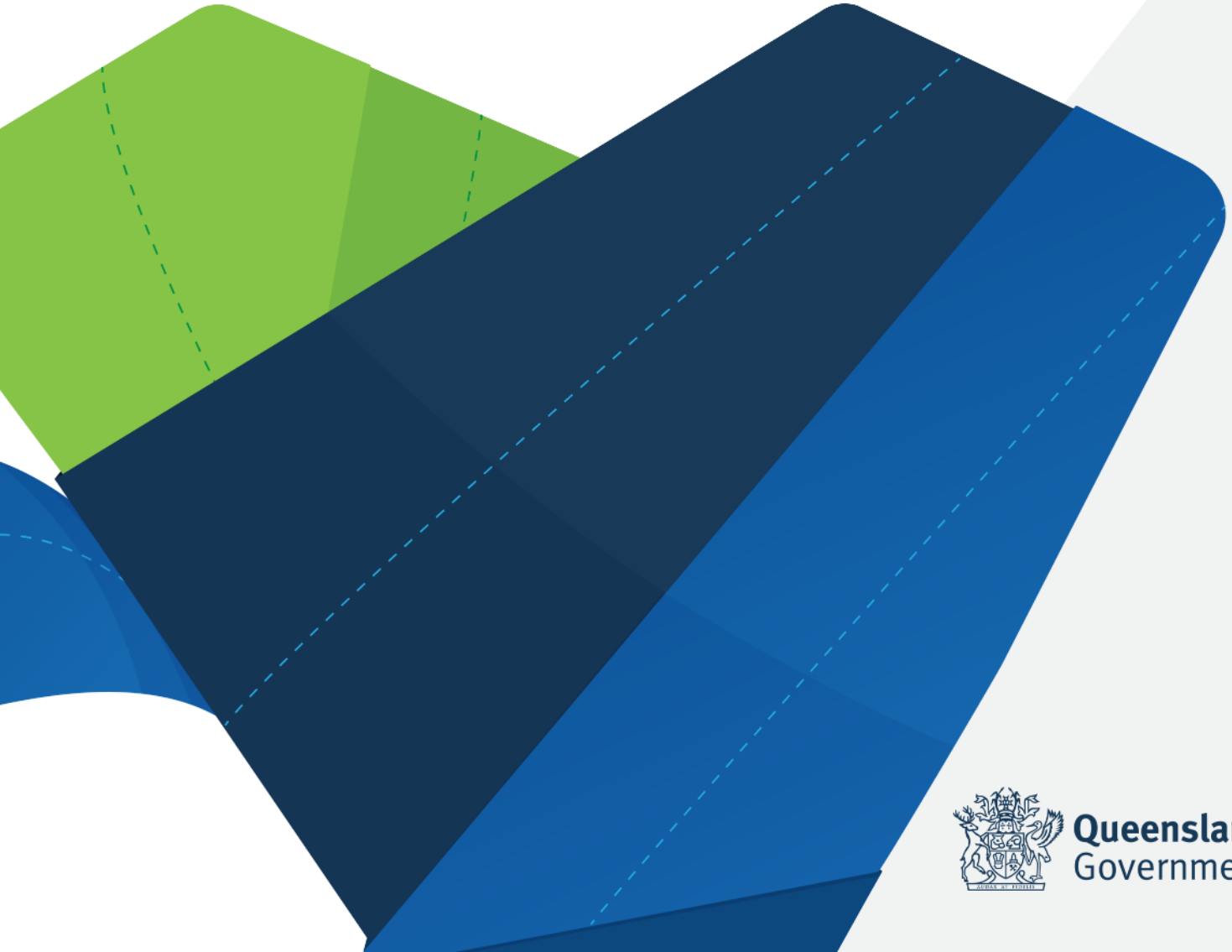
What Pharmacists Need to Know

The new Medicines and Poisons Act 2019, Medicines and Poisons (Medicines) Regulation 2021 and associated Departmental Standards regulatory framework



Queensland Government

The new Medicines and Poisons Act 2019, Medicines and Poisons (Medicines) Regulation 2021 and associated Departmental Standards regulatory framework

Published by the State of Queensland (Queensland Health), September 2021

For more information contact:

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An electronic version of this document is available at https://www.health.qld.gov.au/system-governance/licences/pharmacy/community-pharmacy-compliance-survey

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Introduction

This guide 'What Pharmacists Need to Know' has been developed to assist pharmacists and community pharmacy owners in meeting their regulatory responsibilities under the new *Medicines and Poisons Act 2019* (MPA), the *Medicines and Poisons (Medicines) Regulation 2021* (MPMR) and associated Departmental Standards.

Special note for community pharmacists. The information below will help guide you in your understanding of the new legislative framework and provide assistance to you as you participate in the community pharmacy compliance survey (CPCS) process.

Background

On 26 September 2019, the MPA and the *Therapeutic Goods Act 2019* (TG Act (Qld)) became law in Queensland, however, did not commence in entirety until 27 September 2021. The MPA can be accessed at the web address:

https://www.legislation.qld.gov.au/view/pdf/inforce/current/act-2019-026

This document will focus on the MPA and the MPMR. For key information on the (TG Act (Qld)) please refer to Box 1 below.

Box 1. Purpose of the *Therapeutic Goods Act 2019*

The purpose of the TG Act (Qld) is to manage health and safety risks posed by therapeutic goods by applying Commonwealth regulatory controls on those to whom it does not already apply, for example, 'individuals' manufacturing therapeutic goods and trading within the limits of Queensland.

The provisions of the TG Act (Qld) will replace parts of the Health Regulation 1996 (e.g. 'duties of a manufacturer' and advertising provisions.)

The Commonwealth Therapeutic Goods Laws already apply to 'corporations' in Queensland.

On its commencement, the MPA repealed and replaced the *Health Act 1937* and the *Pest Management Act 2001.* The *Health (Drugs and Poisons) Regulation 1996*, (HDPR), *Health Regulation 1996* and *Pest Management Regulation 2003* were also repealed and replaced, with the making of new Regulations and Standards to support the MPA.

The regulations are the:

- MPMR;
- *Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021*; and
- *Medicines and Poisons (Pest Management) Regulation 2021.*
- The MPMR is the primary regulation that a pharmacist will work under, and the focus of this document, and can be accessed at the: New medicines, poisons and pest management regulatory framework

Aim of the new regulatory framework

The new regulatory framework modernises and streamlines the regulation of medicines, poisons, prohibited substances, pesticides, and fumigants. It will ensure requirements are easier for industry and the community to understand and apply in practice.

The regulatory framework aims to protect public health and safety by:

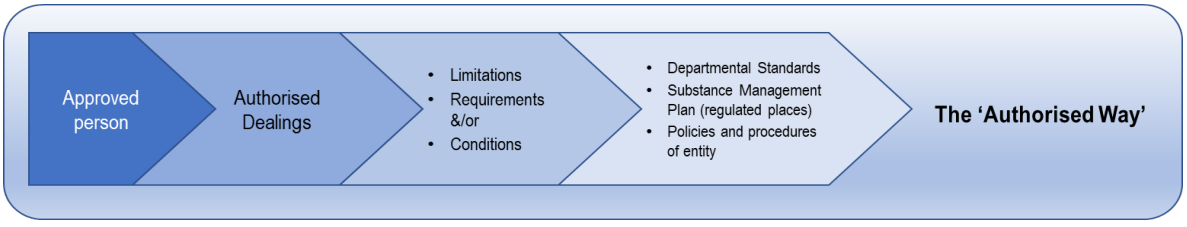
- ensuring health and safety risks arising from the use of regulated substances are appropriately managed;
- requiring persons using regulated substances to have competencies to carry out the activities safely and effectively; and
- ensuring regulated substances are made, sold, used and disposed of appropriately.

Fundamentals

The way in which access to medicines was controlled in the HDPR, continues to apply under the new regulatory framework in many ways. For example, only authorised prescribers can prescribe, there are requirements for a prescription to be lawful, and there are requirements around the dispensing of medicines and the sale of S2 and S3 medicines.

What has changed includes, but is not limited to, the introduction of new and modified terminology; how someone is authorised to deal with medicines; how offence provisions work; and the introduction of Departmental Standards and a Substance Management Plan, (SMP). A SMP recognises the importance of systems in managing the risks associated with access to medicines. Schedule 17 of the MPMR prescribes the regulated places that must have a SMP and who is responsible for making the plan at that place. A community pharmacy is required to have an SMP. A key fundamental principle of the MPA is to ensure a 'regulated substance' is 'dealt with' in an 'authorised way' which is summarised in Figure 1.

Figure 1 Summary of what doing something in an 'authorised way' means



So, what is new?

Terminology

The MPA introduces some new and modified terminology. The full list of terms and associated definitions can be found in the Dictionary in Schedule 1 of the MPA. Sections 8-31 of the MPA provides for the interpretation and meaning of key terms and activities when **'dealing with'** regulated substances, these terms include manufactures, buys, possesses, supplies (an umbrella term that includes dispense), administers, prescribes, and disposes of waste from a regulated substance.

> It is highly recommended that pharmacists view the above sections of the MPA and the Dictionary in Schedule 22 of the MPMR which will provide an insight into the new terminologies to be used.

The MPMR also has new terms, new categories of medicines, and other modified terminology. The new categories of medicines listed in Schedule 2 of the MPMR are Restricted medicines, High-risk medicines, Diversion-risk medicines and Monitored medicines and are denoted by the type of risks associated with these medicines and the controls of use to safeguard public health.

The category of restricted medicines replaces the HDPR concept of regulated controlled drugs (e.g. amphetamines {now spelt amfetamines}) and regulated restricted drugs (e.g. isotretinoin for human oral use). There are still limits on who can prescribe restricted medicines.

There are specific offences connected to the above categories of medicines and pharmacists should view Sections 39-42 of the MPA. There is an offence for a person fraudulently obtaining or attempting to obtain diversion risk medicines. An offence exists for health practitioners who self-administer high risk medicines and a new offence for a health practitioner self-prescribing a high-risk medicine. There are new offences for a prescriber or dispenser of a monitored medicine, as it is now mandatory that the monitored medicines database is checked to see whether a person has previously been prescribed or supplied a monitored medicine. Monitored medicines are those that will be monitored under QScript, -(Refer to the section on real-time reporting of monitored medicines in this document for more information). There is an offence if waste from a S8 medicine is not disposed of in the correct way.

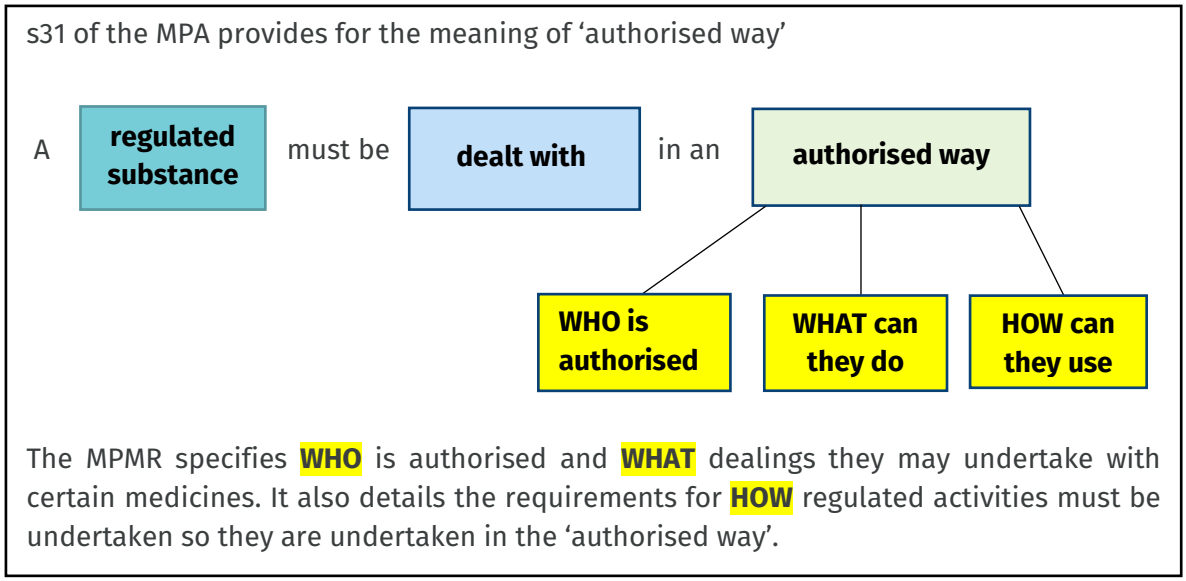
Authorised way

A key principle of the MPA is to ensure a 'regulated substance' is 'dealt with' in an 'authorised way' which is illustrated in Figure 2.

- S17 of the MPA defines a **'regulated substance'** as a medicine, poison, prohibited substance, fumigant, or pesticide.

- S11 of the MPA defines a **'medicine'** as a substance intended for therapeutic use to which schedules 2, 3, 4 & 8 of the Poisons Standard applies. The MPA uses the terms S2, S3, S4 and S8 medicines.

Figure 2. Illustrated meaning of 'authorised way'



Approved person

The MPA specifies how a person may be authorised to deal with a regulated substance.

Some health practitioners may also be authorised to perform specific dealings with a regulated substance under an Extended Practice Authority (EPA) within the limitations and conditions of the EPA. (Refer to the section on Extended Practice Authorities within this document for more detail on EPAs).

An **'approved person'** is a member of a class of persons prescribed by Section 13 of the MPMR via the listed Schedules (3 to 15). The term 'approved person' replaces the term 'particular endorsement' previously used in the HDPR. The Schedules will specify WHO is authorised and What dealings (e.g. dispense, possess, and administer activities etc.) they may undertake with certain medicines.

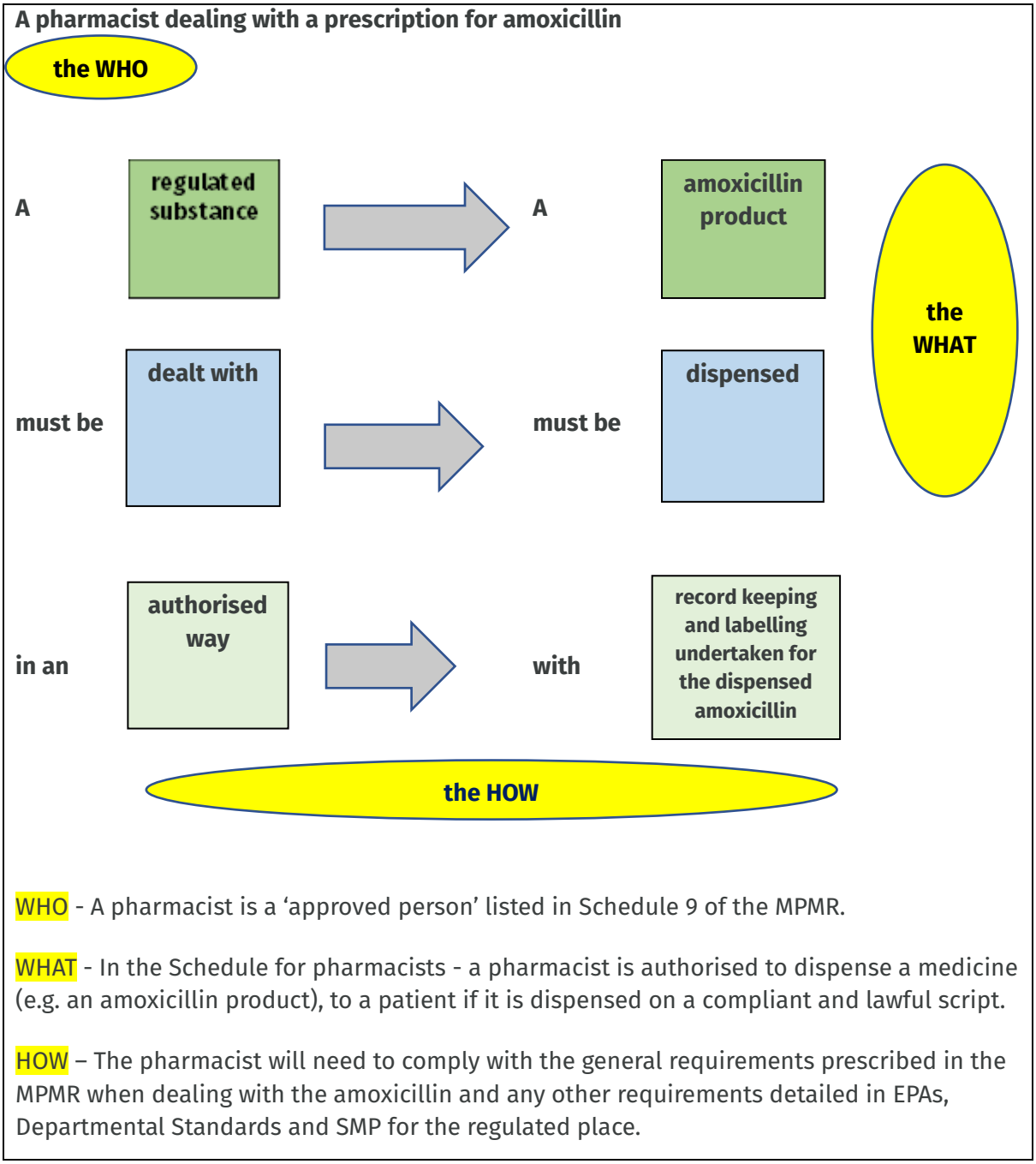
- For example, there are listed Schedules for (but not limited to) dentistry professions, medical practitioners and assistants, nursing & midwifery professions, and pharmaceutical professions. Schedule 9 of the MPMR lists the class of persons for pharmaceutical professions and includes pharmacists, intern and trainee pharmacists, dispensary pharmacy assistants, general pharmacy assistants and hospital pharmaceutical technicians.

The Schedules within the MPMR may also stipulate limitations for certain dealings with medicines.

- For example, the MPMR lists in Schedule 9 that a pharmacist is authorised to administer an approved opioid, but a listed limitation is the medicine is administered on a prescription.

Doing something in the 'authorised way' (Operational example in Figure 3) means that the person is authorised to carry out an activity as specified by the MPMR and complies with the legislated requirements for that activity including any requirements set out in an SMP for the place.

Figure 3. Operational Example - Pharmacist dealing with a "script" in the authorised way



WHO - A pharmacist is a 'approved person' listed in Schedule 9 of the MPMR.

WHAT - In the Schedule for pharmacists - a pharmacist is authorised to dispense a medicine (e.g. an amoxicillin product), to a patient if it is dispensed on a compliant and lawful script.

HOW – The pharmacist will need to comply with the general requirements prescribed in the MPMR when dealing with the amoxicillin and any other requirements detailed in EPAs, Departmental Standards and SMP for the regulated place.

Authorised dealings

The MPA explains what 'deals with' a regulated substance means while the general requirements for 'how' to carry out a dealing is detailed in the MPMR.

Section 18 of the MPA defines a person as 'dealing' with a regulated substance and includes the activities - manufactures, buys, possesses, supplies, administers, prescribes, and disposes of waste from a regulated substance. A person also deals with a regulated substance if the person asks or directs another person to undertake these activities.

For example, The MPA defines 'buys' a regulated substance as a dealing and the MPMR then details the requirements for buying the regulated substance using a purchase order.

It is timely to note that under Section 20 of the MPA a 'regulated activity' is a dealing with a regulated substance. For example, the buying of a scheduled medicine from a drug wholesaler is a regulated activity.

General requirements

Chapter 4 of the MPMR has general requirements on how to perform dealings and the associated record keeping and reporting obligations provide the core requirements for HOW medicines are to be dealt with in an 'authorised way' and cover the following parts :

Parts in Chapter 4 of the MPMR	**Section number for each Part**
Part 2. Manufacturing by compounding	Section 45
Part 3. Buying by giving purchase orders	Section 48
Part 4. Supplying stock	Section 54
Part 5. Possessing stock for delivery	Section 75
Part 6. Prescribing medicines	Section 79
Part 7. Making standing orders	Section 101
Part 8. Dispensing medicines	Section 112
Part 9. Giving treatment doses of medicines	Section 129
Part 10. Administering medicines	Section 139
Part 11. Disposing of waste from diversion-risk medicines	Section 143

The associated record keeping and reporting obligations in the new medicines' legislation are fundamentally similar to those in the previous HDPR.

Disposal of S8 medicine waste

There are **new arrangements for the destruction of S8 medicines** in the MPMR. Unwanted or expired S8 medicines should not be sent to Forensic and Scientific Services, Queensland Health.

The MPMR stipulates the requirements for disposing of waste from diversion-risk medicines, including S8 medicines. Most medicine waste may be sent to an approved waste management contractor for high temperature incineration.

If the waste is from an S8 medicine, it must first be destroyed (rendered unusable and unidentifiable) before being sent away for disposal. The specific requirements for destroying S8 medicines are detailed in the information sheet - *Disposal of S8 medicine waste* and can be accessed at the: New medicines, poisons and pest management regulatory framework

Extended Practice Authorities (EPAs)

In essence, what you may have known as, Drug Therapy Protocols have now become EPAs to better reflect their function as an instrument that extends a practitioner's scope of practice beyond that which is provided for in the MPMR. A pharmacist's authority to administer vaccinations, for example, is provided via an EPA. EPAs may state the places or contexts in which an approved person may deal with a regulated substance, may impose conditions on dealing with a substance, and / or require a person to hold specified qualifications or training. EPAs are listed in Schedule 1 of the MPMR and are published on the Queensland Health website.

Other requirements in the MPMR

Like the previous HDPR there are other obligations on pharmacists as part of their roles as stewards for the medicines access system overall. In addition to the authorised way requirements, the MPMR specifies how authorised persons must deal with electronic prescription management systems, medicines storage systems, labelling, packaging and containers, and the recording and reporting of particular matters. These matters include, for example, reporting lost & stolen medicines and fraudulent prescriptions. Some of these requirements will also need consideration and compliance with Departmental Standards.

Pharmacy assistants

Pharmacy assistants make up classes of **'approved persons'** listed in Schedule 9 of the MPMR. The classes include **hospital pharmaceutical technicians**, **dispensary pharmacy assistants** and **general pharmacy assistants**.

Pharmacy assistants and pharmacists must note that Schedule 9 of the MPMR specifies the dealings (e.g. possession, compounding, selling by retail and the giving of purchase orders) that can be undertaken by a pharmacy assistant with certain medicines. There are also stipulated limitations for pharmacy assistants' dealing with these medicines. For example, the MPMR stipulates in Schedule 9 that a pharmacy assistant can only undertake dealings for certain medicines under the **supervision** or **direct supervision** of a pharmacist.

The Schedule 22 definition of ***direct supervision*** in the MPMR means supervision of the pharmacy assistant by a pharmacist as being in physical proximity to the pharmacy assistant; or the pharmacist uses technology that allows the pharmacist to see and communicate with the pharmacy assistant in real time. Example – online streaming.

With pharmacy assistants now making up a class of **'approved persons'** there are now accompanying obligations for both pharmacy assistants and their supervising pharmacists. The authority for pharmacy assistants provided for in Schedule 9 imposes conditions. A pharmacy assistant will commit an offence if these conditions are not met. For example, under Section 164 of the MPMR, a pharmacy assistant must notify a pharmacist of any S8 medicines stock discrepancy between a S8 medicine wholesaler's invoice and stock received. Similarly, under Section 165 of the MPMR, a pharmacy assistant must not sell an S2 medicine other than in the manufacturer's pack.

Under Section 211 of the MPMR there is an offence for both a pharmacist and pharmacy assistant if an S8 safe is accessed for a dealing (e.g. accessing or stocking an S8 medicine) and no record is made within the S8 medicine register within 24 hours. If a pharmacy assistant is making the record in the S8 register then the supervising pharmacist must counter signature the entered pharmacy assistant's name.

Pharmacists must carefully consider Departmental Standards when developing and implementing a SMP for the pharmacy as it must cater for authorised pharmacy employees such as pharmacy assistants; include training and supervision; and any documented processes to be followed. Standards for consideration (listed in next section) include the:

- *Departmental Standard – Secure storage of S8 medicines;*
- *Departmental Standard – Compounding;* and
- *Departmental Standard – Substance management plans for medicines.*

Tasks or activities that involve pharmacy assistants, must be articulated in writing within the SMP for a pharmacy, such as the:

- ordering of medicines stock;
- receiving of medicines stock;
- S8 medicines record keeping
- storing of S2, S3 & S4 medicines; and
- the storing of S8 medicines.

For example, the task of how a pharmacy assistant may access a S8 storage receptacle (i.e. the S8 safe) to store an S8 medicine under the direct supervision of a pharmacist must be articulated within the SMP. A pharmacist may for instance give the pharmacy assistant the actual physical key to open a S8 safe. The pharmacy assistant stores the S8 medicine and locks the safe and returns the key to the pharmacist. A pharmacy assistant must not be able to access a S8 safe when the pharmacist is not present at the pharmacy. If a S8 safe has only a combination lock, a pharmacist must not give the combination of the safe to a pharmacy

assistant. In Attachment 2 there is an example of how a pharmacy assistant could order S8 medicines and then deal with the S8 medicines when they are delivered to the pharmacy.

Departmental Standards and Substance Management Plans

A Departmental Standard outlines, for professions and industries, the mandatory expectations and specific requirements needed to ensure regulatory compliance with the MPA and the MPMR.

Depending on the pharmacy services undertaken, you will need to comply with all or some of the following Standards which are listed in Schedule 1 of the MPMR and titled:

- *Departmental Standard – Secure storage of S8 medicines;*
- *Departmental Standard – Monitored medicines;*
- *Departmental Standard – Pseudoephedrine recording;*
- *Departmental Standard – Compounding;*
- *Departmental Standard – Requirements for an electronic prescription management system;* and
- *Departmental Standard – Substance management plans for medicines.*

Departmental Standard – Secure storage of S8 medicines

The purpose of this Standard is to prescribe the applicable minimum requirements and level of security for the storage of S8 medicines in Queensland to prevent the unauthorised removal of, or interference with these medicines. Compliance with this Standard will limit the opportunity for S8 medicines to be misused, abused, or diverted.

If you have a previously compliant HDPR controlled drug receptacle, it will meet the requirements of this Standard.

Lawful approaches for storing S8 medicines, in addition to a traditional safe, are presented in this Standard and consider such things as the nature and quantity of the medicines being stored and the location and security features with which premises are equipped. For example, a pharmacist in a community pharmacy may apply to keep S8 medicines in an electronic storage and supply unit. An application can be made via an approved form and by contacting the Healthcare Approvals and Regulation Unit at HARU@health.qld.gov.au.

Departmental Standard – Pseudoephedrine recording

In order to minimise the risk of pseudoephedrine being diverted for illicit use, a pharmacist who sells pseudoephedrine is required by Section 162 of the MPMR to make a record of the sale in a way that complies with this Standard. A record made in accordance with this Standard will need to be available in an online, real-time electronic form, that is visible to

other pharmacists to assist them to make an informed decision on the appropriateness of a proposed sale.

Departmental Standard – Compounding

The purpose of this Standard is to define necessary infrastructure, in terms of the compounding environment, equipment, and systems requirements to ensure that compounded medicines are safe, efficacious and of a high quality.

All persons engaged in compounding are responsible for ensuring that quality is built into the compounding of medicines and must under Section 47 of the MPMR ensure medicines are compounded in accordance with this Standard. This Standard does not remove or conflict with the expectations of the Pharmacy Board of Australia and in fact requires pharmacists to refer to current guidelines published by the Pharmacy Board of Australia and the current version of the Australian Pharmaceutical Formulary and Handbook for other requirements with respect to compounding medicines.

Departmental Standard – Monitored Medicines

Monitored medicines are defined in the MPMR as a certain class or category of prescription medication. The MPMR requires health practitioners to comply with the Departmental Standard - Monitored Medicines when they prescribe a monitored medicine for dispensing or giving a treatment dose for a patient, or when they dispense a monitored medicine for a patient. The Departmental Standard - Monitored Medicines sets the minimum mandatory requirements prescribers and dispensers must comply with when these events occur. The object of the standard is to protect and improve patient health and wellbeing and reduce patient harms arising from the use of monitored medicines, by encouraging early identification and appropriate management of monitored medicine-related health risks. The list of monitored medicines is prescribed in Schedule 2, Part 4 of the MPMR.

Section 126 of the MPMR requires pharmacists to comply with the Monitored Medicines Standard (the Standard) when dispensing a monitored medicine.

Whilst this section of the document is about Departmental Standards it is timely to discuss the real time reporting of monitored medicines.

Real-time reporting of monitored medicines (known as QScript)

What is QScript?
QScript is a read-only real-time prescription monitoring system which allows authorised health practitioners to review a patient's monitored medicine prescription history at the point of care.

What information is contained in QScript?
QScript contains records of monitored medicines that have been prescribed for supply to a patient or dispensed to a patient (provided on prescription) in Queensland pharmacies. All monitored medicines dispensed in Queensland pharmacies (other than those dispensed in public sector hospitals) will be recorded in QScript regardless of whether they are subject to

the Pharmaceutical Benefits Scheme (PBS) or Repatriation Schedule of Pharmaceutical Benefits (RPBS) subsidy or are a private prescription.

QScript also contains other monitored medicine-related information which may assist clinical decision-making—such as whether a patient is or has been registered on the Queensland Opioid Treatment Program (QOTP).

Key information for pharmacists includes but is not limited to:

1. Under s41 of the MPA, pharmacists will need to check QScript prior to dispensing or giving a treatment dose of a monitored medicine for a patient. For 'staged supply' arrangements (i.e. when providing dispensed medicine to a patient in instalments) the requirement to check QScript only applies when the medicine is initially dispensed.
2. All pharmacists (other than those practising in public sector hospitals) must process all monitored medicine prescriptions (including QOTP prescriptions) via dispensing software that is integrated with a Prescription Exchange Service, to facilitate the real-time upload of prescription data to QScript.
3. Pharmacists no longer need to manually submit S8 prescription data to Queensland Health through the electronic File Upload System.
4. All prescriptions for monitored medicines (including S4s) will require the patient's date of birth to be included on the prescription and recorded in the relevant dispensing software.
5. S8 prescriptions must still describe the amount of medicine in words and numbers, however this no longer needs to be handwritten.
6. Prescribers treating drug dependent patients with monitored medicines (excepting approved opioids for the QOTP) do not need to obtain treatment approvals from the Department.
7. Psychiatrists treating adults with dexamfetamine, lisdexamfetamine or methylphenidate may prescribe up to specified dosages in certain specified circumstances, without having to obtain a prescribing approval.
8. Any medical practitioner can prescribe Schedule 8 medicinal cannabis products to any patient if the medical practitioner believes they will be of therapeutic benefit. For unregistered medicinal cannabis products, the medical practitioner must hold the relevant Commonwealth Department of Health Therapeutic Goods Administration approval.

Key changes for pharmacists and dispensing medical practitioners relating to the Queensland Opioid Treatment Program (QOTP)

1. Opioid Replacement Therapy (Medication-Assisted Treatment for opioid dependence), under the Queensland Opioid Treatment Program, can now be prescribed and dispensed using a standard prescription. However, all QOTP computer-generated paper prescriptions will be required to be on Queensland Health authorised security paper, and contain the prescriber's approval number. The

public sector Alcohol and Drugs Services' QOTP prescriptions will be issued with an electronic signature from the CIMHA system.

2. Pharmacists and dispensing medical practitioners (other than those practising in public sector hospitals) will be required to process QOTP prescriptions via dispensing software integrated with a Prescription Exchange Service, to facilitate the real-time upload of prescription data to QScript. This will need to occur prior to or at the time of the initial supply of medicine on each QOTP prescription.
3. Pharmacists and dispensing medical practitioners no longer need to send reconciled QOTP Written Instructions to Queensland Health.

For further information on Real-time reporting of monitored medicines (QScript) you can make contact via: Website: www.health.qld.gov.au/QScript Email: mmu@health.qld.gov,au and Phone: 13 7846

Departmental Standard – Requirements for an electronic prescription management system

This Standard will have relevance to a pharmacy if the pharmacy is involved in the dispensing of electronic prescriptions.

Chapter 8, part 1 of the MPMR states the requirements for an electronic prescription management system, (EPM system).

The EPM system must comply with the requirements stated in this Standard.

An EPM system comprises end-to-end conformant prescribing, prescription delivery and dispensing components. To enable safe and secure interconnected electronic prescription transactions, the 'prescribing component' and 'dispensing component' of the EPM system must be connected to a conformant prescription delivery service (PDS) to store, exchange and record prescription information and dispensing activities.

> This Standard **does not** apply to paper prescriptions that are sent as a digital image, such as by fax or email, to a dispenser.

For more information you can contact:

Chief Medical Officer and Healthcare Regulation Branch, Prevention Division, Queensland Health, GPO Box 48, Brisbane QLD 4001, email HLIU@health.qld.gov.au.

Departmental Standard – Substance Management Plans for medicines

A requirement in the MPA is that a responsible person for a regulated place must make a substance management plan (SMP) specific to the place. Section 92 of the MPA defines what a regulated place and a SMP are. A SMP is a written articulation of how the risks associated with dealing with regulated substances will be managed at a place.

Note: Regulated places have one year after the commencement of the MPA to make a SMP. The SMP must be in place by 27 September 2022.

Schedule 17 of the MPMR prescribes **regulated places** and **responsible persons** that are required to have an SMP. As stated earlier, a **community pharmacy** is prescribed as a regulated place and is required to have an SMP.

The responsible person for:

- a community pharmacy other than a specified pharmacy is **each pharmacist who owns** the community pharmacy; and
- a specified pharmacy is the pharmacist who is manager for the pharmacy. ***Specified pharmacy*** means— a community pharmacy operated by a friendly society or the Mater Misericordiae Health Services Brisbane Limited; or a pharmacy supplying medicines only to inpatients of a hospital.

A SMP must include the specific requirements listed in Chapter 4, Part 2 of the MPA, including addressing the matters that are set out in regulation. Section 173 of the MPMR specifies that an SMP for medicines must address the matters set out in this Departmental Standard.

Dependant on the scope of pharmacy activities undertaken at a pharmacy, the SMP will be required to have systems and/or describe or reference processes and procedures for regulated activities such as the manufacture, buying, possession, supply, sale, administration, prescribing, dispensing, record keeping and notifications, disposal and reviewing of incidents involving medicines.

When developing (and reviewing) your SMP, a risk that must be considered and addressed for each regulated activity in the SMP will be staff having insufficient training, qualifications, or experience to perform the activity. As such, the SMP should address processes and procedures related to staff training, competency, and supervision.

Example: The SMP for pharmacies providing immunisation services should include how they ensure persons administering vaccines at the pharmacy have the qualifications, registration, and expertise to carry out the activity. The procedures around vaccine use and the suitability of a place in which to undertake administration of the vaccines will need to be documented.

There will be a need for staff supervisory arrangements (e.g. for pharmacy employees) to be described in the SMP for a pharmacy. A SMP must describe or reference (where required) how adequate supervision:

- of administration and supply of medicines is provided;
- is provided for persons who can only possess medicines temporarily, under direct supervision or at the direction of an authorised person;
- when witnessing the disposal of S8 medicine waste is provided; and
- of the manufacturing and or compounding process is maintained and recorded.

It is important to note that a community pharmacy may already have existing policies, procedures, and accreditation documents, which will contribute to the development of **or meet the requirements** of an SMP.

It is also important to realise that though there may be many commonalities between SMP's for regulated places, it is likely that each SMP will be unique and specific to the regulated place's specific set of circumstances. How the risks that may be expected at a pharmacy can be managed and how other regulatory obligations may be met will depend on the 'regulated activities' undertaken at the pharmacy.

For example, where a community pharmacy offers vaccination, the SMP may include procedures for setting up, cleaning, and maintaining a clinical space for vaccinations, and the consent and record-keeping procedures to be followed. The SMP would also describe local procedures in place to enable lawful self-destruction of S8 medicines, e.g. the specific persons who are lawfully able to witness destruction and what specific method is used at the pharmacy to render the S8 medicines unusable.

For more information contact:

Chief Medical Officer and Healthcare Regulation Branch, Prevention Division, Queensland Health, GPO Box 48, Brisbane QLD 4001, email HLIU@health.qld.gov.au

Transitional arrangements for the new legislative framework

It is important to note that the MPA includes transitional arrangements to deal with any matters that were outstanding when the *Health Act 1937* and *Pest Management Act 2001* were repealed. The MPA also recognises that time may be needed to implement some of the new requirements of the regulatory regime. The repeal, savings and transitional provisions are located in Chapter 8 of the MPA.

Please note that Chapter 10 of the MPMR also has a number of transition arrangements. For example, Section 252 of the MPMR stipulates that a controlled drug register under Section 50 of the HDPR is taken to be a medicine register for S8 medicines under the MPMR.

Temporary extension to image-based prescription arrangements

Until **31 December 2021**, while the PBS special arrangements are in place, there is a temporary exemption to the requirement to send the original paper prescription to the dispensing pharmacy for Schedule 4 medicines other than diversion-risk medicines.

See Image based prescriptions - Information for prescribers and dispensers - factsheet (health.qld.gov.au)

Transition of documents

Prescriptions

Under Section 274 of the MPA, a prescription given under the *Health Act 1937*, continues in force under the MPA until the earliest of the following—

(a) the substance is dispensed, supplied, or administered; or

(b) the prescription is cancelled by a person who had the authority to cancel the prescription under the Health Act; or

(c) the period, stated on the prescription or provided for under the Health Act, during which the substance must be supplied or administered ends.

Purchase orders

Under Section 275 of the MPA, a purchase order for the supply of a substance other than medicated animal feed given under the *Health Act 1937*, continues in force under the MPA until the earliest of the following—

(a) the substance is supplied under the order; or

(b) the order is cancelled by a person who had the authority to cancel the order under the Health Act; or

(c) the period, stated on the order or provided for under the Health Act, during which the substance must be supplied ends.

See Section 275 for specific requirements relating to medicated animal feed purchase orders.

Standing orders

Under Section 276 of the MPA, a HDPR standing order in effect immediately before the commencement of the MPA.

A continues in force for 6 months from the day of commencement. During that time period, the Health Act continues to apply to the HDPR standing order as if MPA had not commenced.

Extended periods for compliance

Substance management plans (transition period)

Under Section 280 of the MPA, a responsible person for a community pharmacy or specified pharmacy (refer to section on *Departmental Standard – Substance Management Plans for medicines* in this document for definitions) has a **1 year transition period** from the date of commencement of the MPA and MPMR before having to have a fully compliant SMP in place at the pharmacy.

Further information on the transition period for other authorisations and substance authority(s) are also provided under Section 280 of the MPA.

Procedures until monitored medicines database operational (transition period)

Section 281 of the MPA provides for a transition period with accompanying procedures until the monitored medicines database is fully operational. The transition period starts on the commencement date of the MPA and MPMR and ends on a day prescribed under Section 146 of the MPMR.

The procedures in the transition period include:

(a) a person is not liable to be prosecuted for a contravention of section 41 or 226 of the MPA; and

(b) a person to whom the HDPR, section 84(2) to (10) or 84A(3) and (4) applied immediately before the commencement must continue to comply with the section as if the MPA had not commenced;

> **Note—The HDPR, sections 84 and 84A provided for a dispenser to send particular information to the chief executive.**

(c) a person to whom the HDPR, section 120, 122, 213 or 213A applied immediately before the commencement must continue to comply with the section as if the MPA had not commenced.

> **Note—The HDPR, sections 120, 122, 213 and 213A provided for approvals for the treatment of drug dependent persons.**

(3) Section 281 does not prevent a person complying with the MPA to the extent practicable if, during the transition period, the monitored medicines database is able to be used.

Where to find further information

Further information on the new medicines legislative framework including legislation, departmental standards, extended practice authorities, fact sheets and supporting documents, approvals, manufacturing, wholesaling, and retail of scheduled medicines, key partners and updates and alerts can be accessed from the New medicines, poisons and pest management regulatory framework

The Principal Compliance Facilitator, Pharmacy Inquiry Response Program is available to assist in any Community Pharmacy Compliance Survey **(CPCS)** matters a pharmacist may have. Contact can be made with the Pharmacy Inquiry Response Program via email at pharmacy.compliance@health.qld.gov.au

Attachment 1 - Handy hints to access legislation

Hint 1. How do I access legislation?

All current Queensland legislation can be accessed via the following Queensland Government website In force legislation - Queensland Legislation - Queensland Government

- Once you are in the Queensland legislation website, to find the Medicines and Poisons Act 2019 click on the letter "M" in the Acts row. All Queensland Acts commencing with the letter "M" will appear. Scroll down the list to access the current version of the MPA.
- To find the Medicines and Poisons (Medicines) Regulation 2021, click on the letter "M" in the Subordinate Legislation row. All Queensland regulations commencing with the letter "M" will appear. Scroll down the list to access the current version of the MPMR.

Hint 2. How and where do I commence my search?

If you are not a regular user of legislation, a simple way to start looking for a section of law or information is to go to the Contents (index) page of the Act or regulation and scroll down the contents page. You will note there are Chapters, Parts and Divisions which are **in bold type.** They provide useful headings for you to consider and will assist you to narrow down your search for the topic and section(s) of law you are looking for.

Once you identify a **bolded heading** or **title** relating to a topic you are interested in, then click on the heading or title in the contents page. This will take you directly to this section of law within the Act or regulation. You will now note that the individual sections of legislation are also now **in bold type** to make it easier for you to identify the section(s) of law you are looking for. Tip! - Always scroll forward and backwards from the section of legislation you have just identified to determine if there are other sections of legislation that have relevance to your topic.

An alternative option is to utilise the search function tool in the Act or regulation to access a topic you are interested in. This option can be effective and quick for experienced users of legislation but can limit the "full picture" and understanding of sections of legislation if a user is not careful.

Hint 3. Read the *Interpretation* & *Dictionary* parts of the Act or regulation?

ALWAYS - Read the *Interpretation* and *Dictionary* parts of an Act or regulation to better understand the meaning of a term or wording contained within a section of legislation. The meaning of a legislative term may have a very specific meaning and be different to what you may think and are used to.

The *Interpretation* part is in Chapter 1. Part 2. and the *Dictionary* is in Schedule 22 of the MPMR.

The *Interpretation* part is in Chapter 1. Part 4. and the *Dictionary* is in Schedule 1 of the MPA.

Hint 4. A specific Chapter, Part, Division, or individual section(s) of law may have its own definitions within

Once you have identified the section(s) of law you are interested in, have a quick look within the Chapter, Part, and Division of the Act or regulation to determine if there are additional legislative definitions and meanings for the terms and wording you are looking at.

For example, Chapter 8 Offences; Part 2 Secure storage systems of the MPMR has its own definitions within Section 195. These are in addition to the definitions found in the Schedule 22, Dictionary of the MPMR. Section 195 has definitions for access; medicine store; S8 safe; and authorised user for example. A person must read these definitions to gain a correct understanding of the law for this part of the MPMR.

Worked example - how to identify sections of law for "dispensing"

The following information is a worked example on using *Handy Hints 1-4* to identify legislation relating to the dispensing and record keeping requirements of the MPMR. For a pharmacist **dealing** in dispensing and record keeping for medicines, you would be well aware that these are dealings that are generally undertaken on a daily basis.

Step 1. Go to the Queensland Government legislation website In force legislation - Queensland Legislation - Queensland Government

Step 2. To find the *Medicines and Poisons (Medicines) Regulation 2021*, click on the letter "M" in the Subordinate Legislation row. Scroll down the list and click on the *Medicines and Poisons (Medicines) Regulation 2021.*

Step 3. The MPMR will now appear in standard view with the Contents listed in the column on the left-hand side of the page. You have a choice to use this view or choose another (possibly better option). Click on either the ***View as whole SL*** tab or the ***PDF*** tab located just above the MPMR title on the page.

Step 4. As discussed in Handy Hint 2, by scrolling down the *Contents* page of the legislation, you identify that ***Chapter 4 General requirements for dealings*** is a likely location where the requirements for dispensing and record keeping can be found. As you scroll down further, you note the titles of the different parts in this chapter which indicate you are on the

correct path. Parts such as ***Buying by giving purchase orders***; ***Supplying stock***; and ***Prescribing medicines*** are identified and then the required ***Part 8 Dispensing medicines*** is located.

Step 5. Within ***Part 8 Dispensing medicines*** you identify ***Division 1 Patients and animals*** and note in Sections 112 to 124, the legislative requirements for dispensing prescriptions; the labelling of dispensed medicines; the record keeping for dispensed medicines; and identify when dispensing is not permitted. **Question** - *Is the information you have just identified – sufficient and all that you need to know about dispensing?* You have just read the requirements for dispensing prescriptions, when not to dispense and you now understand and know what is required for the labelling and record keeping for dispensed medicines. The answer can either be *yes* or *no* and depends on the class of medicine you are **dealing** with.

> Hint 2 suggested that you scroll forward/backward from the section of law you first identify (See step 6)

Step 6. By scrolling forward, you identify that there is a **Patients only** division in this part which lists additional compliance requirements for dispensing monitored medicines, diversion-risk medicines, and generic medicines. If you did not scroll forward you may have missed the *requirements* listed in Figure 4. for dealing with these classes of medicines.

Figure 4. Worked example flowchart

Contents

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Chapter 4 General requirements for dealings

Part 2 Manufacturing by compounding
Part 3 Buying by giving purchase orders
Part 4 Supplying stock
Part 5 Possessing stock for delivery
Part 6 Prescribing medicines
Part 7 Making standing orders
Part 8 Dispensing medicines
Division 1 Patients and animals
Subdivision 1 Preliminary
Subdivision 2 Prescriptions
Subdivision 3 Medicines
Subdivision 4 Dispensing in appropriate circumstances
Subdivision 5 Records
Division 2 Patients only
S125 Application of division
S126 Compliance with monitored medicines standard
S127 Dispensing diversion-risk medicine
S128 Dispensing generic medicine

Attachment 2 – Pharmacy assistant flowchart

An example of how a pharmacy assistant could order S8 medicines and then deal with the S8 medicines when they are delivered to the pharmacy