of subsection 12(3) of the Act, the application fee set out in the table in clause 1 of Schedule 1 for a cannabis-related manufacture permit is prescribed.

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Division 2—Conditions of manufacture licences

39 Condition that manufacture licence holder employ or engage suitable staff

Classes of unsuitable persons

(1) Each of the following classes of persons is prescribed for the purposes of paragraph 12H(1)(d) of the Act:
  (a) persons who are undertaking, or who have undertaken, treatment for drug addiction;
  (b) persons who have a drug addiction;
  (c) persons who are undischarged bankrupts under the *Bankruptcy Act 1966*.

Circumstances in which persons are taken not to be suitable

(2) For the purposes of subsection 12H(2) of the Act, the following circumstances are prescribed as circumstances in which a person is taken not to be suitable to carry out activities authorised by a manufacture licence at a particular time:
  (a) the person has, during the period of 5 years (the ***exclusion period***) before that time, used illicit drugs;
  (b) the person has, during the exclusion period, been convicted of a drug related offence;
  (c) the person has, during the exclusion period, been convicted of an offence against a law of the Commonwealth, a State or a Territory that:
    (i) involves theft; and
    (ii) is punishable by a maximum penalty of imprisonment for not less than 3 months.

40 Condition that manufacture licence holder notify the Secretary of certain matters

(1) For the purposes of paragraph 12N(1)(d) of the Act, the following matters are prescribed in relation to a manufacture licence:
  (a) a security breach, a suspected security breach, an unauthorised access or a suspected unauthorised access, in relation to the location, premises or facilities covered by the licence;
  (b) a theft, or a suspected theft, of drugs or starting material from the location, premises or facilities covered by the licence;
  (c) a loss, or a suspected loss, of drugs or starting material at the location, premises or facilities covered by the licence;
  (d) a discrepancy, or a suspected discrepancy, in the quantity of drugs or starting material in the possession or under the control of the licence holder;
  (e) a loss, or a suspected loss, of drugs or starting material in the possession or under the control of the licence holder, other than at the location, premises or facilities covered by the licence, including during transportation of the drugs or starting material;

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(f) a serious incident involving drugs or starting material in the possession or under the control of the licence holder during transportation of the drugs or starting material;

(g) an adverse finding or a recommendation, relating to security matters, made in a security audit report or other report relating to the location, premises or facilities covered by the licence;

(h) a change made, or proposed to be made, by the licence holder in relation to premises, security arrangements, conduct of activities, record-keeping, staff or contractors, or other arrangements relating to the licence, in response to any of the following:

(i) a direction of the Secretary under section 14P of the Act;

(ii) a new condition imposed on the manufacture licence under the Act;

(iii) a variation of the licence or of a permit that relates to the licence;

(iv) a finding or a recommendation notified to the licence holder and arising from the monitoring, inspection or investigation of the activities covered by the licence;

(i) the licence holder commences to manufacture drugs under the licence;

(j) the licence holder ceases to manufacture drugs, or ceases to undertake any other activities, under the licence;

(k) if the licence holder is a body corporate—a transaction that results in, or a proposed transaction that will result in, a change to the type, name or number of shares in the body corporate that are held by a person;

(l) if the licence holder is a body corporate—a change, or a proposed change, in any of the directors or officers of the body corporate;

(m) the licence holder has been notified that a Commonwealth, State or Territory agency has commenced to inquire into, or investigate, any actions, conduct or activities relating to the location, premises or facilities covered by the licence.

(2) For the purposes of paragraph 12N(2)(a) of the Act, the period for a matter covered by paragraph (1)(a), (b), (c), (d), (e) or (f) of this section is 72 hours starting when the matter comes to the attention of the licence holder.

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Division 3—Variation, suspension and surrender of manufacture licences and manufacture permits

Subdivision A—Variation of manufacture licences and permits

41 Circumstances in which a manufacture licence or permit must not be varied

For the purposes of paragraph 13(3)(b) of the Act, a manufacture licence or manufacture permit must not be varied on application by a licence holder if, had the proposed variation been included as part of the application for a manufacture licence, the Secretary would have been required to refuse to grant the licence under section 11J or 11K of the Act.

42 Application for variation of manufacture licence or permit—information requirements

For the purposes of paragraph 13A(1)(a) of the Act, an application by the holder of a manufacture licence for a variation of the manufacture licence or a manufacture permit that relates to the licence must contain information that explains the need for, and the purpose and effect of, the proposed variation.

43 Application for variation of manufacture licence or permit—document requirements

For the purposes of paragraph 13A(1)(c) of the Act, an application by the holder of a manufacture licence for a variation of the manufacture licence or a manufacture permit that relates to the licence must be accompanied by documents that support the application.

43A Application fee for variation of cannabis-related manufacture licence or permit

For the purposes of subsection 13A(2) of the Act, the application fee set out in the table in clause 1 of Schedule 1 for a variation of a cannabis-related manufacture licence or cannabis-related manufacture permit is prescribed.

Subdivision B—Suspension of manufacture licences and permits

44 Suspension of manufacture licences and permits

For the purposes of section 13D of the Act, this Subdivision makes provision for and in relation to the suspension of manufacture licences and permits.

45 Secretary may suspend manufacture licences and permits

(1) The Secretary may, by notice in writing given to the holder of a manufacture licence, suspend the licence, or a manufacture permit that relates to the licence, if the Secretary is satisfied on reasonable grounds that a ground exists under

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subsection 13B(2) of the Act to revoke the manufacture licence or manufacture permit.

(2) The suspension of a manufacture licence or a manufacture permit takes effect on the day specified in the notice under subsection (1).

(3) The day specified in the notice must be:
  (a) if paragraph (b) does not apply—at least 20 business days after the day the notice is given to the holder of the manufacture licence; or
  (b) if the Secretary is satisfied on reasonable grounds that there is a risk that drugs or narcotic preparations or starting materials may be lost, diverted or stolen if the suspension does not take effect immediately—the day the notice is given to the holder of the licence.

(4) If a manufacture licence is suspended, any manufacture permit that relates to the licence is taken to be suspended at the time of the suspension of the licence.

(5) The suspension ends on the earlier of the following:
  (a) the day specified in the notice under subsection (1);
  (b) if the licence ceases to be in force during the period of suspension—on the day the licence ceases to be in force;
  (c) if the suspension is revoked—on the day the suspension is revoked.

(6) The period of suspension must not be more than 6 months and must be set out in the notice under subsection (1).

46 Secretary to notify of proposed suspension of manufacture licence or permit

(1) Before suspending under section 45 a manufacture licence, or a manufacture permit that relates to the licence, the Secretary must give written notice of the proposed suspension to the licence holder.

(2) Subsection (1) does not apply if the licence or permit is suspended in the circumstances mentioned in paragraph 45(3)(b).

(3) A notice under subsection (1) in relation to a manufacture licence or a manufacture permit must:
  (a) state that the Secretary proposes to suspend the licence or permit, as the case requires, and the reasons for the proposed suspension; and
  (b) invite the licence holder to make a written submission to the Secretary about the proposed suspension.

(4) A notice under subsection (1) must specify a period within which the licence holder may make a submission under paragraph (3)(b). The period must be a reasonable period in the circumstances.

(5) In deciding whether to suspend a manufacture licence or a manufacture permit, the Secretary must have regard to any submission made under paragraph (3)(b).

(6) If this section requires a notice to be given to a licence holder stating the reasons for a proposed suspension, the Secretary:

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(a) must not disclose information identified as sensitive law enforcement information under subsection 14LA(1) or (2) of the Act in the notice; and

(b) if the Secretary relies upon such information in relation to the proposed suspension—must, in the case of information identified under subsection 14LA(1) of the Act, consult the giver of the information before giving the notice.

47 Effect of suspension of manufacture licence or permit

(1) During the period of suspension of a manufacture licence or manufacture permit, the licence or permit has no force or effect, but the period of currency of the licence or permit continues to run.

(2) Despite subsection (1), if, under section 45, the Secretary suspends a manufacture licence that authorises the manufacture of a drug, the licence holder is authorised during the period of suspension to store, possess and control any drugs, narcotic preparations or starting materials in the licence holder's possession or control as authorised by the licence at the time of the suspension.

(3) The suspension of a manufacture licence or manufacture permit does not prevent the revocation of the licence or permit.

48 Revocation of suspension of manufacture licence or permit

Revocation of suspension

(1) If a manufacture licence, or a manufacture permit that relates to the licence, is suspended, the Secretary may revoke the suspension, by written notice given to the licence holder:

(a) on the Secretary's own initiative; or

(b) on application by the licence holder.

Applicant must provide reasons for revocation

(2) An application under paragraph (1)(b) must include reasons why the applicant considers the suspension should be revoked.

Grounds for revoking suspension

(3) The Secretary may revoke the suspension of the licence or permit if the Secretary is satisfied on reasonable grounds that:

(a) the grounds for suspending the licence or permit no longer exist; and

(b) no other grounds exist for suspending the licence or permit.

49 Matters not affected by suspension of manufacture licence or permit

(1) To avoid doubt, the following continue to have effect according to their terms during a period of suspension of a manufacture licence or a manufacture permit that relates to the licence:

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(a) a condition to which the manufacture licence is subject under Division 2 of Part 2 of Chapter 3 of the Act;

(b) a notice under subsection 14J(2) of the Act requiring a holder of a licence to give the Secretary further information or documents;

(b) a direction under Part 3 of Chapter 5 of the Act given to a person who is a licence holder.

(2) To avoid doubt, the suspension of a manufacture licence, or a manufacture permit that relates to the licence, does not affect the powers of an authorised inspector under Part 4 of Chapter 4 of the Act in relation to licensed premises.

Subdivision C—Surrender of manufacture licences and permits

50 Surrender of manufacture licences and permits

For the purposes of section 13D of the Act, this Subdivision makes provision for and in relation to the surrender of manufacture licences and manufacture permits.

51 Licence holder may surrender manufacture licence or permit

(1) The holder of a manufacture licence or manufacture permit may surrender the licence or permit by giving the Secretary a written notice of surrender in accordance with this section.

(2) The notice must be signed by the holder and must contain the following information:

(a) details of the manufacture licence or manufacture permit being surrendered;

(b) the day on which the surrender is proposed to take effect;

(c) if the activities authorised by the licence or permit have not ceased—the day the activities are expected to cease;

(d) if the activities authorised by the licence or permit have ceased—the day the activities ceased;

(e) details of the manner in which any drugs, narcotic preparations or starting materials (the ***authorised product***), in the holder's possession or control as authorised by the licence or permit, have been, or will be, dealt with by the holder, including the following details:

(i) if the authorised product has been supplied, or will be supplied, to another holder of a manufacture licence—the name of that other holder, when the authorised product was, or will be, supplied to that other holder, and the amount of authorised product supplied, or that will be supplied, to that other holder;

(ii) if the authorised product has been supplied, or will be supplied, to an end user of the authorised product—the name of that end user, when the authorised product was, or will be, supplied to that end user, and the amount of authorised product supplied, or to be supplied, to that end user;

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(iii) if the authorised product has been, or will be, disposed of or destroyed—the day on which, and the location at which, the disposal or destruction took place, or will take place, and details of all persons who carried out, or will carry out, the disposal or destruction;

(f) details of the manner in which any equipment or material used to manufacture the authorised product has been, or will be, disposed of by the holder;

(g) the address and location at which the holder's records, books, electronic data and other documents relating to the licence or permit will be kept after the licence or permit is surrendered;

(h) the name, address, telephone number and email address of a person who the Secretary may contact for further information after the licence or permit has been surrendered.

(3) If the holder notifies the Secretary in accordance with this section, the licence or permit ceases to be in force on the later of the following:

(a) the day specified in the notice as the day on which the surrender is to take effect;

(b) if, on the day the person gives the Secretary the notice of surrender, the activities authorised by the licence or permit have ceased and the authorised product has been disposed of or destroyed—20 business days after the day the holder gives the Secretary the notice of surrender;

(c) if, on the day the person gives the Secretary the notice of surrender, the activities authorised by the licence or permit have not ceased and the authorised product has not been disposed of or destroyed—20 business days after the day the holder gives the Secretary a further notice in writing stating that the activities authorised by the licence or permit have ceased and the authorised product has been disposed of or destroyed.

(4) However, if, after the holder notifies the Secretary in accordance with this section, the Secretary gives the holder written notice that the licence or permit is to cease to be in force on a specified day that:

(a) is earlier or later than the day worked out under subsection (3); and

(b) is agreed by the holder and the Secretary;

the licence or permit ceases to be in force on the specified day.

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Part 4—Review of decisions

52 Reviewable decisions

For the purposes of subsection 15E(2) of the Act, each of the following decisions of the Secretary is a ***reviewable decision***:

(a) a decision under section 26 to suspend a cannabis licence or a cannabis permit that relates to the licence;

(b) a decision under subsection 27(1) to refuse to permit specified production of cannabis or cannabis resin during a period of suspension of a cannabis licence;

(c) a decision under subsection 27(2) to refuse to permit specified production of cannabis or cannabis resin during a period of suspension of a cannabis permit;

(d) a decision under section 30 to refuse to revoke a suspension of a cannabis licence or a cannabis permit that relates to the licence;

(e) a decision under section 45 to suspend a manufacture licence or a manufacture permit that relates to the licence;

(f) a decision under section 48 to refuse to revoke a suspension of a manufacture licence or a manufacture permit that relates to the licence;

(g) a decision under section 53;

(h) a decision under subsection 54A(2) about whether research that an applicant proposes to undertake will be undertaken for non-commercial purposes, or primarily for non-commercial purposes;

(i) a decision under subsection 54AA(3) about whether manufacturing that a licence holder undertakes is undertaken:

(i) for research for non-commercial purposes; or

(ii) primarily for research for non-commercial purposes;

(j) a decision under subsection 54AB(3) about whether manufacturing that an applicant proposes to undertake will be undertaken:

(i) for research for non-commercial purposes; or

(ii) primarily for research for non-commercial purposes.

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Part 5—Other matters

Division 1—Inspection fees

54 Inspection fees

(1) If an inspection of land or premises is conducted in relation to an application for:
  (a) a licence; or
  (b) a permit that relates to a licence; or
  (c) a variation of a licence; or
  (d) a variation of a permit that relates to a licence;

then, for the purposes of paragraph 28(1)(c) of the Act, a fee (the ***inspection fee***) of $3,670 is payable for the inspection.

(2) The inspection fee:
  (a) is payable to the Secretary on behalf of the Commonwealth by the applicant; and
  (b) must be paid on or before the last day for payment of the fee shown on an invoice issued to the applicant by the Secretary; and
  (c) is recoverable as a debt due to the Commonwealth.

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Division 1A—Charges

54A Classes of cannabis research licences for the purposes of charge

Commercial cannabis research licence

(1) For the purposes of paragraph 28(1)(e) of the Act, a cannabis research licence is a ***commercial cannabis research licence*** if, when granting the licence, the Secretary does not notify the applicant for the licence in accordance with subsection (2).

Non-commercial cannabis research licence

(2) For the purposes of paragraph 28(1)(e) of the Act, a cannabis research licence is a ***non-commercial cannabis research licence*** if, when granting the licence, the Secretary notifies the applicant for the licence in writing that the Secretary is reasonably satisfied that the research that the applicant proposes to undertake will be undertaken for non-commercial purposes, or primarily for non-commercial purposes.

Matters to which the Secretary must have regard

(3) In making a decision under subsection (2) about research that an applicant proposes to undertake, the Secretary must have regard to the following:
  (a) the primary purpose of the research;
  (b) who will benefit from the research;
  (c) how any products that may be developed as a result of the research will be used;
  (d) the source of the funds for the research;
  (e) who owns or operates the research facilities in which the research will be undertaken.

Other matters

(4) Subsection (3) does not limit the matters to which the Secretary may have regard in making a decision under subsection (2).

54AA Classes of cannabis-related manufacture licences for the purposes of charge—licences granted on the basis of applications made before 1 November 2020

Application

(1) This section applies to a cannabis-related manufacture licence if the licence was granted on the basis of an application made before 1 November 2020.

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Commercial cannabis-related manufacture licence

(2) For the purposes of paragraph 28(1)(e) of the Act, a cannabis-related manufacture licence to which this section applies is a ***commercial cannabis-related manufacture licence*** if the Secretary has not notified the holder of the licence in accordance with subsection (3).

Non-commercial cannabis-related manufacture licence

(3) For the purposes of paragraph 28(1)(e) of the Act, a cannabis-related manufacture licence to which this section applies is a ***non-commercial cannabis-related manufacture licence*** if, on application by the licence holder, the Secretary notifies the holder in writing that the Secretary is reasonably satisfied that the manufacturing that the holder undertakes under the licence is undertaken:

(a) for research for non-commercial purposes; or

(b) primarily for research for non-commercial purposes.

Application for decision under subsection (3)

(4) An application by a licence holder for a decision of the Secretary under subsection (3) that the manufacturing that the applicant undertakes under the licence is for, or primarily for, research for non-commercial purposes must:

(a) be made in the form or manner approved in writing by the Secretary; and

(b) include the following details about the manufacturing and research:

(i) the primary purpose of the manufacturing and research;

(ii) who benefits from the manufacturing and research;

(iii) how any products that may be developed as a result of the manufacturing and research will be used;

(iv) the source of the funds for the manufacturing and research;

(v) who owns or operates the manufacturing facilities in which the manufacturing and research are undertaken.

Matters to which the Secretary must have regard

(5) In making a decision under subsection (3) about manufacturing that a licence holder undertakes, the Secretary must have regard to the matters mentioned in paragraph (4)(b).

Other matters

(6) Subsection (5) does not limit the matters to which the Secretary may have regard in making a decision under subsection (3).

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54AB Classes of cannabis-related manufacture licences for the purposes of charge—licences granted on the basis of applications made on or after 1 November 2020

Application

(1) This section applies to a cannabis-related manufacture licence if the licence was granted on the basis of an application made on or after 1 November 2020.

Commercial cannabis-related manufacture licence

(2) For the purposes of paragraph 28(1)(e) of the Act, a cannabis-related manufacture licence to which this section applies is a ***commercial cannabis-related manufacture licence*** if, when granting the licence, the Secretary does not notify the applicant for the licence in accordance with subsection (3).

Non-commercial cannabis-related manufacture licence

(3) For the purposes of paragraph 28(1)(e) of the Act, a cannabis-related manufacture licence to which this section applies is a ***non-commercial cannabis-related manufacture licence*** if, when granting the licence, the Secretary notifies the applicant for the licence in writing that the Secretary is reasonably satisfied that the manufacturing that the applicant proposes to undertake under the licence will be undertaken:

(a) for research for non-commercial purposes; or

(b) primarily for research for non-commercial purposes.

Matters to which the Secretary must have regard

(4) In making a decision under subsection (3) about manufacturing that an applicant proposes to undertake, the Secretary must have regard to the matters mentioned in paragraph 35(2)(fa).

Other matters

(5) Subsection (4) does not limit the matters to which the Secretary may have regard in making a decision under subsection (3).

54B Payment of charge

(1) This section is for the purposes of subparagraph 28(1)(e)(i) of the Act.

(2) Charge payable on a licence is payable to the Secretary on behalf of the Commonwealth.

(3) An amount of charge payable on a licence is due and payable on the day specified in an invoice for the amount given to the holder of the licence by the Secretary.

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54C Recovery of charge

For the purposes of paragraph 28(1)(e) of the Act, an amount of charge that is due and payable:

(a) is a debt due to the Commonwealth; and

(b) may be recovered by the Secretary on behalf of the Commonwealth by action in a court of competent jurisdiction.

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Division 2—Other matters

55 Secretary to notify States and Territories of certain matters

For the purposes of subsection 25B(2) of the Act, the following matters are prescribed in relation to a licence or permit that relates to land or premises situated wholly or partly in a State or Territory:

(a) the granting of the licence or permit;

(b) the following details of the licence or permit:

(i) the name and contact details of the holder of the licence or permit;

(ii) details of the location and premises covered by the licence or permit;

(iii) the conditions of the licence (other than conditions that are specified in the Act);

(iv) the period during which the licence or permit is in force;

(c) a variation of the licence or permit;

(d) the suspension or revocation of the licence or permit;

(e) a proposal to suspend or revoke the licence or permit (including details of the day on which the licence or suspension is proposed to be suspended or revoked);

(f) the surrender of the licence or permit.

56 Modification of operation of Chapters 2 and 3 of the Act

For the purposes of paragraph 27(4)(g) of the Act:

(a) paragraph 8G(1)(a) of the Act does not apply if the applicant for the medicinal cannabis licence is an agency of a State or Territory; and

(b) paragraph 9F(1)(a) of the Act does not apply if the applicant for the cannabis research licence is an agency of a State or Territory; and

(c) paragraph 10K(1)(a) of the Act does not apply if the holder of the cannabis licence is an agency of a State or Territory; and

(d) paragraphs 10P(1)(b) and (c) of the Act do not apply if the holder of the cannabis licence is an agency of a State or Territory; and

(e) paragraph 11J(1)(a) of the Act does not apply if the applicant for the manufacture licence is an agency of a State or Territory; and

(f) paragraph 12N(1)(a) of the Act does not apply if the holder of the manufacture licence is an agency of a State or Territory; and

(g) paragraphs 13B(1)(b) and (c) of the Act do not apply if the holder of the manufacture licence is an agency of a State or Territory.

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Part 6—Application, saving and transitional provisions

57 Application provisions relating to the *Narcotic Drugs Amendment (Cannabis) Regulations 2018*

(1) The amendments of section 5 made by the *Narcotic Drugs Amendment (Cannabis) Regulations 2018* apply in relation to applications made under section 8E of the Act on or after the commencement of this section.

(2) Sections 7A and 7B, as inserted by the *Narcotic Drugs Amendment (Cannabis) Regulations 2018*, apply in relation to applications made under section 8E of the Act on or after the commencement of this section.

(3) The amendments of section 11 made by the *Narcotic Drugs Amendment (Cannabis) Regulations 2018* apply in relation to applications made under section 9D of the Act on or after the commencement of this section.

(4) Section 13A, as inserted by the *Narcotic Drugs Amendment (Cannabis) Regulations 2018*, applies in relation to applications made under section 9D of the Act on or after the commencement of this section.

(5) The amendments of sections 14 and 15 made by the *Narcotic Drugs Amendment (Cannabis) Regulations 2018* apply in relation to applications made under section 9N of the Act on or after the commencement of this section.

(6) The amendment of section 19 made by the *Narcotic Drugs Amendment (Cannabis) Regulations 2018* applies in relation to medicinal cannabis licences granted under the Act on or after the commencement of this section.

(7) Subsection 20(2), as added by the *Narcotic Drugs Amendment (Cannabis) Regulations 2018*, applies in relation to matters arising on or after the commencement of this section, whether the cannabis licences were granted under the Act before, on or after the commencement of this section.

(8) Subsection 28(6), as added by the *Narcotic Drugs Amendment (Cannabis) Regulations 2018*, applies in relation to notices given under subsection 28(1) on or after the commencement of this section.

(9) The amendments of sections 35 and 36 made by the *Narcotic Drugs Amendment (Cannabis) Regulations 2018* apply in relation to applications made under section 11G of the Act on or after the commencement of this section.

(10) Section 36A, as inserted by the *Narcotic Drugs Amendment (Cannabis) Regulations 2018*, applies in relation to applications made under section 11G of the Act on or after the commencement of this section.

(11) Section 37, as substituted by the *Narcotic Drugs Amendment (Cannabis) Regulations 2018*, applies in relation to applications made under section 11G of the Act on or after the commencement of this section.

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(12) The amendments of section 38 made by the *Narcotic Drugs Amendment (Cannabis) Regulations 2018* apply in relation to applications made under section 12 of the Act on or after the commencement of this section.

(13) Subsection 40(2), as added by the *Narcotic Drugs Amendment (Cannabis) Regulations 2018*, applies in relation to matters arising on or after the commencement of this section, whether the manufacture licences were granted under the Act before, on or after the commencement of this section.

(14) Subsection 46(6), as added by the *Narcotic Drugs Amendment (Cannabis) Regulations 2018*, applies in relation to notices given under subsection 46(1) on or after the commencement of this section.

(15) Section 56, as added by the *Narcotic Drugs Amendment (Cannabis) Regulations 2018*, applies in relation to:

(a) in the case of paragraphs 56(a), (b) and (e)—applications made on or after the commencement of this section; and

(b) in the case of paragraphs 56(c), (d), (f) and (g)—licences granted on or after the commencement of this section.

(16) The amendments of clause 1 of Schedule 1 made by the *Narcotic Drugs Amendment (Cannabis) Regulations 2018* apply in relation to applications made on or after the commencement of this section.

58 Application provisions relating to the *Narcotic Drugs Amendment (Review Recommendations) Regulations 2019*

Amendments etc. affecting applications for medicinal cannabis licences

(1) The amendments of sections 5 and 7B, and the repeal and substitution of section 7A, by the *Narcotic Drugs Amendment (Review Recommendations) Regulations 2019* apply in relation to applications for medicinal cannabis licences made on or after 1 January 2020.

Amendments affecting applications for medicinal cannabis permits

(2) The amendments of sections 8 and 9 by the *Narcotic Drugs Amendment (Review Recommendations) Regulations 2019* apply in relation to applications for medicinal cannabis permits made on or after 1 January 2020.

Amendments etc. affecting applications for cannabis research licences

(3) The amendments of section 11, and the repeal and substitution of section 13A, by the *Narcotic Drugs Amendment (Review Recommendations) Regulations 2019* apply in relation to applications for cannabis research licences made on or after 1 January 2020.

Amendments etc. affecting applications for cannabis research permits

(4) The amendments of sections 14 and 17, and the repeal of section 15, by the *Narcotic Drugs Amendment (Review Recommendations) Regulations 2019* apply

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in relation to applications for cannabis research permits made on or after 1 January 2020.

Amendments affecting conditions on medicinal cannabis licences

(5) The amendments of section 19 by the *Narcotic Drugs Amendment (Review Recommendations) Regulations 2019* apply in relation to medicinal cannabis licences granted on or after 1 January 2020.

Amendments affecting surrender of cannabis licences and permits

(6) The amendments of section 34 by the *Narcotic Drugs Amendment (Review Recommendations) Regulations 2019* apply in relation to notices, of surrender of cannabis licences or cannabis permits, given on or after 1 January 2020.

Amendments etc. affecting applications for manufacture licences

(7) The amendments of sections 35 and 37, and the repeal and substitution of section 36A, by the *Narcotic Drugs Amendment (Review Recommendations) Regulations 2019* apply in relation to applications for manufacture licences made on or after 1 January 2020.

Amendments affecting surrender of manufacture licences and permits

(8) The amendments of section 51 by the *Narcotic Drugs Amendment (Review Recommendations) Regulations 2019* apply in relation to notices, of surrender of manufacture licences or manufacture permits, given on or after 1 January 2020.

59 Application provisions relating to the *Narcotic Drugs Amendment (Fees) Regulations 2020*

(1) The repeal of section 53, and the amendment of Schedule 1, by the *Narcotic Drugs Amendment (Fees) Regulations 2020* apply in relation to applications made on or after 15 July 2020.

(2) The amendment of subsection 54(1) made by the *Narcotic Drugs Amendment (Fees) Regulations 2020* applies to inspections started on or after 15 July 2020.

(3) The repeal and substitution of section 54B by the *Narcotic Drugs Amendment (Fees) Regulations 2020* applies to charge on a licence in force on or after 15 July 2020.

(4) The amendment of section 54C by the *Narcotic Drugs Amendment (Fees) Regulations 2020* applies to charge on a licence in force on or after 15 July 2020.

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Section 60

60 Application provisions relating to the Narcotic Drugs Amendment (Cannabis-Related Manufacture Licences and Permits) Regulations 2020

(1) The amendment of section 35 by the *Narcotic Drugs Amendment (Cannabis-Related Manufacture Licences and Permits) Regulations 2020* applies in relation to applications made on or after 1 November 2020.

(2) Sections 36AA, 38A and 43A apply in relation to applications made on or after 1 November 2020.

(3) The amendments of Schedule 1 by the *Narcotic Drugs Amendment (Cannabis-Related Manufacture Licences and Permits) Regulations 2020* apply in relation to applications made on or after 1 November 2020.

61 Application provisions relating to the *Narcotic Drugs Amendment (Fees) Regulations 2021*

(1) The amendment of subsection 54(1) by the *Narcotic Drugs Amendment (Fees) Regulations 2021* applies to inspections started on or after 1 July 2021.

(2) The amendments of clause 1 of Schedule 1 by the *Narcotic Drugs Amendment (Fees) Regulations 2021* apply in relation to applications made on or after 1 July 2021.

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Schedule 1—Application fees

Note: See sections 7, 10, 13, 16, 24, 36AA, 38A and 43A.

1 Table of application fees

The following table specifies application fees for applications specified in the table.

Application fees

Item	Column 1 Application	Column 2 Fee ($)
1	Application for a cannabis-related licence, except an application covered by item 2 or 3	8,030
2	Applications made at the same time for: (a) a medicinal cannabis licence and a cannabis research licence; or (b) a medicinal cannabis licence and a cannabis-related manufacture licence; or (c) a cannabis research licence and a cannabis-related manufacture licence; that are to authorise activities at the same licensed premises	8,650 (total for both applications)
3	Applications made at the same time for: (a) a medicinal cannabis licence; and (b) a cannabis research licence; and (c) a cannabis-related manufacture licence; that are to authorise activities at the same licensed premises	9,320 (total for all applications)
4	Application for a cannabis-related permit	3,440
5	Application for a variation of a cannabis-related licence that is a simple application according to the variation application classification document	1,100
6	Application for a variation of a cannabis-related licence other than an application described in item 5	5,500
7	Application for a variation of a cannabis-related permit that is a simple application according to the variation application classification document	120
8	Application for a variation of a cannabis-related permit other than an application described in item 7	2,900

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Endnotes

Endnote 1—About the endnotes

The endnotes provide information about this compilation and the compiled law.

The following endnotes are included in every compilation:

Endnote 1—About the endnotes
Endnote 2—Abbreviation key
Endnote 3—Legislation history
Endnote 4—Amendment history

Abbreviation key—Endnote 2
The abbreviation key sets out abbreviations that may be used in the endnotes.

Legislation history and amendment history—Endnotes 3 and 4
Amending laws are annotated in the legislation history and amendment history.

The legislation history in endnote 3 provides information about each law that has amended (or will amend) the compiled law. The information includes commencement details for amending laws and details of any application, saving or transitional provisions that are not included in this compilation.

The amendment history in endnote 4 provides information about amendments at the provision (generally section or equivalent) level. It also includes information about any provision of the compiled law that has been repealed in accordance with a provision of the law.

Editorial changes
The *Legislation Act 2003* authorises First Parliamentary Counsel to make editorial and presentational changes to a compiled law in preparing a compilation of the law for registration. The changes must not change the effect of the law. Editorial changes take effect from the compilation registration date.

If the compilation includes editorial changes, the endnotes include a brief outline of the changes in general terms. Full details of any changes can be obtained from the Office of Parliamentary Counsel.

Misdescribed amendments
A misdescribed amendment is an amendment that does not accurately describe the amendment to be made. If, despite the misdescription, the amendment can be given effect as intended, the amendment is incorporated into the compiled law and the abbreviation "(md)" added to the details of the amendment included in the amendment history.

If a misdescribed amendment cannot be given effect as intended, the abbreviation "(md not incorp)" is added to the details of the amendment included in the amendment history.

Endnote 2—Abbreviation key

ad = added or inserted

am = amended

amdt = amendment

c = clause(s)

C[x] = Compilation No. x

Ch = Chapter(s)

def = definition(s)

Dict = Dictionary

disallowed = disallowed by Parliament

Div = Division(s)

ed = editorial change

exp = expires/expired or ceases/ceased to have effect

F = Federal Register of Legislation

gaz = gazette

LA = *Legislation Act 2003*

LIA = *Legislative Instruments Act 2003*

(md) = misdescribed amendment can be given effect

(md not incorp) = misdescribed amendment cannot be given effect

mod = modified/modification

No. = Number(s)

o = order(s)

Ord = Ordinance

orig = original

par = paragraph(s)/subparagraph(s) /sub-subparagraph(s)

pres = present

prev = previous

(prev…) = previously

Pt = Part(s)

r = regulation(s)/rule(s)

reloc = relocated

renum = renumbered

rep = repealed

rs = repealed and substituted

s = section(s)/subsection(s)

Sch = Schedule(s)

Sdiv = Subdivision(s)

SLI = Select Legislative Instrument

SR = Statutory Rules

Sub-Ch = Sub-Chapter(s)

SubPt = Subpart(s)

underlining = whole or part not commenced or to be commenced

Endnote 3—Legislation history

Name	Registration	Commencement	Application, saving and transitional provisions
Narcotic Drugs Regulation 2016	14 Oct 2016 (F2016L01613)	29 Oct 2016 (s 2(1) item 1)	
Narcotic Drugs Amendment (Licence Charges) Regulation 2016	9 Dec 2016 (F2016L01894)	10 Dec 2016 (s 2(1) item 1)	—
Narcotic Drugs Amendment (Cannabis) Regulations 2018	13 Feb 2018 (F2018L00106)	14 Feb 2018 (s 2(1) item 1)	—
Narcotic Drugs Amendment (Review Recommendations) Regulations 2019	20 Nov 2019 (F2019L01485)	1 Jan 2020 (s 2(1) item 1)	—
Narcotic Drugs Amendment (Fees) Regulations 2020	10 July 2020 (F2020L00904)	15 July 2020 (s 2(1) item 1)	—
Narcotic Drugs Amendment (Cannabis-Related Manufacture Licences and Permits) Regulations 2020	20 Oct 2020 (F2020L01328)	1 Nov 2020 (s 2(1) item 1)	—
Narcotic Drugs Amendment (Fees) Regulations 2021	15 June 2021 (F2021L00757)	1 July 2021 (s 2(1) item 1)	—

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Endnote 4—Amendment history

Provision affected	How affected
Part 1	
s 2	rep LA s 48D
s 4	am F2019L01485; F2020L00904; F2020L01328
s 4A	ad F2018L00106
	am F2019L01485
Part 2	
Division 1	
s 5	am F2018L00106; F2019L01485
s 7A	ad F2018L00106
	rs F2019L01485
s 7B	ad F2018L00106
	am F2019L01485
s 8	am F2019L01485
s 9	am F2019L01485
Division 2	
s 11	am F2016L01894; F2018L00106; F2019L01485
s 13A	ad F2018L00106
	rs F2019L01485
s 14	am F2018L00106; F2019L01485
s 15	am F2018L00106
	rep F2019L01485
s 17	am F2019L01485
Division 3	
s 19	am F2018L00106; F2019L01485
s 20	am F2018L00106
Division 4	
Subdivision B	
s 28	am F2018L00106
Subdivision C	
s 34	am F2019L01485
Part 3	
Division 1	
s 35	am F2018L00106; F2019L01485; F2020L01328
s 36	am F2018L00106
s 36AA	ad F2020L01328
s 36A	ad F2018L00106

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Endnote 4—Amendment history

Provision affected	How affected
	rs F2019L01485
s 37	rs F2018L00106
	am F2019L01485
s 38	am F2018L00106
s 38A	ad F2020L01328
Division 2	
s 40	am F2018L00106
Division 3	
Subdivision A	
s 43A	ad F2020L01328
Subdivision B	
s 46	am F2018L00106
Subdivision C	
s 51	am F2019L01485
Part 4	
s 52	am F2016L01894; F2020L01328
Part 5	
Division 1	
Division 1 heading	rs F2020L00904
s 53	rep F2020L00904
s 54	am F2020L00904; F2021L00757
Division 1A	
Division 1A	ad F2016L01894
s 54A	ad F2016L01894
s 54AA	ad F2020L01328
s 54AB	ad F2020L01328
s 54B	ad F2016L01894
	rs F2020L00904
s 54C	ad F2016L01894
	am F2020L00904
Division 2	
s 56	ad F2018L00106
Part 6	
Part 6	ad F2018L00106
s 57	ad F2018L00106
s 58	ad F2019L01485
s 59	ad F2020L00904
s 60	ad F2020L01328

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Endnote 4—Amendment history

Provision affected	How affected
s 61	ad F2021L00757
Schedule 1	
Schedule 1 heading.....	am F2020L00904
Schedule 1	am F2018L00106; F2020L00904; F2020L01328; F2021L00757