Compliance, monitoring and enforcement

Medicines and Poisons Act 2019

September 2021

Queensland Government

Contents

Regulatory approach

Queensland Health implements five major activities to meet its responsibilities for administering the regulatory framework for medicines (refer Figure 1).

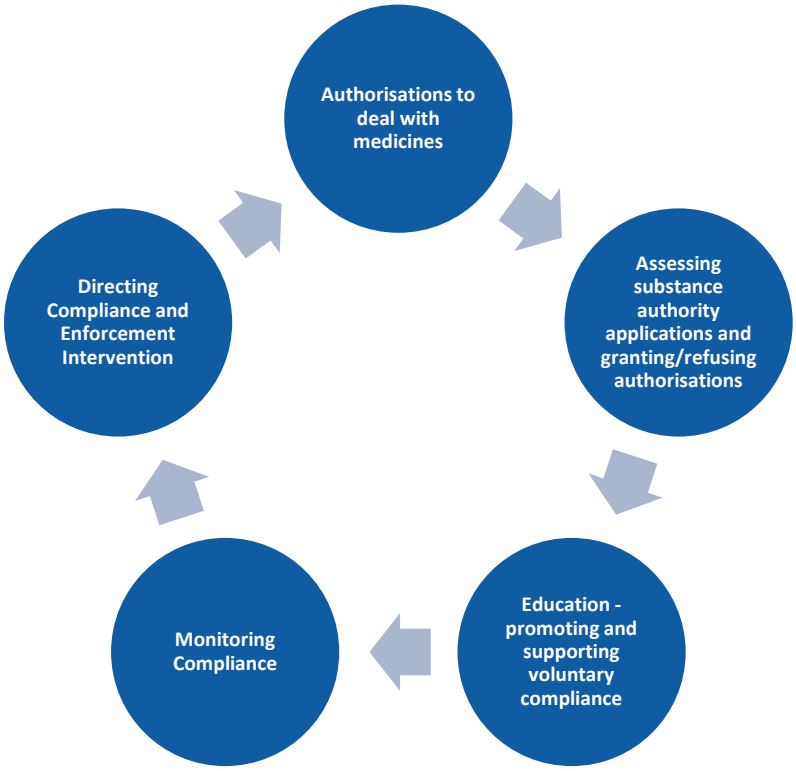

Figure 1. Regulatory approach

These activities progress from the types of authorisations that should be in place to deal with medicines; assessing applications to be authorised through substance authorities and granting/refusing authorisations; promoting and supporting compliance through education; monitoring compliance with the legislation; and directing compliance and undertaking enforcement action where required.

Authorisations to deal with medicines

The legislation provides for how persons are authorised to deal with medicines and poisons. Queensland Health manages changes to authorisations such as new Extended Practice Authorities or changed Schedules relating to approved persons.

Assessing substance authority applications and granting authorisations

Queensland Health assesses substance authority applications and makes decisions on granting or refusing authorisations.

Education – promoting and supporting voluntary compliance

A fundamental premise of Queensland Health's regulatory approach is that people who are authorised to deal with medicines must understand their legislative obligations and be empowered with the information and tools necessary to achieve compliance without intervention.

Therefore, a continuing focus on promoting compliance through education, to ensure authorised persons understand their obligations, is an important element in Queensland Health's regulatory approach to administering the legislation.

Monitoring compliance

Queensland Health uses a combination of proactive and reactive strategies to monitor compliance with the MPA and MPMR.

The *Monitored Medicines Monitoring Strategy*, outlines Queensland Health's approach to monitoring QScript (the monitored medicines database) and the *Monitored Medicines Standard*.

Directing compliance and enforcement interventions

The directing compliance options available to Queensland Health in relation to non-compliance with the MPA and MPMR include:

- giving warning letters
- giving compliance notices

The enforcement options available to Queensland Health in relation to non-compliance with the MPA and MPMR include:

- serving a Penalty Infringement Notice (PIN)
- giving a Show Cause Notice
- taking administrative action
- commencing legal proceedings (prosecutions).

The Compliance and Enforcement Pyramid shown in Figure 2 illustrates the escalation of regulatory responses and enforcement interventions used by Queensland Health to manage non-compliance based on the risk it poses to public safety.

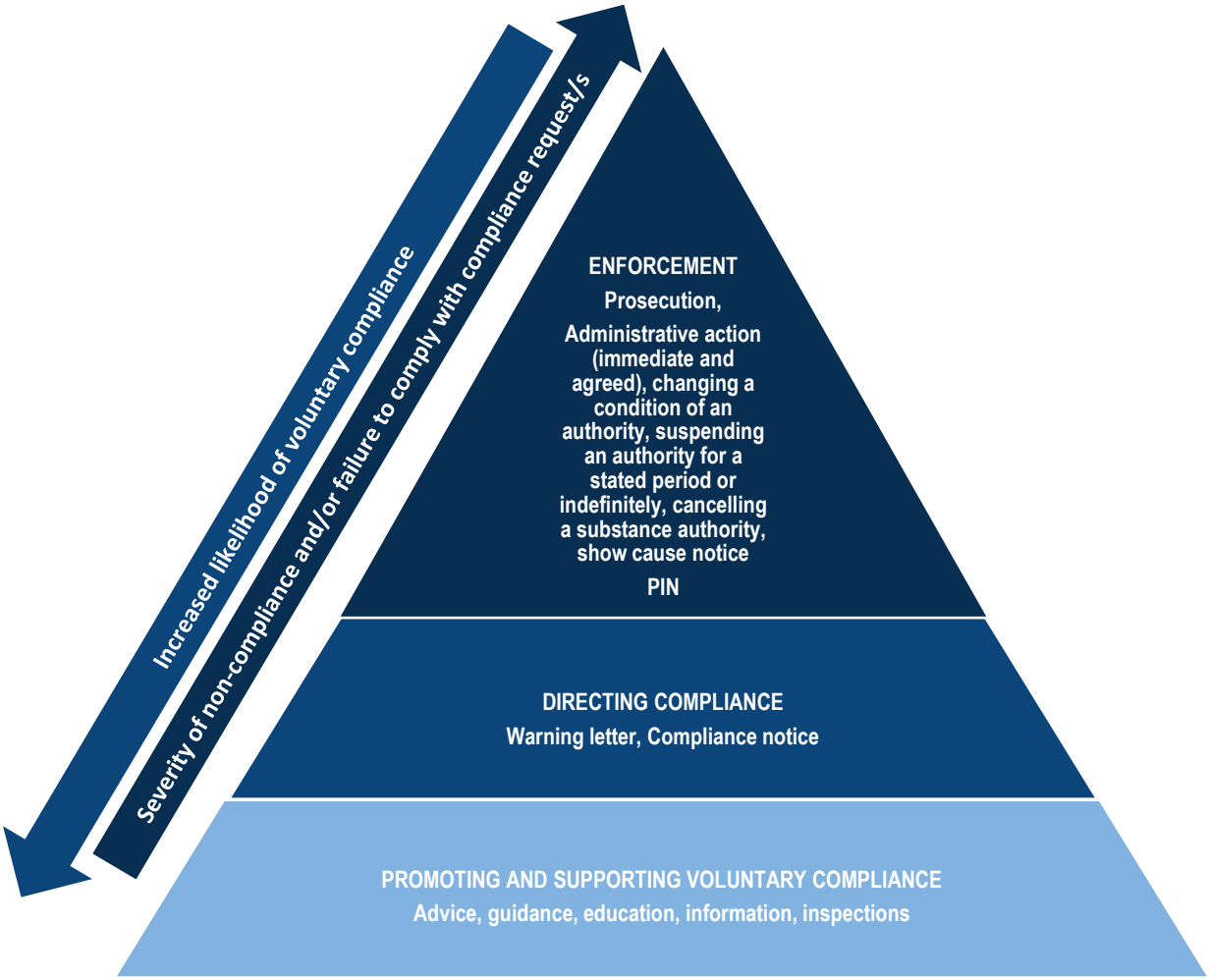

Figure 2: Compliance and Enforcement Pyramid

Verbal advice/education

The focus during the initial implementation of the MPA and MPMR is on advice and education regarding the new legislation. Verbal advice and education should be used in circumstances where there has been no prior non-compliance, there is a low risk to human health and it is believed that the advice/education will be sufficient to ensure compliance.

It is important that all verbal advice and education is documented as this evidence may be required if future non-compliance is identified and the enforcement intervention is to be escalated.

Warning letter

Where there is evidence that non-compliances have occurred, written warnings may be given. The totality of the offences will be considered in deciding the appropriate course of action. Written warnings will, for example, detail the nature of the alleged offence, cite relevant clauses of the legislation and specify the maximum penalty for the offence, in addition to the intention to enforce the legislation. Where significant non-compliance is evident, escalated enforcement action may be appropriate.

Compliance Notice – Chapter 4, Part 4 of the MPA

A compliance notice is given to a person and requires them to take specified steps to remedy substantiated non-compliance within a specified timeframe. The MPA provides for the chief executive. Queensland Health, or inspectors appointed under the MPA, to give compliance notices in circumstances where:

- a person has contravened a provision of the MPA and/or MPMR and the chief executive/inspector believes that it is likely the contravention will continue or be repeated
- the matter relating to the contravention is reasonably capable of being rectified
- it is appropriate to give the person an opportunity to rectify the matter.

A compliance notice must identify the substantiated breaches of the MPA and/or MPMR in relation to a particular matter, how the person is believed to have contravened the provision, the evidence used to substantiate the breach, and the reasonable steps to be taken to rectify the non-compliance. The notice must specify the timeframe in which the person is expected to rectify the non-compliance by undertaking the steps identified and advise Queensland Health that the requirements of the notice have been fulfilled; evidence may be required to be submitted as part of this notification.

It is an offence to fail to comply with a compliance notice unless the person has a reasonable excuse.

Queensland Health retains discretion when determining whether an excuse presented by a person is reasonable in the circumstances.

Penalty Infringement Notice (PIN)

Five offences in the MPA have been identified as suitable for the serving of PINS under the *State Penalties Enforcement Act 1999* as detailed in Table 3.

During the initial implementation of the MPA and MPMR the focus of Queensland Health is to provide advice and education regarding the new legislation.

Administrative Action – Chapter 4, Part 3 of the MPA

Prosecution

Prosecution will only be used for the most serious offences which may have, or has, resulted in a significant impact on human health, where a PIN, compliance notice or administrative action would not be sufficient due to the severity of the non-compliance, or the wilful and intentional nature of the non-compliance.

Offences

Both the MPA and the MPMR set out the offences and maximum penalties in the new legislated framework that are associated with unauthorised activities with medicines, as outlined in Table 1 and Table 2.

Table 1: MPA offences

	Authorised way offences in MPA
MPA s32	Offence to deal with prohibited substance
MPA s33	Offence to manufacture medicines or hazardous poisons
MPA s34	Offence to buy or possess S4 or S8 medicines or hazardous poisons
MPA s35	Offence to supply medicines or hazardous poisons
MPA s36	Offence to administer medicines
MPA s38	Offence to prescribe or make standing orders
MPA s42	Offence to dispose of waste from diversion-risk medicines

	Other offences associated with dealings with medicines in MPA
MPA s37	Offence to supply or administer animal medicines to humans
MPA s39	Unlawfully buying diversion-risk medicines
MPA s40	Offences for self-prescribing or self-administering high-risk medicines
MPA s41	Requirement to check database for particular dealings with monitored medicines
MPA s48	Offence for giving or keeping false, misleading or incomplete information and records
MPA s71	Failure to comply with substance authority conditions
MPA s93	Requirements for substance management plans
MPA s 94	Compliance with substance management plans
MPA s 226	Giving information

Additional offences are specified in the MPMR, as outlined in Table 2.

Table 2: MPMR offences

	Other offences associated with dealings with medicines in the MPMR
MPMR s184 - 193	Chapter 8, Part 1 - Electronic prescription management systems
MPMR s194 - 220	Chapter 8, Part 2 – Secure storage systems
MPMR s221	Chapter 8, Part 3 – Containers
MPMR s222 - 225	Chapter 8, Part 4 - Recording and keeping information
MPMR s226 - 233	Chapter 8, Part 5 - Reporting particular matters
MPMR s234 - 235	Chapter 8, Part 6 – Advertising and vending machines

	Requirement to comply with Departmental Standards
MPMR s47	Compounding
MPMR ss93, 126	Monitored Medicines
MPMR s162	Pseudoephedrine recording
MPMR s186	Requirements for an electronic prescription management system
MPMR s187	Substance management plans for medicines
MPMR s197	Secure storage of S8 medicines

Table 3:

Penalty infringement notice (PIN) offences
Failure to check the monitored medicines database (QScript) prior to prescribing or dispensing a monitored medicine as required by section 41(2) of the MPA. The PIN fine for this offence is two (2) penalty units.
Failure to comply with substance authority conditions as required by section 71 of the MPA. The PIN fine for this offence is five (5) penalty units.
Failure to comply with the requirements for a substance management plan as required by section 93 of the MPA. The PIN fine for this offence is six (6) penalty units.
Failure to return inspector identity card as required by section 137 of the MPA. The PIN fine for this offence is one (1) penalty unit.
Failure to provide prescribed information to the chief executive at the time, and in the way, prescribed by regulation as required by section 226 of the MPA. The PIN fine for this offence is ten (10) penalty units.

Monitored Medicines Monitoring Strategy

Risk-based, education first approach

Queensland Health is committed to a risk-based, education first, approach to monitoring and enforcement of monitored medicines offences under the *Medicines and Poisons Act 2019* (MPA) and the Medicines and Poisons (Medicines) Regulation 2021 (MPMR).

A key purpose of the new legislative framework is to protect public health and safety. To ensure the legislation is robust in achieving this, it is necessary to include the option for regulatory action to promote compliance and enable effective enforcement.

A phased approach to monitoring and enforcement of monitored medicines offences will be implemented with a heavy focus on education and guidance in the first 12 months. Education about how to register and use QScript (the monitored medicines database), and clinical best practice eLearning modules designed to enhance clinical practice on the prescribing and dispensing of monitored medicines are available at https://www.health.qld.gov.au/clinical-practice/guidelines-procedures/medicines/prescription-monitoring

If non-compliance is identified, education and assistance for people to voluntarily comply with the legislation will always be the starting point. If this is not effective, Queensland Health may direct compliance by giving a person a compliance notice.

If non-compliance continues, regulatory action may need to be escalated by, for example, taking administrative action such as cancelling the person's substance authority, or an approved person's authorisation. Prosecution of offences would only be considered as a final action where compliance is not being achieved and there is a continuing risk to the public.

> Whilst the initial focus is on education and voluntary compliance, actions of significant risk will always be investigated. A faster progression to more serious regulatory intervention e.g. giving show cause notices or taking immediate administrative action, will be considered if high risk activities are identified.

The key monitoring strategies that will be implemented in the first 12 months of the new legislation will be the:

1. Not Look Up (NLU) Strategy;
2. Monitored Medicines Standard (MMS) Strategy;
3. Self-Prescribe (SP) Strategy and
4. Amfetamine and Methylphenidates (AM) Strategy.

1. Not Look Up (NLU) Strategy - Guidance for health practitioners re compliance with s41 MPA

Before prescribing, dispensing or giving a treatment dose of a monitored medicine for a person, relevant practitioners must check the monitored medicines database (QScript) to see whether information recorded in the database shows that the person has previously been prescribed, dispensed or given any monitored medicine.

General statement – education approach

The NLU strategy will be implemented in the initial 12-month transition period following the introduction of QScript and the MPA and MPMR provisions relevant to QScript.

No action will be taken during the first two months after full commencement of the MPA, as section 41 of the MPA will not commence until 27 October 2021. A second month of no action will be implemented to enable practitioners to complete QScript registration and training and to become familiar with the new system.

The NLU strategy will have a heavy focus on guidance through education and warning letters before more directed compliance / other regulatory action is considered.

Letters will include information about the introduction of the new legislation, how to register for QScript (if relevant), how to access training and a practitioner's obligations under the legislation.

General statement – reasonable excuse

Section 41(3)(b) of the MPA provides that if a practitioner has a reasonable excuse for not checking QScript, they do not commit an offence and no further action will be taken by Queensland Health.

Practitioners are encouraged to document their reasons for not looking up QScript so that this information can be provided to Queensland Health if requested.

If a practitioner is unable to access QScript for technical reasons, it is recommended that they document attempt/s to access QScript so that this information can be provided to Queensland Health if requested.

This information will be assessed to determine whether regulatory action is required and the appropriate level of action. Queensland Health will adopt a consistent approach to assessing and responding to this information.

Not being a registered user of QScript is not considered to be a reasonable excuse for not complying with the requirements of section 41 of the MPA.

However, if a practitioner is identified for non-compliance with section 41 of the MPA during the initial transition period, education and guidance will be provided prior to any further regulatory action being taken.

2. Monitored Medicines Standard (MMS) Strategy - Guidance for health practitioners re compliance with s93 MPMR and s126 MPMR

Section 93 of the MPMR states a prescriber must prescribe a monitored medicine, whether orally or by written prescription, in accordance with the departmental standard called 'Monitored medicines' (the Monitored Medicines Standard (MMS)).

Section 126 of the MPMR states 'a dispenser must dispense a monitored medicine in accordance with the departmental standard called 'Monitored medicines' MMS.

Part 1 of the MMS applies if a prescriber prescribes a monitored medicine for dispensing or giving a treatment dose for a patient i.e. if a prescriber directs a person, orally or in writing, to:

- dispense a monitored medicine for the treatment of a person
- give a treatment dose of a monitored medicine for the treatment of a person.

Part 2 of the MMS applies if a dispenser dispenses a monitored medicine for a patient, irrespective of whether the prescription for the monitored medicine:

- was an oral or written prescription
- was prescribed in Queensland or another jurisdiction.

General statement – education approach

The MMS describes six high-risk clinical scenarios for patients and identifies minimum requirements that health practitioners must comply with when a high-risk clinical scenario has been identified. The six high-risk clinical scenarios are as follows:

Scenario A: Patient currently registered on the Queensland Opioid Treatment Program

Scenario B: Patient previously registered on the Queensland Opioid Treatment Program

Scenario C: Patient receiving monitored medicines from multiple prescribers

Scenario D: Increased patient overdose risk— daily opioids of 100mg OME or greater

Scenario E: Increased patient overdose risk—opioid and benzodiazepine/z-drug combination

Scenario F: Patient receiving an opioid or benzodiazepine/z-drug for the first time in 90 days

The MMS companion document provides general guidance and compliance guidance to assist health practitioners to comply with the departmental standard.

A series of MMS compliance checklists have been developed to enable health practitioners and Queensland Health to assess compliance with the MMS.

The MMS compliance checklists will be used in two ways to assess compliance with the MMS:

1. Targeted selection of prescribers and dispensers – prescribers and dispensers will be selected based on risk e.g. upon receipt of a complaint, an overdose event, identified patients with high-clinical scenarios in isolation or in combination. Identified prescribers

or dispensers will be requested to complete the relevant MMS checklist and provide documentation for identified high-risk patients.

2. Random selection of prescribers and dispensers generated from QScript – identified prescribers and dispensers will be requested to complete and return the MMS checklist for a nominated number of patients e.g. a patient with the highest Oral Morphine Equivalent (OME) or other high-risk identifier will be selected to audit compliance.

It would be difficult for a practitioner to comply with the MMS without checking QScript first to identify if one or more of the six high-risk clinical scenarios exist. As a result, auditing compliance with the MMS will not be implemented until 6 months after commencement of the relevant provisions of the MPA or when over 75% of practitioners are registered for QScript, whichever is the latest.

This is to focus efforts under the NLU strategy to ensure that the relevant practitioners are registered on QScript and are checking it prior to prescribing, dispensing or giving a treatment dose of a monitored medicine in the first instance.

The random selection of prescribers and dispensers strategy will not commence until 12 months after the implementation of QScript and the MMS.

Once QScript and the MMS become standard practice, further education will not be required and a warning letter or compliance notice may be given prior to consideration of administrative action. Deliberate or repeated non-compliance with the MMS, despite education and warning, will be indicators for regulatory action.

3. Self-prescribe (SP) Strategy - Guidance for health practitioners re compliance with s40 MPA

Section 40 of the MPA includes a specific offence for self-prescribing high-risk medicines.

The definition of high-risk medicines in the MPMR includes all S8 medicines and the following S4 medicines:

- all benzodiazepines
- codeine
- gabapentin
- pregabalin
- quetiapine
- tramadol
- zolpidem and
- zopiclone.

This is a change to the legislative requirements under the Health (Drugs and Poisons) Regulation 1996 (the Regulation).

The main difference is that it will be a new offence to self-prescribe/administer certain S4 medicines. There is essentially no change from the Regulation to the MPA for self-prescribing S8 medicines. However, the MPA makes it clear that self-prescribing S8 medicines and certain S4 medicines is an offence unless the person has a reasonable excuse.

The Self-prescribe Strategy will include:

- a Self-prescribing S4 Transition Strategy; and
- the continuation of the Self-prescribing S8 Strategy.

However, unlike the NLU Strategy, the education letters are planned to commence one month after enactment of the new legislation for prescribers who are identified as self-prescribing a high-risk S4 medicine.

Prescribers who are identified as self-prescribing a high-risk S8 medicine may be given a warning letter in the first instance prior to consideration of further regulatory action.

However, where high-risk matters are identified, for example, repeated self-prescribing of concern or other indicators of non-compliance with the MPA, other regulatory action may be taken.

4. Amfetamine and Methylphenidates (AM) Strategy – Guidance for health practitioners re dealing with amfetamines or methylphenidates

Under the MPMR, a prescribing approval is **NOT** required to treat a patient with amfetamines or methylphenidates under the following circumstances:

You are a **medical practitioner** prescribing the medicine for the treatment of a relevant condition:

- narcolepsy—of a patient of any age
- brain damage, or attention deficit disorder (ADD), of a child patient who is at least 4 years

  (Schedule 6, Part 1, Division 5 MPMR)

You are a **paediatrician** prescribing the medicine for the treatment of a relevant child condition:

- brain damage, or ADD, of a child patient *(Schedule 6, Part 2, Division 15 MPMR).*

You are a **psychiatrist** prescribing the medicine, within the **maximum dosage**, for treatment of a relevant adult condition:

- ADD of an adult patient (*Schedule 6, Part 2, Division 16 MPMR*).

> **maximum dosage**, of a medicine, means—
> (a) if the medicine is dexamfetamine—a dose of the medicine that does not exceed 40mg a day; or
> (b) if the medicine is lisdexamfetamine—a dose of the medicine that does not exceed 70mg a day; or
> (c) if the medicine is methylphenidate—a dose of the medicine that does not exceed 80mg a day *(Schedule 6, Part 2, Division 16 MPMR).*

You are a **psychiatrist** prescribing the medicine for treatment of a relevant child condition:

- brain damage, or ADD, of a child patient *(Schedule 6, Part 2, Division 16 MPMR).*

All other prescribing of amfetamines and methylphenidates requires a prescribing approval under section 67 of the MPA.

This means that patient class treatment approvals are no longer required for psychiatrists to prescribe amfetamines or methylphenidates within maximum dosage levels specified in *Schedule 6, Part 2, Division 16* of the MPMR for ADD of an adult patient.

Further, that a medical practitioner (who is not a psychiatrist) cannot prescribe amfetamines or methylphenidates to a patient over the age of eighteen (18) years without a prescribing approval, unless the patient has narcolepsy (a relevant condition).

The Amfetamines and Methylphenidates Strategy will adopt an education first approach prior to consideration of further regulatory action as per the Not Look Up (NLU) Strategy. However, unlike the NLU Strategy, the education letters are planned to commence one month after enactment of the new legislation.

The Amfetamines and Methylphenidates Strategy will:

1. provide education to practitioners who are prescribing amfetamines and/or methylphenidates without a prescribing approval;
2. provide education to practitioners who are prescribing amfetamines and/or methylphenidates at dosage levels to a patient above the relevant prescribing approval; and
3. provide education to psychiatrists who are prescribing above the as-of-right maximum dosage levels or are prescribing to a patient above the relevant prescribing approval.

Review

These monitoring strategies will be reviewed 12 months after the implementation of QScript and the MMS.

Administrative Action

Administrative action is taken under authority of Chapter 4, Part 3 of the MPA and means action taken by Queensland Health that has the following effect:

- changing a condition of an authority; or
- suspending an authority for a stated period or indefinitely; or
- cancelling a substance authority (s95 MPA).

'Authority' means a substance authority or an approved person's authorisation (s95 MPA).

Section 96 of the MPA states that the chief executive, Queensland Health, may take administrative action in relation to an authority if the chief executive believes:

(a) a relevant person for the authority has contravened a requirement under the MPA or a corresponding law; or

(b) the administrative action is reasonably necessary to prevent or minimise a health risk; or

(c) relevant person for the authority is not a fit and proper person; or

(d) a relevant person for the authority has made a materially false or misleading representation to obtain the authority.

However, the chief executive may take administrative action under section 96 of the MPA only if the chief executive has considered giving a compliance notice to the person about the matter to which the proposed administrative action relates.

Where administrative action is proposed, a "Show Cause Notice" must be given to the holder of the authority, which must state the following:

(a) that the chief executive proposes to take the administrative action; and

(b) the proposed administrative action, including whether it applies to—,

(i) all regulated activities with regulated substances to which the authority relates; or

(ii) a particular regulated activity or regulated substance; and

(c) the reasons for the proposed administrative action; and

(d) that the holder may, within a stated period of at least 21 days (the show cause period), give the chief executive a written response to the Show Cause Notice (s97 MPA).

Immediate or agreed administrative action

Administrative action may be:

- immediate action taken because there is an urgent need to prevent a serious health risk to any person, including to the holder (s102 MPA), or
- agreed administrative action taken if a relevant person to whom the action applies agrees to the action being taken (s103 MPA).

The chief executive may decide to take immediate administrative action in relation to an authority on a ground described in section 96(1) of the MPA without giving the holder of the authority a show cause notice (s102 MPA).

Request by holder to review administrative action

Section 105 of the MPA states that the holder of an authority in relation to which administrative action has been taken may—

(a) ask the chief executive, in writing, to review the administrative action; and

(b) give the chief executive information supporting the holder's request under paragraph (a).

However, the holder may make a request under subsection (1) only on or after the review day for the administrative action.

'Review day', for administrative action, means the earliest day on which the chief executive is required under this part to consider ending or changing the administrative action (s95 MPA).

A review day is included in the following information notices:

- Notice of decision to take administrative action (s100 MPA)
- Notice of decision to take immediate administrative action (s102 MPA)
- Notice of decision to take agreed administrative action (s103 MPA)
- Notice of decision after reviewing administrative action on request (s106 MPA)

The following form is to be completed to apply for review of administrative action on or after the review day for the administrative action under section 105 of the MPA.

Request by holder of a substance authority to review administrative action relating to medicines form

Request by holder of an authority as an approved person for medicines to review administrative action form

Review process must start with Internal review

An 'affected person' (defined in s.196 of the MPA) for an original decision may apply to the Queensland Civil and Administrative Tribunal (QCAT) for a review of the decision only if a decision on an application for internal review of the decision has been made, or is taken to be made, under Chapter 6, Part 1, Division 2 of the MPA (s197 MPA).

The following approved form is to be completed to apply for an internal review of an original decision as described in sections 197, 198 and 199 of the MPA.

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

Application for internal review of an original decision relating to an authorisation as an approved person for medicines form

Further information

If you require further information regarding a substance authority, please email: HARU@health.qld.gov.au.

If you require further information regarding an authorisation for an approved person, please email: MedicinesCompliance@health.qld.gov.au