

Application for a Licence to Manufacture or Supply Drugs of Addiction

(Poisons and Therapeutic Goods Act 1966 and Poisons and Therapeutic Goods Regulation 2008)



When to use this form

This form is for applicants who wish to apply for a licence to manufacture or supply drugs of addiction.

If you are applying for a licence to manufacture or supply a cannabis medicine, you must complete and submit the Supplementary Pages with this application. Before you apply for this licence you must undertake some assessment of the product to ensure you are able to satisfy your obligations under State and Commonwealth laws. The Supplementary Pages can be found at <https://www.health.nsw.gov.au/pharmaceutical/licences/Pages/app-forms-licences-ptga.aspx>.

Approval process

The approval process will take up to four weeks from the date the NSW Ministry of Health receives the completed application. This includes the time taken for assessment, interviews and inspection if required. An application for a licence to manufacture or supply drugs of addiction can be refused if the Secretary, NSW Health is of the opinion that the applicant is not a fit and proper person to hold the licence or that the premises are not appropriate for the manufacture or supply by wholesale drugs of addiction.

Where an applicant submits an incomplete application or is required to produce further documentation the approval process will be delayed. More information about the approval process including the timeframes for the different phases of the process can be found on the "Processing times" page of the website.

<https://www.health.nsw.gov.au/pharmaceutical/licences/Pages/timeframe-drug-licence.aspx>

After submission of the completed form the applicant will be provided with a written acknowledgement of the application. The acknowledgement may include a request for omitted or incomplete documents if required. Once all documents have been received assessment of the application will take place and a recommendation will be made to either grant or refuse the application. If the recommendation approves granting the licence, the licence will be issued to the applicant. If the recommendation is to refuse the licence the reasons for the refusal will be provided to the applicant.

Payment

The prescribed application fee (non-refundable) for a licence to manufacture or to supply drugs of addiction is \$765.

Payment is to be made online at NSW Ministry of Health payment portal www.health.nsw.gov.au/payments/Pages/default.aspx

Submitting the application

Please email the completed application form together with the required documents (including Supplementary Pages, if applicable) and a copy of the payment receipt to MOH-PharmaceuticalLicensing@health.nsw.gov.au.

Notes

- The application and documents submitted will not be accepted with electronic signatures.
- The applicant is required to retain the original documents.

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SECTION A – Applicant details

Full name of company making the application: _____

Business address: _____

Suburb: _____ State: _____ Postcode: _____

Details of the contact person: _____

Full Name: _____ Position: _____

Postal address: _____

Suburb: _____ State: _____ Postcode: _____

Phone: _____ Email: _____

SECTION B – Details of premises that will be used for manufacture or supply by wholesale drugs of addiction

Premises name: _____

Business address: _____

Suburb: _____ State: _____ Postcode: _____

SECTION C – Substances to which this application relates

Provide details of the substances that will be manufactured or supplied by wholesale.

Is the substance to be manufactured or supply a cannabis medicine? Please the relevant box **Yes** **No**

If you intend to manufacture or supply a cannabis medicine then you are also required to complete the [Supplementary Pages Application Form](#).

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SECTION D – Documents and information to include with this application

1. In the case of application by a corporation, a full company extract (certificate of incorporation) obtained from the Australian Securities and Investment Commission (ASIC) is required that shows the following:
 - a. the address of the registered office of the corporation; and
 - b. the full name, date and place of birth, residential address and position of:
 - i. each current director of the corporation,
 - ii. the principal executive officer of the corporation,
 - iii. the secretary or, if there is more than one, each secretary of the corporation.

2. Statutory Declaration Form completed by each person who is an applicant or each officer of the organisation (as defined under the *Corporations Act 2001*) applying for this licence. Please ensure that all sections of the Form are completed and strike out and initial where not applicable.

3. Fitness and Probity Check Form completed by each person who is an applicant or each officer of the organisation (as defined under the *Corporations Act 2001*) applying for this licence.

4. National Criminal Record Check (NCRC) in the form of a National Police Certificate (NPC) for each person who is an applicant or each officer of the organisation (as defined under the *Corporations Act 2001*) applying for this licence.

An NPC issued within the last three years together with a declaration signed by the person stating that they have not been charged or convicted of any offences since the date of NPC. An NCRC can be obtained through:

- Australian Criminal Intelligence Commission if you do more than 500 checks per three years (www.acic.gov.au), or
- NSW Business Link, or
- NSW Police if you do more than 150 checks per annum, or
- Any other accredited agencies or private brokers
- Individuals can also apply through NSW Police, other state police services or the Australian Federal Police for an NPC.

5. A copy of the certificate of registration of business name from ASIC.

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SECTION E – Declaration by applicant or agent on behalf of applicant

If signing on behalf of the applicant please state in what capacity.

I declare that all the information I have given on this application form is true to the best of my knowledge and belief.

I enclose a copy of the payment receipt for the licence application fee.

Privacy Statement: I understand that NSW Health may provide any or all of the contents of this application and information provided with it, including personal information as defined in the *Privacy and Personal Information Protection Act 1988*, to law enforcement and regulatory agencies in the Commonwealth, States and Territories as necessary, in order to ensure compliance with all laws and regulations.

Print name: _____ Position: _____

Signature: _____ **Print and Sign** Date: _____ (dd/mm/yyyy)

Payment details:

Payment of the licence application fee to be made online at the NSW Ministry of Health payment portal www.health.nsw.gov.au/payments/Pages/default.aspx.

Submitting the application:

Please email the completed application form together with the required documents (including Supplementary Pages, if applicable) and a copy of the payment receipt to MOH-PharmaceuticalLicensing@health.nsw.gov.au.