

Application for internal review of an original decision relating to a substance authority for medicines

Medicines and Poisons Act 2019 (the MPA), sections 197, 198, 199

This form is to be used to apply for an internal review of an original decision relating to a substance authority for medicines.

- An affected person for an original decision may apply to the Queensland Civil and Administrative Tribunal (QCAT) for a review of a decision, only if a decision on an application for internal review of the decision has been made.
- An affected person for an original decision may apply to the chief executive for a review of the decision.
- If the affected person has not been given an information notice for the original decision, the affected person may ask the chief executive for an information notice for the decision.
- An application for internal review of an original decision must be made:
 - in this approved form; and
 - for a person who has been given an information notice for the decision - include enough information to enable the chief executive to decide the application; and
 - be made to the chief executive within:
 - for a person who has been given an information notice for the decision - 14 days after the day the person is given the notice; or
 - for a person who has not been given an information notice for the decision - 28 days after the day the person becomes aware of the decision.
- An affected person, in relation to a decision, means:
 - if the decision is an original decision - a person who is given, or is entitled to be given, an information notice for the decision; or
 - if the decision is an internal review decision - the person who applied for the internal review.

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Enquiries to Healthcare Approvals and Regulation Unit: HARU@health.qld.gov.au

MPA-199SA

Version 1: 09/2021

Page 1



**Queensland
Government**

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 MPA and *Medicines and Poisons (Medicines) Regulation 2021 (MPMR)*. 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. Failure to provide information may render the form incomplete, which may constitute an offence under the MPA and MPMR. 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.

What will happen when this application is received?

- Pursuant to **section 200** of the **MPA** the chief executive (or delegate) must within 28 days after received the application for internal review:
 - review the original decision; and
 - decide to –
 - **confirm** the original decision; or
 - **amend** the original decision; or
 - **substitute** another decision for the original decision; and
 - give the affected person for the original decision a QCAT information notice for the decision.
- The chief executive and the affected person may agree to a longer period for the chief executive to review the decision.

Section 1 – Details of affected person

Full Name: _____

Name of organisation: _____

Trading as: _____

Address: _____

Contact number: _____ Email Address: _____

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Postal address (if different than above):

Section 2 – Reference number/s

Substance Authority Number
(if applicable):

Application number
(if applicable):

Section 3 – Details of original decision

I **attach** a copy of the original decision with this application

Copy attached

Section 4 – Any other relevant information (if applicable)

Section 5 – Reason/s for seeking a review of the original decision

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MPA-199SA
Version 1: 09/2021

Section 6 – Attachment/s

Note: please attach all relevant documents that will enable the chief executive (or delegate) to decide this application

Section 7 – Declaration

- I declare that I have the authority to make this application.
- 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 agree to advise the chief executive if my circumstances change, or if I become aware of any matter that would make the information provided in, or with this form, false or misleading.

Section 8 – Are you the affected person?

- Yes.** Please complete Section 9.
- No.** Please complete Section 10.

Section 9 – Signature of affected person (if applicable)

Signature: _____ Date: _____

Section 10 – Details and signature of authorised representative (if applicable)

Full Name: _____

Company _____

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Address: _____

Contact number: _____ Email Address: _____

Signature: _____ Date: _____

Submit completed form and any supporting documents via email to:

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

