Medicines and Poisons Legislation
Objectives

1. Discuss the history and place of Medicine and Poisons legislation
2. Describe the general regulatory environment for pharmacists in Western Australia
3. Describe the intent and structure of the Medicines and Poisons Act 2014
4. Identify the new aspects of the Medicines and Poisons Act 2014
5. Describe the intent and structure of the Medicines and Poisons Regulations 2016
6. Identify the new aspects of the Medicines and Poisons Regulation 2016
Poisons

- Mary Ann Cotton (1832 -1873)
- Convicted serial killer
- Victims died of arsenic poisoning
ANNO PRIMO

GEORGII QUINTI REGIS,
VII.

No. 7 of 1910.

AN ACT compiling certain Acts of Parliament relating to Pharmacy and the Sale of Poisons.

[Assented to 22nd December, 1910.]

WHEREAS by resolution of the Legislative Council passed on the third day of August, one thousand nine hundred and nine, it was resolved that the Pharmacy and Poisons Act, 1894, and its amendments be compiled in accordance with the Statutes Compilation Act, 1905: And whereas such resolution was, on the eighth day of September, one thousand nine hundred and nine, concurred in by the Legislative Assembly: And whereas the compiled Act set forth in Appendix B has been certified under the hand of the Attorney General as being a true and correct compilation of the Pharmacy and Poisons Act, 1894, and the amendments thereof specified in Appendix A: Be it therefore enacted by the King's Most Excellent Majesty, by and with the advice and consent of the Legislative Council and Legislative Assembly of Western Australia, in this present Parliament assembled, and by the authority of the same as follows:—

1. This Act may be cited as the Pharmacy and Poisons Act, 1910.
All such matter shall be so printed that the purchaser of the article can plainly see the same.

30. (1.) No person shall sell any arsenic or strychnine, or any preparation of arsenic or strychnine, unless, in the case of arsenic or any uncoloured preparation of arsenic, it is mixed, before the sale or delivery, with soot or some other black substance in the proportion of one ounce of soot or other black substance at least to one pound of arsenic, and so in proportion for any greater or less quantity, and unless, in the case of strychnine or any uncoloured preparation of strychnine, it is coloured with Armenian bole or some other red colouring matter before the sale or delivery thereof.

(2.) Provided that, whenever the purchaser states that the arsenic or strychnine, or any preparation thereof respectively, is not required for any pastoral or agricultural use or for the destruction of vermin, but is required for a purpose for which such admixture with colouring matter would, according to the representation of the purchaser, render it unfit (a statement of which purpose is entered in the book required by section twenty-six to be kept and signed as thereby required or specified in the letter therein referred to, as the case may be), such poison may be sold without such admixture.

(3.) Every person failing to comply with or acting contrary to any of the provisions of this section shall be guilty of an offence against this Act, and, upon conviction, be liable to the same fine or imprisonment as is mentioned in section thirty-two.

31. No person shall sell any poison to any person who is apparently under eighteen years of age, or to any person who is unknown to the vendor, unless the sale be made in the presence of some witness who is known to the vendor, and to whom the purchaser is known, and such witness signs his name, together with his place of abode, to the required entry before the delivery of the poison to the purchaser.

32. (1.) Any person who—

(a.) Sells any poison contrary to the provisions of this Act; or

(b.) Neglects or omits to comply with any of the provisions of this Act regulating the sale or keeping of poisons; or
POISONS.

13° Elizabeth II., No. LXX.

AN ACT to regulate and control the Possession, Sale and Use of Poisons and other Substances; to constitute a Poisons Advisory Committee; and for incidental and other purposes.

[Assented to 11th December, 1964.]

BE it enacted by the Queen's Most Excellent Majesty, by and with the advice and consent of the Legislative Council and the Legislative Assembly of Western Australia, in this present Parliament assembled, and by the authority of the same, as follows:—

PART I.—INTRODUCTORY PROVISIONS.

1. This Act may be cited as the Poisons Act, 1964.
Regulatory Environment

- Industrial
  - DANGEROUS GOODS
  - PESTICIDES
  - MISUSE OF DRUGS
- Medicine
  - MEDICINES & POISONS
  - NICNAS
  - AG VET
  - VET SURGEONS
  - PHARMACY ACT
  - NATIONAL HEALTH PRACTITIONER REGULATION & ACCREDITATION
  - NATIONAL HEALTH (PBS)
  - THERAPEUTIC GOODS
  - PUBLIC HEALTH
  - MARITIME LAW
Medicines and Poisons - Intent

• An Act
  – to regulate and control the manufacture and supply of medicines and poisons; and
  – to repeal the Poisons Act 1964, the White Phosphorus Matches Prohibition Act 1912 and various regulations; and
  – to amend the Health Act 1911, Misuse of Drugs Act 1981 and various other written laws; and
  – for incidental and related purposes.
MPA - Objectives

• Supports
  – overall intent to protect public from poisons
  – regulatory process for manufacture, sale, use of medicines and poisons
  – national consistency
  – broad range of health care practitioners to safely handle medicines
  – control over drugs of addiction

• New features
  – clearer layout and parts
  – simpler language
  – some parts moved from Act into Regulations
MPA - Overview

• Poisonous substances are restricted goods
  – not freely available to general public

• Classified according to toxicity / risk

• Classification determines level of access

• Access only via:
  – health professional
  – license or permit

• Applies various “controls” on supply to reduce risk of misadventure
MPA - Restrictions

• Schedule
  S2, S3 supply only
  S4, S8 possession, use and supply
  S5, S6 manufacture and supply
  S7 manufacture, possession, supply
  S9 any possession
  S10 “strictly controlled substances” – supply

• Regulated aspects
  – storage, handling, transport, disposal, record keeping
  – vending machines

• Penalties
  – updated
MPA - Classification system

- Schedules – Adopts SUSMP

<table>
<thead>
<tr>
<th>Schedule</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Pharmacy only medicines</td>
</tr>
<tr>
<td>3</td>
<td>Pharmacist only medicines</td>
</tr>
<tr>
<td>4</td>
<td>Prescription medicines</td>
</tr>
<tr>
<td>5</td>
<td>Poison – Caution</td>
</tr>
<tr>
<td>6</td>
<td>Poison</td>
</tr>
<tr>
<td>7</td>
<td>Dangerous Poison</td>
</tr>
<tr>
<td>8</td>
<td>Controlled Drug</td>
</tr>
<tr>
<td>9</td>
<td>Prohibited (illicit)</td>
</tr>
<tr>
<td>10</td>
<td>Prohibited (danger to health)</td>
</tr>
</tbody>
</table>

- Strictly controlled drugs (now Schedule 10)
MPA - Health Practitioners

• Any class of person prescribed by regulation
  – registered health practitioner
  – registered Vet
  – other person named in Regulation

• Possession / supply by pharmacy business
  – taken as under authority of pharmacist with overall responsibility
  – send wholesaler your annual pharmacy registration

• Any authority conferred can be restricted or removed
  – if grounds exist
MPA - License and Permit

• Types described in Regulations
  – S9 license / permit – research, experimentation, education
  – corporate license / permit
  – annual only - 1 year from date of issue

• Holders must be
  – fit and proper, sufficient knowledge, resource and premises

• Licenses / Permits can be restricted or removed
  – if grounds exist

• Fees and charges updated

• Register of Licenses / Permits to be kept
MPA – Drugs of Addiction

• Drug Dependent Person and Oversupplied Person

• Prescribing and supply restricted
  – protection of vulnerable persons
  – general intention: one person – one prescriber – one dispenser

• Drugs of Addiction Record
  – collection of information
  – permissible sharing of information
  – protected uses of information

• Schedule 4 reportable
  – permits collection and sharing of information on named S4 items
MPA – Compliance Activities

• Appointment of investigators
  – named DOH officers
  – includes Police
  – must show ID

• Purpose
  – monitoring compliance
  – suspected contraventions

• Powers of investigators
  – entry, inspection, seize poisons, request documents
  – give a direction
What new legislation?
The Medicines and Poisons Act 2014 (the “Act”) and its subsidiary legislation the Medicine and Poisons Regulations 2016 (the “Regulations”) have been enacted into law, and will replace the Poisons Act 1964 and Poisons Regulations 1965.

The new legislation is intended to prevent harm from medicine and poisons use in Western Australia, by regulating the availability of domestic and industrial chemicals, agricultural and veterinary agents, poisons, medicines and related therapeutic agents.

It provides for the legitimate use, sale and supply of medicines and poisons in circumstances including, but not limited to:

- the sale and supply of medicines by health professionals
- the use of veterinary medicines
- the use of poisons by business and industry
- wholesale and retail sale of medicines and poisons
- the manufacture of poisons and medicines
- the sale and supply of prohibited and illicit drugs.

A Code provides specific advice regarding the prescribing of Schedule 8 Medicines.

What is the difference between an Act, a Regulation and a Code?
The Act is legislation passed by the Parliament, and prescribes the broad legal and policy principles that will apply to Medicines and Poisons regulation in Western Australia.

The Regulations are subsidiary to the Act, and represent the detailed guidelines that will assist you to correctly interpret your rights and responsibilities under the new Act.

A Code of Practice is a practical guide to assist you further, in complying with the new Act and Regulations.

Key changes in the new laws
While the intent of the new legislation remains unchanged, the layout, structure and language of the legislation has been enhanced for greater clarity, and designed to streamline services and be more responsive to the needs of practice and industry. See overleaf for a summary of key changes.
MPR – Types of Controls

- Who can buy and use
- Who can supply
- Instructions needed to approve sale or supply
- Storage
- Labelling
- Packaging
- Transport
- Disposal
- Keeping records
- Reporting
- Advertising
<table>
<thead>
<tr>
<th>Part</th>
<th>Regulations</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Preliminary (definitions)</td>
</tr>
<tr>
<td>2</td>
<td>Classifications (schedules)</td>
</tr>
<tr>
<td>3</td>
<td>Strictly controlled poisons</td>
</tr>
<tr>
<td>4</td>
<td>Prescriptions</td>
</tr>
<tr>
<td>5</td>
<td>Supply (Schedule 4 &amp; 8)</td>
</tr>
<tr>
<td>6</td>
<td>Structured administration and supply arrangements</td>
</tr>
<tr>
<td>7</td>
<td>Authorisation of health professionals</td>
</tr>
<tr>
<td>8</td>
<td>Licences and permits</td>
</tr>
<tr>
<td>9</td>
<td>Manufacture, storage, transport, disposal</td>
</tr>
<tr>
<td>10</td>
<td>Needle and syringe programmes</td>
</tr>
<tr>
<td>11</td>
<td>Schedule 8s</td>
</tr>
<tr>
<td>12</td>
<td>Record keeping and reporting</td>
</tr>
<tr>
<td>13</td>
<td>Transitional matters</td>
</tr>
</tbody>
</table>
I, ANTHONY GILL, a delegate of the Secretary to the Department of Health for the purposes of paragraph 52D(2)(b) of the Therapeutic Goods Act 1989 (the Act) and acting in accordance with the Secretary’s power under that paragraph of the Act, prepare this new Poisons Standard, in substitution for the current Poisons Standard.

(Signed by)

ANTHONY GILL
Delegate of the Secretary to the Department of Health

Dated this 4th January 2017
MPR - Prescribing

- **Requirements**
  - minimum information
  - format of prescriptions
    - paper – handwritten
    - computer generated – compliant system
    - electronic – must be approved system

- **Medication charts**
  - hospitals and residential care facilities

- **Direction to administer S4 or S8 medicine**
  - clinical record, med chart, verbal (with confirmation within 24 hours)
MPR - Prescribing

• S8 scripts
  – Pt DOB (human only)
  – repeat interval
  – S8 only (no S4)
  – Handwriting not required on computer printed script

• Emergency supply
  – direction by telephone or other means
  – prescriber to dispatch written prescription within 24 hours
  – pharmacist to inform DOH if S8 script not received in 5 days
MPR - Supply

• Dispensing
  – pharmacist to be satisfied
    • script is complete - has all required elements
    • health practitioner is a class of person authorised to prescribe
  – dispense as per prescription
  – mark script
  – keep record of supply

• S8 supply
  – keep at pharmacy
  – can be transferred direct to other pharmacy if approved by DOH
• S8 confirmation
  – reasonable steps
  – authenticity, prescriber, patient or agent
  – supply 2 days if not able to confirm

• Cancellation
  – expired scripts
  – S4 = 12 months
  – S8 = 6 months
  – incomplete / altered / illegible / forged / false

• Repeats
  – S4 – issue repeat form
MPR - Supply

• Emergency supply
  – pharmacist can make judgement
    • S4 only
    • patient already under treatment with medicine
    • impractical to obtain a prescription
    • patient harm likely from interruption
    • 3 days or smallest indivisible quantity
  – vet use included

• Supply to other health practitioners
  – pharmacist satisfied that person authorised
  – requisition documents provided
MPR - Health Professionals

- Authority to
  - obtain
  - possess
  - sell or supply
  - prescribe
  - administer

- Basic authority via professional group
  - registration AHPRA
  - generally unchanged (doctor, vet, dentist, pharmacist)

- New groups
  - paramedics
  - aboriginal health practitioners

- Authority can be revoked or conditions added (as previous)
  - in response to misconduct, theft, etc.
Authorities for health practitioners working with medicines

Under the Medicines and Poisons Regulations, health practitioners are legally authorised to do certain things with medicines, such as purchase, prescribe or administer.

What a practitioner can do is dependent on their individual profession and any additional training or endorsement they hold.

Types of medicines authorities

Authorities of different professions

Important restrictions

Guidance for each profession

- Aboriginal health practitioners and workers (Word 383KB)
- Anaesthetic technicians (Word 384KB)
- Dental professionals (Word 386KB)
- First aid providers on ships and vessels (Word 363KB)
- Medical practitioners (Word 385)
- Nurses and midwives (Word 367KB)
- Optometrists (Word 384KB)
- Paramedics (Word 385KB)
- Pharmacists (Word 386KB)
- Podiatrists (Word 384KB)
- Veterinary professionals (Word 384KB)
Under the Medicines and Poisons Regulations, health practitioners are legally authorised to do certain things with medicines, such as purchase, prescribe or administer.

What a practitioner can do is dependent on their individual profession and any additional training or endorsement they hold.

### Types of medicines authorities

### Authorities of different professions

The basic authorities for each category of health practitioner is outlined below:

<table>
<thead>
<tr>
<th>Practitioner type</th>
<th>Obtain</th>
<th>Possess</th>
<th>Administer</th>
<th>Supply</th>
<th>Dispense</th>
<th>Prescribe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacist</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td>Medical practitioner</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td>Veterinary surgeon</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td>Dentist</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td>Nurse/Midwife</td>
<td></td>
<td>Y</td>
<td>Y</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Optometrist</td>
<td></td>
<td>Y</td>
<td>Y</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Podiatrist</td>
<td></td>
<td>Y</td>
<td>Y</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Endorsed practitioner*</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td></td>
<td></td>
<td>Y</td>
</tr>
<tr>
<td>Paramedic</td>
<td></td>
<td>Y</td>
<td>Y</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aboriginal health practitioner/worker</td>
<td></td>
<td>Y</td>
<td>Y</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anaesthetic technician</td>
<td></td>
<td>Y</td>
<td>Y</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vessel first aider</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Nurse, Midwife, Optometrist, Podiatrist

Some professions can also supply in limited circumstances under Structured Administration and Supply Agreements. For clarity, some restricted authorities are not listed here.
Working with medicines

Dental Professionals

Regulations
Dentists and other dental professionals, registered with the national board, have various authorities under the Medicines and Poisons Regulations 2016 to purchase, hold and use prescription medicines.

Authority
The following table outlines dental professionals with authority to use medicines under the Regulations:

<table>
<thead>
<tr>
<th>Practitioner</th>
<th>Type of Authority</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Obtain (purchase)</td>
</tr>
<tr>
<td>Dentist</td>
<td>✓</td>
</tr>
<tr>
<td>Dental therapist, Dental hygienist, Oral health therapist</td>
<td>×</td>
</tr>
</tbody>
</table>

Authority is limited to the lawful practice of the professional and includes:
- for dental practice only;
- within scope of practice / general professional limitations;
- for patients under the care of the health practitioner;
- at usual place of business;
- in the course of operating the business / as part of employment; and
- any relevant restrictions or conditions imposed on the individual practitioner.

Scope of practice for dental professionals is defined by the Dental Board of Australia.
MPR - Structured Arrangements

- Written arrangements
  - administration / supply without *individual* prescription ("standing orders")

- 3 types
  - CEO
  - hospital or permit holder (e.g. SJA)
  - medical practitioner

- Strict requirements
  - who can issue
  - who can use
  - who can authorise
  - permitted circumstances
  - permitted medicines
  - regular review
  - withdraw if directed (when unsafe)
# MPR - SASA Types

<table>
<thead>
<tr>
<th>Type</th>
<th>CEO</th>
<th>Health Organisation</th>
<th>Medical Practitioner</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Issued by</strong></td>
<td>Department of Health</td>
<td>Hospital</td>
<td>GP</td>
</tr>
<tr>
<td><strong>Applies to:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Practitioner</td>
<td>Any named class of person</td>
<td>Named class of Authorised Health Practitioner only</td>
<td>Named Authorised Health Practitioner only</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Employed by hospital</td>
<td>Employed by doctor</td>
</tr>
<tr>
<td>Patient</td>
<td>Any named type</td>
<td>Patients of hospital</td>
<td>Patients of doctor</td>
</tr>
<tr>
<td>Medicine</td>
<td>Any named class 2,3,4,8</td>
<td>Named medicine 2,3,4,8*</td>
<td>Named medicine 2,3,4</td>
</tr>
<tr>
<td></td>
<td>Any</td>
<td>Acute / Public Health</td>
<td>Acute / Public Health</td>
</tr>
<tr>
<td>Format</td>
<td>Standard information</td>
<td>Standard information</td>
<td>Standard information</td>
</tr>
<tr>
<td></td>
<td>Published on website</td>
<td>Made available</td>
<td>Made available</td>
</tr>
<tr>
<td>Valid</td>
<td>Indefinite</td>
<td>Two years</td>
<td>Two years</td>
</tr>
<tr>
<td>Approvals</td>
<td>CEO</td>
<td>CE approval</td>
<td>Doctor Signature</td>
</tr>
<tr>
<td></td>
<td>DTC approval</td>
<td>Senior Doctor signature</td>
<td></td>
</tr>
<tr>
<td>Example</td>
<td>Pharmacist vaccination</td>
<td>Remote area supply</td>
<td>Local vaccine program</td>
</tr>
</tbody>
</table>
Structured Administration and Supply Arrangements

Most medicines authorities (such as administer, dispense or prescribe) for registered health practitioners are listed in the Medicines and Poisons Regulations. These are linked to national registration categories and are fixed. Only a person authorised to prescribe may write a prescription or instruct another practitioner to administer a medicine.

In some other specific circumstances a Structured Administration and Supply Arrangement can be used authorise a health practitioner (who is not a prescriber) to supply or administer a medicine.

What is a SASA?

Types of SASA

CEO of Health SASA

The CEO of Health may authorise any practitioner or person in WA to use medicine through a SASA. These SASA provide authority to supply or administer medicines to health practitioners outside of any standard medicines authority linked to national registration.

The current SASA that have been issued by the CEO are listed below. Each contains a number of important and mandatory conditions that must be observed by any person utilising the SASA. The SASA only applies to the persons and circumstances named within, and are only valid when all the conditions are met, including any additional training required of the health practitioner.

1. Registered Nurses – vaccination (Word 91KB)
2. Midwives – vaccination (Word 90KB)
3. Registered nurses – remote area nursing posts (Word 97KB)
4. WA Country Health Service nurses – starter packs (Word 90KB)
5. WA Country Health Service nurses – trachoma (Word 85KB)
6. WA Country Health Service nurses – STI (Word 89KB)
7. Pharmacists – influenza vaccination (Word 88KB)
8. Pharmacists – continued dispensing (Word 85KB)
9. Podiatrists – local anaesthetics for podiatric use (Word 83KB)
10. Midwives – medicines for midwifery use (Word 89KB)
11. Podiatrists – medicines for podiatric use (Word 92KB)
Structured Administration and Supply Arrangement (SASA)

| TITLE:         | Administration of Influenza Vaccines by Pharmacists |

1. Authority:
Issued by the Chief Executive Officer of Health under Part 6 of the Medicines and Poisons Regulations 2016.

2. Scope:
This authorises Pharmacists trained in immunisation to administer influenza vaccines at a Registered Pharmacy in Western Australia.

3. Criteria:
This SASA authorises the actions specified in the table below.

<table>
<thead>
<tr>
<th>Practitioner:</th>
<th>Registered Pharmacists who have completed approved training in accordance with Appendix 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Practice setting:</td>
<td>At a Registered Pharmacy in Western Australia that complies with Appendix 2</td>
</tr>
<tr>
<td>Approved activity:</td>
<td>Administration</td>
</tr>
<tr>
<td>Approved medicines:</td>
<td>Influenza vaccine</td>
</tr>
<tr>
<td>Medical conditions:</td>
<td>Immunisation of adults (18 years of age and over) against seasonal influenza</td>
</tr>
</tbody>
</table>

4. Conditions:
The administration of approved medicines under this SASA is subject to the conditions that:
a. The pharmacist must have successfully completed an approved course of training;
b. Sites where immunisation is being conducted must be appropriately equipped to treat patients in the event of an anaphylactic reaction;
c. Patient selection and follow up care should be in accordance with the Part 2 of the Australian Immunisation Handbook;
d. Written or documented verbal consent must be obtained from the person, parent or guardian, before each instance of vaccination;
APPENDIX 2

Approved Setting

Registered Pharmacists may only administer influenza vaccine in accordance with this SASA at community pharmacy registered in WA.

1. The pharmacy must have minimum equipment to safely perform immunisation procedures, in accordance with the *Australian Immunisation Handbook*, and as below:
   
   a. Screened area or private room ensuring:
      
      i. Patient privacy and confidentiality;
      
      ii. Sufficient space to comfortably accommodate patient, carer, immuniser and all required immunisation equipment;
      
      iii. That in the event of a severe adverse or anaphylactic reaction the patient can safely lie prone and there is access for emergency staff to perform resuscitation procedures without hindrance;

   b. Area suitable for direct visual observation of seated patients, for 15 minutes post vaccination;

   c. Hand washing facilities;

   d. Equipment for disposal of sharps and clinical waste;

   e. In-date, complete anaphylaxis response kit;

   f. Access to current editions of the *Australian Immunisation Handbook* and *National Vaccine Storage Guidelines: Strive for 5*;

   g. Up-to-date, written procedures covering provision of immunisation services.

2. The pharmacy must maintain minimum staffing during vaccination service periods to ensure patient safety in post-vaccination monitoring and adverse event management:

   a. Ideally, at least two pharmacists will be available on-site during any immunisation period, and where this is not possible, the pharmacy must have additional staff on-site holding a current first aid and CPR certificate that can assist with follow up care or management of an emergency situation; and

   b. Workflow must allow the pharmacist conducting immunisations to be able to provide uninterrupted care to individual patients during assessment, vaccine administration and follow up care.
## MPR - Licences and Permits

### Types

<table>
<thead>
<tr>
<th>Licence</th>
<th>Permit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indent</td>
<td>Health Service</td>
</tr>
<tr>
<td>Schedule 2 retail</td>
<td>Department / Hospital</td>
</tr>
<tr>
<td>Schedule 7 retail</td>
<td>Public Sector</td>
</tr>
<tr>
<td>Schedule 9</td>
<td>Government</td>
</tr>
<tr>
<td>Wholesale</td>
<td>Industrial</td>
</tr>
<tr>
<td></td>
<td>Pharmaceutical Sample</td>
</tr>
<tr>
<td></td>
<td>Research / Education</td>
</tr>
<tr>
<td></td>
<td>Schedule 9</td>
</tr>
<tr>
<td></td>
<td>Stockfeed</td>
</tr>
<tr>
<td></td>
<td>Veterinary</td>
</tr>
</tbody>
</table>

### General conditions
- supply to authorised persons, require a requisition, keep records

### Fees (Schedule 1)
MPR - Handling

- containers / packaging
- labelling – including dispensed items
- exemptions (must pass public safety test)
- Schedule 2 and 3
  - storage
    - no public access
    - outside a pharmacy – not visible to public
    - S3 restricted – not in retail area of pharmacy
  - supply
    - retail sale only by pharmacy (or S2 retailer)
    - requires therapeutic assessment and quantities to be reasonable
    - S3 – pharmacist – intern or tech (under supervision)
  - restricted S3 (pseudoephedrine)
    - purchaser identity to be known or be verified through photographic ID
    - labelled
  - advertising
    - Appendix H allowed
MPR - Handling

• Schedule 4
  – storage
    • pharmacy - no public access
    • health practitioner – locked, only accessible by authorised persons
    • may possess small quantities when visiting patients
  – advertising
    • trade journals
MPR - Handling

- Schedule 8 and 9
  - storage
    - summary of safe arrangements
    - determined on quantity held: < 250 doses, < 500 doses, > 500 doses
    - small safe >> large safe >> detection device >> strong room
    - hospital ward – supervised = cabinet, unsupervised = small safe
    - health practitioner – < 250 doses = small safe, small quantities when visiting patients
    - pharmacy – large safe + detection, cabinet when supervised
    - wholesaler – strongroom + detection
    - keys kept on person
    - safe to be kept locked
  - advertising
    - trade journals only
  - packaging
    - separately, plain wrapping and unmarked
    - wholesaler return slips - separate requirements
MPR – Vending Machines

• Permitted but regulated
  – medicines only
  – use by authorised persons
  – machine and placement must be approved
  – must be:
    • secure
    • only a health practitioner may access machine
    • access procedures
    • access is recorded in each case
  – NOT include a device inside a pharmacy only used to dispense
Security
What is the weight of unit?
Is the unit mobile?
Is the unit permanently fixed? How is it fixed and to what is it fixed?
If not, is the unit chained, tethered or otherwise secured? How is it secured and to what is it secured?
Is the unit video monitored?
Is the area video monitored?
Is the unit alarmed for movement, tampering or other?
Is the area alarmed for movement, break-in or other?
Are these alarms back to base monitored?
Who are they monitored by?
What is the response procedure for an alarm?
What are the area lighting arrangements?
Is there direct line of the unit by staff when not in direct use?
Is the unit further protected by the location, for example stored in a dedicated room?
Is the room locked? How is the room accessed?

Authorised Persons
What persons / class of persons will be authorised to access the unit?
Will different persons / class of persons have different levels of access depending on their role?
How does the unit alert to attempts at access by unauthorised persons?

Access Codes
What type of access code is used?
Is there an organisational policy on access codes and their security?
How are access codes issued?
Who is responsible for issuing the codes?
Is each access code individual for the person?
How are access codes removed (e.g. for staff termination, resignation)?
How sophisticated is the access code? Numbers, Letters, Case Sensitive?
How often must the access code be altered?
Can an access code be reused?
What unique system identifier is connected to each person's access code?
MPR - Miscellaneous

- Report loss of Schedule 7, 8, 9
- Report theft of Schedule 4, 7, 8, 9

- Specific storage directions
  - written notice
  - risk to public health
  - secure, destroy, not use, deliver
MPR - Needles and Syringes

• Approval of needle and syringe programmes
  – defence for persons handling used / residual S9 substances
  – approved by DOH
  – appointed coordinator
  – responsibilities – e.g. annual reports
  – conditions

• Limited change to previous regulations
MPR - Schedule 8 medicines

- Requirements for prescribing
  - approval of prescribers
  - general S8s (opioids, benzodiazepines)
  - stimulants
  - opioid pharmacotherapy (methadone program)
  - cannabis-based products

- Adopts “Schedule 8 Medicines Prescribing Code”
PART 3: Opioid pharmacotherapy

3.1 Overview
Part 3 outlines when S8 medicines, as pharmacotherapy, may be prescribed and administered to a patient for the purposes of treating opioid dependence. It details how to apply for authorisation to prescribe pharmacotherapy for opioid dependence or administer opioid pharmacotherapy for detoxification. General rules and conditions for the prescribing and administration of pharmacotherapy for opioid dependence are outlined below.

3.2 Scope
This Part applies to methadone and buprenorphine, in any formulation approved for the treatment of opioid dependence (addiction). Rules relating to the use of methadone and buprenorphine for the treatment of pain are contained in Part 2.

3.3 Authority
This Part is issued under provisions of the Medicines and Poisons Regulations 2016, Part 11, Division 5.

3.4 Opioid substitution therapy
A health practitioner may not prescribe or administer an S8 medicine to a person for the treatment of dependence, without the prior permission of the CEO. For the prescribing and administration of S8 medicines for medical purposes that are not treatment of dependence, other Parts of this Code apply.

In Western Australia, Opioid Substitution Therapy (OST) for the treatment of drug dependence is managed through the Community Program for Opioid Pharmacotherapy (CPOP) framework, established under the Medicines and Poisons Regulations 2016. S8 medicines may only be prescribed and dispensed to treat opioid dependence within the CPOP. Treatment must be by an authorised prescriber, from an authorised dispenser and to an authorised patient.

Approved treatments in the CPOP include:

- methadone syrup/solution;
- Subutex® tablets; and
- Suboxone® film.

OST supplied under the CPOP is funded via the Commonwealth Section 100 Opiate Dependence Treatment Program. This program is open to those pharmacies approved by the Department of Health, WA. Treatments funded under this program may not be used or supplied for other purposes.

3.4.1 Prescriber authorisation

3.4.1.1 Prescriber requirements
Registered medical practitioners and nurse practitioners (within their nominated scope of practice) are eligible to be authorised as CPOP prescribers. Professional registration must not have conditions or undertakings relevant to the prescribing of S8 medicines.

The applicant must have first successfully completed the approved training and assessment package delivered by the Community Pharmacotherapy Program (CPP). A practitioner may be authorised to prescribe methadone, Subutex® and Suboxone®, or they may be authorised as a Suboxone® only prescriber.
MPR - Records

• Supply records
  – produced on demand of authorised officers
  – S3 R
    • approved system
    • date, name/address of purchaser, medicine, quantity, unique number
    • keep for 2 years
  – supply / admin of S4 / S8
    • kept in clinical record
    • medicine, form, quantity, patient name & address, date
    • if dispensed - script reference no
    • S8 – DOB patient, prescriber name and address
    • S4 – 2 years
    • S8 - 5 years
  – S8 records – pharmacies to provide at end of month
MPR - Records

• Registers
  – S8 and S9 - recordable events
    • manufactured, received, stored, supplied, administered, transported
  – must be made/kept by authorised person in approved form
  – information to keep
    • medicine, form, quantity, date, name & address of persons involved, prescriber, script ref number, balance, signature
  – destruction
    • record to be made, reason, witness (any authorised person)
  – electronic registers
    • must be approved
    • requirements laid out
  – inventory
    • monthly
    • report discrepancy to DOH straight away
MPR - Transitions

• Current approvals issued under Poisons Regulations 1965
  – transfer automatically to equivalent Medicines and Poisons Regulation
  – existing licenses and permits
  – container and label exemptions
  – S8 safe exemptions
  – needle and syringe programs
  – approved electronic recording or prescribing systems
  – approved prescribers - S8s, methadone, stimulants, etc.
  – other
Summary of changes

• Oversupplied / Drug Dependent person
• Provisions to share S8 records
• Adoption of Schedule 10
• Removal of “regulation 38s”
• Pharmacy license no longer required
• New license / permit types and rules for renewal
• New practitioner classes authorised
• Structured Supply and Administration Arrangements
• Vending machine provisions
• Electronic prescribing provisions
• Schedule 8 Code
• Cannabis Based Product provisions
• S8 storage requirements based on quantity held
• S8 disposal
• Poisons Advisory Committee abolished
Medicines and poisons

New legislation, designed to provide a modern and flexible framework for the regulation of medicines and poisons in Western Australia, has come into effect.

The *Medicines and Poisons Act 2014* and its subsidiary legislation, the *Medicines and Poisons Regulations 2016*, contain a number of key reforms for health practitioners and businesses handling medicines.


Read about the [Medicines and Poisons Regulation Branch](https://www.health.wa.gov.au/).