Queensland Health

Regulatory framework for medicines offences

An overview of Queensland Health's compliance monitoring and enforcement of medicines offences under the Medicines and Poisons Act 2019

Queensland Government

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Published by the State of Queensland (Queensland Health), June 2024

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An electronic version of this document is available at www.health.qld.gov.au/__data/assets/pdf_file/0019/1111717/compliance-monitoring-enforcement.pdf

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1 Purpose

The purpose of this document is to provide stakeholders an overview of Queensland Health's approach to compliance monitoring and enforcement of medicines offences under the *Medicines and Poisons Act 2019* (MPA) and Medicines and Poisons (Medicines) Regulation 2021 (MPMR).

The document describes:

- Queensland Health's general regulatory approach to medicines offences
- key regulatory strategies relevant to particular monitored and high-risk medicine offences.

2 Offences and requirements

The MPA and the MPMR set out the offences and maximum penalties associated with unauthorised activities with medicines, as outlined below.

2.1 MPA offences – 'authorised way'

A fundamental concept of the MPA is that any activity performed with a regulated substance must be performed by a person who is authorised to perform the activity in the **'authorised way'**. A person carries out a regulated activity with a regulated substance in the authorised way if:

- the person is authorised under:
  - Section 54(4) (i.e. as an approved person); or
  - Section 57 (i.e. a person acting under an emergency order); or
  - Section 62 (i.e. the holder of a substance authority or another person acting under a substance authority)

  to carry out the regulated activity with the regulated substance; and
- the person complies with the requirements specified for the person under Section 91(1) for carrying out the regulated activity with the regulated substance (these requirements may be prescribed by regulation); and
- the person complies with any substance management plan that applies to the person.

Chapter 2 of the MPA contains a range of offence provisions which relate to persons not carrying out activities in the authorised way as per **Table 1**, below.

Table 1: MPA offences – 'authorised way'

MPA reference	'Authorised way' offence
Section 32	Offence to deal with prohibited substances
Section 33	Offence to manufacture medicines or hazardous poisons
Section 34	Offence to buy or possess S4 or S8 medicines or hazardous poisons
Section 35	Offence to supply medicines or hazardous poisons
Section 36	Offence to administer medicines
Section 38	Offence to prescribe or make standing orders
Section 42	Offence to dispose of waste from diversion-risk medicines

2.2 MPA offences – other medicines offences

In addition to 'authorised way' offences, the MPA sets out a range of other medicines offences, as described in **Table 2**, below.

Table 2: MPA offences – other medicines offences

MPA reference	Other offences associated with dealings with medicines in the MPA
Section 37	Offence to supply or administer animal medicines to humans
Section 39	Unlawfully buying diversion-risk medicines
Section 40	Offences for self-prescribing or self-administering high-risk medicines
Section 41	Requirement to check database for particular dealings with monitored medicines
Section 48	Offence for giving or keeping false, misleading or incomplete information and records
Section 71	Failure to comply with substance authority conditions
Section 93	Requirements for substance management plan
Section 94	Compliance with substance management plan
Section 226	Giving information

2.3 MPMR offences

Additional medicines offences are specified in the MPMR, as outlined in **Table 3**, below.

Table 3: MPMR offences

MPMR reference	Other offences associated with dealings with medicines in the MPMR
Chapter 8, Part 1	Electronic prescription management systems
Chapter 8, Part 2	Secure storage systems
Chapter 8, Part 3	Containers
Chapter 8, Part 4	Recording and keeping information
Chapter 8, Part 5	Reporting particular matters
Chapter 8, Part 6	Advertising and vending machines

2.4 Requirements to comply with departmental standards

The MPA allows the chief executive (or delegate), to make a **departmental standard** about carrying out a regulated activity with a regulated substance and other matters relating to the purposes and administration of the MPA.

The MPMR prescribes six (6) departmental standards which particular persons/entities must comply with. **Table 4**, below, lists each standard and the relevant provisions of the MPMR which specify the details of when compliance with each standard is required.

Table 4: Departmental standard compliance requirements

MPMR reference	Name of departmental standard
Section 47	Compounding
Section 93 Section 126	Monitored medicines
Section 162	Pseudoephedrine recording
Section 173	Substance management plans for medicines

MPMR reference	Name of departmental standard
Section 186	Requirements for an electronic prescription management system
Section 197	Secure storage of S8 medicines

All departmental standards are available on Queensland Health's Legislation, standards and extended practice authorities page.

3 General regulatory approach

Queensland Health is committed to a risk-based, education-first approach to monitoring and enforcement of medicines offences under the MPA and MPMR.

A key purpose of the 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 medicines offences has been implemented with a focus on education and guidance.

- If non-compliance is identified, education and assistance for people to voluntarily comply with the legislation is typically 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.

The **Compliance and enforcement pyramid for medicines offences** shown in **Figure 1** illustrates the escalation of regulatory responses and enforcement interventions used by Queensland Health to manage non-compliance based on the risks posed to public safety.

Queensland Health uses a combination of proactive and reactive strategies to monitor compliance with the MPA and MPMR. Compliance monitoring and enforcement activities for medicines offences are undertaken by entities both within the Department of Health and the Hospital and Health Services (e.g. Public Health Units).

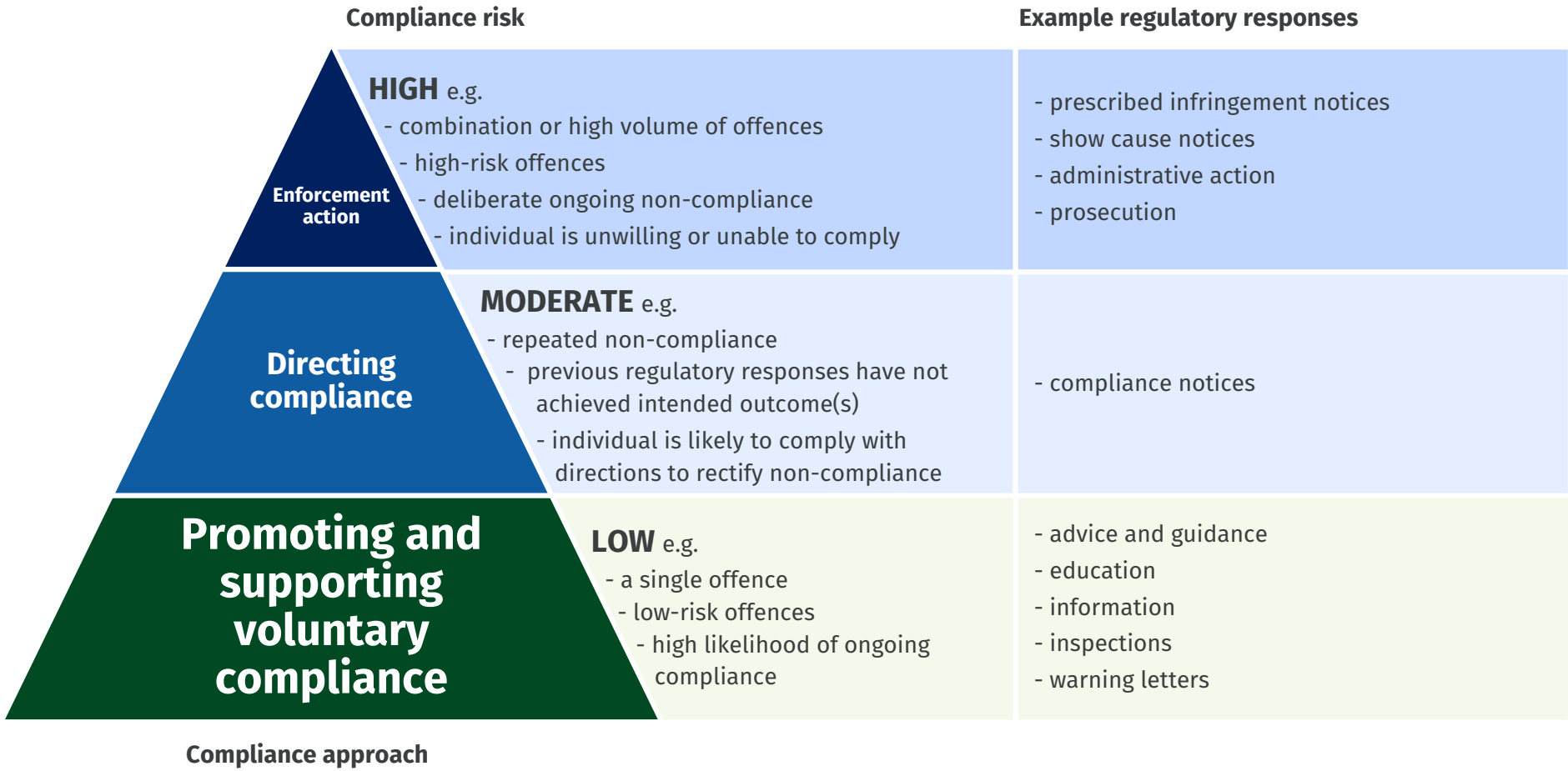

Figure 1: Compliance and enforcement pyramid for medicines offences. The risks and responses described are indicative only and not exhaustive; matters are dealt with on a case-by-case basis. Where high-risk matters or a combination of indicators of non-compliance is identified, regulatory responses may be escalated.

Whilst the 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.

3.1 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 and supporting voluntary compliance through advice, guidance, education, information and inspections—to ensure authorised persons understand their obligations—is an important element in Queensland Health's regulatory approach to administering the legislation.

Verbal advice and education is typically 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.

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

Where significant non-compliance is evident, escalated enforcement action may be appropriate.

3.2 Directing compliance

A compliance notice (Chapter 4, Part 4 of the MPA) may be given to a person requiring 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 the chief executive or an inspector believes:

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

A compliance notice identifies 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.

Compliance notices 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.

3.3 Enforcement action

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

- serving a Prescribed Infringement Notice (PIN)
- giving a show cause notice
- taking administrative action
- commencing legal proceedings (prosecutions).

3.3.1 PINs

A PIN is an infringement notice issued in accordance with the requirements of the *State Penalties Enforcement Act 1999* (Qld) which results in a financial impost on the offender. The fine is calculated on the number of penalty units attributed to the offence and the cost per penalty unit as gazetted.

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 the table below.

MPA reference	PIN offence
Section 41	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.
Section 71	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.
Section 93	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.

MPA reference	PIN offence
Section 137	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.
Section 226	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.

3.3.2 Show cause notices

Under Section 97 of the MPA, if the chief executive proposes to take **administrative action** (see section 3.3.3 below) in relation to an authority under Section 96, the chief executive must first give the holder of the authority a **show cause notice** stating:

- that the chief executive proposes to take the administrative action; and
- the proposed administrative action—including whether it applies to all regulated activities with regulated substances to which the authority relates; or a particular regulated activity or regulated substance; and
- the reasons for the proposed administrative action; and
- 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.

See Chapter 4, Part 3, Division 2 of the MPA for more information about show cause notices.

> If the chief executive considers it is reasonably necessary to take administrative action immediately because there is an urgent need to prevent a serious health risk to any person, the chief executive may decide to take administrative action without giving the holder of the authority a show cause notice.[1]

[1] Chapter 4, Part 3, Division 3 of the MPA.

3.3.3 Administrative action

Administrative action, in relation to a substance authority or an approved person's authorisation, means:

- changing a condition of an authority; or
- suspending an authority for a stated period or indefinitely; or
- cancelling a substance authority[2].

Under Section 96 of the MPA, the chief executive may take administrative action in relation to an authority if they believe:

- a relevant person for the authority has contravened a requirement under the MPA or a corresponding law; or
- the administrative action is reasonably necessary to prevent or minimise a health risk; or
- a relevant person for the authority is not a fit and proper person; or
- a relevant person for the authority has made a materially false or misleading representation to obtain the authority.

Administrative action may be:

- **immediate administrative action**—taken because there is an urgent need to prevent a serious health risk to any person, including to the authority holder (see Section 102 of the MPA); or
- **agreed administrative action—**taken if a relevant person to whom the action applies agrees to the action being taken (see Section 103 of the MPA).

For more information about administrative action, please see Chapter 4, Part 3 of the MPA.

3.3.3.1 Requesting a review of an administrative action

Section 105 of the MPA states that the holder of an authority in relation to which administrative action has been taken (other than administrative action that is the cancellation of a substance authority) may:

- ask the chief executive, in writing, to review the administrative action, and
- give the chief executive information supporting the holder's request.

The holder may make such a request only on or after the 'review day' for the administrative action.

[2] Section 95 of the MPA.

Review day, for administrative action, means the earliest day on which the chief executive is required under Chapter 4, Part 3 of the MPA to consider ending or changing the administrative action (Section 95 of the MPA).

A review day is included in the following information notices:

- Notice of decision to take administrative action (Section 100 of the MPA)
- Notice of decision to take immediate administrative action (Section 102 of the MPA)
- Notice of decision to take agreed administrative action (Section 103 of the MPA)
- Notice of decision after reviewing administrative action on request (Section 106 of the MPA).

To request a review of an administrative action under Section 105 of the MPA, complete and submit the appropriate form **on or after the review day**:

- Request by holder of a substance authority to review administrative action relating to medicines
- Request by holder of an authority as an approved person for medicines to review administrative action

3.3.3.2 Applying for an internal review of an original decision

Chapter 6, Part 1, Division 2 of the MPA covers applications for internal reviews of original decisions made under the MPA.

An **affected person** for an **original decision** (both defined in Section 196 of the MPA) may apply to the chief executive for a review of the decision under this division (an **internal review**).

An application for internal review of an original decision must be in the appropriate approved form:

- Application for internal review of an original decision relating to a substance authority for medicines
- Application for internal review of an original decision relating to an authorisation as an approved person for medicines

3.3.3.3 Applying to QCAT for a review of an original decision

Chapter 6, Part 1 of the MPA covers Queensland Civil and Administrative Tribunal (QCAT) reviews of decisions.

Under Section 197 of the MPA, an affected person for an original decision (other than decisions about compensation made under Section 128 of the MPA) may apply to 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 have been made, under Chapter 6, Part 1, Division 2 of the MPA.

3.3.3.4 Requesting information from the administrative action register

Under Section 228(a) of the MPA, the chief executive must keep a register about administrative action taken under Chapter 4, Part 3 of the MPA. This is called the administrative action register.

In accordance with Section 229 of the MPA, the administrative action register contains the following information about administrative action taken in relation to a person:

- the name of the person; and
- a brief description of the administrative action taken in relation to the person.

Under Section 231(2) of the MPA, the chief executive of Queensland Health (or delegate) may give information, including confidential information, from the administrative action register to a person seeking the information, if the chief executive (or delegate) is satisfied it is in the public interest to do so. Individuals can use this form to request information from the administrative action register (PDF 267 kB)

3.3.4 Prosecution

Prosecution is only used for the most serious offences which have, or may have, 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.

4 Specific strategies for monitored and high-risk medicines

'Monitored medicines' and 'high-risk medicines' are specified in Schedule 2, Part 4 and Schedule 2, Part 2 of the MPMR, respectively. Currently, the lists of monitored medicines and high-risk medicines are identical, comprising:

- all schedule 8 medicines
- all benzodiazepines
- codeine
- gabapentin
- pregabalin
- quetiapine
- tramadol
- zolpidem
- zopiclone.

Queensland Health has implemented a range of regulatory strategies relevant to particular monitored and high-risk medicine offences, including (but not limited to):

1. Not Look Up (NLU) Strategy
2. Monitored Medicines Standard (MMS) Strategy
3. Self-Prescribe (SP) Strategy
4. Amfetamines and Methylphenidate (AM) Strategy
5. Managing reports and notifications

These strategies are regularly reviewed.

The strategies described in this document:

- are indicative only
- describe selected, key activities undertaken by Department of Health regulators—it is not an exhaustive list of all regulatory activities undertaken by Department of Health and Hospital and Health Services regulatory officers
- may be modified at any time without notice.

Matters are dealt with on a case-by-case basis. Where high-risk matters or a combination of indicators of non-compliance is identified, Queensland Health may escalate regulatory action.

4.1 NLU Strategy

Context

Section 41 of the MPA requires that 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.

'Relevant practitioners' are specified in Schedule 18, Part 1 of the MPMR as:

- dentists
- medical practitioners
- nurse practitioners
- endorsed midwives
- pharmacists and intern pharmacists
- endorsed podiatrists and podiatric surgeons.

The NLU Strategy aims to promote and support compliance with the requirement for relevant practitioners to check QScript.

General statement – exempted circumstances

Section 41(3)(a) of the MPA provides that a relevant practitioner is not required (under Section 41(2) of the MPA) to check QScript before prescribing, dispensing or giving a treatment dose of a monitored medicine for a person if the proposed dealing happens in circumstances prescribed by regulation to be exempt from this requirement.

Prior to 1 July 2024, there were no exemptions from mandatory QScript look-up specified in the MPMR.

From 1 July 2024, Schedule 18, Part 1A of the MPMR specifies a range of circumstances in which relevant practitioners are exempted from the mandatory requirement to check QScript. Practitioners are encouraged to document when an exempted circumstance applies, so that this information can be provided to Queensland Health if requested.

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.

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 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.

Monitoring approach

The NLU strategy has a continued focus on guidance through education and warning letters before more directed compliance / other regulatory action is considered. The strategy involves both proactive and reactive compliance monitoring.

As of 1 November 2023, the NLU Strategy includes the following approaches:

- **Reminder to register:** Relevant practitioners who are identified as prescribing or dispensing monitored medicines who are not registered for QScript will receive a warning letter. Ongoing non-compliance may result in an additional warning letter, a compliance notice, disclosure of information to the Office of the Health Ombudsman (OHO) and/or administrative action.
- **Reactive approach**: Queensland Health may undertake a reactive review of a relevant practitioner's QScript usage in response to triggers such as a complaint or a coronial information request.
  - If a reactive review identifies non-compliance with QScript look-up requirements, the practitioner will typically receive an education email in the first instance.
  - Ongoing non-compliance may result in a warning letter (+/- proactive monitoring for a period of time), a compliance notice and/or disclosure of information to the OHO.

- **Proactive, 'top-down' approach**: Proactive monitoring of compliance with QScript look-up requirements is focused on the highest risk prescribers and dispensers who frequently fail to check QScript (as opposed to a general bulk email approach).
  - Relevant practitioners identified via proactive monitoring will typically receive an education email in the first instance, and their QScript look-ups will be monitored for a period of time. During this monitoring period, Queensland Health may communicate with the practitioner regarding their NLU compliance rate and to provide support and guidance.
  - If low rates of compliance continue after the monitoring period, the practitioner will be issued a warning letter and monitoring will continue for an additional period of time.
  - Ongoing high levels of non-compliance may result in further warning letters, a compliance notice and/or disclosure of information to the OHO.

4.2 MMS Strategy

Context

Under Section 93 of the MPMR, a prescriber prescribing a monitored medicine to be dispensed or given as a treatment dose must prescribe the medicine in accordance with the departmental standard called 'Monitored medicines' (the Monitored Medicines Standard (MMS)). This requirement applies to both oral and written prescriptions.

Under Section 126 of the MPMR, dispensers must dispense a monitored medicine in accordance with the MMS. This requirement applies irrespective of whether the prescription for the monitored medicine:

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

The MMS Strategy aims to promote and support compliance with the requirement for prescribers and dispensers to comply with the MMS.

Monitoring approach

Reactive reviews of a practitioner's MMS compliance may be undertaken (e.g. in response to a complaint).

A proactive compliance monitoring strategy for version 2 of the MMS (in effect from 1 July 2024) is currently being developed.

4.3 SP Strategy

Context

Section 40 of the MPA includes a specific offence for self-prescribing and self-administering **high-risk medicines,** which are specified in Schedule 2, Part 2 of the MPMR as:

- all schedule 8 medicines
- all benzodiazepines
- codeine
- gabapentin
- pregabalin
- quetiapine
- tramadol
- zolpidem
- zopiclone.

Monitoring approach

The SP strategy involves both proactive and reactive compliance monitoring.

- Health practitioners who are identified as self-prescribing a high-risk medicine may be given a warning letter in the first instance, prior to consideration of further regulatory action.
- Ongoing non-compliance may result in an additional warning letter, compliance notice, disclosure of information to the OHO and/or administrative action.

4.4 AM Strategy

Context

The prescribing of amfetamines and methylphenidate (collectively referred to in this document as **psychostimulants**) is subject to range of controls specified in the MPA and MPMR.

While some health practitioners have as-of-right authority to prescribe psychostimulants in certain circumstances, in most cases, a practitioner seeking to prescribe these medicines is required to hold a prescribing approval, issued under Section 67 of the MPA, authorising this.

Guidance on the legislative requirements for psychostimulant prescribing—including when a prescribing approval is or is not required—is available in the Prescribing psychostimulants fact sheet.

The AM Strategy aims to ensure psychostimulants are only prescribed by authorised persons in authorised circumstances.

General statement – prescribing psychostimulants for narcolepsy

The MPA and MPMR provide all medical practitioners with as-of-right authority to prescribe psychostimulants to patients for the treatment of narcolepsy.[3]

To determine whether a medical practitioner required a prescribing approval to have lawfully prescribed a psychostimulant to a particular patient, Queensland Health typically needs to know the medical condition for which the psychostimulant was prescribed.

Medical practitioners can assist Queensland Health by proactively (and voluntarily) notifying us when they are prescribing psychostimulants to patients for the treatment of narcolepsy. A notification process for this is currently in development.

Monitoring approach

The AM strategy involves both proactive and reactive compliance monitoring and adopts an education first approach to practitioners identified as prescribing psychostimulants without an authority or appropriate prescribing approval.

Proactive monitoring is undertaken using a risk-based approach, with a focus on general practitioners identified as having prescribed psychostimulants without a prescribing approval on a specified number of occasions (i.e. above a specified threshold) during the specified monitoring period.

- Prescribers identified (through either proactive or reactive reviews) as having prescribed psychostimulants without an authority may receive an education email in the first instance.
- Ongoing non-compliance may result in a further education email and/or warning letters.

4.5 Managing reports and notifications

Context

Chapter 8, Part 5 of the MPMR requires people dealing with medicines to report particular matters to the chief executive in a range of circumstances (e.g. when the loss or theft of a Schedule 8 medicine is suspected or when prescriptions or purchase orders are suspected to be unlawful e.g. false or fraudulent). All reports and notifications of this nature are recorded, assessed and—if necessary—investigated and managed by authorised officers.

Individuals can use online approved forms on the Reporting medicines matters to the chief executive page to meet their reporting and notification requirements under the MPA and MPMR.

[3] Schedule 6, Part 1, Division 5 of the MPMR.

Monitoring approach

The management of reports and notifications is a reactive regulatory activity, and no structured proactive monitoring of compliance with notification requirements is undertaken.

However, Queensland Health may undertake a reactive review of a person's compliance with notification requirements in response to triggers such as a complaint or a coronial information request.

5 Glossary

Term	Definition
AM Strategy	Amfetamines and Methylphenidate Strategy
MMS Strategy	Monitored Medicines Standard Strategy
monitored medicines	Medicines specified in Schedule 2, Part 4 of the Medicines and Poisons (Medicines) Regulation 2021.
MPA	*Medicines and Poisons Act 2019* (Qld)
MPMR	Medicines and Poisons (Medicines) Regulation 2021 (Qld)
NLU Strategy	Not Look Up Strategy
OHO	Office of the Health Ombudsman
PIN	Prescribed Infringement Notice
SP Strategy	Self-Prescribe Strategy

6 Further information

If you require further information about Queensland Health's compliance monitoring and enforcement framework for the MPA, please email: MedicinesCompliance@health.qld.gov.au