

Application for a Licence to Manufacture and Supply by Wholesale, 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 (individuals or companies) who wish to apply for a licence to manufacture and supply by wholesale, drugs of addiction. If you wish to renew or amend an existing licence or apply for a licence to supply drugs of addiction you should use another form.

Approval process

The approval process will take up to thirteen 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 and or supply drugs of addiction can be refused if the **Secretary** 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 and or supply of 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 is available on the website.

After submission of the completed form the applicant will be provided with a written acknowledgement of the application. The acknowledgement will 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 licence fee to manufacture and supply by wholesale drugs of addiction is \$624 for all applicants.

Payment can be made by EFT, see EFT form for details, or cheque made payable to NSW Ministry of Health. If paying by EFT on date of payment please send email as requested on the EFT form. Cheques should be included with the completed form. Please return the completed form together with the required documents to the address as below.

**Private Health Care Unit
Legal and Regulatory Services
NSW Ministry of Health
Locked Mail Bag 961
NORTH SYDNEY NSW 2059**

Application for a Licence to Manufacture and Supply by Wholesale, Drugs of Addiction

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

SECTION A

Applicant details			
Full name of applicant: (Individual person or corporation)			
Postal address:			
Suburb:	State:	Postcode:	
Details of the contact person (contact person on behalf of the applicant and in what capacity)			
Full name:		Position:	
Address:			
Suburb:	State:	Postcode:	
Phone:	Fax:	Email:	

SECTION B

Details of premises that will be used for manufacture, or supply by wholesale, drugs of addiction		
Premises name:		
Address:		
Suburb:	State:	Postcode:

SECTION C

Substances to which this application relates
List Names of Substances:

SECTION D

Documents and information to include with this application
<p>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:</p> <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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 the NPC. An NCRC can be obtained through:
 - CrimTrac if you do more than 500 checks per three years (www.crimtrac.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, which you can find by searching the internet or referring to CrimTrac's list of accredited brokers at www.crimtrac.gov.au/documents/AccreditedAgenciesListforCrimTracwebsite.pdf
 Individuals can also apply through NSW Police, other state police services or the Australian Federal Police for an NPC.
7. A copy of the certificate of registration of business name.

SECTION E

Declaration by applicant or agent on behalf of applicant	
<p>If signing on behalf of the applicant please state in what capacity.</p> <p>I declare that all the information I have given on this application form is true to the best of my knowledge and belief.</p> <p>I enclose the prescribed licence application fee for Manufacture and Supply by Wholesale, Drugs of addiction.</p>	
Print Name:	Position:
Signature:	Date:

Please return the completed form together with the required documents as listed in Section D to the address as below. If paying by EFT on date of payment please send email as requested in EFT letter. Cheques should be included with the completed form.

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