Application form – Manufacturing licence (medicines) – Initial application

August 2022

Information about this application form

This application form is to be used to apply for a licence to **manufacture medicines** and prohibited substances for therapeutic purposes under section 75 of the *Medicines and Poisons Act 2019* (**MPA**).

Medicines are schedule 2, 3, 4 and 8 substances as listed in the Commonwealth *Poisons Standard* (section 11 of the MPA). Prohibited substances are those listed in schedules 9 and 10 of the Poisons Standard (section 13 of the MPA).

To manufacture poisons or prohibited substances for non-therapeutic use, please complete the form Application for a manufacturing licence – poisons.

Commonwealth licence holders

Persons who hold an authority to manufacture regulated substances granted under a Commonwealth law (e.g. a licence from the Therapeutic Goods Administration, the Office of Drug Control or the Australian Pesticides and Veterinary Medicines Authority) **do not** require a manufacturing licence under the MPA to manufacture the same substances at the same place within the same conditions.

'Commonwealth law manufacturers' (defined in schedule 14, part 1 of the *Medicines and Poisons (Medicines) Regulation 2021* (**MPMR**)) are authorised to possess, and supply by wholesale, the regulated substances they manufacture at the authorised site under schedule 14 of the MPMR. Any activity beyond this will likely require a manufacturing or wholesaling licence under the MPA from Queensland Health. Check with Healthcare Approvals and Regulation Unit (HARU) via medicines.applications@health.qld.gov.au if you are unsure.

Scope of a manufacturing licence

The holder of a substance authority, including a person acting under a substance authority, is authorised to carry out a regulated activity with a regulated substance in the authorised way (section 31 of the MPA). A *manufacturing licence* is a type of substance authority that may be granted under the MPA (section 61 of the MPA).

A manufacturing licence authorises the licence holder (including persons stated in the licence to be acting for the licence holder) to carry out the following regulated activities with the regulated substances stated in the licence (section 63 of the MPA):

1. Manufacture of the substances stated in the licence at the places stated in the licence.

2. Possession of the substances at the premises stated in the licence.
3. Possession of the substances for transportation to a place where a person is authorised, or where it is not unlawful for a person, to possess the substances.
4. Supply of the substances by wholesale to:
    a. if the licence states a class of persons to whom the substances may be supplied - a person who is a member of the class; or
    b. otherwise - a person who is authorised, or for whom it is not unlawful, to carry out a regulated activity with the substances.
5. Disposal of waste from the substances.
6. If stated in the licence, the buying and possession of other stated substances for manufacturing the substances to be manufactured under the licence (the final product).
7. If stated in the licence, the manufacture and disposal of waste from, another stated substance that is a by-product of the manufacture of the final product.

Authorised way – section 31 of the MPA

All substance authorities are subject to the requirements and standard conditions specified in the relevant regulation, in this case the MPMR, that applies to that type of substance authority, and any additional or varied conditions specified on the substance authority. These conditions may limit or specify how the regulated activities must be carried out.

Any person carrying out a regulated activity with a regulated substance must do so in the authorised way and a person to whom a substance authority applies must comply with the conditions of the authority. Failure to comply with these requirements may result in regulatory action being taken, including prosecution, which may attract a significant penalty.

Requirements and standard conditions for manufacturing licences

There are requirements and standard conditions that apply to all manufacturing licences, as well as particular requirements and standard conditions that apply to manufacturers of medicated feed and particular requirements for manufacturers of medicines other than medicated feed.

Unless stated otherwise in the licence, the following requirements and standard conditions described in sections 70 and 91 of the MPA and specified in the following chapters of the MPMR, apply to manufacturing licences:

- chapter 3 of the MPMR ‘Standard conditions for substance authorities’ – part 2 ‘Manufacturing licences’ and part 6 ‘All substance authorities’
- chapter 4 of the MPMR ‘General requirements for dealings’ – part 3 ‘Buying by giving purchase orders’, part 4 ‘Supplying stock’, part 5 ‘Possessing stock for delivery’ and part 11 ‘Disposing of waste from diversion-risk medicines’
- chapter 5 of the MPMR ‘Special requirements for dealings’ – part 5 ‘Wholesale representatives’ and
- chapter 8 of the MPMR ‘Offences’ – part 2 ‘Secure storage systems’, part 4 ‘Recording and keeping information’, and part 5 ‘Reporting particular matters’.

All manufacturers

1. The licence holder must appoint an appropriately qualified person(s) to supervise manufacturing under the licence and take all reasonable steps to ensure medicines are manufactured under the supervision of that person (s20 of the MPMR).
2. The licence holder must take reasonable steps to ensure the medicines manufactured are fit for their intended use and free from contamination – a licence holder meets this condition if the licence holder complies with a code, guideline, standard or quality assurance scheme that is recognised for promoting best practice in the industry for the type of manufacturing authorised under the licence (s21 of the MPMR).
3. For buying stock of a medicine (including raw materials), a licence holder and persons acting under a licence must comply with the requirements stated in chapter 4, part 3 of the MPMR 'Buying by giving purchase orders'.
4. For disposing of waste from a diversion-risk medicine, the licence holder and persons acting under the licence must comply with the requirements stated in chapter 4, part 11 of the MPMR (while this requirement applies to manufacturers of medicated feed, these manufacturers are unlikely to use diversion-risk medicines – see schedule 2, part 3 of the MPMR for the list of diversion-risk medicines).
5. A licence holder, including any wholesale representatives employed by the holder, must report the loss or theft of a diversion-risk medicine that was in the possession of the licence holder immediately before the loss or theft, as soon as practicable, but no later than the end of the next business day, to the chief executive of Queensland Health (or delegate) in the approved form and to the Queensland Police Service (s226 of the MPMR).
6. A licence holder must ensure any records required to be kept under the MPA in relation to an authorised place stated in the licence are available for inspection from the place, and if the records are kept electronically, a licence holder must ensure the records for each authorised place stated in the licence are available for inspection from the primary place of business of the licence holder (s41 of the MPMR).
7. Where a record must be made or kept, licence holders must take all reasonable steps to ensure (s224 of the MPMR):
    a. the record is kept in a retrievable form but is kept securely to ensure it cannot be altered, obscured, deleted or removed without detection; and
    b. the record is kept for a period of two years after it is made, or for a medicine register, for two years after the last entry in the register is made.
8. A licence holder must give notice to the chief executive of Queensland Health (or delegate) in the approved form if any of the following changes are proposed by the licence holder (s42 of the MPMR):
    a. a change to an authorised place stated in the licence;
    b. a change to a relevant person stated in the licence; and
    c. another change to the licence holder's circumstances that substantially affects the holder's ability to comply with a condition of the licence.
9. Where a licence holder proposes to stop carrying out a dealing with a medicine under a licence, the holder must give the chief executive of Queensland Health (or delegate) a notice in the approved form stating the following information (s43 of the MPMR):
    a. the day the dealing is proposed to stop;

b. the amount of medicines that are likely to be unused on that day, if any; and
c. how the licence holder proposes to deal with any unused medicines.

Manufacturers of medicated feed

10. A licence holder must not supply medicated feed to a farmer of a group of animals unless the farmer has a written prescription for the feed from a veterinary surgeon (s24 of the MPMR).

11. Licence holders should be aware of the requirements for veterinary surgeons prescribing S4 medicines and medicated feed in chapter 5, part 4 of the MPMR 'Veterinary surgeons prescribing S4 medicines and medicated feed', including what must be stated in prescriptions for an S4 medicine or medicated feed for a group of animals and sending such prescriptions to manufacturing licence holders.

12. When delivering, or arranging for delivery of, medicated feed to a farmer of a group of animals, a licence holder must ensure a notice stating the name of the farmer and the street address for delivery is attached to the medicated feed or accompanies the medicated feed (if it is not reasonably practicable to attach the notice to the feed) (s26 of the MPMR).

13. When supplying medicated feed to a farmer of a group of animals, a licence holder must give the farmer an invoice or other document stating the following information (s25 of the MPMR)—
    a. a unique identifier for the invoice or document;
    b. the date of the supply;
    c. the name and address of the farmer (if the medicated feed is to be delivered to the farmer – the address must be the street address for delivery of the feed);
    d. the unique identifier on the prescription held by the farmer;
    e. details about the form, strength and amount of the feed supplied.

14. A licence holder must keep a copy of the invoice (or other document) or a record of the details contained in the invoice and give a copy of the invoice to the veterinary surgeon who prescribed the feed, if asked to do so by the veterinary surgeon (section 25(3) of the MPMR).

Manufacturers of medicines other than medicated feed

15. A licence holder must ensure stock of a medicine is only handled by an appropriately qualified adult employed by the licence holder (s70 of the MPMR).

16. A licence holder must comply with, and take all reasonable steps to ensure a person employed by the licence holder complies with, the *'Australian code of good wholesaling practice for medicines in schedules 2, 3, 4 and 8'* published by the Therapeutic Goods Administration (s71 of the MPMR).

17. For supplying stock of a medicine, a licence holder and persons acting under a licence must comply with the requirements stated in chapter 4, part 4 of the MPMR 'Supplying stock', including that a licence holder must supply stock of a medicine only if (ss56-59 of the MPMR):

a. the supplier reasonably believes that the buyer of the medicines is authorised under the MPA, or under a corresponding law or another law to give a purchase order or otherwise buy the stock of medicines; and
b. the buyer gives the licence holder a compliant purchase order for the medicines.

18. A licence holder must not supply stock of a medicine to a buyer unless the container of the medicines and the labelling on the medicine complies with the requirements of the Poisons Standard or an alternative way approved, or taken to be approved, by the chief executive of Queensland Health (or delegate) (s73 of the MPMR).
19. A licence holder must not supply a medicine on an expired purchase order (more than one year old), or where the licence holder reasonably suspects that a purchase order has been unlawfully obtained or prepared, cancelled, fulfilled or otherwise doesn't comply with the MPA (s60 of the MPMR).
20. A licence holder must give the buyer an invoice or other notice stating the following information (s61(1) of the MPMR):
    a. a unique identifier for the invoice;
    b. the date of the supply;
    c. the name and address of the buyer;
    d. if the stock is delivered – the place to which the stock is delivered;
    e. the details of the buyer's authorisation or permission to buy the stock;
    f. the name, form and strength of the medicine supplied; and
    g. the amount of stock of the medicine supplied.
21. A licence holder must keep a copy of the invoice or a record of the details contained in the invoice (s61(2) of the MPMR).
22. When a licence holder supplies the stock on a purchase order, the licensee must (S62 of the MPMR):
    a. mark the purchase order in a way that shows the order has been supplied and, if applicable, delivered; and
    b. keep a copy of the marked purchase order.
23. For transporting stock of a medicine, a licence holder and persons acting under a licence must comply with the requirements stated in chapter 4, part 4 of the MPMR 'Supplying stock' and part 5 'Possessing stock for delivery', including that a licence holder must ensure delivery of the stock is to the street address stated on the purchase order for the stock (ss67 and 78 of the MPMR).
24. A licence holder must not deliver, or arrange to deliver, stock of a medicine to a buyer unless (ss64 and 65 of the MPMR):
    a. the medicine is sealed in a securely closed package that is likely to show if the package breaks or anyone tampers with it; and
    b. the package is clearly labelled with the name of the buyer and the street address for delivery stated on the purchase order for the stock; and
    c. if the medicine is an S8 medicine:
        i. the package is not mixed with anything other than S8 medicines; and
        ii. the package has no label or mark on it that indicates it contains an S8 medicine.

25. A licence holder may engage a carrier only if the licence holder reasonably considers the carrier is capable of complying with the requirements of the MPMR (s66 of the MPMR), such as maintaining temperature limits for the safe storage of stock, obtaining receipt of delivery and not leaving stock unattended except in a secure area (ss76-78 of the MPMR) and those requirements in chapter 8, part 2, division 4 'Carriers'.
26. Before arranging with the carrier to deliver the stock, the licence holder must notify the carrier of the temperature limits for the stock that are recommended by the manufacturer of the medicine (s66(2) of the MPMR).
27. When delivering or arranging delivery of stock of an S8 medicine to a buyer, the licence holder must obtain and keep a signed notice from the buyer, or from an adult acting or purportedly acting on behalf of the buyer at the buyer's street address, acknowledging receipt of the delivery. If the licence holder has not received a signed notice of receipt within 5 business days after the date of delivery, the licence holder must notify the chief executive of Queensland Health (or delegate) about the buyer's failure to confirm receipt of delivery (ss68-69).
28. Where a licence holder employs wholesale representatives (s70 of the MPMR):
    a. the licence holder must make and keep records showing the details of any stock given to a wholesale representative;
    b. the licence holder must ensure each wholesale representative is aware of requirements under the Act applying to the supplier and representative; and
    c. the representatives must comply with the requirements of chapter 5, part 5 of the MPMR 'Wholesale representatives' and the conditions of the licence.
29. A licence holder and persons acting under the licence must securely store medicines in accordance with the requirements stated in chapter 8, part 2 of the MPMR 'Secure storage systems'.
30. A licence holder and persons acting under the licence must establish and maintain a medicines register, to track all the regulated activities with medicines under the licence until medicines are completely used or destroyed, in accordance with chapter 8, part 2, division 3 of the MPMR 'Medicines registers'.

Information about manufacturing licences

Manufacturing supervisors

Manufacturing licence holders must appoint an appropriately qualified person (or persons) to supervise manufacturing under the licence and take all reasonable steps to ensure medicines are manufactured under the supervision of that person (s20 of the MPMR). To support applicants determine what is considered by Queensland Health to be 'appropriately qualified', the guideline *Competency requirements for medicines manufacturing supervisors* has been prepared.

As part of the application, all persons who are intended to supervise the manufacture of the regulated substances, must complete a Details of relevant person form (MPA-76) with supporting documentation on their qualifications and experience certified by a Justice of the Peace (JP) or Commissioner for Declarations (Cdec).

Wholesale representatives

Wholesale representatives who act as an agent for the licence holder, may possess and supply S2, S3, or S4 medicines (other than monitored medicines) in starter packs to authorised practitioners in accordance with the '*Australian code of good wholesaling practice for medicines in schedules 2, 3, 4 and 8*' and the other requirements specified in chapter 5, part 5 and schedule 14 of the MPMR.

Wholesale representatives must not possess more than is reasonably necessary to meet the business needs of the representative for a 6-month period.

Substance management plans

A substance management plan (**SMP**) is a document setting out how known and foreseeable risks associated with any regulated activity with a regulated substance are to be managed at a regulated place (section 92 of the MPA). Applicants for manufacturing licences must have an SMP that meets the requirements specified in s93 of the MPA and in the *Departmental Standard: Substance management plans for medicines* under the MPMR, detailing what governance is in place to ensure that medicines will be managed effectively. A guideline for developing an SMP for medicines is available on the Queensland Health website.

To provide sufficient time for licensees to comply with this new requirement, **an SMP is not required until 1 year after the commencement of the MPA**, i.e. 27 September 2022 (s280 MPA). Despite this, applicants should be able to demonstrate how they intend to manage and mitigate risks, by having in place appropriate procedures and protocols – as was required under the *Health (Drugs and Poisons) Regulation 1996* (**HDPR**). Please note however, that **Queensland Health does not approve SMPs** – read more about SMPs for medicines here.

Change of name, location or circumstances

Substance authorities are not transferable across different entities. Accordingly, substance authority holders must notify Queensland Health if the authorised entity intends to change their name or ACN/ABN; change premises; or has another change in circumstances during the term of the substance authority, because this may mean that the authority is no longer valid. If the change is due to a change in ownership of the entity, or the chief executive of Queensland Health (or delegate) otherwise considers the change to be substantial, a new application will likely be required; in other circumstances, an amendment application may be required.

Applying for a licence

Fees

Licences may authorise the holder to carry out regulated activities at multiple sites, however a separate licence fee is payable for each site. The fees payable for medicines licences are in accordance with chapter 9, part 2 and schedule 19 of the MPMR. Where a fee has been paid for a licence to manufacture poisons at the same site (under the *Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021*), no fee is payable for an S2, S3 or S4 medicines manufacturing licence.

There is a fee payable per site per year for an initial application for a manufacturing licence for an S8 medicine and a separate fee payable per site per year for an initial application for a manufacturing licence for an S2, S3 or S4 medicine. Where a manufacturing licence covers both S8 medicines and S2, S3 or S4 medicines at a site, then both fees are payable.

In addition to the annual fees, a processing fee is payable for initial applications. Again, where a manufacturing licence covers both S8 medicines and S2, S3 or S4 medicines, then two fees are payable.

To pay for an application, applicants must **first submit the attached** application form, accompanied by all supporting documents (certified where required) to:

> The Chief Executive, Queensland Health
> c/o Healthcare Approvals and Regulation Unit (HARU)
> medicines.applications@health.qld.gov.au

Once an application is received, applicants will be given a biller code and a reference number to pay the applicable fees electronically via the BPOINT platform. To avoid delays, applicants should promptly send through their proof of payment.

Payment of the correct application fee is required for an application to be valid. See our page on fees, which contains the current schedule of fees and further information on calculating the fee payable including a simple calculator.

Assessment

In determining the application, the matters described in section 76 of the MPA may be taken into consideration.

Queensland Health assesses all information relevant to an application including:

- whether a relevant person under the application is a fit and proper person, which may take into consideration any prior compliance history, and also the background, skills and qualifications of persons who will be responsible for overseeing activities to be carried out or will have access to regulated substances;
- which regulated substances are to be included in the substance authority;
- proposed activities and locations where regulated substances are to be used and stored; and
- the documented governance arrangements in place relevant to the substance authority.

An inspection of the premises may also be undertaken.

All applications are assessed individually, and there is no guarantee that a substance authority will be granted to any applicant.

Under chapter 3, part 3, division 4 of the MPA, applications are decided within 90 days of the application (final consideration day – section 86 of the MPA), or the latest day the chief executive of Queensland Health (or delegate) receives information from the applicant (section 89 of the MPA), unless a later date is agreed (s88 of the MPA). Applications not decided by this time are taken to have been refused (s89(4) of the MPA).

Queensland Government

Queensland Health
Medicines and Poisons Act 2019

MPA-75MML
Version 2:08/2022

INITIAL APPLICATION FOR A MANUFACTURING LICENCE – MEDICINES

Privacy statement – please read carefully

Personal information collected by Queensland Health is handled in accordance with the *Information Privacy Act 2009*. Queensland Health is collecting your personal information on this form under authority of the *Medicines and Poisons Act 2019*. The information is being collected to ensure that health risks arising from the use of regulated substances are appropriately managed. All personal information will be securely stored and only accessible by Queensland Health. Your personal information will not be disclosed to any other third parties without consent unless the disclosure is authorised or required by law. For information about how Queensland Health protects your personal information or to learn about your right to access your own personal information, please see our website at www.health.qld.gov.au/global/privacy.

Section 1 – Applicant (entity) details

Provide details of the legal entity (individual/organisation) seeking the licence

Type of entity seeking the approval		Specify type (if another entity)	
Name of entity (e.g. individual (surname, given names), partnership, company, incorporated association)			
Trading name (if applicable)		ACN (if applicable)	
Entity phone		Entity email	
Postal address		Town/ Suburb	P/C
Contact person		Phone	Email

☐ Attach a current **company extract** from the Australian Securities and Investments Commission (ASIC) (if applicable)

Section 2 – Relevant persons (s76 MPA)

All applications must include completed Details of relevant person forms (MPA-76) for each of the following:

1. (a) If the licence is to be issued to a sole trader, the **applicant** must complete the relevant person form.
   (b) If the licence is to be issued to a partnership, **each partner** must complete the relevant person form.
   (c) If the licence is to be issued to a body corporate or company, **an executive officer** (executive director, company secretary, chief executive officer, general manager or chief financial officer) must complete the relevant person form.
2. A manufacturing supervisor must be nominated for each premises on the licence. **Each manufacturing supervisor** must complete the relevant person form.

☐ Attach completed **details of relevant person** forms for each person relevant to this application

Section 3 – Premises where manufacturing and possession are to occur (s63(1)(a) and (b) MPA)

Provide details of the physical address where substances are to be manufactured and stored. To include additional sites/locations on the same licence, please attach further details.

Manufacturing site 1

Site address		Town/ Suburb	P/C
Name of entity conducting operations (e.g. storing, picking, transporting) at/from this location			
Contact person		Phone	Email
Commonwealth manufacturing / HDPR licence reference for this location (if applicable)			
Have you applied for, or do you currently hold, a licence to wholesale poisons or prohibited substances (non-therapeutic use) at this location?	☐ Yes	☐ No	
If yes, provide details e.g. licence number/application number or date			
Does the storage at this location meet the requirements of ss197-199 of the MPMR?	☐ Yes	☐ No	

INITIAL APPLICATION FOR A MANUFACTURING LICENCE – MEDICINES

Manufacturing site 2

Site address		Town/ Suburb		P/C	
Name of entity conducting operations (e.g. storing, picking, transporting) at/from this location					
Contact person		Phone		Email	
Commonwealth manufacturing / HDPR licence reference for this location (if applicable)					
Have you applied for, or do you currently hold, a licence to wholesale poisons or prohibited substances (non-therapeutic use) at this location?	☐ Yes	☐ No			
If yes, provide details e.g. licence number/application number or date					
Does the storage at this location meet the requirements of ss197-199 of the MPMR?	☐ Yes	☐ No			

Section 4 – Substances proposed to be manufactured under this licence (s63(1)(a) MPA)

Provide details of the final (finished) products to be manufactured, with reference to the schedule and descriptor (name) used in the most current Poisons Standard.
Where a final product is unscheduled (due to, for example, pack size, use, form, strength etc.) state "unscheduled" in the column titled 'Schedule', name the product and provide all other details. To include additional substances, please attach

Schedule	Poisons Standard descriptor	Form	Strength	Pack size/Volume/Use
-				
-				
-				
-				
-				

Section 5 – Buying and possession of other substances for manufacturing (s63(2)(a) MPA)

Provide details of any scheduled substances required to manufacture the final products specified in Section 4 above (i.e. raw ingredients). To include additional substances, please attach further details.

Schedule	Poisons Standard descriptor	Form	Strength	Details
-				
-				
-				
-				
-				

Section 6 – Manufacture and disposal of waste from by-products (s63(2)(b) MPA)

Provide details of any scheduled substances that are by-products produced from the manufacture of the final products stated in Section 4 above. State which final product the by-product relates to and relevant details, including form and strength of the substance where this impacts on the scheduling. To include additional by-products, please attach further details.

Schedule	Poisons Standard descriptor	Form	Strength	Details (including which final product)
-				
-				
-				
-				
-				

Section 7 – Supply of substances by wholesale (s63(1)(d) MPA)

Only final products listed in Section 4 may be permitted to be supplied by wholesale. Provide details of the classes of persons to whom you intend to supply these substances.

☐ Manufacturers	☐ Podiatrists
☐ Wholesalers	☐ Optometrists
☐ Other substance authority holders	☐ Nurse practitioners
☐ Farmers	☐ Midwives
☐ Veterinary surgeons	☐ Other health practitioners, please specify
☐ Pharmacists	
☐ Doctors	☐ Other persons, please specify
☐ Dentists	

Section 8 – Substance management plan (s93 MPA, Chapter 6 and Schedule 17 MPMR)

The responsible person for a place where a medicine is manufactured under a manufacturing licence (regulated place), must make a substance management plan before any regulated activity happens with a regulated substance at, or in connection with, a regulated place, unless the person has a reasonable excuse.

The substance management plan must:

- state the following:
  - the day the plan starts;
  - the location of the place;
  - the regulated activities and regulated substances to which the plan applies;
  - the persons (staff) to whom the plan applies; and
- address the matters specified in the Departmental standard: 'Substance management plans for medicines' under the MPMR; and
- be written in a way that is likely to be easily understood by staff.

The responsible person must ensure the substance management plan:

- is made available to staff when it is made; and
- is reviewed at the time specified in the MPMR.

NOTE: A SUBSTANCE MANAGEMENT PLAN IS NOT REQUIRED UNTIL 27 SEPTEMBER 2022 (s280 MPA)

Have you prepared a substance management plan that meets the criteria above and the Departmental standard: 'Substance management plans for medicines' of the MPMR?	☐ Yes	☐ No

INITIAL APPLICATION FOR A MANUFACTURING LICENCE – MEDICINES

Section 9 – Duration of the substance authority (s69 MPA)

*Medicines manufacturing licences may be issued for up to two years, but a **shorter term** may be requested/granted.*

Please specify the term of licence sought:

☐ 1 year ☐ 2 years ☐ Another term, please specify

Section 10 – Additional information and attachments

Provide any additional information to support your application

Provide/specify which attachments are attached to support this application:

☐ A current **company extract** from the Australian Securities and Investments Commission (ASIC)

☐ Details of **relevant person forms** for each person relevant to the application (directors, supervisors etc.)

☐ Other **relevant documents** please specify

Section 11 – Consent and declaration

By making this application:

☐ I declare that I have authority to make this application on behalf of the applicant.

☐ I consent to Queensland Health making enquiries of, and exchanging information with, the authorities of any Australian state or territory, or of the Commonwealth, regarding any matters relevant to this application. If relevant information cannot be obtained from other entities, Queensland Health will determine the application on the information available.

☐ I consent to Queensland Health collecting, using and disclosing information submitted with this application including to, for example, the Medicines Expert Advisory Group (or similar) for the purpose of determining this application and any matters relevant to the related substance authority.

☐ I declare that, to the best of my knowledge, all information provided in and with this application form is true and correct in every detail.

☐ I understand that if anything has been stated in this application form, or in an attachment provided with this application, that is false or misleading, any substance authority granted may be suspended or cancelled.

Full name of applicant or authorised representative (where applicant is a body corporate or another entity)	Designation (position) of applicant or authorised representative

Signature of applicant or authorised representative (where applicant is a body corporate or another entity)	Date (DD/MM/YYYY)

Clear form