Medicines and Poisons Act 2019

Factsheet – current as at October 2023

Fees – medicines

What are substance authorities?

One of the ways under the Act for a person to be 'authorised' to carry out a regulated activity with a regulated substance is if they are the holder of a substance authority, being either a licence or approval, or they are another person acting under a substance authority.

To obtain a substance authority a person needs to apply for it.

Do I need to pay a fee for a substance authority?

The Act provides that regulations may be made about fees for applications for substance authorities and other matters under the Act.

Accordingly, chapter 9, part 2 of the *Medicines and Poisons (Medicines) Regulation 2021* (**MPMR**) provides the detail about fees payable under the Act in relation to a substance authority for a dealing with a medicine. The fees payable are provided in Schedule 19 of the MPMR.

Fees are payable for licences under the Act. Applications for approvals do not involve payment of a fee.

Importantly, applicants should note that a licensing fee for a substance authority is payable for **each site** for the authority for **each year** of the term of the authority.

However, for any part of the term of a substance authority that is not a full year, the licensing fee payable in relation to that part of the term is the proportion of the licensing fee attributable to the number of months, rounded up to whole months, of that year that are in the term.

What fees are payable?

Schedule 19 of the MPMR sets out the relevant fee units payable and the *Acts Interpretation (Fee Unit) Amendment Regulation 2023* specifies the value of a fee unit.

Fees payable under Queensland legislation change regularly.

From 1 October 2023, the fees payable are specified below:

		Fee unit[1]	Amount $
1	Initial application for a manufacturing licence or wholesale licence for an S8 medicine (Act, s 75(c))	603.50	639.71
2	Initial application for a manufacturing licence or wholesale licence for an S2, S3 or S4 medicine (Act, s 75(c))	603.50	639.71
3	Initial application for an S2 retail licence (Act, s 75(c))	210.50	223.13
4	Amendment application for a manufacturing licence or wholesale licence for a medicine to add another site (Act, s 78(2)(c))	603.50	639.71
5	Amendment application for an S2 retail licence to add another site (Act, s 78(2)(c))	210.50	223.13
6	Renewal application for a manufacturing licence or wholesale licence for an S8 medicine (Act, s 82(2)(c))	603.50	639.71
7	Renewal application for a manufacturing licence or wholesale licence for an S2, S3 or S4 medicine (Act, s 82(2)(c))	603.50	639.71
8	Renewal application for an S2 retail licence (Act, s 82(2)(c))	210.50	223.13
9	Processing fee for an initial application for a substance authority for a dealing with a medicine	140.50	148.93

The first time an application is made for a substance authority for dealing with a medicine, a processing fee of $148.93 is payable, along with the applicable yearly licence fee specified in items 1-3 (inclusive) above.

The fee for renewal of a licence is specified in items 6-8 (inclusive) above. There is no requirement to pay a processing fee, provided the requirements for a renewal application are established.

[1] The value of a fee unit is—

(a) from 1 October 2022 - $1.025 – see the Acts Interpretation (Fee Unit) Regulation 2022;

(b) from 1 October 2023 - $1.060 - see the *Acts Interpretation (Fee Unit) Amendment Regulation 2023*.

The fees were last indexed on 1 October 2023, with the value of the fee unit prescribed being $1.060.

Are there any exemptions?

A licensing fee for an initial application or renewal application for a manufacturing licence for S2, S3, or S4 medicines or a wholesale licence for S2, S3 or S4 medicines (a **later application**) is not required to be paid, if:

- an initial application or renewal application for a **manufacturing licence** for an S7 poison or **wholesale licence** for an S7 poison (**first application**) has been made, and not withdrawn or refused, under the MPMR; and
- the site the subject of the later application is the same as the site the subject of the first application; and
- the term proposed for the later application ends no later than the last month of
  - the term proposed for the first application; or
  - if the chief executive has granted the first application—the term of the substance authority granted on the first application; and
- all fees payable under the Act for the first application have been paid.

How are refused or withdrawn applications dealt with?

If an applicant has paid the applicable licensing fee for an application for a substance authority for a medicine and the application is refused by the chief executive or withdrawn by the applicant, the chief executive must refund the applicant the licensing fee for the application.

Please note that the licensing fee is specified in items 1-8 (inclusive) in the table above and does not include the processing fee specified in item 9. Accordingly, the processing fee will not be refunded.

What happens if a licence is granted for a shorter term than I applied for?

If an applicant has paid a licensing fee for a particular term and an application is granted for a shorter term, a proportional refund will be given.

What happens if I choose to surrender my licence?

If the holder of a substance authority has paid a licensing fee for a particular term and the authority is surrendered before the end of the granted term, a proportional refund will be given.

What is the process for dealing with applications for approvals and licences?

Approvals and licences are generally assessed, processed and determined by delegates of the chief executive who are officers within the Healthcare Approvals and Regulation Unit (**HARU**).

For guidance on what action is required from you for the approval or licence type you are seeking, please refer to the relevant application form/s.

How can I pay the applicable licence fee?

Applications for licences are only considered valid once an application is received and the accompanying prescribed fee is paid.

- For new (initial) applications and amendment applications to add a site to an existing licence, once an application has been made, HARU will be in contact via email to provide the application reference number and amount payable that can be used when making payment via the BPoint gateway.
- Fees for renewal applications may be paid via the BPoint gateway using the applicable licence number. A receipt must be attached with the application.

Associated guidance documents

- Substance authorities – factsheet
- Information on each relevant licence page: http://www.health.qld.gov.au/system-governance/licences/medicines-poisons/medicines/licensing

Further information

For further information, contact the Medicines Approvals and Regulation Unit:

- Email: MARU@health.qld.gov.au

To submit an application for a licence or approval for medicines, submit the required application and supporting documents to:

- Email: medicines.applications@health.qld.gov.au