Government of **Western Australia**
Department of **Health**

Requirements of the Medicines and Poisons Legislation: a summary for public health service facilities

Explanatory notes to accompany MP 0139/20 *Medicines Handling Policy*

Contents

1. Background

This document is intended to provide background information about the regulatory controls that underpin MP 0139/20 *Medicines Handling Policy* and the related document, *Risk based requirements for medicines handling*.

The document also provides information about the relationship between legislation, policies, procedures and guidelines.

MP 0139/20 *Medicines Handling Policy* recognises that many health service facilities operated by Health Service Providers (HSPs) are large complex organisations and the minimum requirements of the Medicines and Poisons Legislation are not considered sufficient to ensure best practice risk management of medicines, particularly in relation to theft, misuse and other actions which may constitute staff misconduct.

MP 0139/20 *Medicines Handling Policy* builds on the legislative controls over medicines. Staff members with a role in handling medicines need an understanding of the requirements of the *Medicines and Poisons Act 2014* and the Medicines and Poisons Regulations 2016. Copies are available from the *Western Australian legislation website*.

Note: this document does not cover every aspect of the Medicines and Poisons Legislation and is not a substitute for seeking legal advice in relation to interpreting the legislation as it applies to particular circumstances. The information is provided as an aid to compliance by public health service facilities and their staff with the Western Australian regulatory controls over medicines.

1.1. Relationship between legislation, policies, procedures and guidelines

The *Medicines and Poisons Act 2014* (the Act) is the formal medicines and poisons law passed in Western Australia (WA). The Act sets out the broad framework regarding the handling of medicines and poisons and provides a head of power for the making of subsidiary legislation.

The Medicines and Poisons Regulations 2016 (subsidiary legislation, the Regulations) are a more detailed set of requirements, created to support the framework established in the *Medicines and Poisons Act 2014*.

Both the Act and Regulations are legally binding to the whole of WA and are equally applicable to the public sector and the private sector, including non-government organisations.

Acts of Parliament may include mechanisms to allow Departmental documents such as codes and policies to be included as part of a regulatory regime. These documents lack independent legal authority but can be mandated through regulatory instruments. An example of this is the Schedule 8 Medicines Prescribing Code (the Code), with which prescribers must comply. Section 132 of the *Medicines and Poisons Act 2014* allow regulations to be made that adopt codes and the Code is defined and referenced in the Medicines and Poisons Regulations 2016.

A similar situation exists for the Department's Policy Frameworks. Under section 26 of the *Health Services Act 2016* the Director General of the Department of Health may issue binding policy frameworks to ensure a consistent approach to a range of core business functions. MP 0139/20 *Medicines Handling Policy* is part of the suite of policies issued under the *Public Health Policy Framework* and is mandatory for all Health Service Providers.

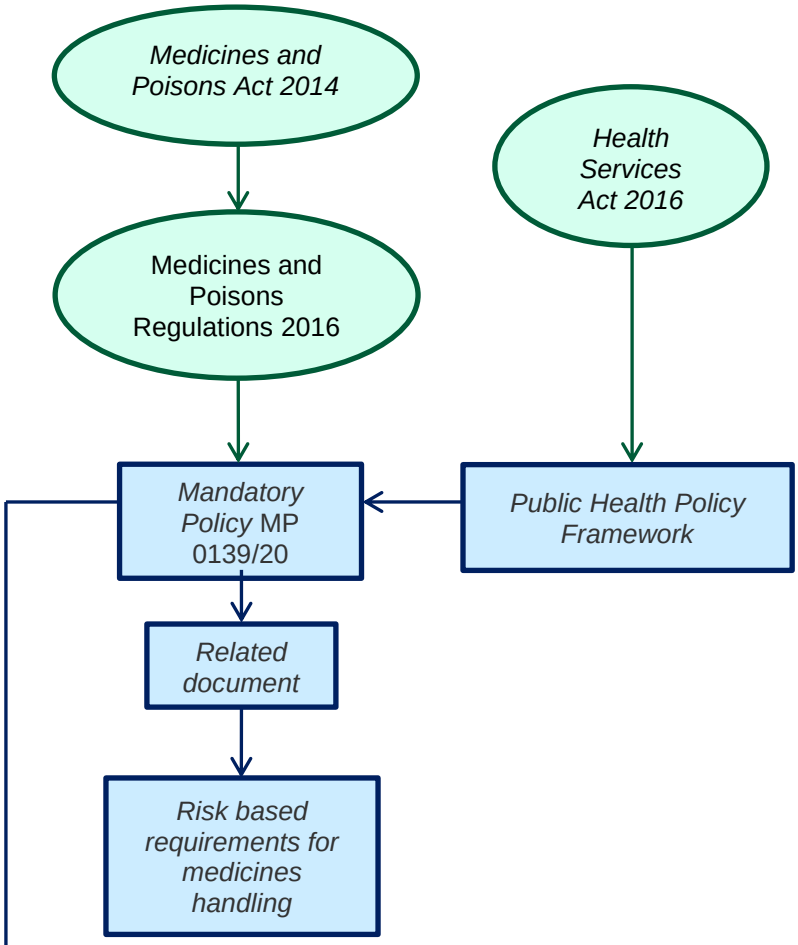
Figure 1: Summary of relationship between legislation, policies, procedures and guidelines

Mandatory for all HSP

WA Legislation

Applies to all scheduled medicines and poisons in WA.

Applies to all public and private hospitals, community pharmacies, medical, dental and veterinary practices etc.



Department of Health (System Manager)

Applies to scheduled medicines and poisons in all health service facilities operated by HSP.

Facilities vary from large teaching hospitals to small country hospitals and remote nursing posts.

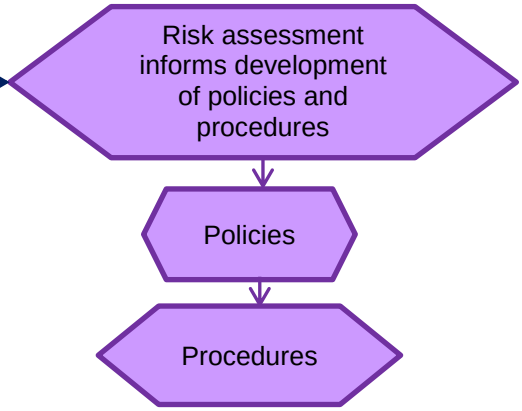
Department of Health (System manager)

Guidelines to inform or support HSP to implement MP 0139/20

- Requirements of the Medicines and Poisons Legislation: summary for health service facilities
- Distribution of medicines
- Administration and record keeping for S8 and S4R medicines
- Oral liquid S8 and S4R medicines
- Pharmacy Department access
- Management of patient's own medicines
- Continuation of opioid substitution therapy in health service facilities.
- Health practitioner initiated non-prescription medicines

Individual Health Service Providers

Each HSP develops their own policies and procedures in relation to: purchasing, storage, distribution, use and disposal of medicines based on a risk assessment to minimise diversion, misuse and theft of medicines.



2. Intent and general structure of the Medicines and Poisons Legislation

The main aim of the *Medicines and Poisons Act 2014* and its subsidiary legislation is to protect public health. This is achieved primarily by controlling how consumers access medicines and poisons. The intent is to minimise accidental and deliberate poisoning, minimise medicines misadventure and reduce diversion and illicit use of pharmaceuticals.

The Medicines and Poisons Legislation divides medicines and poisons into a series of lists, known as the "schedules". The substances within a particular schedule have a similar level of risk to human health. This then allows a particular set of regulatory controls to be applied to all the substances within that schedule.

Which medicines and poisons are included in each schedule is agreed nationally. The WA legislation adopts the national schedules, as detailed in the national Poisons Standard (also known as the Standard for the Uniform Scheduling of Medicines and Poisons, SUSMP). The current version of the *Poisons Standard* is available online via the Commonwealth Therapeutic Goods Administration.

This means WA is nationally aligned with respect to whether a medicine is available:

- over the counter from a pharmacy: Schedule 2 (pharmacy medicine) and Schedule 3 (pharmacist only medicine),
- is a prescription medicine: Schedule 4 or
- is a controlled drug: Schedule 8.

Many Schedule 2 and Schedule 3 medicines are simply smaller boxes of medicines that would otherwise be in Schedule 4. Often Schedule 2 and Schedule 3 medicines will only be available for specific indications and in lower dosages.

The Medicines and Poisons Legislation also includes controls over poisons which are included in Schedules 5, 6 and 7. Schedule 7 poisons are dangerous poisons and are not available for use in domestic settings. Schedule 5 and Schedule 6 poisons are labelled with the word CAUTION or POISON, respectively. Many common household poisons such as bleach and oven cleaners, garden chemicals and pool chemicals are classified as Schedule 5 and 6 poisons.

Chemical substances, including medicines, are only "scheduled" where there is both risk to human health and a likelihood of access by consumers. Many dangerous industrial chemicals are not scheduled because the chance of a consumer accessing these chemicals is very small.

There are also medicines that are not included in the schedules. These medicines can be sold to consumers in any retail outlet, such as in supermarkets and health food stores. Sometimes the medicine will not appear in the schedules at all or sometimes only some smaller packs for specific indications with particular dosing instructions and warning statements will be "exempted from scheduling". Examples of exempted products are small packs of simple analgesics such as paracetamol and ibuprofen and small packs of medicines for heartburn and hayfever. Most vitamin products are also unscheduled.

The types of regulatory controls used by the Medicines and Poisons Legislation include:

- only allowing certain health professionals to prescribe and supply scheduled medicines to consumers
- licences issued to wholesalers to allow them to sell scheduled medicines and poisons

- permits issued to businesses, health service facilities and research entities to allow them to purchase and use medicines and poisons
- labelling and packaging requirements
- mandatory storage controls, such as safes for storing Schedule 8 medicines
- requirements for records of supply by wholesalers and health professionals.

The Medicines and Poisons Legislation relies on there being a robust system for ensuring each type of health professional granted access to scheduled medicines has adequate training and consistent competencies. This is achieved by limiting activities such as prescribing and supplying scheduled medicines to patients to registered health practitioners.

For other activities, such as distribution and transport of scheduled medicines, there are clauses that allow other employees to undertake these type of tasks. However, the employee must be acting within their authority: the tasks being undertaken must be duties consistent the employee's role in the organisation. In this situation, there are penalties for non-compliance applicable to both the employee and their employer.

The Medicines and Poisons Legislation uses a combination of outcome based controls and prescriptive controls. For example, Schedule 4 medicines must be stored so they are "accessible only by an authorised health professional or a person who is personally supervised by an authorised health professional". Details of the construction of the storage receptacle or the locking mechanism to achieve this are not included. By contrast, information that must be written on a prescription or on a medicine label is specifically outlined. There are even requirements for font size and colour for some label elements.

Extensive information about the Medicines and Poisons Legislation is available on the Department's website.

3. Authorisation of health professionals to handle scheduled medicines

Section 25 of the Act is about the making of regulations to allow health professionals to do certain things in relation to the use of scheduled medicines such as prescribe, administer, dispense and supply. The Act allows regulations to specify classes of health professionals and does not limit these health professionals to registered health practitioners.

Part 7 of the Regulations details the activities each class of health professional can undertake. For example, medical practitioners can administer, possess, prescribe and supply both Schedule 4 and Schedule 8 medicines. Only a pharmacist can dispense a prescription: for other health professionals the term used in the legislation is "supply" rather than "dispense".

All authorised activities involving scheduled medicines must be in "the lawful practice of their profession". Standards, guidelines and other information published by the various registration Boards and professional practice peak bodies can be used to determine what constitutes a health practitioner's "lawful practice of their profession". Individual health practitioners must also consider their personal scope of practice in determining "the lawful practice of their profession".

Further information is available on the Department's website.

4. Procuring scheduled medicines

Under the Act, public health service facilities must hold a current and valid Health Service Permit to have authority to use scheduled medicines at the premises listed on the Permit, for the purposes specified on the Permit. The Permit indicates to anyone authorised to supply scheduled medicines, such as a licensed pharmaceutical wholesaler or manufacturer, that the public health service facility is authorised to procure the scheduled medicines listed on their Permit. Permits issued to the Pharmacy Department at public hospitals will be issued for medicines in all schedules: Schedule 2, Schedule 3, Schedule 4 and Schedule 8.

5. Distribution

The Act includes clauses which allow a person to be in possession of a Schedule 4 or Schedule 8 medicine for the purposes of delivering it to an authorised person. There are no possession offences relating to Schedule 2 and Schedule 3 medicines: these medicines are primarily subject to supply controls.

The Act also allows employees to handle scheduled medicines under certain circumstances (see section 2 above). This means non-pharmacist staff of the Pharmacy Department at a hospital can be involved with the distribution of medicines within public health service facilities.

6. Storage

The Regulations include specific storage requirements for Schedule 8 medicines within public health service facilities, with particular requirements within the Pharmacy Department. The quantity of Schedule 8 medicines stored in the Pharmacy Department will necessitate installation of a monitored alarm system in accordance with the Regulations.

A safe or strongroom, which meets the requirements of the Regulations, must be used to store Schedule 8 medicines in any area of the public health service facility that is not supervised by authorised staff at all times. In other words, unless a ward or patient care area is fully operational all the time (24/7), it is likely a safe rather than a “secure cabinet” (metal or hardwood cupboard securely fixed to a floor or wall) will be required for storing Schedule 8 medicines.

The Regulations include clauses which allow the Department of Health to approve alternative storage arrangements for Schedule 8 medicines. These clauses may be used by public health service facilities when storage receptacles already in place do not meet the requirements of the Regulations or where particular circumstances, such as the need for refrigeration of a Schedule 8 medicine, apply. However, the Regulations do not obligate the Department to approve a request for alternative arrangements for the storage of Schedule 8 medicines.

Secure cabinets, safes and strongrooms where Schedule 8 medicines are stored must be kept locked when not in use. Safes must be located in an area that is not accessible to members of the public.

7. Prescribing

Only certain health practitioners are authorised by the Medicines and Poisons Legislation to write prescriptions (for dispensing by a pharmacist) or write directions on medication charts, for Schedule 4 and Schedule 8 medicines. Authorised prescribers include:

- Medical practitioners

- Nurse practitioners
- Dentists
- Endorsed midwives
- Endorsed podiatrists
- Endorsed optometrists

The Medicines and Poisons Legislation does not preclude a public health service facility from limiting the classes of health practitioners who are allowed to prescribe within the facility or from placing additional restrictions on which medicines particular classes of health practitioners can prescribe. For example, it is common for there to be restrictions through policy on the prescribing of antibiotics (such as through Antibiotic Stewardship Programs) and the prescribing of high-cost and non-formulary medicines.

What can be prescribed is also affected by other regulatory and policy requirements including funding under the Commonwealth's Pharmaceutical Benefits Scheme (PBS) and whether the medicine is approved for marketing across Australia by the Commonwealth's Therapeutic Goods Administration (TGA).

The Regulations include details of the information which must be included on a prescription. All prescriptions must include all of the following information:

- name, address and telephone number of the prescriber (these details may be pre-printed on prescription stationery)
- name and address of the patient
- date of birth of the patient if the prescription is for a Schedule 8 medicine
- medicine name, strength and formulation
- precise directions for use (dosage and frequency)
- quantity to be dispensed
- number of repeats permitted
- interval between repeats if the prescription is for a Schedule 8 medicine
- date the prescription was issued
- signature of the prescriber.

Prescriptions for Schedule 8 medicines must be written on a separate form to a prescription for Schedule 4 medicines. If the same Schedule 8 medicine is being prescribed in multiple dosage forms, such as slow release morphine tablets and morphine mixture, all dosage forms can be written on the same form. Otherwise, a separate prescription form is required for each item.

The Regulations also include clauses about the attributes of systems for computer generated prescriptions. In particular, these systems must be designed so that only someone authorised to prescribe can generate a prescription using the system.

Under previous legislation (rescinded early 2017), prescribers were required to rewrite parts of computer generated prescriptions in their handwriting. This is no longer required.

The Regulations place an obligation on pharmacists to verify the authenticity of prescriptions for Schedule 8 medicines, before supplying the patient. This often means the pharmacist must contact the prescriber, usually by telephone to verify the prescription. This is particularly applicable to hospital discharge prescriptions presented to community pharmacies, where the patient may not have previously been treated with the Schedule 8 medicine (for example, opioid for post-operative pain) and where the community pharmacist is less likely to be familiar with the prescriber's handwriting or signature.

The Regulations do allow a pharmacist to dispense up to two days supply of the prescribed Schedule 8 medicine, where the pharmacist is unable to contact the prescriber, where the prescription appears otherwise valid and where the pharmacist assesses there is a need for the patient to commence treatment with the medicine prior to the prescription being verified. This may be particularly applicable where a discharged patient presents a prescription to a community pharmacy and the prescriber is not on shift at the hospital at the time when the prescription is presented.

7.1. Verbal and electronic directions to administer or supply

The Regulations include specific provisions for verbal directions and directions transmitted by electronic means, such as by fax.

If a direction to administer is provided other than in writing, such as verbally (face to face) or by telephone, the Medicines and Poisons Legislation requires the prescriber record their direction on the patient's medication chart and sign the chart within 24 hours of issuing the direction.

The Regulations allow prescribers to direct a community pharmacy to supply a patient with a Schedule 4 or Schedule 8 medicine on the basis of a telephoned direction or a copy of a prescription faxed to the community pharmacy by the prescriber (often described as emergency or urgent supply provisions). In this circumstance, the prescriber must dispatch a covering prescription directly to the supplying pharmacy, within 24 hours of giving the direction. Covering prescriptions must not be given to the patient to deliver to the supplying pharmacy, as this does not guarantee the pharmacy will receive the covering prescription. For Schedule 8 medicines, pharmacists are obligated to contact the Department if they do not receive a covering prescription within five working days.

These "emergency supply" provisions are more likely to be used when telehealth consultations occur or in rural/remote areas where the visiting medical officer may not be present at the hospital.

7.2. Schedule 8 Medicines Prescribing Code

Where the patient will be using the medicine as an outpatient or after discharge from the public health service facility, including after attendance at an emergency department, prescriptions written for Schedule 8 medicines must comply with the *Schedule 8 Medicines Prescribing Code* (the Code). The Code is made under the Medicines and Poisons Legislation, which means compliance with the Code is mandatory for all prescribers.

The Code is not applicable when doses of a Schedule 8 medicine are being administered to the patient, such as when they are in the emergency department or are an admitted patient.

Under the Code, written authorisation from the Chief Executive Officer of the Department of Health (or their delegate) is required before a prescription for Schedule 8 medicines can legally be written, when certain high risk criteria are met. These criteria relate to:

- the medicine - including the dose and the dosage form,
- the patient - such as a history of drug dependency or oversupply and/or
- the class of prescriber – for example, a dentist or nurse practitioner can only prescribe up to 14 days supply of a Schedule 8 medicine without authorisation.

Prescribers should take steps to determine whether their prescribing will meet any of the high risk criteria set out in the Code, prior to writing a prescription for Schedule 8 medicines. If any of the high risk criteria are met and the prescriber wishes to write a Schedule 8 prescription, an application to prescribe must be submitted to the Department.

For stimulant medicines in Schedule 8 (dexamfetamine, lisdexamfetamine and methylphenidate), prescribing can only be initiated by a specialist prescriber (such as a psychiatrist) who has been specifically authorised as a stimulant prescriber. The Medicines and Poisons Regulations 2016 allow prescribers based in hospitals to continue current stimulant treatment (with the same medicine, at the same dose and frequency) only whilst the patient is in hospital, which means discharge prescriptions for stimulant medicines in Schedule 8 cannot be issued.

Generally, discharge prescriptions for opioid medicines in Schedule 8 do not require prior authorisation, where prescribing is associated with that episode of care (for example, a small quantity of an opioid medicine for post-operative pain). Authorisation will still be required where the patient is recorded as a drug dependent person or an oversupplied person (sometimes termed a “doctor shopper”).

The Schedule 8 Medicines Prescribing Code and relevant application forms are available via the WA Health corporate website.

8. Administration

Part 7 of the Regulations details which health professionals are authorised to administer Schedule 4 and Schedule 8 medicines. A prescriber is authorised to administer the same medicines they are authorised to prescribe. Other health professionals authorised to administer scheduled medicines include: registered nurses, midwives, enrolled nurses[1], Aboriginal health practitioners, Aboriginal health workers and anaesthetic technicians.

The Medicines and Poisons Legislation is silent about who can administer doses of Schedule 2 and Schedule 3 medicines. These medicines are packaged and labelled in a manner which includes directions and warnings to allow a consumer to safely self-administer doses.
All administration of medicines must be within the health professional’s personal scope of practice and within the general scope for their particular profession.

The Medicines and Poisons Legislation does not preclude a public health service facility from limiting the classes of health professionals who are allowed to administer Schedule 8 medicines within the facility or from placing additional restrictions on which medicines (including dosage forms and routes of administration) particular classes of health professionals can administer.

Medicines in Schedules 4 and Schedule 8, which have been dispensed at a pharmacy and supplied to an individual patient (which are considered “patient’s own medicines”) fall outside the jurisdiction of the Medicines and Poisons Legislation because this legislation has already been fully applied. Notwithstanding this, Section 14 of the *Medicines and Poisons Act 2014* specifically allows “carers” to be in possession of Schedule 4 and Schedule 8 for the purpose of helping the patient take doses of their medicines. The term “carer” is defined as including both paid carers and unpaid carers, such as relatives and friends.

[1] Provided the enrolled nurse does not have the notation “Does not hold Board-approved qualifications in administration of medicines” on their registration.

9. Structured Administration and Supply Arrangements (SASAs)

Structured administration and supply arrangements (SASAs) are described in Part 6 of the Regulations. These documents can be used to authorise the administration of doses and supply of Schedule 4 medicines and the administration of doses of Schedule 8 medicines. SASAs allow a health professional without prescribing rights to initiate administration or supply of a medicine in the circumstances described in the SASA.

SASAs can only be issued to facilitate management of acute health conditions or for the purpose of conducting public health programs, such as immunisation programs.

SASAs are intended to facilitate timely patient care, particularly where access to a prescriber is not readily available. However, in many situations, a SASA is not required and directions written on the patient's medication chart or directions in relation to the individual patient, given verbally or by telephone, are preferable.

There are strict regulatory rules about the governance and authorisation process for SASAs.

Two types of SASAs are applicable to public health service facilities: SASAs issued by the Chief Executive Office of the Department of Health (CEO SASAs) and SASAs issued by a health organisation.

Once a health organisation, including a public health service facility, has issued a SASA, a copy must be sent to the CEO of Health, as soon as practicable.

Further information is available on the Department's website: *Structured Administration and Supply Arrangements*

10. Dispensing and supply

The Regulations include specific requirements for the packaging and labelling of Schedule 4 and Schedule 8 medicines supplied to patients, such as at discharge or as an outpatient. These requirements are applicable regardless of whether the Schedule 4 or Schedule 8 medicine is dispensed by a pharmacist, supplied by a prescriber, or supplied by a health professional authorised by a SASA.

Labels on prescription medicines and controlled drugs supplied to patients must include:

- the name, address and telephone number of the supplying pharmacy or public health service facility
- the name of the medicine, its strength and dosage form (capsules, tablets, mixture etc)
- adequate directions for use
- the total quantity of medicine in the container
- the words KEEP OUT OF REACH OF CHILDREN (in red on a white background)
- if the medicine is for external use, the word POISON or the words FOR EXTERNAL USE ONLY (in red on a white background)
- the patient's name
- the date of supply
- if dispensed by a pharmacist, a prescription reference number.

Some medicines which are well known to cause drowsiness must also include a warning label about the risks of driving and operating machinery. A small list of medicines also require other warnings to be included on the labelling, when they are supplied to patients. For example, retinoid medicines must include warnings about not becoming pregnant.

Unless a SASA authorising supply is in place, only a prescriber (or a pharmacist dispensing a prescription) can supply a Schedule 4 medicine to their patient. SASAs authorising supply can only be for the purpose of:

- treatment of acute health conditions or
- public health programs, such as prophylaxis or treatment of sexually transmissible infections.

Only the prescriber, or a pharmacist dispensing a prescription, can supply a Schedule 8 medicine to a patient. A SASA cannot be used to authorise supply of a Schedule 8 medicine.

Unless a Schedule 2 or Schedule 3 medicine is being supplied to the patient in the original manufacturer's pack, these medicines must be treated as if they are Schedule 4 medicines.

11. Record keeping

The Regulations require a detailed record of the supply of a Schedule 4 or Schedule 8 medicine to a patient be made in the patient's clinical record. In the case of the Pharmacy Department, a patient's clinical record is the dispensing system software.

The Regulations require records about transactions involving Schedule 8 medicines to be retained for five (5) years and records about transactions involving Schedule 4 medicines to be retained for two (2) years.

All records relating to the ordering, receipt, distribution, administration, dispensing, supply, destruction, disposal and discrepancies for Schedule 8 medicines must be retained for the statutory period and be available on demand by the Chief Executive Officer of the Department of Health (or their delegate) or an investigator (designated under the *Medicines and Poisons Act 2014*).

Note: Depending on the nature of the record, longer retention periods may be required by the policies made under the *Information Management Policy Framework*. In particular, longer retention periods will be required where the record about the medicine is considered a record about patient information, such as records of administration of doses.

11.1. Schedule 8 Registers

The Regulations require transactions involving S8 medicines to be recorded in an approved Register. The Register must be kept in a way that ensures the quantity of each Schedule 8 medicine on hand at any time is clearly identifiable.

Schedule 8 Registers are a legal document kept for the purpose of the Act.

Registers used in public health service facilities must be either:

- a hard copy Register approved by the CEO of Health or
- a CEO of Health approved electronic Register.

Within the Pharmacy Department the approved hard copy Register is designated HA176 and in patient care areas the approved hard copy Register is designated HA14. The approved Registers have columns for recording information relevant to the situation in which the Register will be used.

A separate Register must be kept for each separate location where Schedule 8 medicines are stored. For example, if there are multiple safes within a clinical area, there must be a Register for each safe such that the quantity of each medicine within each safe can be determined at any point in time.

11.2. Schedule 8 Inventories

The Regulations require an inventory of each Schedule 8 medicine to be made at intervals of not more than one month. The inventory must be recorded in the Schedule 8 Register on the day the inventory is made.

The Regulations do not prevent a public health service facility from taking an inventory more frequently than once a month, in accordance with local policy.

If the quantity on hand of the medicine is different to the quantity recorded in the Register, the Department of Health must be immediately notified. For Health Service Providers, compliance with MP 0103/19 *Reporting of Schedule 4 Restricted and Schedule 8 Medicines Discrepancies Policy* achieves this regulatory requirement.

12. Destruction of Schedule 8 medicines

Destruction of Schedule 8 medicines is the one task in the Regulations where it is mandatory for two authorised persons to be involved: a person undertaking the destruction and a witness to the destruction.

Destruction of a Schedule 8 medicine is different to the discarding of a partly used ampoule or similar, as part of administering a dose to a patient. Destruction will be undertaken when a Schedule 8 medicine cannot be used to treat patients, such as when stock is expired, has been stored at an inappropriate temperature, is contaminated in some way or is otherwise substandard.

If a health professional is authorised to prescribe, dispense, administer or supply a Schedule 8 medicine, they are also authorised to be a signatory to the destruction of Schedule 8 medicines.

Health professionals who are not authorised by the Regulations to handle Schedule 8 medicines cannot be involved in the destruction of these medicines.

In addition to the usual information to be included in the Schedule 8 Register, for destruction the following additional information is required:

- name, contact details and category of qualified person (for example, registered nurse, pharmacist) of both the person destroying the Schedule 8 medicine and the witness,
- the reason for destruction (for example, expired stock) and
- the method of destruction (for example, crushed ampoules and disposed of in pharmaceutical waste bin).

For further information:

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Prepared by the Medicines and Poisons Regulation Branch, May 2020.

This document can be made available in alternative formats on request for a person with disability.