



Australian Government

Department of Health

Office of Drug Control

Manufacture Licence ML040/19

I, Darren Jones, delegate of the Secretary of the Department of Health for the purposes of section 11H of the *Narcotic Drugs Act 1967* (the Act), hereby grant iX Syrinx (the licence holder) a manufacture licence to undertake the authorised activities, for the specified period, at the specified premises (the licensed premises), for the specified drugs. This licence is subject to the requirements and conditions of the *Narcotic Drugs Act 1967*, the *Narcotic Drugs Regulation 2016* (the Regulation) and conditions specified in Schedule 1 and Schedule 2 of this licence.

- Licence holder:** iX Syrinx
- ABN:** 20 149 728 825
- Licence period:** Valid from 2 December 2019 to 2 December 2020 inclusive
- Licensed premises:** 110 Merrindale Drive
Croydon South, VIC, 3136
- Specified drugs:** Extracts and tinctures of cannabis and cannabis resin
- Activities authorised:** This licence authorises the licence holder to undertake the following activities in specified areas of the licensed premises as provided for in the site plan lodged with the application.
- a) the manufacture of a drug in accordance with one or more manufacture permits;
 - b) activities relating to such manufacture, including but not limited to the following (as applicable):
 - i. the supply of the drug;
 - ii. the packaging, transport, storage, possession and control of the drug;
 - iii. the disposal or destruction of the drug.

These activities are only authorised to the extent prescribed in one or more valid manufacture permits, issued by the Office of Drug Control, held by the licence holder for the licensed premises.



Australian Government

Department of Health

Office of Drug Control

Manufacture Licence ML040/19

Persons authorised to engage in activities under this licence within the specified licensed premises

Name
Albert Ho
Melissa Gan
Dr Janakan Krishnarajah

Note that other persons may undertake the authorised activities if they are employed or engaged under the processes provided by the licence holder to the Office of Drug Control, and that such employment or engagement complies with the condition of a manufacture licence that the licence holder employ or engage suitable staff, as prescribed in the circumstances under section 12H of the Act and section 39 of the Regulation.

Directions in relation to destruction

The Secretary may, in accordance with section 15 of the Act, require the destruction of, or other dealings with, cannabis, cannabis resin, drugs or narcotic preparations in the possession of, or under the control of, the licence holder or a previous licence holder.

Supply of medicinal cannabis products

Medicinal cannabis products manufactured under this licence must only be:

- supplied for the purposes of use in a clinical trial that is, or is likely to be, approved under the *Therapeutic Goods Act 1989* or notified to the Secretary under that Act; or
- otherwise supplied in accordance with an approval or authority under the *Therapeutic Goods Act 1989*; or
- supplied in circumstances prescribed by the regulations; or
- supplied as registered goods within the meaning of the *Therapeutic Goods Act 1989*.

Dated this 2day of December 2019

Darren Jones
Delegate of the Secretary of the Department of Health



Australian Government

Department of Health

Office of Drug Control

Manufacture Licence ML040/19

Schedule 1 - Statutory Conditions

Conditions of manufacture licences under Chapter 3, Part 2, Division 2 of the Act

1. Condition that manufacture licence holder inform people of obligations

- (1) It is a condition of a manufacture licence that the licence holder inform any person authorised by the licence to engage in the manufacture of drugs, or activities related to such manufacture, of the following:
 - a) each condition that is relevant to that person, including each variation or revocation of such a condition;
 - b) the revocation of the licence and of any permit that relates to the licence and is relevant to the person;
 - c) the giving of one or more directions in relation to the licence under Part 3 of Chapter 5.
- (2) Requirements in relation to the manner in which information is provided under subsection (1) may be:
 - a) prescribed by the regulations; or
 - b) specified by the Secretary.
- (3) A reference in subsection (1) to a licence holder or a person authorised under a manufacture licence is, in the case of revocation of the licence, taken to be a reference to the person who was the licence holder, or was so authorised, immediately before that revocation.

2. Condition that manufacture licence holder employ or engage suitable staff

- (1) It is a condition of a manufacture licence that the licence holder take all reasonable steps not to employ or engage a person to carry out activities authorised by the licence if:
 - a) the person is aged under 18 years; or
 - b) the person has been convicted of a serious offence during the period of 5 years before the employment or engagement; or
 - c) the person is taken not to be suitable to carry out activities authorised by a manufacture licence under regulations made for the purposes of subsection (2); or
 - d) the person is included in a class of persons prescribed by the regulations for the purposes of this paragraph.
- (2) The regulations may prescribe circumstances in which a person is taken not to be suitable to carry out activities authorised by a manufacture licence, including but not limited to circumstances relating to the following:
 - a) a person's criminal record;
 - b) a person's employment history.

Note: Section 39 of the Regulation is a prescribed circumstance for the purpose of this condition. See condition 8 of this document.



Australian Government

Department of Health

Office of Drug Control

Manufacture Licence ML040/19

3. Condition that manufacture of drugs is in accordance with a manufacture permit

It is a condition of a manufacture licence that the licence holder, and other persons authorised by the licence to manufacture a drug, do so in accordance with a manufacture permit.

4. Condition about monitoring and inspection

It is a condition of a manufacture licence that, if a person is authorised by the licence:

- a) to manufacture a drug; or
- b) to engage in activities related to such manufacture;

the person allow the Secretary, or a person authorised by the Secretary, to:

- a) enter the premises at which the person is present and where the manufacture or activity is being undertaken, for the purposes of the following:
 - b) inspecting or monitoring the manufacture or activity;
 - c) checking whether the manufacture or activity is being carried out as authorised by the licence in accordance with a manufacture permit, and whether licence conditions are being complied with; and
 - d) take samples of any thing at such premises and remove and test such samples.

5. Condition for manufacture licences authorising manufacture of drugs that are medicinal cannabis products

It is a condition of a manufacture licence that authorises the manufacture of one or more drugs that are medicinal cannabis products that the licence holder does not supply the medicinal cannabis products other than as mentioned in paragraph 11K(2)(b) or (c).

6. Condition for manufacture licences authorising manufacture for medicinal cannabis research

It is a condition of a manufacture licence that authorises the manufacture of one or more drugs for the purposes of research in relation to medicinal cannabis products that the manufacture of those drugs is undertaken solely for those purposes.

7. Condition that licence holder notify the Secretary of certain matters

- (1) It is a condition of a manufacture licence that the licence holder notify the Secretary if any of the following matters comes to the attention of the licence holder:
 - a) a matter that may affect whether the licence holder is a fit and proper person to hold the licence, or whether a business associate of the licence holder (in relation to a business relating to the licence or in relation to any other business) is a fit and proper person to be associated with the holder of such a licence;
 - b) a breach of the licence;
 - c) any other matter that may require or permit the Secretary to revoke the licence;
 - d) any other matter prescribed by the regulations.

Note 1: Section 40 of the Regulation is a prescribed circumstance for the purpose of this condition. See condition 9 of this document.

Note 2: Section 24B of the Act deals with the privilege against self-incrimination.



Australian Government

Department of Health

Office of Drug Control

Manufacture Licence ML040/19

- (2) The licence holder must notify the Secretary of a matter referred to in subsection (1):
 - a) if the regulations prescribe a period within which the matter must be notified to the Secretary—before the end of that period; or
 - b) otherwise—as soon as reasonably practicable after the matter comes to the attention of the licence holder.

Conditions of manufacture licences under Part 3, Division 2 of the Regulation

8. 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.

9. 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;



Australian Government

Department of Health

Office of Drug Control

Manufacture Licence ML040/19

- 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;
 - 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.



Australian Government

Department of Health

Office of Drug Control

Manufacture Licence ML040/19

Schedule 2 - Imposed Conditions

As a delegate of the Secretary under section 11L of the *Narcotic Drugs Act 1967*, I impose the following additional conditions to this manufacture licence:

1. The licence holder must nominate to the Commonwealth a responsible person, and deputies, who can act on behalf of the licence holder for matters required by the Commonwealth to be complied with by the licence holder under this manufacture licence and the Act, including for notification and requests for information by the Secretary or his delegate. The address and contact numbers of those persons must be provided to the Commonwealth prior to commencing any authorised activity under this manufacture licence. Any changes to those nominated persons must be notified in writing to the Commonwealth as soon as possible, prior to the commencement of the employment of the new person(s).
2. The licence holder must ensure that contractors engaged in relation to other authorised activities have the appropriate skills, qualifications, approvals and resources to ensure the security of cannabis, cannabis resin, drugs and narcotic preparations while undertaking other authorised activities.
3. The licence holder must satisfy the Secretary, prior to engaging a contractor for the purpose of conducting other authorised activities, that the contractor has met the same suitability criteria applied to staff under Condition 2, Schedule 1 of this licence.
4. Before the end of each calendar month, the licence holder must provide a report to the Commonwealth detailing all authorised activities in the previous month in a format approved by the Office of Drug Control on behalf of the Commonwealth.
5. The licence holder must provide written reports or information to the Commonwealth that the Commonwealth may reasonably require in relation to the authorised activities. The report or required information must be provided within 20 business days after the written request, unless the request specifies an earlier date.
6. The licence holder must comply with any written direction by the Commonwealth requiring the licence holder to take specified measures or other arrangements in relation to authorised activities in the manufacture licence.
7. The licence holder must maintain at all times a system of security measures that incorporates all reasonably practicable steps to prevent illegal or unauthorised removal from the licensed premises of cannabis, cannabis resin, drugs or narcotic preparations.
8. The licence holder must operate in accordance with the risk management plan supplied to the Commonwealth at all times.



Australian Government

Department of Health

Office of Drug Control

Manufacture Licence ML040/19

9. The licence holder must notify the Commonwealth within one working day of becoming aware of any serious incident involving starting material, drugs or narcotic preparations, including but not limited to unauthorised destruction of starting material, drugs or narcotic preparations, occurring at the licensed premises, or during the conduct of authorised activities including, but not limited to, manufacture, packaging, transport, storage, possession, testing, and control of cannabis, cannabis resin, starting material, drugs, or narcotic preparations.
10. The licence holder must notify local law enforcement immediately on becoming aware of:
 - 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;
 - 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;
11. The licence holder must cooperate with any investigation undertaken by any State or Commonwealth authority into any matters relevant to the licensed premises and/or authorised activities, including but not limited to those matters specified in Condition 10 of Schedule 2 of this licence.
12. The licence holder must advise the Commonwealth and provide details within 20 business days of its receipt of any security audit or other report relating to the licensed premises, location or facilities that contain an adverse finding, or recommendation, relating to security matters, and shall simultaneously provide a written plan of action to the Commonwealth to address those findings or recommendations.
13. The licence holder must notify the Commonwealth within 14 business days of any government department or authority making inquiries of the licence holder relating to a suspected or possible breach of any condition imposed on an authorisation or licence issued under any legislation in force in Australia.



Australian Government

Department of Health

Office of Drug Control

Manufacture Licence ML040/19

14. The licence holder must destroy all unused cannabis, cannabis resin, starting material, drugs, or narcotic preparations as soon as reasonably possible, so as not to create a stockpile for which there is no authorised end use.
15. Prior to commencing manufacture of the specified drugs under this manufacture licence and at all times while it manufactures those drugs, the licence holder must hold all authorisations or licences required under Victorian legislation in relation to the manufacture, possession and supply of the specified drugs at the licensed premises. A copy of all such authorisations and licences must be provided to the Commonwealth prior to commencing manufacture of the specified drugs. The licence holder shall inform the Commonwealth within 7 days if it ceases to hold any authorisation or licence required under Victorian legislation.
16. The licence holder must in relation to the manufacture of the specified drugs and in the management of the licensed premises, comply with any condition applied under any licence or approval issued under any Victorian legislation.
17. The licence holder must maintain a relationship with local emergency services, including advising police of the authorised activities conducted at the site, and fire emergency services of the likely hazardous nature of the substances held at the site.
18. The above conditions must be complied with in line with the standard operating procedures and security details lodged by the licence holder to the Office of Drug Control.
 - a) Subject to paragraphs i) and ii), no modification to the standard operating procedures and security details must be made and implemented by the licence holder in carrying out the activities authorised in the licence without liaising with the Office of Drug Control to determine if the proposed modification is:
 - minor in nature and requires only a written notification to the Office of Drug Control, describing details of the changes and when such changes will be implemented, or
 - substantial in nature and may require a variation of the licence.
19. Interpretation
 - a) 'the Act' means the Narcotic Drugs Act 1967
 - b) 'cannabis' has the same meaning as the Act
 - c) 'cannabis resin' has the same meaning as the Act
 - d) 'cannabis plant' has the same meaning as the Act
 - e) 'drug' has the same meaning as the Act
 - f) 'licence holder' means the holder of a manufacture licence
 - g) 'licensed premises' has the same meaning as the Act
 - h) 'manufacture' has the same meaning as the Act
 - i) 'manufacture licence' has the same meaning as the Act



Australian Government

Department of Health

Office of Drug Control

Manufacture Licence ML040/19

- j) 'starting material' means any or all cannabis, cannabis resin, cannabis plant material or drug to be used in manufacture
- k) 'the Commonwealth' means the Department of Health on behalf of the Commonwealth, and notice may be given to the Commonwealth by notifying, advising or informing the Director, Drug Control Section, Department of Health
- l) 'security details' means:
 - i. arrangements in place to control all persons entering the licensed premises and areas where authorised activities are conducted (including storage of drugs and starting materials used in the manufacture of drugs)
 - ii. arrangements in place to prevent unauthorised access to the licensed premises and areas where authorised activities are conducted
 - iii. equipment (such as visual monitoring equipment, visual recording devices and intrusion detection systems) and any other arrangements that will be used to monitor, detect and prevent unauthorised access to the licensed premises and areas where authorised activities are conducted.
 - iv. floor plans
 - v. site plans
 - vi. risk management plans

Dated this 2 day of December 2019

A handwritten signature in blue ink, appearing to read 'D. Jones'.

Darren Jones
Delegate of the Secretary of the Department of Health